

**FELLOWSHIP AWARD LETTER/GRANT LETTER**  
**FROM THE FUNDING AGENCY**  
**(2021-2022)**



Avula Samatha <dra.samatha@gmail.com>

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## MOU - Velmeni & Sibar - Institute of Dental Sciences, Guntur

4 messages

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**Mini Suri** <mini@velmeni.com>

Tue, Dec 14, 2021 at 10:13 PM

To: Avula Samatha <dra.samatha@gmail.com>

Cc: Alan Friedel <aefriedel@gmail.com>, Rajeev Handa <rajeev@triviumcs.com>

Dear Dr. Samatha

Please accept this as our agreement to continue the working arrangement between Velmeni Inc and the University.

The monetary compensation paid to the school will be equal to the amount paid during the year 2021 in the sum of INR 5.5 Lakhs and will continue for a term of five years. Velmeni will introduce you to potential partners in the academic community so that you may jointly participate in research projects. This will especially include those where diverse populations are a requirement for good research to be accomplished.

The university will conduct research using Velmeni models in 2D and 3D formats using data taken from the college. The publication will be authored by school researchers and Velmeni team members. Processing fees for publication will be shared by Velmeni,

You will continue to provide any such 2D and 3D radiographic images required by the Velmeni Research team, used strictly for research, calibration, and testing.

As of this date, our relationship has been mutually beneficial. We look forward to continued progress for the aid of dentistry in the years to come.

Sincerely,

Mini Suri

Alan E. Friedel, DDS

Alan E Friedel, DDS

Bus: 305-933-6991

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*Kind regards,*

**Mini Suri**

Chief Executive Officer at Velmeni.ai  
Pioneering AI-driven Patient Care

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P 201-289-3500 E mini@velmeni.com



  
**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

# VELMENI

Velmeni, Inc.  
333 West Maude Ave  
Sunnyvale, CA 94085 USA  
Velmeni.ai  
India: +91.9765888861  
USA: +1.201.289.3500

## LETTER OF AGREEMENT

This INDEPENDENT CONTRACTOR AGREEMENT (this "Agreement") is effective as of October 1, 2021 (the "Effective Date") by and between Velmeni, Inc., a Delaware corporation (the "Company"), and XXX. The Company desires to retain Contractor as an independent contractor to perform services for the Company, and Contractor is willing to perform such services, on the terms set forth in this Agreement. In consideration of the mutual promises contained herein, the parties hereby agree as follows:

### 1. Services; Compensation.

1.1 Services. During the Term (as defined below), Contractor shall perform for the Company the services described in Exhibit A hereto (the "Services") on the terms described in Exhibit A hereto. Contractor acknowledges and agrees that (a) the Company entered into this Agreement to retain Contractor to perform the Services; and (b) the Services are unique to the Company and the Company has determined that Contractor is uniquely qualified to perform the Services. Only Contractor, and any employees of Contractor ("Contractor Personnel") that (i) are approved in writing by the Company and (ii) have executed a confidentiality and assignment of inventions agreement, in a form reasonably acceptable to the Company ("Authorized Personnel"), will provide the Services; the Services are not to be performed by any person or entity other than Contractor (and any Authorized Personnel), without the prior written consent of the Company.

1.2 Compensation. The Company shall pay Contractor the compensation set forth in Exhibit A as sole compensation for the performance of the Services. The parties intend to establish an

independent contractor relationship. Contractor (and any Contractor Personnel) shall not participate in any of the Company's employee benefit plans or perquisites. Contractor further disclaims any intention or right to participate in any of the Company's employee benefit plans or perquisites even if Contractor's (or any Contractor Personnel's) status with the Company is determined by a third-party tribunal to be that of an employee.

### 2. Confidentiality; Assignment.

The Contractor will not share, disclose or duplicate the work he/she has done for the company, in any form whatsoever with any individual, company, competitor, Research firm, from same field or different field of work as long as they are associated with Velmeni Inc.

3. Term; Termination. This Agreement will commence on the Effective Date and will continue until a date as may be agreed to in writing by the Company and Contractor after the Effective Date; or (b) the date this Agreement is terminated in accordance with this Section 3 (the "Term"). Either the Company or Contractor may terminate this Agreement at any time upon giving 10 days prior

  
Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

written notice thereof to the other party. The Company may, in addition to any other rights it may have at law or in equity, terminate this Agreement immediately and without prior notice if Contractor refuses to or is unable to perform the Services or is in breach of any material provision of this Agreement. Upon the termination of this Agreement, all rights and duties of the parties toward each other shall cease, subject to Section 4; provided, however, that the Company shall be obliged to pay, within 30 days of the effective date of termination, all amounts owing to Contractor for Services actually performed and reimbursable expenses (if any) actually incurred prior to such termination in accordance with the provisions of Section 1.

**4 Survival.** Section 2, this Section 4, Section 5 through Section 14 hereto shall survive termination or expiration of this Agreement.

**5 Assignment.** Neither this Agreement nor any right hereunder or interest herein may be assigned or transferred by Contractor without the prior written consent of the Company. The Company may assign any or all of its rights and obligations under this Agreement without Contractor's written consent (a) to an affiliate of the Company; or (b) otherwise by way of merger, acquisition, consolidation or sale or transfer of all or substantially all of the Company's assets or capital stock. Any attempted assignment, delegation or transfer to a third party in violation hereof shall be null and void. Subject to the foregoing, this Agreement shall be binding on the parties and their successors and assigns.

**6 Independent Contractor: No Agency.** Nothing in this Agreement shall in any way be construed to constitute Contractor (or Contractor Personnel) as an agent, employee or representative of the Company, but Contractor (and any Authorized Personnel) shall perform the Services hereunder as an independent contractor. Contractor acknowledges and agrees that (a) Contractor is obligated to report as income all compensation received by Contractor pursuant to this Agreement the obligation to pay all employment and other taxes

thereon; and (b) Contractor (and any Contractor Personnel) will not be eligible for any employee benefits from the Company and expressly waives any entitlement to such benefits. Contractor further agrees to indemnify the Company (and its affiliates, stockholders, directors, officers, employees and representatives) and hold them harmless to the extent of any obligation imposed on the Company (or its affiliates, stockholders, directors, officers, employees and representatives) (i) to pay withholding taxes or similar items or (ii) resulting from Contractor's (or any Contractor Personnel) being determined not to be an independent contractor. Except insofar as it would preclude Contractor from providing the Services under this Agreement or violate any term of this Agreement, Contractor is free to perform services for any other person or entity. Contractor further acknowledges and agrees to the following:

(A) While providing Services, Contractor is, and shall at all times be and remain, an independent contractor of the Company.

(B) Nothing in this Agreement or otherwise shall be construed as identifying Contractor (or any Contractor Personnel) as an employee, agent or legal representative of the Company (or any of its affiliates) during the Term for any purpose whatsoever.

(C) Contractor is not authorized to transact business, incur obligations, sell goods, receive payments, solicit orders or assign or create any obligation of any kind, express or implied, on behalf of the Company (or any of its affiliates), or to bind in any way whatsoever, or to make any promise, warranty or representation on behalf of the Company (or any of its affiliates) with respect to any matter, except with the prior written consent of the Company.

(D) While Contractor will receive instruction on the objects and goals for which Contractor is responsible, the Company has no right to control the manner in which Contractor performs Services under this Agreement and Contractor is free to perform Services in the manner Contractor deems fit and in



accordance with recognized standards for such Services.

(E) Neither party shall use the other party's trade names, trademarks, service names or service marks without the prior written consent of the other party.

(F) If, at any time, Contractor's (or any Contractor Personnel's) status with the Company as an independent contractor changes or Contractor (or any Contractor Personnel) is ever deemed to be an employee of the Company, each of the covenants set forth above and this Agreement remain in full force and effect in its entirety until and unless such covenant is replaced with a subsequent and superseding agreement.

7. **Amendment.** This Agreement may not be amended in any respect other than by written instrument executed by the Company and Contractor.

8. **Entire Agreement.** This Agreement (including the exhibits hereto) constitutes the entire agreement between the parties and supersedes all previous agreements and understandings, whether oral or written, between the parties hereto with respect to the subject matter hereof, and no agreement or understanding varying or extending the same shall be binding upon either party hereto unless in a written document which expressly refers to this Agreement and which is signed by the party to be bound thereby.

9. **Governing Law; Jurisdiction.** This Agreement shall be governed by and construed in accordance with the internal laws of the State of California, without reference to its principles of conflict of laws. Contractor hereby agrees to consent to personal jurisdiction of the state and federal courts situated within the County of San Francisco, California for purposes of enforcing this Agreement, and waive any objection that Contractor might have to personal jurisdiction or venue in such courts.

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**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

**Company:**

Velmeni, Inc.

By:



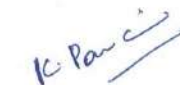

Name: Mini Suri

Title: CEO, Velmeni, Inc.

Email ID: info@velmeni.ai

**Contractors:**

1. Dr. Y. Samatha,  
Professor & Head, Department of oral medicine and radiology,  
Sibar Institute of Dental Sciences. Email ID: samatha.dentalai@gmail.com
2. Dr. Purna Chandra Rao Naik,  
Professor, Department of oral medicine and radiology,  
Sibar Institute of Dental Sciences. Email ID: purnachandraraonaik@gmail.com
3. Dr. Pingili Shruthi,  
Assistant Professor, Department of oral medicine and radiology,  
Sibar Institute of Dental Sciences. Email ID: shruthi.pingili@gmail.com
4. Dr. S. Sethu Manjusha,  
Assistant Professor, Department of oral medicine and radiology,  
Sibar Institute of Dental Sciences. Email ID: drsethuphanindra@gmail.com
5. Dr. K. Pavani,  
Assistant Professor, Department of oral medicine and radiology,  
Sibar Institute of Dental Sciences. Email ID: kothaapavani@gmail.com
6. Dr. M. Sanjana,  
Assistant Professor, Department of oral medicine and radiology,  
Sibar Institute of Dental Sciences. Email ID: sanjanamarpuri@gmail.com



**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

This Investigator Initiated Study Agreement (the “**Agreement**”) is made effective as of the last date of the signatures below (the “**Effective Date**”), by and between

**DENTSPLY IH AB**, a company incorporated in Sweden under registration No. 556051-8812, with office located at Aminogatan 1 (P.O. Box 14), SE 431 21 Mölndal, Sweden (“**DS**”);

Department of Conservative Dentistry and Endodontics, Sibar Institute of Dental Sciences, Takkellapadu, Guntur 522509, Andhra Pradesh, India (the “**Sponsor**”) and;

Dr. Nagesh Bolla, Department of Conservative Dentistry and Endodontics, Sibar Institute of Dental Sciences, Takkellapadu, Guntur 522509, Andhra Pradesh, India. Email: drnageshendo@sids.ac.in (the “**Principal Investigator**” or the “**PI**”)

Co-investigators:

Dr. Roopadevi Garlapati, Department of Conservative Dentistry and Endodontics, Sibar Institute of Dental Sciences

Dr.Yedla.Sahitya, Department of Conservative Dentistry and Endodontics, Sibar Institute of Dental Sciences

Lahari Bolla, Department of Conservative Dentistry and Endodontics, Sibar Institute of Dental Sciences

### Recitals

- (A) WHEREAS, the Sponsor and the PI wishes to conduct a research study concerning “*Evaluation of the effectiveness of SLP Endo Activator Sonic Activation using ATP Bioluminescence meter : An In- vitro study*”, **E-2022-01** and has made a study proposal as specified in Appendix 1 to this Agreement (the “**Study Protocol**”) and where; (i) DS has no sponsor responsibilities for the study and (ii) DS’ contribution to the study is limited to 50 % of the total study cost whether the contribution consists of money, Study Products (as defined in Section 1.1 below) or others, altogether referred to as (the “**Investigator Initiated Study or Study**”)
- (B) WHEREAS, the Sponsor, the PI and DS share a mutual interest and benefit of the outcome of the Study and the Sponsor and PI have no medical, scientific or ethical concerns regarding its conduct.

### Agreement

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

#### 1 **DS Support**

- 1.1 DS obligations under the Study will be explicitly limited to provide:
- DS products/components in sufficient amount in order to complete the Study, see Appendix 2 (the “**Study Product**”).
  - Funding which does not exceed UDS 2 000 payable in one instalment in accordance with Appendix 3.
- 1.2 The Parties acknowledge that the amounts to be paid by DS under this Agreement are reasonable compensation, and represents DS’s full and complete obligation for any and all work performed by Sponsor, PI and Study Site Staff (as defined below). All payments made by DS under this Agreement are inclusive of value added taxes, sales taxes or similar taxes and fees.
- 1.3 The Parties confirm that the rights and obligations arising out of this Agreement do not relate to or influence in any way whatsoever potential future business relationship between the Parties including but not limited to the formation of pricing concerning the procurement of medical devices. This Agreement has not been set up to influence decisions of Sponsor relating to its

procurement planning of medical products. The Parties hereby exclude any expectation of preferred treatment as a consequence of this Agreement. Sponsor is free to introduce any other products than DS's products at any time and to stop using DS's products at any time without giving reason to DS.

## 2 **Representations and warranties**

- 2.1 To safeguard the ethical conduct of the Study and the appropriate use of the Study Products it is hereby agreed that the Sponsor and the PI will be responsible for, and do hereby represent, warrant and covenant to DS that:
- 2.1.1 PI shall conduct the Study on a day-to-day basis, including delegation of specified Study responsibilities, training Study staff and supervising their work.
- 2.1.2 The Study is carried out in accordance with this Agreement, the Study Protocol, the ISO 14155 standard, all applicable laws and requirements, any condition required by a regulatory authority and/or an independent ethics committee/institutional review board (the "IEC/IRB").
- 2.1.3 Sponsor shall report all product claims that may occur to DS's local representatives.
- 2.1.4 The forms to be provided to potential persons in the Study to secure their informed consent to participate in the Study (the "**Informed Consent Forms**"), as approved by the IEC/IRB, must disclose that the Study is supported by DS and that Study documentation may be provided to representatives and affiliates of DS anywhere in the world and may be provided to any regulatory authority. DS shall be entitled to review the Informed Consent Forms to ensure that the Sponsor is clearly identified and that DS's support is correctly described.
- 2.1.5 There will be adequate time and resources to conduct the Study within the agreed time-schedule and to complete the Study before October 2022. In the event it has been determined by the Parties that the date for Study completion shall be postponed, the Parties agree that an amendment will be prepared in writing extending the completion date of the Study and agreed by authorized representatives of each Party.
- 2.1.6 DS gets informed of any changes (e.g. in equipment, or Study procedures) that may affect the use of the Study Products or completion of the Study.
- 2.1.7 The Study Products will be used only for this Study and only in accordance with the Study Protocol, Appendix 1 of this Agreement and in accordance with DS's instructions for use or other guidance. The Study Product shall remain the exclusive property of DS until used during the course of the Study. All unused Study Products shall, at Sponsor's expense, be returned to DS promptly upon the completion of the Study, unless otherwise notified by DS.
- 2.1.8 The medical (hospital/practice) records for each patient contain information according to local regulatory requirements.
- 2.1.11 Sponsor, PI and all those investigators, employees, agents, students and others who are engaged by Sponsor and/or PI in the conduct of the Study (the "**Study Site Staff**") will be properly registered with appropriate registration bodies and are sufficiently qualified by training and experience for conduct of the Study.
- 2.1.12 Neither Sponsor nor PI is subject to any conflicting obligations or legal impediments that might interfere with the performance of the Study or that might impair the acceptance of the resulting data by any regulatory authority or the grant of rights to DS hereunder, and no such obligations or impediments will be incurred or permitted during the course of this Agreement.
- 2.1.13 Sponsor and PI shall provide DS with the following information and materials:
- A copy of the Study Protocol
  - A status report every six (6) months during the duration of the Study, which shall summarize the work performed and the results achieved in connection with the Study



- At DS' request, preliminary high level study reports for DS to use for regulatory submissions and/or marketing purposes (the "**Preliminary Study Data**")
- A final report of Study results within 30 days after completion of the Study
- A copy of the Health Authority approval, if applicable

### **3 Publication, review and disclosure of Study Data**

- 3.1 **Publication.** Sponsor and PI shall be entitled to use or present all records, accounts, notes, reports and data, collected, generated or used in connection with the Study (the "**Study Data**") at conferences and submit the Study Data for publication in medical/dental journals of his/her/its choosing, provided this is (i) consistent with academic standards, (ii) is not false or misleading, and (iii) is not for commercial purposes.

An acknowledgment in all material aspects as set out below, is required when submitting the Study research results to society meetings and for publication in medical journals: 'This research was conducted with support from Dentsply Sirona.' This wording shall appear on all posters, as a sentence within all abstracts and as an acknowledgement in all manuscripts and presentations, as well as in any financial disclosure information.

Sponsor and PI further agree that, if PI publishes the results of the Study, DS is hereby granted a royalty-free license to make and distribute copies of such publication under any copyright privileges that Sponsor and/or PI may have. PI/Sponsor shall also be free to use such Study Data for his/her/its own internal teaching, research and patient care programs.

- 3.2 **Review.** Sponsor and PI agrees that prior to any presentation or publication of Study Data, DS shall have a period of thirty (30) days from receipt of the proposed publication or presentation to review its contents, and Sponsor and PI agrees, if requested, to delete any Confidential Information, at DS's sole discretion. When submitted and approved for publication, Sponsor and PI should communicate this to DS.

If requested in writing by DS, Sponsor and PI shall delay the submission of such publication or presentation for an additional period, not to exceed a further sixty (60) days, to file a patent application or take such other measures as DS reasonably deems appropriate to establish and preserve the parties' proprietary rights in any intellectual property disclosed in the material being submitted for publication or presentation.

- 3.3 **Disclosure.** DS will not disclose the Study Data to any third party as long as such Study Data remains unpublished or publicly undisclosed by Sponsor and/or PI, except that DS may disclose such Study data to its affiliates on a need-to-know basis in order to evaluate such information.

It's noted that DS may disclose the Preliminary Study Data before the Study Data has been made public, provided prior written approval from the Sponsor and the PI has been obtained in each case and such disclosure would not be in conflict with future publications of the Study Data as set forth in Section 3.1.

### **4 Confidentiality**

- 4.1 For purposes of this Agreement, confidential information means any information of DS, whether of a technical, business or other nature, including, but not limited to, information that relates to DS's trade secrets, products, promotional material, developments, proprietary rights or business affairs, together with any DS IP ("**Confidential Information**").

At all times during the Term of this Agreement (as defined below) and for a period of five (5) years following termination or expiration of this Agreement, neither Sponsor nor PI shall, without DS's prior written consent, publish, disseminate or otherwise disclose to any third party (except as may be permitted by this Agreement) any Confidential Information, and shall use such Confidential Information solely for purposes of performing its obligations under this Agreement. Sponsor and PI shall restrict the dissemination of Confidential Information to only those persons

who have a need to know, and shall ensure that all persons involved in carrying out this Agreement are aware of this Agreement and bound by non-disclosure agreements at least as protective of Confidential Information as those set forth in this Agreement. Sponsor shall use at least the same care and discretion in maintaining the confidentiality of the Confidential Information as it uses with its most sensitive confidential information.

- 4.2 The obligations of confidentiality in Section 1 shall not extend to any Confidential Information that: (a) Sponsor can prove was lawfully obtained from a third party without any obligation of confidentiality, (b) Sponsor can prove was known to it prior to the date of this Agreement and was not subject to any confidentiality restrictions, or (c) is or becomes part of the public domain through no act or violation of any obligation of Sponsor or PI.
- 4.3 Neither Party shall make any public announcement relating to this Agreement or the transactions covered by it or mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its affiliates in any publication, press release, promotional material or other form of publicity without the prior written approval of that Party in each instance.

## 5 **Personal Data**

Each Party shall be responsible for its own processing of information and data that is directly or indirectly referable to a natural person who is alive ("**Personal Data**") and shall ensure that any Personal Data relating to Sponsor, PI and/or Study Site Staff, is collected, stored, used, disclosed and transferred in accordance with all applicable supranational and national privacy laws.

## 6 **Liability of the Parties**

- 6.1 DS is liable for any defects in the Study Product in accordance with general warranty terms and product liability legislations, save to the extent the Sponsor has an obligation towards DS pursuant to section 6.2 below.
- 6.2 Sponsor agrees to be liable and hold harmless DS and its officers, directors, partners, employees and agents from and against any and all liability, claims, losses, damages and expenses (including attorneys' fees) that arise as a result of any breach by PI or Sponsor of any representation, warranty, covenant, condition or obligation set forth in this Agreement. DS shall have the exclusive right to retain counsel of its choosing to represent itself and shall retain exclusive control of the litigation; provided, however, that DS will not compromise or settle any such litigation without the prior consent of Sponsor, which shall not be unreasonably withheld or delayed.
- 6.3 Each Party hereto agrees to be responsible and assume liability for its own wrongful or negligent acts or omissions, or those of its officers, agents or employees to the full extent required by law.

## 7 **Term and Termination**

- 7.1 This Agreement shall commence upon the Effective Date and shall continue until the completion of the Study (the "**Term**"), unless this Agreement is earlier terminated in accordance with this Article 7.
- 7.2 Either Party have the right to terminate this Agreement upon thirty (30) days' notice to the respective Party. In the event of termination, DS shall reimburse the PI/Sponsor for all work completed to the date of termination, provided that Sponsor and PI shall return and repay to DS any unused funds and materials. The reimbursement from DS shall however not exceed the funding and Study Products specified in Appendix 2 and Appendix 3 of this Agreement.
- 7.3 Upon termination or expiration of this Agreement or upon DS's earlier request, Sponsor and PI shall promptly return to DS all Confidential Information.

## 8 **Miscellaneous**

- 8.1 **Assignment.** This Agreement may not be assigned by either Party in whole or in part without

the prior written consent of the other Party, except that DS without such consent may assign this Agreement and its rights and obligations hereunder to any of its affiliates or any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of the business to which this Agreement relates. DS shall always have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its affiliates.

- 8.2 Governing Law. This Agreement shall be governed by the laws of Sweden.
- 8.3 Entire Agreement. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter of the Agreement. This Agreement supersedes all prior agreements, whether written or oral, with respect to the subject matter of the Agreement. All Appendix referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement. In the event of any inconsistency between any such Appendix and this Agreement, the terms of this Agreement shall govern.
- 8.4 Amendment. Any amendment or modification of this Agreement must be in writing and signed by authorised representatives of both Parties.



Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**Execution**

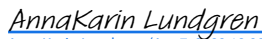
This Agreement has been duly executed in two (2) original copies, one to each Party.

**DENTSPLY IH AB**

Date (YYYY-MM-DD):

2022-04-07

Signature:



AnnaKarin Lundgren (Apr 7, 2022 13:23 GMT+2)

Name: AnnaKarin Lundgren

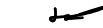
Title: Director Center of Clinical  
Research  
Clinical Research and Scientific  
Support

**SPONSOR (on behalf of Institution)**

Date (YYYY-MM-DD):

2022-04-11

Signature:



Dr L Krishna Prasad (Apr 11, 2022 15:19 GMT+5.5)

Name: Dr. L. Krishna Prasad

Title: Dean

AGREED AND CONSENTED TO BY:

Date (YYYY-MM-DD):

2022-04-07

Signature:



Nagesh Bolla (Apr 7, 2022 17:03 GMT+5.5)

Name: Dr. Nagesh Bolla

Title: Principal Investigator

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.



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**APPENDIX 1**  
**Clinical Investigation Plan (CIP)**

See next page.

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

<b>Applicant information</b>	
Principal Investigator <i>(Title and name)</i>	Dr. Nagesh Bolla Professor and Vice-Dean
Name of Institution/ Clinic Address	Department of Conservative Dentistry and Endodontics Sibar Institute of Dental Sciences Takkellapadu, Guntur 522509, Andhra Pradesh, India
E-mail address	drnageshendo@sids.ac.in
Please list all investigators who will be involved in your study <i>(Please specify name, title, anticipated function, instiution/clinic)</i>	Dr. Roopadevi Garlapati, Reader Anticipated Function: Observation/Sample collection Dr. Yedla.Sahitya - Postgraduate Anticipated Function: Sample collection/Practical Procedures Lahari Bolla - Undergraduate Anticipated Function: Data Collection/Supporting documentation
Please indicate the reason for your interest in collaboration with Dentsply Sirona	To determine the effectiveness of the SLP Endo Activator in tooth disinfection and to determine the additional amount of cellular debris that is removed from the endodontic cavity by using the SLP Endo Activator (Based on ATP Values and CFU Count).
<b>Information about the study</b> <i>(Please be detailed, if required additional documents can be attached as an appendix)</i>	
<b>Study title</b>	Evaluation of the effectiveness of SLP Endo Activator Sonic Activation using ATP Bioluminescence meter : An In-vitro study
<b>Study objectives</b> <i>(Including hypothesis)</i>	<ul style="list-style-type: none"> <li>- To determine the additional amount of cellular debris removed from root canal of an extracted tooth irrigated with distilled water when using SLP Endo Activator.</li> <li>- To determine the effectiveness of the SLP Endo Activator in the presence of NaOCl to activate disinfecting solution during root canal treatment procedures and the levels of ATP present in the root canal.</li> </ul> <p><b>Hypothesis</b> - The use of SLP Endo Activator will result in more cellular debris being removed from root canal during root canal irrigation and will result in lower levels of ATP being detected inside of a root canal.</p>
<b>Importance of results</b> <i>(Please detail the scientific, practical or clinical relevance of the findings of the study)</i>	Study will help justify the application of SLP Endo Activator sonic activation as an important adjunct during root canal procedure.



**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

<b>Study centre(s)</b> <i>(The site(s) were the majority of the research will be conducted)</i>	DEPARTMENT OF CONSERVATIVE DENTISTRY & ENDODONTICS, SIBAR INSTITUTE OF DENTAL SCIENCES, GUNTUR, ANDHRA PRADESH.
<b>Estimated study period</b> <i>(DD/MM/YYYY)</i>	07/04/2022 - 06/07/2022
<b>Milestones</b> <i>(Detail the different milestones /important events in the study and at which date you estimate them to occur. Examples of milestones are first patient included, all patients included, last follow up conducted or end of an experimental serie)</i>	11/03/2022 IRB approval taken – copy attached 15/07/2022 complete experiment and submit data (DEPENDS ON PANDEMIC )

<b>Investigational product/comparator</b> <i>(State the devices/ products that will be investigated/ used and for comparative studies also the comparator/s)</i>	SLP EndoActivator Endocator ATP tester
<b>Outcome variables</b> <i>(Describe which variables will be included in the study i.e. what will be measured and how it related to the results)</i>	-Cleaning and Disinfection ability of SLP Endo Activator is evaluated by measuring ATP levels before activation, throughout the procedure and at the end of the procedure. -At each level ATP values will be different depending on remaining test bacteria in the root canal. - During the procedure, ATP values will be compared with the Colony Forming Units (CFU's)
<b>Materials and methods</b> <i>(Detail the procedures, methods and measurements that will be conducted within the study)</i>	<p><i>Further details attached</i></p> <ul style="list-style-type: none"> <li>- For this study eighty (n=80) freshly extracted Palatal roots of maxillary molars / Distal roots of mandibular molars will be selected, missing wall of the teeth will be restored with composite with specific volume of pulp chamber maintained.</li> <li>- Root canals will be negotiated and enlarged up to a size of 25-06%, rinsed with 2ml of 17% EDTA for 2min, followed by 5.25% NaOCl for 10 min, final rinse with distilled water.</li> <li>- Root apices will be sealed with flowable composite to prevent leakage. Apices of all root tips and all surplus pulpal canal orifices will be sealed with adhesive and flowable composite so that only the orifice of the shaped canal remains open. Teeth will then be sterilized and the apical portion of the teeth will be re-sealed if required.</li> <li>- Root canals will be rinsed with 5ml room temperature distilled water for 30 seconds, measure the ATP levels.</li> <li>- Insert growth media (TEST BACTERIA) into the root canals, incubate at 37°C for 4 weeks, replace growth media (TEST BACTERIA) twice per week. At the end of 4 weeks, all samples will be rinsed with 5ml of distilled water at room temperature with a 30 gauge syringe.</li> <li>- Measure inoculation <b>ATP level and CFU count as a baseline.</b></li> <li>- <b>“Rinsing procedure”</b> Always 30 gauge needle will be used while rinsing procedure and teeth and irrigants at room temperature</li> </ul> <p><b>“Sampling procedure” followed while taking ATP level and CFU count</b></p> <ul style="list-style-type: none"> <li>- Surplus water will be removed from pulp cavity using an uncapped saliva ejector. If required, root canal will be refilled with distilled water to canal orifice. Sample will be taken after 10 seconds soaking time. Syringe with 30 gauge needle will be pre-loaded</li> </ul>

	<p>with 200µl of distilled water. Needle tip will be placed 3 mm short of working length without actively scraping the canal walls. Fully aspirate liquid, fully reinject, then fully aspirate a final time. 100µl liquid will be used for ATP reader and 100µl for CFU count. After ATP reading, a drop of orthotolidine will be added to the ATP sample to check for NaOCl contamination. In case of contamination, ATP and CFU sample's will be retaken”</p> <ul style="list-style-type: none"> <li>- Teeth will be randomly divided into four groups: <ul style="list-style-type: none"> <li><b>Group1 (n=20)</b> : Fill root canal and pulp cavity with 2ml distilled water for30 sec, no SLP Endo Activator used. rinse the canal with 3 ml of distilled water</li> <li><b>Group 2 (n=20)</b> : Fill root canal and pulp cavity with 2ml distilled water ,use SLP Endo Activator at high speed for 30 Sec, rinse the canal with 3 ml of distilled water</li> <li><b>Group 3 (n=20)</b> :(GOLD STANDARD) Fill root canal and pulp cavity with 2 ml of 1%NaOCl -30 Sec exposure time , rinse the canal with 3 ml of distilled water and no SLP Endo Activator</li> <li><b>Group 4 (n=20)</b> : Fill root canal and pulp cavity with 2 ml of 1%NaOCl and then use SLP Endo Activator at high speed for 30 Sec, rinse the canal with 3 ml of distilled water</li> </ul> </li> <li>- The irrigation protocol will be repeated nine (9) more times for a total of 5 minutes of activation. Irrigation protocol will be followed at each level of activation. <p><b><u>FOR 4 GROUPS PROTOCOL FOR FINAL IRRIGATION:</u></b></p> <ol style="list-style-type: none"> <li>1. Rinse with 3ml room temperature distilled water within 30 seconds</li> <li>2. Leave the distilled water in place, treat each group for 60 sec with EA at high speed</li> <li>3. Measure residual ATP level and CFU count per sampling procedure.</li> </ol> </li> <li>- At each level ATP values will be different depending on test bacteria in the root canal. So, during the procedure, significant ATP values will be compared with the Colony Forming Units (CFU's).</li> </ul>
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 DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
 GUNTUR-522509, A.P., India.




<p><b>Study design</b> (A brief summary of major study design features i.e. in vitro, animal or clinical study, follow up times and study end point)</p>	<p>- In vitro study for evaluation of ATP levels during root canal irrigation procedure.</p>
<p><b>Study population</b> (For clinical/animal study describe target population, indication studied and inclusion/exclusion criteria's)</p>	<p>Extracted teeth will be collected from the Oral and Maxillofacial Surgery Department, Sibar Institute of Dental Sciences, Guntur after IRB approval.</p>
<p><b>Number of planned patients</b> (If multi-centre study also describe the distribution per study site)</p>	<p>Eighty (n=80) extracted distal roots of mandibular molars/palatal roots of maxillary molars for periodontal reasons (indicated for extraction)</p>

  
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<b>Statistical methods</b> <i>(Detail the statistical tests, populations for comparison, sample size, intention to treat, per-protocol and any interim analyses)</i>	Results will be analysed using one way analysis of variance. Multiple pair wise comparisons will be done using Tukey's Post-hoc test.
<b>Publications &amp; presentatio</b> <i>(Describe plans for publication or public presentations of results also give examples of journals to submit to or conferences/ meetings to attend)</i>	<b>PUBLICATIONS &amp; PRESENTATIONS - SEE ATTACHED</b>  <b>PLANS FOR PUBLICATION/PRESENTATIONS:</b> After getting approval from Dentsply, Study can be submitted to <ol style="list-style-type: none"> <li>1. International Endodontic Journal</li> <li>2. Journal of Endodontics</li> <li>3. Dental Research Journal</li> <li>4. Restorative Dentistry &amp; Endodontics</li> <li>5. Journal of Conservative Dentistry,.....etc...</li> </ol>
<b>Research experience as principal investigator</b> <i>(If applicable, please describe your previous research experience and number of published articles in international peer-reviewed journals with you as principal investigator)</i>	<b>NUMBER OF PUBLICATIONS: 59</b>  <b>NUMBER OF YEARS OF EXPERIENCE: 18 YEARS</b>

<b>Total study cost</b> <i>(Estimate a reasonable total budget for the study. Detail costs for materials, products, staff, procedures, measurements, ethical approvals etc.)</i>	Two lakhs Eighty Thousand Indian rupees (Approximately) / approximately 4,000 USD. In addition, shipping fess of 4,000 USD and product costs of approximately 5,000 USD. Total sum is approximately 14,000 USD. <ol style="list-style-type: none"> <li>A. Materials /Products Cost: One Lakh Indian Rupees (Approximately)</li> <li>B. STAFF: One Lakh Indian Rupees (Approximately)             <ol style="list-style-type: none"> <li>a. Investigator's: 2 (Approximate payment for 3 Months: Sixty Thousand Indian Rupees)</li> <li>b. Microbiologist: 1 (Approximate payment for 3 Months: Twenty Thousand Indian Rupees)</li> <li>c. Microbiology Technician: 1 (Approximate payment for 3 Months: Twenty Thousand Indian Rupees)</li> </ol> </li> <li>C. Procedures: Fifty thousand Indian Rupees (Approximately) {Incubator, Laminar airflow cabinet}</li> <li>D. MEASUREMENTS: Twenty Five thousand Indian Rupees (Approximately) {Manual, Digital CFU counting}</li> <li>E. Ethical Approvals: Five thousand Indian Rupees (Approximately)</li> </ol>
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<b>Requested Support from Dentsply Sirona</b>	
<b>Support requested</b> <i>(Products and funding. For funding detail the amount to be covered by requested support. For products detail these in the next section)</i>	Study Material and financial support of 2,000 USD. <div style="text-align: right; margin-top: 20px;">   <b>Dr. L. KRISHNA PRASAD</b>          DEAN  <b>SIBAR INSTITUTE OF DENTAL SCIENCES</b>          GUNTUR-522509, A.P., India.       </div>

<p><b>Further support</b> <i>(Did you or do you plan to request further support by anyother person/ institution/ company?)</i></p>	<p>If required we may take additional support from Sibar Health and Research Foundation, Guntur, Andhra Pradesh.</p>
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DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.


<b>Details of products requested</b> (Only Dentsply Sirona products)		
<b>Product</b>	<b>Ref. No.</b>	<b>Quantity</b>
Neo Spectra ST HV Syringe Refill A1 (1 syringe)	60701981	16 syringes
Neo Spectra ST flow Syringe Shade A1 Refill (2 syringes)	60701921	8 syringes
SLP Endo Activator	-	2 units
SmartLite Pro EndoActivator Barrier Sleeves (QTY 100)	644434	300 sleeves
SLP Endo Activator tips medium	644436	100 tips
SLP Endo Activator tips medium long	644437	100 tips
SLP Endo Activator tips small	644435	100 tips
ProTaper Gold S1 25MM (8 files per blister)	A0410225G0103	40 files
ProTaper Gold S1 31MM	A0410231G0103	40 files
ProTaper Gold S2 25MM	A0410225G0203	40 files
ProTaper Gold S2 31MM	A0410231G0203	40 files
ProTaper Gold F1 25MM	A0411225G0103	40 files
ProTaper Gold F1 31MM	A0411231G0103	40 files
ProTaper Gold F2 25MM	A0411225G0203	40 files
ProTaper Gold F2 31MM	A0411231G0203	40 files
ProTaper Gold F3 25MM	A0411225G0303	40 files
ProTaper Gold F3 31MM	A0411231G0303	40 files
<p><b>Products will be distributed to the below contact person and address:</b></p> <p><b>Dr.Nagesh Bolla</b>  <b>Professor and Vice-Dean</b>  <b>Department of Conservative Dentistry and</b>  <b>EndodonticsSibar Instirute of Dental Sciences</b>  <b>Takkellapadu, Guntur 522509</b>  <b>Andhra Pradesh</b>  <b>India</b></p>		



**Dr. L. KRISHNA PRASAD**  
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 GUNTUR-522509, A.P., India.



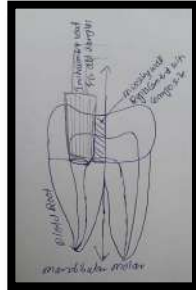
1. The investigator, or the Investigator's responsible Medical Institution, will act as the Sponsor for the IIS and will fulfill all the obligations of being a Sponsor.
2. The IIS will be conducted in accordance with this study proposal, and ISO 14155 or respective FDA requirements (if conducted in North America), as well as with all furtherregulatory requirements and local laws.
3. The Investigator will ensure that the IIS is approved by the Institution's IEC/IRB and, if appropriate, by the relevant regulatory authorities.
4. Major changes in study design and support requests, which are proposed after decision, might require a new application to be submitted.
5. When submitting the Study proposal, applicant information, such as name and title of the Investigator and the persons who will be involved in the study will be processed and stored in a central database, used by DENTSPLY IH AB (data controller) or any of its affiliates ("Dentsply Sirona"), for the purpose of documenting Dentsply Sirona's decision on whether to support the proposed study. You do not have any obligation to submit this information to us. However, the processing is based on a proposed contractual relation (legal ground for the processing); in so that we cannot proceed with your application should you not agree to us processing the above listed personal data. The personal data will furthermore be processed and stored in order to follow up on the studies that have been submitted as well as for statistical purposes. Depending on where the study will be conducted, the personal data may be transferred to countries outside of the European Economic Area (EEA), where the local laws may not grant the same level of data protection as is guaranteed by the EU General Data Protection Regulation (or similar legislation). All transfer of personal data will be done to support the objectives described above and we will make sure that appropriate safety measures are in place for the processing of the personal data. The personal data will not be stored longer than what is necessary considering the objective of the processing and in accordance with our corporate retention policy, unless we are legally obliged to keep it longer. The data subjects have the right to once a year and for free, request a copy of the information that Dentsply Sirona holds about them and to, at any time, request any inaccuracies in this information to be corrected, or that the information is deleted. In such a case, the data subject should use a written request and sign it personally and send it to DENTSPLY IH AB, Att: The Data Protection Officer, Box 14, 431 21 Mölndal, Sweden. For any questions regarding the processing of the personal data, please contact the Data Protection Officer, at [privacyoffice@dentsplysirona.com](mailto:privacyoffice@dentsplysirona.com). If there are any complaints regarding our processing that you do not want to present directly to us, you may turn to your local data protection authority.

<b>Investigator</b>	<input type="checkbox"/> I accept the conditions listed above. <input type="checkbox"/> I declare that all given information is correct.	
<i>Date (DD/MMM/YYYY)</i>	<i>Name (Principal Investigator)</i>	<i>Signature (omit if submitted digitally)</i>
07/02/2022	Dr. NAGESH BOLLA	

  
**Dr. L. KRISHNA PRASAD**  
 DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
 GUNTUR-522509, A.P., India.

## METHODOLOGY:

Eighty freshly extracted Human molar teeth (n=80)  
Palatal roots of maxillary molars / Distal roots of mandibular molars will be selected, missing wall of the teeth will be restored with composite with specific volume of pulp chamber maintained.



Root canals will be negotiated and enlarged up to a size of 25-06%, rinsed with 2ml of 17% EDTA for 2min followed by 5.25% NaOCl for 10 min, final rinse with distilled water.  
“Seal apices of all root tips and all surplus pulpal canal orifices with adhesive and flowable composite so that only the orifice of the shaped canal remains open”



Teeth will undergo Autoclave sterilization



Reseal the root apices if required  
Root canals will be rinsed with 5ml room temperature distilled water for 30 seconds, measure the ATP levels.



Insert growth media (TEST BACTERIA) into the root canals, incubate at 37°C for 4 weeks, replace growth media (TEST BACTERIA) twice per week.



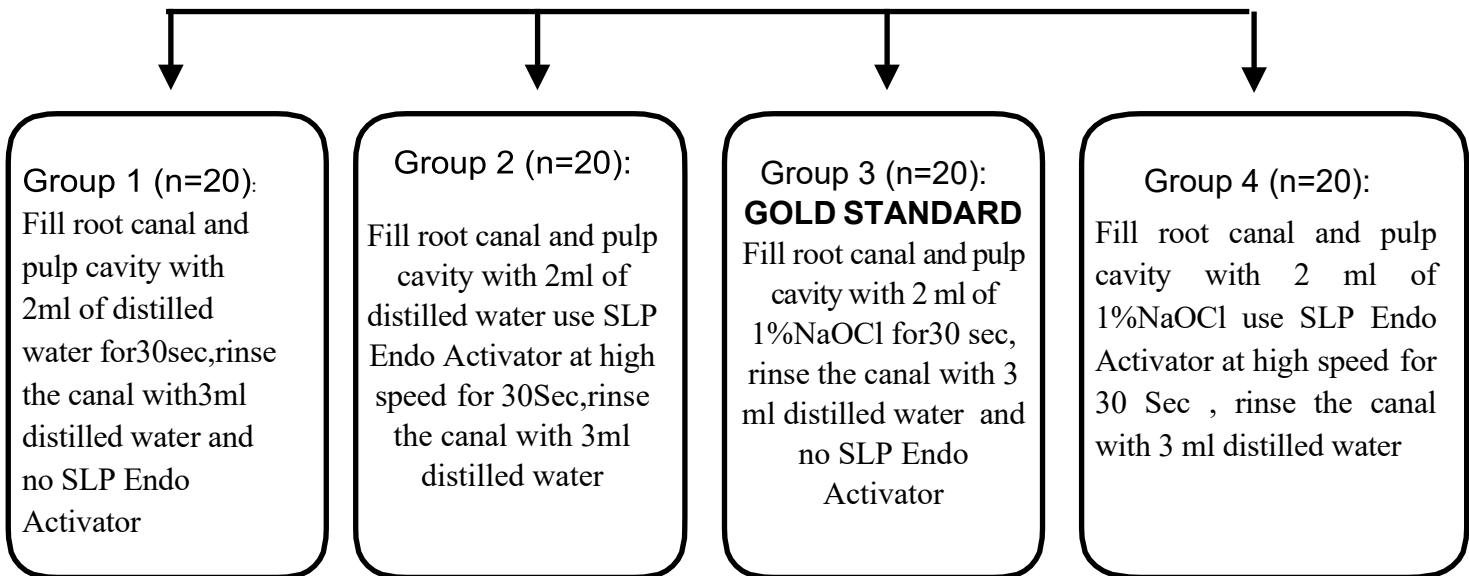
At the end of 4 weeks, all samples will be rinsed with 5ml of distilled water at room temperature with a 30 gauge syringe. “**Rinsing procedure**”: Always 30 gauge needle will be used while rinsing procedure and teeth and irrigants at room temperature.

### **“Sampling procedure” followed while taking ATP level and CFU count**

- Surplus water will be removed from pulp cavity using an uncapped saliva ejector. If required, root canal will be refilled with distilled water to canal orifice. Sample will be taken after 10 seconds soaking time. Syringe with 30 gauge needle will be pre-loaded with 200µl of distilled water. Needle tip will be placed 3 mm short of working length without actively scraping the canal walls. Fully aspirate liquid, fully reinject, then fully aspirate a final time. 100µl liquid will be used for ATP reader and 100µl for CFU count. After ATP reading, a drop of orthotolidine will be added to the ATP sample to check for NaOCl contamination. In case of contamination, ATP and CFU sample's will be retaken”. Measure inoculation ATP level and CFU count as a baseline.

TEETH WILL BE DIVIDED INTO FOUR GROUPS

## IRRIGATION PROCEDURE



### Irrigation ATP level and CFU count

1. Measure ATP level (CFU)
2. Re-enter irrigation procedure for 9 more times (for 5min total irrigation time)
3. Irrigation protocol followed at each level of activation

### FOR 4 GROUPS PROTOCOL FOR FINAL IRRIGATION:

1. Rinse with 3ml room temperature distilled water within 30 seconds
2. Leave the distilled water in place, treat each group for 60 sec with EA at high speed
3. Measure residual ATP level and CFU count per sampling procedure.

**Total 80 samples are involved no need of RE USE extracted teeth**

## **MATERIALS REQUIRED:**

1. Endomotors
2. SLP Endo Activator with Tips
3. Endo Cater ATP with Testers
4. Rotary Files
5. K-Files
6. Diamond disc for sectioning
7. Composites for missing wall replacement
8. Composite hand instruments with matrix system
9. Airotors
10. Access Opening Burs
11. Endo EZ Burs
12. Irrigating Syringes
13. Distilled Water
14. Sodium Hypochlorite (1%)
15. 17% EDTA
16. Paperpoints
17. Hand Instruments
18. Sterilization pouches
19. Test medium
20. Test Bacteria
21. Inoculation Loupe
22. Petridishes
23. Anaerobic Jar
24. Incubator
25. Laminar Airflow cabinet
26. Test Agar
27. Colony Counter etc...

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
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GUNTUR-522509, A.P., India.



**APPENDIX 2****Details of products to be provided:**

<b>Product</b>	<b>Ref. No.</b>	<b>Quantity</b>
Neo Spectra ST HV Syringe Refill A1 (1 syringe)	60701981	16 syringes
Neo Spectra ST flow Syringe Shade A1 Refill (2 syringes)	60701921	8 syringes
SLP Endo Activator	-	2 units
SmartLite Pro EndoActivator Barrier Sleeves (QTY 100)	644434	300 sleeves
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ProTaper Gold F3 25MM	A0411225G0303	40 files
ProTaper Gold F3 31MM	A0411231G0303	40 files

**Products will be distributed to the below contact person and address:**

Dr. Nagesh Bolla  
 Department of Conservative Dentistry and Endodontics  
 Sibar Institute of Dental Sciences  
 Takkellapadu, Guntur 522509  
 Andhra Pradesh, India  
 Email: drnageshendo@sids.ac.in



**Dr. L. KRISHNA PRASAD**  
 DEAN  
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 GUNTUR-522509, A.P., India.

## APPENDIX 3

## Financial support to be provided:

		Estimated payment date
One instalment due upon DS's review of final manuscript before submitting for publication	USD 2 000	2022-10

**Total cost: USD 2 000**

**Invoices will be sent to DS at:** Maillefer Instruments Sàrl,  
Att. Ole Brinkmann  
Chemin du Verger 3, CH-1338 Ballaigues,  
Switzerland

**Payments will be made to:** Account holder (Sponsor): Sibar Health and Research Foundation  
Account number: 32850725192  
Name of Bank, City: State Bank of India, Guntur  
Address: arundalpeta 4th Line, 4th Cross Road, Arundelpet, Guntur  
District, Guntur, Andhra Pradesh-522002  
SWIFT code: SBININBB181  
IFS Code: SBIN0001014

The invoice shall include all payment details and DS reference:

**E-2022-01**

Terms of payment: 30 days



**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

This Investigator Initiated Study Agreement (the “**Agreement**”) is made effective as of the last date of the signatures below (the “**Effective Date**”), by and between

**DENTSPLY IH AB**, a company incorporated in Sweden under registration No. 556051-8812, with office located at Aminogatan 1 (P.O. Box 14), SE 431 21 Mölndal, Sweden (“**DS**”);

Department of Conservative Dentistry and Endodontics, Sibar Institute of Dental Sciences, Takkellapadu, Guntur 522509, Andhra Pradesh, India (the “**Sponsor**”) and;

Prof. Nagesh Bolla, Department of Conservative Dentistry and Endodontics, Sibar Institute of Dental Sciences, Takkellapadu, Guntur 522509, Andhra Pradesh, India. Email: drnageshendo@sids.ac.in (the “**Principal Investigator**” or the “**PI**”)

Co-investigators:

Dr.Sayesh Vemuri Head of the department. Department of Conservative Dentistry and Endodontics, Sibar Institute of Dental Sciences, Takkellapadu, Guntur 522509, Andhra Pradesh, India

Dr.Ram Chowdary Basam, Senior lecturer. Department of Conservative Dentistry and Endodontics, Sibar Institute of Dental Sciences, Takkellapadu, Guntur 522509, Andhra Pradesh, India

Dr.Naveen reddy Vajrala – Postgraduate. Department of Conservative Dentistry and Endodontics, Sibar Institute of Dental Sciences, Takkellapadu, Guntur 522509, Andhra Pradesh, India

## Recitals

- (A) WHEREAS, the Sponsor and the PI wishes to conduct a research study concerning “*Evaluation of the efficacy of SLP EndoActivator Sonic Activation using ATP Bioluminescence meter: An In-vivo study*”, **E-2022-02** and has made a study proposal as specified in Appendix 1 to this Agreement (the “**Study Protocol**”) and where; (i) DS has no sponsor responsibilities for the study and (ii) DS’ contribution to the study is limited to 50 % of the total study cost whether the contribution consists of money, Study Products (as defined in Section 1.1 below) or others, altogether referred to as (the “**Investigator Initiated Study or Study**”)
- (B) WHEREAS, the Sponsor, the PI and DS share a mutual interest and benefit of the outcome of the Study and the Sponsor and PI have no medical, scientific or ethical concerns regarding its conduct.

## Agreement

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

### 1 DS Support

- 1.1 DS obligations under the Study will be explicitly limited to provide:
- DS products/components in sufficient amount in order to complete the Study, see Appendix 2 (the “**Study Product**”).
  - Funding which does not exceed USD 2 170 payable in one instalment in accordance with Appendix 3.
- 1.2 The Parties acknowledge that the amounts to be paid by DS under this Agreement are reasonable compensation, and represents DS’s full and complete obligation for any and all work performed by Sponsor, PI and Study Site Staff (as defined below). All payments made by DS under this Agreement are inclusive of value added taxes, sales taxes or similar taxes and fees.
- 1.3 The Parties confirm that the rights and obligations arising out of this Agreement do not relate to

or influence in any way whatsoever potential future business relationship between the Parties including but not limited to the formation of pricing concerning the procurement of medical devices. This Agreement has not been set up to influence decisions of Sponsor relating to its procurement planning of medical products. The Parties hereby exclude any expectation of preferred treatment as a consequence of this Agreement. Sponsor is free to introduce any other products than DS's products at any time and to stop using DS's products at any time without giving reason to DS.

- 1.4 Neither the Sponsor nor the PI shall seek payment from any third party for the services provided to a patient solely as a result of such patient's participation in the Study or the costs incurred in connection therewith.

## **2 Representations and warranties**

- 2.1 To safeguard the ethical conduct of the Study and the appropriate use of the Study Products it is hereby agreed that the Sponsor and the PI will be responsible for, and do hereby represent, warrant and covenant to DS that:
- 2.1.1 PI shall conduct the Study on a day-to-day basis, including delegation of specified Study responsibilities, training Study staff and supervising their work.
- 2.1.2 The Study is carried out in accordance with this Agreement, the Study Protocol, the ISO 14155 standard, all applicable laws and requirements, any condition required by a regulatory authority and/or an independent ethics committee/institutional review board (the "IEC/IRB").
- 2.1.3 Sponsor and PI shall comply with the local requirements relating to the reporting of possible adverse events and serious adverse events ("SAE") to the IEC/IRB and/or the regulatory authority. Sponsor and PI agree to report any SAE that are considered as probably or definitely related to the use of the medical device to DS within one day (i.e. immediately, but no later than the end of the next business day) of when he/she becomes aware of it. In case of a product related SAE, DS may request access to any relevant clinical documentation concerning the patient. Furthermore, Sponsor shall report all product claims that may occur to DS's local representatives.
- 2.1.4 The forms to be provided to potential persons in the Study to secure their informed consent to participate in the Study (the "Informed Consent Forms"), as approved by the IEC/IRB, must disclose that the Study is supported by DS and that Study documentation may be provided to representatives and affiliates of DS anywhere in the world and may be provided to any regulatory authority. DS shall be entitled to review the Informed Consent Forms to ensure that the Sponsor is clearly identified and that DS's support is correctly described.
- 2.1.5 There will be adequate time and resources to conduct the Study within the agreed time-schedule and to complete the Study before August 2022. In the event it has been determined by the Parties that the date for Study completion shall be postponed, the Parties agree that an amendment will be prepared in writing extending the completion date of the Study and agreed by authorized representatives of each Party.
- 2.1.6 DS gets informed of any changes (e.g. in equipment, or Study procedures) that may affect the use of the Study Products or completion of the Study.
- 2.1.7 The Study Products will be used only for this Study and only in accordance with the Study Protocol, Appendix 1 of this Agreement and in accordance with DS's instructions for use or other guidance. The Study Product shall remain the exclusive property of DS until used during the course of the Study. All unused Study Products shall, at Sponsor's expense, be returned to DS promptly upon the completion of the Study, unless otherwise notified by DS.
- 2.1.8 The medical (hospital/practice) records for each patient contain information according to local regulatory requirements. For Study specific information, a case report form provided by Sponsor will be used and considered as source document.
- 2.1.9 Sponsor and PI are responsible for that the Study patients, as in routine health care, are covered by medical insurance for standard of care procedures.

- 2.1.10 Registration of the Study on the “ClinicalTrials.gov” website is made no later than 21 days after enrolment of the first patient.
- 2.1.11 Sponsor, PI and all those investigators, employees, agents, students and others who are engaged by Sponsor and/or PI in the conduct of the Study (the “**Study Site Staff**”) will be properly registered with appropriate registration bodies and are sufficiently qualified by training and experience for conduct of the Study.
- 2.1.12 Neither Sponsor nor PI is subject to any conflicting obligations or legal impediments that might interfere with the performance of the Study or that might impair the acceptance of the resulting data by any regulatory authority or the grant of rights to DS hereunder, and no such obligations or impediments will be incurred or permitted during the course of this Agreement.
- 2.1.13 Sponsor and PI shall provide DS with the following information and materials:
- A copy of the Study Protocol
  - A status report every six (6) months during the duration of the Study, which shall summarize the work performed and the results achieved in connection with the Study
  - At DS’ request, preliminary high level study reports for DS to use for regulatory submissions and/or marketing purposes (the “**Preliminary Study Data**”)
  - A final report of Study results within 30 days after completion of the Study
  - A copy of the Health Authority approval, if applicable

### **3 Publication, review and disclosure of Study Data**

- 3.1 Publication. Sponsor and PI shall be entitled to use or present all records, accounts, notes, reports and data, collected, generated or used in connection with the Study (the “**Study Data**”) at conferences and submit the Study Data for publication in medical/dental journals of his/her/its choosing, provided this is (i) consistent with academic standards, (ii) is not false or misleading, and (iii) is not for commercial purposes.

An acknowledgment in all material aspects as set out below, is required when submitting the Study research results to society meetings and for publication in medical journals: ‘This research was conducted with support from Dentsply Sirona.’ This wording shall appear on all posters, as a sentence within all abstracts and as an acknowledgement in all manuscripts and presentations, as well as in any financial disclosure information.

Sponsor and PI further agree that, if PI publishes the results of the Study, DS is hereby granted a royalty-free license to make and distribute copies of such publication under any copyright privileges that Sponsor and/or PI may have. PI/Sponsor shall also be free to use such Study Data for his/her/its own internal teaching, research and patient care programs.

- 3.2 Review. Sponsor and PI agrees that prior to any presentation or publication of Study Data, DS shall have a period of thirty (30) days from receipt of the proposed publication or presentation to review its contents, and Sponsor and PI agrees, if requested, to delete any Confidential Information, at DS’s sole discretion. When submitted and approved for publication, Sponsor and PI should communicate this to DS.

If requested in writing by DS, Sponsor and PI shall delay the submission of such publication or presentation for an additional period, not to exceed a further sixty (60) days, to file a patent application or take such other measures as DS reasonably deems appropriate to establish and preserve the parties’ proprietary rights in any intellectual property disclosed in the material being submitted for publication or presentation.

- 3.3 Disclosure. DS will not disclose the Study Data to any third party as long as such Study Data remains unpublished or publicly undisclosed by Sponsor and/or PI, except that DS may disclose

such Study data to its affiliates on a need-to-know basis in order to evaluate such information.

It's noted that DS may disclose the Preliminary Study Data before the Study Data has been made public, provided prior written approval from the Sponsor and the PI has been obtained in each case and such disclosure would not be in conflict with future publications of the Study Data as set forth in Section 3.1.

#### **4 Confidentiality**

4.1 For purposes of this Agreement, confidential information means any information of DS, whether of a technical, business or other nature, including, but not limited to, information that relates to DS's trade secrets, products, promotional material, developments, proprietary rights or business affairs, together with any DS IP ("**Confidential Information**").

At all times during the Term of this Agreement (as defined below) and for a period of five (5) years following termination or expiration of this Agreement, neither Sponsor nor PI shall, without DS's prior written consent, publish, disseminate or otherwise disclose to any third party (except as may be permitted by this Agreement) any Confidential Information, and shall use such Confidential Information solely for purposes of performing its obligations under this Agreement. Sponsor and PI shall restrict the dissemination of Confidential Information to only those persons who have a need to know, and shall ensure that all persons involved in carrying out this Agreement are aware of this Agreement and bound by non-disclosure agreements at least as protective of Confidential Information as those set forth in this Agreement. Sponsor shall use at least the same care and discretion in maintaining the confidentiality of the Confidential Information as it uses with its most sensitive confidential information.

4.2 The obligations of confidentiality in Section 1 shall not extend to any Confidential Information that: (a) Sponsor can prove was lawfully obtained from a third party without any obligation of confidentiality, (b) Sponsor can prove was known to it prior to the date of this Agreement and was not subject to any confidentiality restrictions, or (c) is or becomes part of the public domain through no act or violation of any obligation of Sponsor or PI.

4.3 Neither Party shall make any public announcement relating to this Agreement or the transactions covered by it or mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its affiliates in any publication, press release, promotional material or other form of publicity without the prior written approval of that Party in each instance.

#### **5 Personal Data**

Each Party shall be responsible for its own processing of information and data that is directly or indirectly referable to a natural person who is alive ("**Personal Data**") and shall ensure that any Personal Data relating to Sponsor, PI and/or Study Site Staff, is collected, stored, used, disclosed and transferred in accordance with all applicable supranational and national privacy laws.

#### **6 Liability of the Parties**

6.1 DS is liable for any defects in the Study Product in accordance with general warranty terms and product liability legislations, save to the extent the Sponsor has an obligation towards DS pursuant to section 6.2 below.

6.2 Sponsor agrees to be liable and hold harmless DS and its officers, directors, partners, employees and agents from and against any and all liability, claims, losses, damages and expenses (including attorneys' fees) that arise as a result of any breach by PI or Sponsor of any representation, warranty, covenant, condition or obligation set forth in this Agreement. DS shall have the exclusive right to retain counsel of its choosing to represent itself and shall retain exclusive control of the litigation; provided, however, that DS will not compromise or settle any such litigation without the prior consent of Sponsor, which shall not be unreasonably withheld or delayed.



6.3 Each Party hereto agrees to be responsible and assume liability for its own wrongful or negligent acts or omissions, or those of its officers, agents or employees to the full extent required by law.

## **7 Term and Termination**

7.1 This Agreement shall commence upon the Effective Date and shall continue until the completion of the Study (the "**Term**"), unless this Agreement is earlier terminated in accordance with this Article 7.

7.2 Either Party have the right to terminate this Agreement upon thirty (30) days' notice to the respective Party. In the event of termination, DS shall reimburse the PI/Sponsor for all work completed to the date of termination, provided that Sponsor and PI shall return and repay to DS any unused funds and materials. The reimbursement from DS shall however not exceed the funding and Study Products specified in Appendix 2 and Appendix 3 of this Agreement.

7.3 Upon termination or expiration of this Agreement or upon DS's earlier request, Sponsor and PI shall promptly return to DS all Confidential Information.

## **8 Miscellaneous**

8.1 Assignment. This Agreement may not be assigned by either Party in whole or in part without the prior written consent of the other Party, except that DS without such consent may assign this Agreement and its rights and obligations hereunder to any of its affiliates or any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of the business to which this Agreement relates. DS shall always have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its affiliates.

8.2 Governing Law. This Agreement shall be governed by the laws of Sweden.

8.3 Entire Agreement. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter of the Agreement. This Agreement supersedes all prior agreements, whether written or oral, with respect to the subject matter of the Agreement. All Appendix referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement. In the event of any inconsistency between any such Appendix and this Agreement, the terms of this Agreement shall govern.

8.4 Amendment. Any amendment or modification of this Agreement must be in writing and signed by authorised representatives of both Parties.



**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

**Execution**

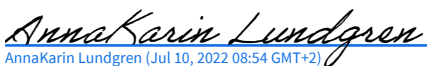
This Agreement has been duly executed in two (2) original copies, one to each Party.

**DENTSPLY IH AB**

Date (YYYY-MM-DD):

2022-07-10

Signature:



AnnaKarin Lundgren (Jul 10, 2022 08:54 GMT+2)

Name: AnnaKarin Lundgren

Title: Director Center of Clinical Research  
Clinical Research and Scientific Support

**SPONSOR (on behalf of Institution)**

Date (YYYY-MM-DD):

2022-07-06

Signature:



L Krishna Prasad (Jul 6, 2022 13:01 GMT+5.5)

Name: Dr. L. Krishna Prasad

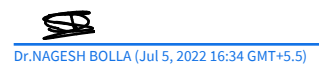
Title: Dean

**AGREED AND CONSENTED TO BY:**

Date (YYYY-MM-DD):

2022-07-05

Signature:



Dr.NAGESH BOLLA (Jul 5, 2022 16:34 GMT+5.5)

Name: Prof. Nagesh Bolla

Title: Principal Investigator



**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

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**APPENDIX 1**  
**Clinical Investigation Plan (CIP)**

See next page.

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

<b>Applicant information</b>	
Principal Investigator <i>(Title and name)</i>	Dr.Nagesh Bolla
Name of Institution/  ClinicAddress	Professor and Vice- Dean Department of Conservative Dentistry and Endodontics Sibar Institute of Dental Sciences Takkellapadu, Guntur 522509 Andhra Pradesh India
E-mail address	drnageshendo@sids.ac.in
Please list all investigators who will be involved in your study <i>(Please specify name, title, anticipated function, institution/clinic)</i>	Dr.Sayesh Vemuri Head of the department Anticipated function: Observation/Guiding Dr.Ram Chowdary Basam, Senior lecturer Anticipated function: Sample collection/Observation Dr.Naveen reddy Vajrala - Postgraduate Anticipated function: Data collection
Please indicate the reason for your interest in collaboration with Dentsply Sirona	To determine the efficacy of SLP Endoactivator in removing the intracanal debris during root canal irrigation.

<b>Information about the study</b> <i>(Please be detailed, if required additional documents can be attached as an appendix)</i>	
<b>Study title</b>	Evaluation of the efficacy of SLP EndoActivator Sonic Activation using ATP Bioluminescence meter: An In-vivo study
<b>Study objectives</b> <i>(Including hypothesis)</i>	To evaluate the effectiveness of SLP EA in cleaning the root canal system. To evaluate the ATP levels in the root canal system after root canal instrumentation and activation with SLP EA. To evaluate the ATP levels in the root canal system after root canal instrumentation with gold standard irrigation protocol. To compare the ATP levels in the root canal system after root canal instrumentation with SLP EA and gold standard irrigation protocol.  Hypothesis: That use of the SLP EndoActivator may result in lower levels of ATP in the root canal system when compared to root canals that did not use the SLP EndoActivator.
<b>Importance of results</b> <i>(Please detail the scientific, practical or clinical relevance of the findings of the study)</i>	Study will help to justify the application of SLP Endoactivator sonic activation as an important adjunct during chemomechanical preparation.

  
**Dr. L. KRISHNA PRASAD**  
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<p><b>Study design</b> <i>(A brief summary of major study design features i.e. in vitro, animal or clinical study, follow up times and study end point)</i></p>	<p>Clinical study for evaluation of ATP levels during root canal irrigation procedure. See Attached document-Materials and Methods for further details.</p>
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**Dr. L. KRISHNA PRASAD**  
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GUNTUR-522509, A.P., India.

<p><b>Study population</b> <i>(For clinical/animal study describe target population, indication studied and inclusion/exclusion criteria's)</i></p>	<p>Inclusion criteria: Patients diagnosed with pulp necrosis. Maxillary and mandibular molar teeth.</p> <p>Exclusion criteria: Patients not willing to participate in the study. Teeth with Apical size&gt;40</p>
<p><b>Number of planned patients</b> <i>(If multi-centre study also describe the distribution per study site)</i></p>	<p>100 Patients referred to department of conservative dentistry and endodontics with diagnosis of pulpal necrosis in relation to maxillary and mandibular molars.</p>
<p><b>Study centre(s)</b> <i>(The site(s) were the majority of the research will be conducted)</i></p>	<p>Sibar Institute of Dental Sciences, Takkellapadu, Guntur.</p>
<p><b>Estimated study period</b> <i>(MMM/YYYY)</i></p>	<p>5/3/2022 - 31/6/2022</p>
<p><b>Milestones</b> <i>(Detail the different milestones /important events in the study and at which date you estimate them to occur. Examples of milestones are first patient included, all patients included, last follow up conducted or end of an experimental serie)</i></p>	<p>28/2/2022 IRB approval 28/3/2022 First patient recruited to the study 31/6/2022 Completion of experiment and submission of data (DEPENDS ON PANDEMIC)</p>

<p><b>Investigational product/comparator</b> <i>(State the devices/ products that will be investigated/ used and for comparative studies also the comparator/s)</i></p>	<p>SLP Endo Activator  Endocator ATP tester</p>
<p><b>Outcome variables</b> <i>(Describe which variables will be included in the study i.e. what will be measured and how is it related to the results)</i></p>	<p>--Cleaning and Disinfection ability of SLP Endo Activator is evaluated by measuring ATP levels</p> <p>(- Baseline ATP level,</p> <p>- Intermediate ATP level-with SLP Endo Activator,</p> <p>-Intermediate ATP Level –gold standard irrigation, ,</p> <p>-Residual ATP Level- with SLP EA.</p> <p>-Recording the lower levels of ATP after cleaning and shaping indicates cleanliness of root canal system.</p> <p>-Recording the lower levels of ATP after cleaning and shaping indicates the clinical efficacy of endoactivator.</p>
<p><b>Materials and methods</b> <i>(Detail the procedures, methods and measurements that will be conducted within the study)</i></p>	<p>See attached</p>

  
**Dr. L. KRISHNA PRASAD**  
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 GUNTUR-522509, A.P., India.




<p><b>Statistical methods</b> <i>(Detail the statistical tests, populations for comparison, sample size, intention to treat, per-protocol and any interim analyses)</i></p>	<p>Results will be analysed using unpaired t test.</p>
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<p><b>Publications &amp; presentation s</b> <i>(Describe plans for publication or public presentations of results also give examples of journals to submit to or conferences/ meetings to attend)</i></p>	<p><b>PUBLICATIONS &amp; PRESENTATIONS - SEE ATTACHED</b></p> <p><b>PLANS FOR PUBLICATION/PRESENTATIONS:</b> After getting approval from Dentsply, Study can be submitted to</p> <ol style="list-style-type: none"> <li>1. International Endodontic Journal</li> <li>2. Journal of Endodontics</li> <li>3. Dental Research Journal</li> <li>4. Restorative Dentistry &amp; Endodontics</li> </ol> <p>Journal of Conservative Dentistry,.....etc</p>
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<p><b>Research experience as principal investigator</b> <i>(If applicable, please describe your previous research experience and number of published articles in international peer-reviewed journals with you as principal investigator)</i></p>	<p><b>NUMBER OF PUBLICATIONS: 59</b></p> <p><b>NUMBER OF YEARS OF EXPERIENCE: 18 YEARS</b></p>
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<p><b>Total study cost</b> <i>(Estimate a reasonable total budget for the study. Detail costs for materials, products, staff, procedures, measurements, ethical approvals etc.)</i></p>	<p>Approximately four lakh Indian rupees or five thousand three fourty (5,340) USD. In addition, products with a sales value approximately 1,000 USD. Total sum is approximately 6,340 USD.</p> <p>Four lakh Indian rupees (Approximately)</p> <ol style="list-style-type: none"> <li>A. Materials /Products Cost: One Lakh and Twenty Five Thousand Indian Rupees (Approximately)</li> <li>B. STAFF: Two Lakh Indian Rupees (Approximately)             <ol style="list-style-type: none"> <li>a. Investigator's: 2 (Approximate payment for 3 Months: Eighty Thousand Indian Rupees)</li> <li>b. Microbiologist: 1 (Approximate payment for 3 Months: Sixty Thousand Indian Rupees)</li> <li>c. Microbiology Technician: 1 (Approximate payment for 3 Months: Sixty Thousand Indian Rupees)</li> </ol> </li> <li>C. Procedures: Forty thousand Indian Rupees (Approximately) {Incubator, Laminar airflow cabinet}</li> <li>D. MEASUREMENTS: Twenty Five thousand Indian Rupees (Approximately) {Manual,/Digital CFU counting}</li> <li>E. SAMPLE TRANSPORT COSTS: Ten thousand Indian Rupees (Approximately)</li> </ol> <p><input type="checkbox"/></p>
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<b>Requested Support from Dentsply Sirona</b>	
<p><b>Support requested</b> <i>(Products and funding. For funding detail the amount to be covered by requested support. For products detail these in the next section)</i></p>	<p>YES. Product for 1000 USD and financial support of 2170 USD.</p> <div style="text-align: right; margin-top: 20px;">   <b>Dr. L. KRISHNA PRASAD</b>              DEAN  <b>SIBAR INSTITUTE OF DENTAL SCIENCES</b>              GUNTUR-522509, A.P., India.           </div>

<p><b>Further support</b> <i>(Did you or do you plan to request further support by anyother person/ institution/ company?)</i></p>	<p>YES Dr.Cross guiding and helping out the protocols and procedures. Dentsply supporting materials and financial.</p>
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**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

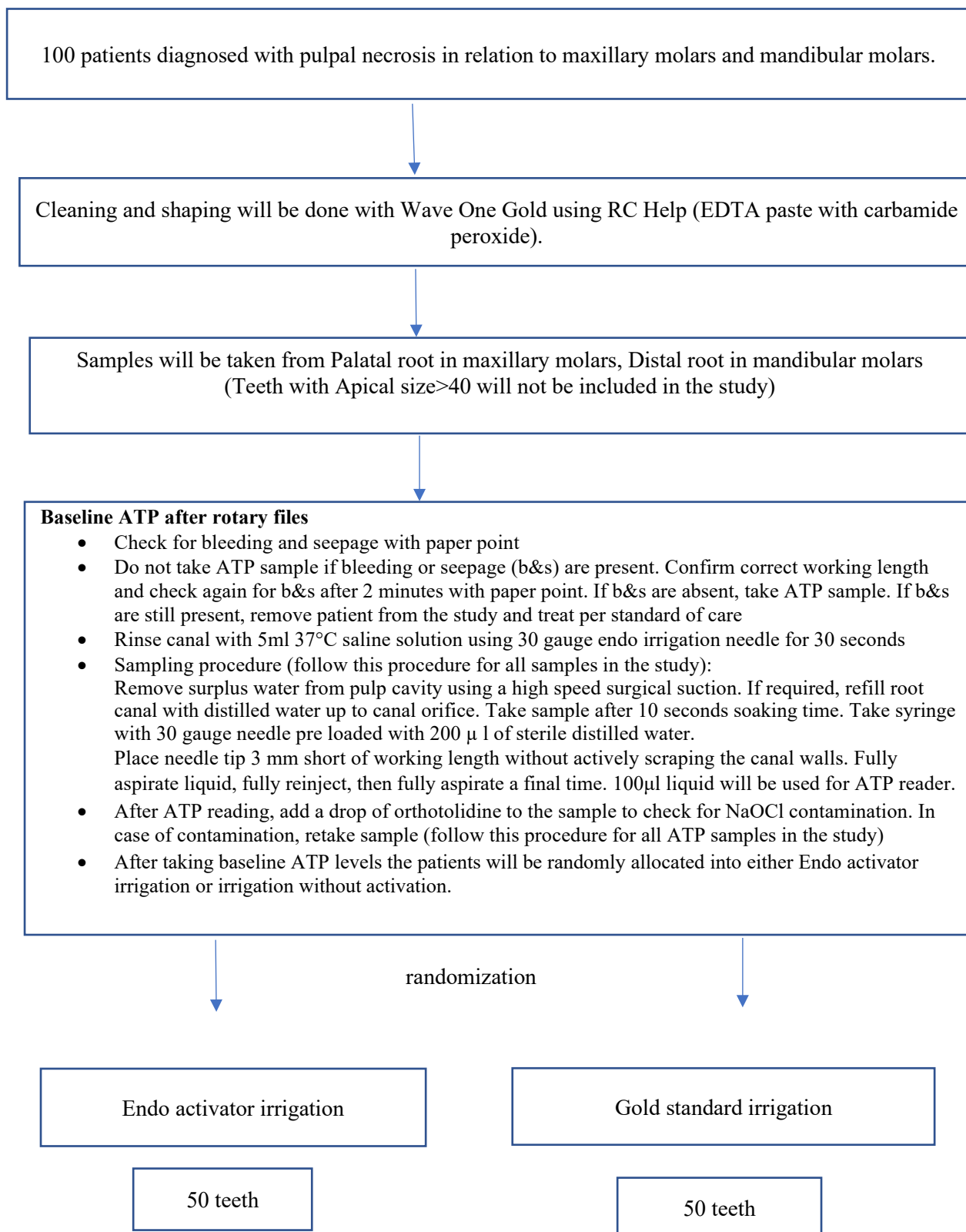
## **MAERIALS AND METHODOLOGY**

### **Materials :**

Endoaccess bur  
K –files  
Endo EZ bur  
Wave one gold rotary files  
Saline  
Distilled water  
17% EDTA  
5.25% NaOCl  
30 guage syringe  
Saliva ejector  
Endo activator  
Endo motor  
SLP Endo Activator  
SLP Endo Activator tips  
Gutta percha points  
Paper points  
AH plus sealer  
Transport media

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

## Methodology



**Intermediate ATP level (after 60 seconds irrigation)**

- Check for bleeding and seepage with paper point
- Fill the canal with 2 ml 5.25% NaOCl using 30 gauge endo irrigation needle up to level of canal orifice.
- Use SLP- Endo Activator at high speed for 60 seconds.
- Rinse canal with 5ml 37°C saline solution using 30 gauge endo irrigation needle for 30 seconds
- Remove liquid from coronal pulp chamber with uncapped disposable saliva ejector
- If required, reapply saline solution to refill canal up to level of canal orifice
- After 10 seconds, measure ATP level

**Intermediate ATP level (after 60 seconds irrigation)**

- Check for bleeding and seepage with paper point
- Fill canal with 2ml 5.25% NaOCl using 30 gauge endo irrigation needle up to level of canal orifice
- Allow for 60 seconds soaking time
- Rinse canal with 5ml 37°C saline solution using 30 gauge endo irrigation needle for 30 seconds
- Remove liquid from coronal pulp chamber with uncapped disposable saliva ejector
- If required, reapply saline solution to refill canal up to level of canal orifice
- After 10 seconds, measure ATP level.

**Residual ATP level**

- Check for bleeding and seepage with paper point
- Rinse canal with 5ml 37°C saline solution using 30 gauge endo irrigation needle for 30 seconds
- Remove liquid from coronal pulp chamber with uncapped disposable saliva ejector.
- If required, reapply 37°C saline solution to refill canal up to level of canal orifice.
- Use SLP-Endo Activator at high speed for 60 seconds.
- If required, reapply 37°C saline solution to canal up to level of canal orifice
- After 10 seconds, measure ATP level

Finish root canal treatment (shaping, cleaning, obturation) per standard of care.

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**APPENDIX 2****Details of products to be provided:**

<b>Product</b>	<b>Ref. No.</b>	<b>Quantity</b>
SLP Endo Activator motor		1
Endo Activator tips (Medium)	644436	100
Endo Activator tips (Medium long)	644437	100
SLP Endo Activator tips small	644435	100
SmartLite Pro EndoActivator Barrier Sleeves (QTY 100)	644434	100

**Products will be distributed to the below contact person and address:**

Prof. Nagesh Bolla  
Department of Conservative Dentistry and Endodontics  
Sibar Institute of Dental Sciences  
Takkellapadu, Guntur 522509  
Andhra Pradesh  
India.  
Email: drnageshendo@sids.ac.in



**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.



## APPENDIX 3

## Financial support to be provided:

Estimated  
payment date

One instalment due upon DS's review of final manuscript for publication	USD 2 170	2022-09
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**Total cost: USD 2170**

## Invoices will be sent to DS at:

Maillefer Instruments Sàrl,  
Att. Ole Brinkmann  
Chemin du Verger 3, CH-1338 Ballaigues,  
Switzerland

## Payments will be made to:

Account holder (Sponsor): Sibar Health and Research Foundation  
Account number: 32850725192  
Name of Bank, City: State Bank of India, Guntur  
Address: arundalpeta 4th Line, 4th Cross Road, Arundelpet, Guntur  
District, Guntur, Andhra Pradesh-522002  
SWIFT code: SBININBB181  
IFS Code: SBIN0001014

The invoice shall include all payment details and DS reference:

**E-2022-02**

Terms of payment: 30 days



**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

To  
The Convener, IEC-SIBAR,  
Takkellapadu, Guntur.

**Project Title:** Evaluation of microbial load with Endocator ATP tester in human root canals before, during and after root canal procedures : An In-vivo study

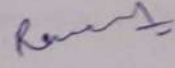
**Department of:** CONSERVATIVE DENTISTRY AND ENDODONTICS  
Sibar Institute of Dental Sciences, Guntur.

**Principal Investigator**

Name : NAGESH BOLLA  
Affiliation : Professor & Vice Dean  
Email : drnageshendo@sids.ac.in  
Mobile. No : 9848885658

Duration of the study : 1 year 6 months  
Sponsors (if any with details) : ATP testers – Dr. Cross  
Instruments and cultures- Sibar institute of dental sciences  
Approval from any other ethics / regulatory committee (if required): No

We shall follow the Good Clinical Practice guidelines and the approved protocol in conducting the research project. Further, we declare that any sort of inclusion of text or pictorial material which amounts to plagiarism will be avoided. In case of any serious adverse events, I/We shall bring it to the notice of IEC-SIBAR

1. Dr. Sayesh Vemuri
2. Dr. Ram sunil .CH
3. Dr. Roopa Garlapati
4. Dr. Ram chowdary. B 
5. Dr. Sravanthi . T



Signature of the Investigator(s)

Signature of the Co-Investigator(s)

  
Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

The proposal has been verified as per the requirement mentioned in the information broacher and forwarded to the IEC- SIBAR for approval. Synopsis of the project, Informed consent form, Case record form and Study flow chart are enclosed.



# INSTITUTIONAL ETHICS COMMITTEE

Sibar Institute of Dental Sciences

Takkellapadu, GUNTUR - 522 509, Andhra Pradesh

(Registration No: ECR/1362/Inst / AP/2020)

Ref No: 2/IEC-SIBAR/CIR/21


Date: 20/07/2021

The protocol No. (Pr.68/IEC/SIBAR/2021) entitled "Evaluation of microbial load with endocator ATP tester in human root canals before, during and after root canal procedures: An in -vivo study" submitted by Dr. Nagesh Bolla, Professor & Vice Dean, in the Department of Conservative Dentistry and Endodontics, has been cleared by IEC - SIBAR for carrying out during July 2021 - Nov 2022.

Any alterations in the protocol is possible only after approval of IEC - SIBAR

1. Six months progression and closure report should be submitted to the IEC - SIBAR
2. Soft copies of all documents related to the execution of the current research project must be submitted to the IEC - SIBAR at closure of the project

  
Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

  
Dr. B. V. Ramana Reddy  
MEMBER SECRETARY  
Institutional Ethics Committee  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR



# COMMERCIAL INVOICE

Hygiena LLC  
 941 Avenida Acaso  
 Camarillo, CA 93012  
 USA  
 Phone: 805-388-8007  
 Fax: 805-388-5531  
 http://www.hygiena.com

Order Number: HLSO346058  
 Order Date: 8/18/2021

**Bill**  
**To:** Quantitative Endodontics  
 Randy Cross  
 475 Sumner ave  
 Aptos, CA 95003  
 USA

**Ship**  
**To:** Dr.NAGESH BOLLA, VICE DEAN  
 DEPARTMENT OF CONSERVATIVE DENTISTRY  
 SIBAR INSTITUTE OF DENTAL SCIENCES  
 TAKKELLAPADU, 522509  
 GUNTUR , ANDHRA PRADESH  
 India

**Terms:**  
**INCOTERMS:** PPDADD  
**Ship Date:** 9/2/2021  
**Due Date:** 08/18/2021  
**Customer Contact:** Randy Cross  
**Customer Phone No.:** (415) 871-6108  
**Customer Email Address:** atpbacterialtesting@gmail.com

**Customer No.:** HLC036158  
**P.O. Number:** DDSRANDYCROSS  
**Sales Manager:** USA OEM  
**Shipping Agent:** Federal Express Corporation  
**Agent Service:** PRIORITY-I

Item No.	Ref. Item No.	Description	UOM	Quantity	Unit Price (USD)	Total Price (USD)
ASY0222	SUS3000	Supersnap Extra Sensitive ATP, White Bx 100 Tests/Box HTS Lot(s) shipped Lot Qty. 3822000002	Box	40	\$235.00	\$9,400.00
ASY0260	SS3	Without Labels 500uL fill - ATP Swab Device SystemSURE PLUS Luminometer HTS Lot(s) shipped Lot Qty. 9027804560	Each	1	\$1,500.00	\$1,500.00

  
**Dr. L. KRISHNA PRASAD**  
 DEAN  
 SIBAR INSTITUTE OF DENTAL SCIENCES  
 GUNTUR-522509, A.P., India.



Subtotal: \$10,900.00  
 Total Sales Tax  
 Total (USD): \$10,900.00



# Commercial Invoice

This invoice must be completed in English.

Page 1 of 1

<b>EXPORTER:</b> Tax ID#: _____ Contact Name: <b>RANDOLPH CROSS</b> Telephone No.: (415) 871-6108 E-Mail: <b>DDS.CROSS@GMAIL.COM</b> Company Name/Address: <b>RANDOLPH CROSS</b> <b>475 SUMNER AVE</b>  <b>APTOS CA 95003</b> Country/Territory: <b>UNITED STATES OF AMERICA</b> Parties to Transaction: <input type="checkbox"/> Related <input checked="" type="checkbox"/> Non-Related	Ship Date: <b>14 Mar, 2022</b> Air Waybill No. /Tracking No.: <b>270861372974</b> Invoice No.: _____      Purchase Order No.: _____  Payment Terms: _____      Bill of Lading: _____  Purpose of Shipment: <b>GIFT</b>
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<b>CONSIGNEE:</b> Tax ID#: _____ Contact Name: <b>DR NAGESH BOLLA , VICE DEAN</b> Telephone No.: 9848885658 E-Mail: <b>BOLLANAGESH@YAHOO.CO.IN</b> Company Name/Address: <b>SIBAR INSTITUTE OF DENTAL SCIENCES</b> <b>DEPT OF CONSERV DESNTISTRY&amp;ENDODONT</b> <b>TAKKELLAPADU , ANDHRA PRADESH</b>  <b>Guntur 522509</b> Country/Territory: <b>INDIA</b>	<b>SOLD TO /IMPORTER (if different from Consignee):</b> <input checked="" type="checkbox"/> Same as CONSIGNEE:  Tax ID#: _____  Company Name/Address:   Country/Territory: <b>INDIA</b>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

If there is a designated broker for this shipment, please provide contact information.

Name of Broker \_\_\_\_\_ Tel. No. \_\_\_\_\_ Contact Name \_\_\_\_\_

Duties and Taxes Payable by  Exporter  Consignee  Other    If Other, please specify \_\_\_\_\_

No. of Packages	No. of Units	Net Weight (LBS /KGS)	Unit of Measure	Description of Goods	Harmonized Tariff Number	Country of Manufacture	Unit Value	Total Value
	25.00	37.80	Pieces	DENTAL SUPPLIES - DONATED DENTAL SUPPLIES/DENTAL CLINIC USE. NOT FOR RESALE		US	12.800000	320.00

Total Pkgs	Total Units	Total Net Weight	(Indicate LBS/KGS)	Total Gross Weight	(Indicate LBS/KGS)	Terms of Sale: <b>FCA</b>	Subtotal:	320.00
1	25.00	37.80	LB	37.80	LB		Insurance:	0.00

Special Instructions:	Freight:	0.00
	Packing:	0.00
Declaration Statement(s):	Handling:	0.00
	Other:	0.00

I declare that all the information contained in this invoice to be true and correct.      Invoice Total: 320.00

Originator or Name of Company Representative if the invoice is being completed on behalf of a company or individual: **RANDOLPH CROSS**      Currency Code: **USD**

Signature /Title /Date: \_\_\_\_\_ 14 Mar, 2022

  
**Dr. L. KRISHNA PRASAD**  
 DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
 GUNTUR-522509, A.P., India.

Randolph Cross D.D.S,  
A Professional Corporation

# Sales Receipt

Date: 3/8/22  
Receipt # 003

**Sold To** Dr. Nagesh Bolla  
Vice Dean, Department of Conservative Dentistry and  
Endodontics  
Sibar Institute of Dental Sciences  
Takkellapadu, Guntur - 522509  
Andhra Pradesh  
India  
(984) 888-5658  
dmageshendo@sids.ac.in

Payment Method	Check No.	Job
Free Samples	NA	Dental Clinic Personal Use

Qty	Item #	Description	Unit Price	Discount	Line Total
80	NA	25 pack of testers	\$4 a pack	\$320	\$320-\$320=\$0

Total Discount	\$320	\$0
Subtotal		\$0
Sales Tax		\$0
Total		\$0

Thank you for your business!

Randolph Cross D.D.S, A Professional Corporation, 475 Sumner Ave, Aptos CA 95003 United States of America

(415) 871-6108 DDSCross@gmail.com

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.



MAILLEFER INSTRUMENTS HOLDING S.A.R.L  
Chemin du Verger 3 1338 Ballaigues  
Switzerland  
UBS MIH CHF (70104701J)  
IBAN: CH210029729770104701J - Swift/BIC: UBSWCHZH80A

Tel. +41 (0)21 843 92 92  
Fax +41 (0)21 843 92 93

info@dentsplymaillefer.c  
www.dentsplymaillefer.c

VAT:CHE-116.355.018 TVA

INVOICE 110109228

Date: 30.03.2022  
Page: 1 of 2

Customer PO: MAIL JGB 23.12.ADD  
Customer No: 120149  
Your VAT No:

Dentsply India PVT LTD.

Khasara No.66/20 & 66/11/2, Gali No. 2, Main Ro  
Road,Mundka Industrial Area  
110041 DEHLI  
India


Delivered to  
Dentsply India PVT LTD.  
Dr.NAGESH BOLLA  
Department of Conservative Dentistry and Endodontics  
Sibar Institute of Dental Sciences  
TAKKELLAPADU  
522509 Guntur, Andhra Pradesh  
India

Sales Order No.: SO0108944  
E-mail: sonia.dilaura@dentsplysirona.com

Terms of payment:  
Delivery term: DDP  
Delivery mode: UPS - EXPRESS SAVER

Packing list no.:

Pos	Product code	Description	Qty	Unit price	Net value
1	BSTTNMM421GLR	TRUNATOMY GLIDER 4-FILES 21MM MU 90184900 CH Quantity: 32 Batch number: 1754722 FREE OF CHARGE / CUSTOMS VALUE CHF. 496.00 UNIT PRICE CHF 15.50	32	15.50	496.00
2	BSTTNMM425GLR	TRUNATOMY GLIDER 4-FILES 25MM MU 90184900 CH Quantity: 80 Batch number: 1748698 FREE OF CHARGE / CUSTOMS VALUE CHF. 1'240.00 UNIT PRICE CHF 15.50	80	15.50	1'240.00
3	BSTTNMM431GLR	TRUNATOMY GLIDER 4-FILES 31MM MU 90184900 CH Quantity: 8 Batch number: 1688451 Quantity: 24 Batch number: 1754727 FREE OF CHARGE / CUSTOMS VALUE CHF. 496.00 UNIT PRICE CHF 15.50	32	15.50	496.00

  
VICE-DEAN 10/5/2022  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509., A.P

Net amount CHF 2'232.00  
Cost 0.00  
Total amount CHF 2'232.00

  
Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.



**PACKING LIST/BOX DETAILS**

DENTSPLY India Pvt. Ltd.  
DENTSPLY India Pvt. Ltd.  
CIN-U74899DL1995PTC073183  
Kh.No. 66/20 & 66/11/2 Gali No.2  
Main Rothak Road  
Mundka Industrial Area  
Delhi  
DELHI  
IN-110041

PACKING LIST NC: PS-272953  
DATE .....: 16/Feb/2022  
LST NO. ....: 07390187419  
CST NO. ....: LC/96/187419/04  
ORDER NO. ....: SO-222701  
Customer PO .....: Dr. Nagesh Bolla

I DENTSPLY MARKETING - SOUTH  
N Capsule Works, #3, Manandi Plaza,  
V 1st Floor (Wing 1 facing towards  
O South), St. Marks Rd, Shanthala  
I Nagar, Ashok Nagar, Bengaluru,  
C Karnataka-560001, India (Next to St.  
E Marks Hotel)  
BANGALORE  
T KARNATAKA  
O IN-560001

S Dr. Nagesh Bolla  
H Dr. Nagesh Bolla  
I Professor & Vice Dean  
P Department of conservative dentistry  
& endodontics  
Sibar institute of Dental Sciences  
Takkellapadu, Guntur, Andhra  
Pradesh  
T Pincode: 522509  
O Mobile: 9848885658

TAKKELLAPADDU  
ANDHRA P.  
IN-522509

CST No. :  
LST No. :

CST No:  
LST No:

Product No.	Description	Batch/Serial No.	Expiry Date	Quantity	BOX
A0756221G0P03	WAVEONE GOLD PRIMARY 6-FILE STER 21mm	1745447	11/Jan/2027	16.00	PR-794116/
A0756225G0L03	WAVEONE GOLD LARGE 6-FILE STER 25mm	1743182	21/Dec/202	24.00	PR-794116/
A0756225G0M03	WAVEONE GOLD MEDIUM 6-FILE STER 25mm	1743439	22/Dec/202	32.00	PR-794116/
A0756225G0P03	WAVEONE GOLD PRIMARY 6-FILE STER 25mm	1743807	23/Dec/202	56.00	PR-794116/
A091200000000	ENDOACTIVATOR HANDPIECE DRIVER	20211018-00		1.00	PR-794116/
A091200000000	ENDOACTIVATOR HANDPIECE DRIVER	20211018-00		1.00	PR-794116/
A091200000000	ENDOACTIVATOR HANDPIECE DRIVER	20211018-00		1.00	PR-794116/
A091302201500	ENDOACTIVATOR ACTIV. TIP SMALL	21062810	31/Dec/209	8.00	PR-794116/
A091302202500	ENDOACTIVATOR ACTIV. TIP MEDIUM	21062810		14.00	PR-794116/
A091302203500	ENDOACTIVATOR ACTIV. TIP LARGE	21071912	31/Dec/209	6.00	PR-794116/
A141021600100	PROTAPER RETREAT D1	1743027		24.00	PR-794116/
A141021800100	PROTAPER RETREAT D2	1743026		10.00	PR-794116/
A141021800100	PROTAPER RETREAT D2	1745864		14.00	PR-794116/
A141022200100	PROTAPER RETREAT D3	1740746		9.00	PR-794116/
A141022200100	PROTAPER RETREAT D3	1745862		15.00	PR-794116/
A175W00000L03	WAVEONE GOLD PAPER POINTS - LARGE	021021	30/Sep/202	10.00	PR-794116/
A175W00000M03	WAVEONE GOLD PAPER POINTS - MEDIUM	021021	30/Sep/202	10.00	PR-794116/
A175W00000P03	WAVEONE GOLD PAPER POINTS - PRIMARY	021021	30/Sep/202	20.00	PR-794116/
A175W00000S03	WAVEONE GOLD PAPER POINTS - SMALL	021021	30/Sep/202	10.00	PR-794116/
B00WGGPF00LRG	WAVEONE GOLD CONFORM FIT™ GUTTA-PERCHA Large - BOX OF 60	0000313331	19/Aug/202	5.00	PR-794116/
B00WGGPF00MED	WAVEONE GOLD CONFORM FIT™ GUTTA-PERCHA Medium - BOX OF	0000307709	01/Aug/202	10.00	PR-794116/
B00WGGPF00PRI	WAVEONE GOLD CONFORM FIT™ GUTTA-PERCHA Primary - BOX OF	0000313359	28/Jul/2025	20.00	PR-794116/



DEPT. OF CONSERVATIVE DENTISTRY  
& ENDOENTONICS  
SIBAR INSTITUTE OF DENTAL SCIENCE  
TAKKELLAPADU (Guntur Dt.)

Page: 1 of 2

Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

# DELIVERY CHALLAN CUM GATE PASS

**DENTSPLY INDIA PVT. LTD.**

Khasara No. 66/20 & 66/11/2, Gali No. 2,  
Main Rohtak Road, Mundka Industrial Area,  
Delhi-110041 India, Telephone +91 11 66210000 / 021  
CIN : U74899DL1995PTC073183  
GST No. : 07AAACD3171E1Z3




DLDC222300 **0237**

Mob-9848885658


Date 02/06/22

To DR. Nagresh Balla, Professor & Vice. Dem,  
Department of Conservative Dentistry & Endodontics  
Talukalpadu Guntur Andhra Pradesh. Pin-522509.

ITEM CODE	DESCRIPTION	HSN CODE	QTY	UNIT PRICE	AMOUNT
644431	Sunlight - Condo	90184900	02	530.85	530.85
644434	4	39239090	01	72561.38	72561.38
644435	1	39219099	02	238.36	476.72
644436	4	11	02	238.36	476.72
644437	4	11	02	244.61	489.22
FOR IN-DLS/22231					
31/05/22					
MKT					
			09		74534.89
 VICE-DEAN SIBAR INSTITUTE OF DENTAL SCIENCES GUNTUR-522509, A.P.			4/6/2022		
Declared Value					RS = 74534.89

RECEIVED

  
**Dr. L. KRISHNA PRASAD**  
 DEAN  
 SIBAR INSTITUTE OF DENTAL SCIENCES  
 GUNTUR-522509, A.P., India.

  
 Authorised Signatory



## PACKING LIST/BOX DETAILS

DENTSPLY India Pvt. Ltd.  
DENTSPLY India Pvt. Ltd.  
CIN-U74899DL1995PTC073183  
Kh.No. 66/20 & 66/11/2 Gali No.2  
Main Rothak Road  
Mundka Industrial Area  
Delhi  
DELHI  
IN-110041

PACKING LIST NC: PS-279937  
DATE .....: 25/May/2022  
LST NO. ....: 07390187419  
CST NO. ....: LC/96/187419/04  
ORDER NO. ....: SO-226443  
Customer PO .....: mail dtd-25/05

I DENTSPLY MARKETING - SOUTH  
N Capsule Works, #3, Manandi Plaza,  
V 1st Floor (Wing 1 facing towards  
O South), St. Marks Rd, Shanthala  
I Nagar, Ashok Nagar, Bengaluru,  
C Karnataka-560001, India (Next to St.  
E Marks Hotel)  
BANGALORE  
T KARNATAKA  
O IN-560001

S Dr. Nagesh Bolla  
H Dr. Nagesh Bolla  
I Professor & Vice Dean  
P Department of conservative dentistry  
& endodontics  
Sibar institute of Dental Sciences  
Takkellapadu, Guntur, Andhra  
Pradesh  
T Pincode: 522509  
O Mobile: 9848885658

TAKKELLAPADDU  
ANDHRA P.  
IN-522509

CST No:  
LST No:

CST No. :  
LST No. :

Product No.	Description	Batch/Serial No.	Expiry Date	Quantity	BOX
60701921	NEO SPECTRA™ ST FLOW SYRINGE REFILL A1	2109000897	31/Jul/2023	4.00	PR-0840151/
60701981	NEO SPECTRA™ ST HV SYRINGE REFILL A1	2203000913	31/Mar/202	16.00	PR-0840151/
<b>Total</b>				<b>20.00</b>	

### SHIPPING DETAILS

No of cartons 0

Total Gross WT

  
**VICE-DEAN**  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
**GUNTUR-522509., A.P**

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

## PACKING LIST/BOX DETAILS

DENTSPLY India Pvt. Ltd.  
DENTSPLY India Pvt. Ltd.  
CIN-U74899DL1995PTC073183  
Kh.No. 66/20 & 66/11/2 Gali No.2  
Main Rothak Road  
Mundka Industrial Area  
Delhi  
DELHI  
IN-110041

PACKING LIST NC: PS-270727  
DATE .....: 11/Jan/2022  
LST NO. ....: 07390187419  
CST NO. ....: LC/96/187419/04  
ORDER NO. ....: SO-221447  
Customer PO ....: Clinical study

I DENTSPLY MARKETING - SOUTH  
N Capsule Works. #3, Manandi Plaza,  
V 1st Floor (Wing 1 facing towards  
O South), St Marks Rd, Shanthala  
I Nagar, Ashok Nagar, Bengaluru,  
C Karnataka-560001, India (Next to St  
E Marks Hotel)  
BANGALORE  
T KARNATAKA  
O IN-560001

S Dr.NAGESH BOLLA  
H Dr.NAGESH BOLLA  
I PROFESSOR & VICE DEAN  
P DEPARTMENT OF  
CONSERVATIVE DENTISTRY AND  
ENDODONTICSSIBAR INSTITUTE  
OF DENTAL SCIENCES  
TAKKELLAPADU, GUNTUR,  
T ANDHRA PRADESH,  
O PIN CODE: 522509

TAKKELLAPADDU  
ANDHRA P.  
IN-522509

CST No:  
LST No:

CST No. :  
LST No. :

Product No.	Description	Batch/Serial No.	Expiry Date	Quantity	BOX
60620112	AH PLUS EXPORT PACK NON EU	2111001027	30/Sep/202	30.00	PR-775210/
659700v	PALODENT V3 INTRO KIT	03783292	31/Dec/209	1.00	PR-775210/
<b>Total</b>				<b>31.00</b>	

### SHIPPING DETAILS

No of cartons            0  
Total Gross WT



Prof. Dr. NAGESH BOLLA  
DEPT. OF CONSERVATIVE DENTISTRY  
& ENDODONTICS  
SIBAR INSTITUTE OF DENTAL SCIENCES  
TAKKELLAPADU (Guntur Dt.)



  
**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.





# Palodent® V3

## Sectional Matrix System

### Designed by Triodent®

Sistemas de Matrices Seccionales  
Système de matrices sectorielles  
Teilmatrizensystem  
Sistema di matrici sezionali  
СЕКЦИОННАЯ МАТРИЧНАЯ СИСТЕМА

Sistema de Matriz Seccional  
Sectioneel Matrix Systeem  
Sektionsmatricesystem  
Sektionsmatrissystem  
Σύστημα τμηματικού τεχνητού τοιχώματος

Częściowe formówki anatomiczne  
Částečný matricový systém  
Čiastočný matricový systém  
Szekcionált matrica rendszer

PALODENT V3 INTRO KIT QTY:01N  
MRP Rs.28695/-(Incl.of all taxes)  
Month & Year of Import: Nov'21  
Imported & Marketed By:  
Dentsply India Pvt. Ltd  
Khasra No. 66/20 & 66/11/2,Gali No.2,  
Mundka Industrial Area, Main Rohtak  
Road, Delhi-110041  
Customer Care No: 18002081011  
E-mail- info.india@dentsplysirona.com  
Registration No.-Dent#p-USA/II/MD/002005

### INTRODUCTORY KIT

ITEM #: 659700V



LOT 03783292



NO EXP

+D002659700V1/\$\$703783292G

LBL-PALODENT-KITS Rev 001

*Dr. L. KRISHNA PRASAD*  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.



Manufactured for  
Dentsply Caulk  
38 West Clarke Avenue  
Milford, DE 19963 USA

Made in USA  
www.dentsplysirona.com  
1-302-422-4511

REF 659700v

EC REP

Dentsply DeTrey GmbH  
De-Trey-Strasse 1  
78467 Konstanz  
Germany

559705v (R 3-10-20)



# AH Plus®

Root Canal Sealing Material  
 Matériau de scellement canalaire  
 Material para sellado de conductos  
 Материал для пломбирования корневых каналов  
 Material de selamento de canais radiculares  
 Kök Kanalı Dolgu Materyali  
 مادة حشوي للأقنية الجذرية  
 根管充填材料

AH PLUS QTY: 01N  
 MRP Rs 5025/- (incl. of all taxes)  
 Month & Year of Import: Dec'21  
 Imported & Marketed By:  
 Dentsply India Pvt. Ltd  
 Khasra No. 66/20 & 66/11/2, Gali No. 2,  
 Mundka Industrial Area, Main Rohtak  
 Road, Delhi-110041  
 Customer Care No.: 18002081011  
 E-mail: info.india@dentsplysirona.com

ReOrder 606.20.112

Export Package

Not for re-export to EU or USA

DENSPLY

AH Plus Tube Export Refill

REF 60620112 MD  
 LOT 2111001027  
 2023-09-30 \*D010606201121/5332309302111001027C\*

Contents:

- 1 Tube Paste A, 4 ml
- 1 Tube Paste B, 4 ml
- 1 Mixing Pad



www.dentsply.eu/IFU



For dental use only

Export Package

DENSPLY

# AH Plus®

Root Canal Sealing Material  
 Matériau de scellement canalaire  
 Material para sellado de conductos  
 Материал для пломбирования корневых каналов  
 Material de selamento de canais radiculares  
 Kök Kanalı Dolgu Materyali  
 مادة حشوي للأقنية الجذرية  
 根管充填材料

AH PLUS QTY: 01N  
 MRP Rs 5025/- (incl. of all taxes)  
 Month & Year of Import: Dec'21  
 Imported & Marketed By:  
 Dentsply India Pvt. Ltd  
 Khasra No. 66/20 & 66/11/2, Gali No. 2,  
 Mundka Industrial Area, Main Rohtak  
 Road, Delhi-110041  
 Customer Care No.: 18002081011  
 E-mail: info.india@dentsplysirona.com

ReOrder 606.20.112

Export Package

Not for re-export to EU or USA

DENSPLY

AH Plus Tube Export Refill

REF 60620112 MD  
 LOT 2111001027  
 2023-09-30 \*D010606201121/5332309302111001027C\*

Contents:

- 1 Tube Paste A, 4 ml
- 1 Tube Paste B, 4 ml
- 1 Mixing Pad



www.dentsply.eu/IFU



For dental use only

Export Package

DENSPLY

# AH Plus®

Root Canal Sealing Material  
 Matériau de scellement canalaire  
 Material para sellado de conductos  
 Материал для пломбирования корневых каналов  
 Material de selamento de canais radiculares  
 Kök Kanalı Dolgu Materyali  
 مادة حشوي للأقنية الجذرية  
 根管充填材料

AH PLUS QTY: 01N  
 MRP Rs 5025/- (incl. of all taxes)  
 Month & Year of Import: Dec'21  
 Imported & Marketed By:  
 Dentsply India Pvt. Ltd  
 Khasra No. 66/20 & 66/11/2, Gali No. 2,  
 Mundka Industrial Area, Main Rohtak  
 Road, Delhi-110041  
 Customer Care No.: 18002081011  
 E-mail: info.india@dentsplysirona.com

ReOrder 606.20.112

Export Package

Not for re-export to EU or USA

DENSPLY

AH Plus Tube Export Refill

REF 60620112 MD  
 LOT 2111001027  
 2023-09-30 \*D010606201121/5332309302111001027C\*

Contents:

- 1 Tube Paste A, 4 ml
- 1 Tube Paste B, 4 ml
- 1 Mixing Pad



www.dentsply.eu/IFU



For dental use only

Export Package

DENSPLY

# AH Plus®

Root Canal Sealing Material  
 Matériau de scellement canalaire  
 Material para sellado de conductos  
 Материал для пломбирования корневых каналов  
 Material de selamento de canais radiculares  
 Kök Kanalı Dolgu Materyali  
 مادة حشوي للأقنية الجذرية  
 根管充填材料

AH PLUS QTY: 01N  
 MRP Rs 5025/- (incl. of all taxes)  
 Month & Year of Import: Dec'21  
 Imported & Marketed By:  
 Dentsply India Pvt. Ltd  
 Khasra No. 66/20 & 66/11/2, Gali No. 2,  
 Mundka Industrial Area, Main Rohtak  
 Road, Delhi-110041  
 Customer Care No.: 18002081011  
 E-mail: info.india@dentsplysirona.com

ReOrder 606.20.112

Export Package

Not for re-export to EU or USA

DENSPLY

AH Plus Tube Export Refill

REF 60620112 MD  
 LOT 2111001027  
 2023-09-30 \*D010606201121/5332309302111001027C\*

Contents:

- 1 Tube Paste A, 4 ml
- 1 Tube Paste B, 4 ml
- 1 Mixing Pad



www.dentsply.eu/IFU



For dental use only

Export Package

DENSPLY

Dr. L. KRISHNA PRASAD  
 DEAN  
 SIBAR INSTITUTE OF DENTAL SCIENCES  
 GUNTUR-522509, A.P., India.



DENTSPLY

# AH Plus®

**Root Canal Sealing Material**

**Matériau de scellement canalair**

**Material para sellado de conductos**

**Материал для пломбирования корневых каналов**

**Material de selamento de canais radiculares**

**Kök Kanalı Dolgu Materyali**

**مادة حشي للأقنية الجذرية**

**根管充填材料**

AH PLUS QTY:01N

MRP Rs.5025/-(Incl.of all taxes)

Month & Year of Import: Dec'21

Imported & Marketed By:

Dentsply India Pvt. Ltd

Khasra No. 66/20 & 66/11/2, Gali No.2,

Mundka Industrial Area, Main Rohtak

Road, Delhi-110041

Customer Care No: 18002081011

E-mail- info.india@dentsplysirona.com

ReOrder 606.20.112

**Export Package**

**Not for re-export to EU or USA**

  
Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.



## Part - A Slip

Unique No. 7012 9131 0941  
Entered Date 12/10/2022 06:04 PM  
Entered By 07AAA CD317 1E1Z3 - Dentsply India Pvt Ltd  
Valid From: Not Valid for Movement as Part B is not entered [1873Kms]

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### Part - A

GSTIN of Supplier 07AAACD3171E1Z3,Dentsply India Pvt Ltd  
Place of Dispatch West Delhi,DELHI-110041  
GSTIN of Recipient URP ,DENTSPLY MARKETING SOUTH  
Place of Delivery guntur,ANDHRA PRADESH-522509  
Document No. DLSI2223011409  
Document Date 12/10/2022  
Transaction Type: Regular  
Value of Goods 149485.07  
HSN Code 39239090 - DENTAL GOODS( +1 )  
Reason for Transportation Outward - Supply  
Transporter 27AAACB0446L1ZS & BLUE DART EXPRESS LIMITED



701291310941

  
Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**HELP FOUNDATION**  
74-6/2-2, CHURCH STREET,  
Ayyappanagar, Vijayawada - 520007,  
Andhra Pradesh, India  
Mail: helpfoundation999@gmail.com

Date: 14/06/2021

To  
Dr. Y. Samata,  
Professor,  
Dept. of Oral Medicine & Radiology,  
Sibar Institute of Dental Sciences,  
Guntur.

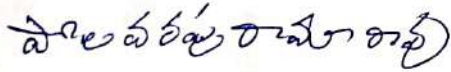
Dear Dr. Y. Samata,

Sub:- Approval of Research Grant – Reg...

On behalf of the HELP FOUNDATION, I am pleased to inform you that with the delegated authority from the HELP FOUNDATION board of directors, I have approved your application for a research grant of Rs. 25,000/- for the project on "Assessment of maxillary sinus pathologies – a cone beam computed tomography study".

Please note that at the end of the project, you are expected to submit a completion report to the HELP FOUNDATION office.

Regards,



Authorized Signatory



**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

# HELP FOUNDATION

74-6/2-2, CHURCH STREET,  
Ayyappanagar, Vijayawada - 520007,  
Andhra Pradesh, India  
Mail: helpfoundation999@gmail.com

Date: 15/09/2021

To  
Dr. T. Ashok Kumar,  
Professor,  
Dept. of Orthodontics,  
Sibar Institute of Dental Sciences,  
Guntur.

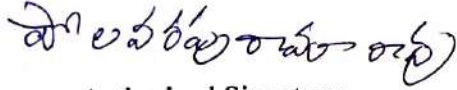
Dear Dr. T. Ashok Kumar,

Sub:- Approval of Research Grant – Reg...


On behalf of the HELP FOUNDATION, I am pleased to inform you that with the delegated authority from the HELP FOUNDATION board of directors, I have approved your application for a research grant of Rs. 20,000/- for the project on "Antimicrobial efficacy of chlorhexidine hexameta phosphate coated elastomeric modules".

Please note that at the end of the project, you are expected to submit a completion report to the HELP FOUNDATION office.

Regards,



Authorized Signatory



Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

# HELP FOUNDATION

74-6/2-2, CHURCH STREET,  
Ayyappanagar, Vijayawada – 520007,  
ANDHRA PRADESH, INDIA  
Mail: helpfoundation999@gmail.com

Date :08/07/2021

To  
Dr. P. Raja Satish,  
Professor,  
Dept. of Oral & Maxillofacial Surgery,  
Sibar Institute of Dental Sciences,  
Guntur.


Dear Dr. P. Raja Satish,

Congratulations! The HELP FOUNDATION has approved a grant of Rs. 25,000/- for your research project titled “Comparative study on effectiveness of intravenous dexmedetomidine and inhalation nitrous oxide – oxygen sedation in day care minor oral surgery procedures”.

Our offer of this grant is subject to your agreement to :

- 1) Use the grant funds only as specified in the grant proposal.
- 2) Maintain the records of accounts of the utilization of grant funds.
- 3) Acknowledge the project in scientific presentations and publications.

Regards



Authorized Signatory



Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.



**HELP FOUNDATION**  
74-6/2-2, CHURCH STREET,  
AYYAPPANAGAR, VIJAYAWADA - 520007,  
ANDHRA PRADESH, INDIA  
Mail: helpfoundation999@gmail.com

Date: 10/8/2021

To  
Dr. V. Sayesh,  
Professor & Head,  
Dept. of Conservative Dentistry & Endodontics,  
Sibar Institute of Dental Sciences,  
Guntur.

Dear Dr. V. Sayesh,

Congratulations! M/s HELP FOUNDATION has approved a grant of Rs. 30,000/- for your research project titled "Evaluation of marginal adaptation and preparation of injectable resin based sealer with different obturation techniques at apical third of root canals". Our offer of this grant is subject to your agreement to:

- 1) Use the grant funds only as specified in the grant proposal.
- 2) Maintain the records of accounts of the utilization of grant funds.
- 3) Acknowledge this project in scientific presentations and publications.

Regards



Authorized Signatory

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

# HELP FOUNDATION

74-6/2-2, CHURCH STREET,  
AYYAPPANAGAR, VIJAYAWADA – 520007,  
ANDHRA PRADESH. INDIA  
Mail: helpfoundation999@gmail.com

Date : 20/11/2021

To  
Dr. P. Chandra Sekhar,  
Professor,  
Dept. of Oral Pathology  
Sibar Institute of Dental Sciences,  
Guntur.

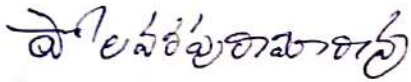
Dear Dr. Chandra Sekhar,

Sub:- Approval of Research Grant – Reg...

On behalf of the HELP FOUNDATION, I am pleased to inform you that with the delegated authority from the HELP FOUNDATION board of directors, I have approved your application for a research grant of Rs. 35,000/- for the project on “Early detection of Oral Cancer by using various Non-Invasive methods”.

Please note that at the end of the project, you are expected to submit a completion report to the HELP FOUNDATION office.

Regards,



Authorized Signatory



Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**FELLOWSHIP AWARD LETTER/GRANT LETTER**  
**FROM THE FUNDING AGENCY**  
**(2020-2021)**



**DST/TDT/WMT/AgWaste/2021/01(G)**  
Government of India  
Ministry of Science & Technology  
Department of Science & Technology

Technology Bhavan  
New Mehrauli Road  
New Delhi- 110 016  
Dated: 23.03.2021

**ORDER**

**Sub:** Financial assistance for the project entitled "Automation of Nano hydroxyapatite production from eggshell waste using continuous flow microwave reactor suitable for industrial scale production for various biomedical and industrial applications", submitted by Dr. E.K. Girija, Assistant Professor, Department of Physics, Periyar University, Salem and Dr. Vivekanand Kattimani, Professor, Department of Oral and Maxillofacial surgery, Sibar Institute of Dental Sciences, Guntur-09, Andhra Pradesh

Sanction of the President is hereby accorded to the approval of the above mentioned project at a total cost of **Rs. 1,83,69,734/- (Rupees One Crore Eighty Three Lakh Sixty Nine thousand Seven Hundred Thirty Four only)** out of which DST Share is Rs.1,64,85,094/- , Host Institute Share is Rs.8,84,640/- and industry share is Rs.10,00,000/- (VB Ceramic Consultants ) for a duration of 3 Years (36 months). The detailed breakup of general as well as capital components are given below

**Periyar University**

General : Rs. 47,40,518/-  
Capital : Rs.52,50,000/-

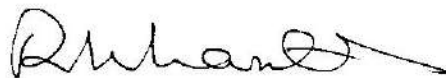
**SIBAR**

General : Rs. 64,94,576/-

2. Sanction of the President is also accorded for the release of **Rs. 33,95,859/- (Rupees Thirty three lakh Ninety five Thousand Eight hundred Fifty nine Only)** out of which Rs.18,38,083/- to Periyar university and Rs.15,57,776/- to SIBAR, under the recurring budget being the first instalment of grant under "General Component" for implementation of the above mentioned project. The item of expenditure for which the total allocation budget of **Rs. 1,12,35,094/-** has been approved for a period of 36 months are given below

**Non-Recurring Items: (DST Component- Periyar University)**

Head	1st Year DST	Total
<b>Equipment:</b>		
1. Mineral extractor		
2. Rolling type- microwave Calcination Chamber		
3. Chelation Chamber	52,50,000	52,50,000
4. Continuous flow microwave Smart reactor		
5. Conveyer and washer		
6. Dryer and Collector		



**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

Recurring Items:- (General – DST Components)

A) Periyar University

S.No	Items	1st Year	2nd year	3rd Year	Total
1	Manpower 2no.JRF @ Rs. 31,000 p.m. with 16% HRA for 1 <sup>st</sup> & 2 <sup>nd</sup> Year				
	Rs.35,000 p.m with 16% HRA for 3 <sup>rd</sup> year	8,63,040	8,63,040	9,74,400	27,00,480
2	Consumables	2,00,000	2,00,000	1,00,000	5,00,000
3	Contingency	50,000	50,000	50,000	1,50,000
4	Other Costs	1,50,000	1,50,000	2,00,000	5,00,000
5	Travel	50,000	50,000	50,000	1,50,000
6	Over Head Charges @ 8%	5,25,043	1,05,043	1,09,952	7,40,038
	<b>Total</b>	<b>18,38,083</b>	<b>14,18,083</b>	<b>14,84,352</b>	<b>47,40,518</b>

B) SIBAR

S.No	Items	1st Year	2nd year	3rd Year	Total
1	Manpower 1no.JRF @ Rs. 31,000 p.m. with 16% HRA for 1 <sup>st</sup> & 2 <sup>nd</sup> Year				
	Rs.35,000 p.m with 16% HRA for 3 <sup>rd</sup> year	4,31,520	4,31,520	4,87,200	13,50,240
	<b>Senior Project Associate 1no .@ Rs.42,000 + 16% HRA</b>	<b>5,84,640</b>	<b>5,84,640</b>	<b>5,84,640</b>	<b>17,53,920</b>
2	Consumables	2,00,000	1,50,000	1,50,000	5,00,000
3	Contingency	50,000	50,000	50,000	1,50,000
4	Travel	50,000	50,000	50,000	1,50,000
5	Other Cost	1,00,000	17,00,000	2,00,000	20,00,000
6	Over Head Charges	1,41,616	2,96,616	1,52,184	5,90,416
	<b>Total</b>	<b>15,57,776</b>	<b>32,62,776</b>	<b>16,74,024</b>	<b>64,9,576</b>

NGO DARPAN ID: AP/2019/0237167 (SIBAR)

3. This sanction is subject to the condition that the grantee organization will furnish to the Department of Science & Technology, financial year wise Utilization Certificate (UC) in the proforma prescribed as per GFR 2017 and audited Statement of Expenditure (SE) along with up to date progress report at the end of each financial year duly reflecting the interest earned/accrued on the grants received under the project. This is also subject to the condition of submission of the final statement of expenditure, utilization certificate and project completion report within one year from the scheduled date of completion of the project.



  
**Dr. L. KRISHNA PRASAD**  
 DEAN  
 SIBAR INSTITUTE OF DENTAL SCIENCES  
 GUNTUR-522509, A.P., India.

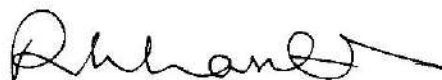



4. **It is mandatory for the grantee organization to purchase the equipment through the Government e-Marketplace (GeM), to the extent available there as the project involves government funding.**
5. The grantee organization will have to enter and upload the Utilization Certificate in the PFMS portal besides sending it in physical form to this Division. The subsequent/final installment will be released only after confirmation of the acceptance of the UC by the division and entry of previous Utilization Certificate in the PFMS.
6. If the grant has been released under capital head through separate sanction order under the same project for purchase of equipment(s), separate SE/UC has to be furnished for the released Capital head grant.
7. The grant-in-aid being released is subject to the condition that:
  - a. A transparent procurement procedure in line with the Provisions of General Financial Rules 2017 will be followed by the Institute/organization under the appropriate rules of the grantee organization while procuring capital assets sanctioned for the above mentioned project and a certificate to this effect will be submitted by the Grantee organization immediately on receipt of the grant:
  - b. While submitting Utilization Certificate/Statement of Expenditure, the organization has to ensure submission of supporting documentary evidences with regard to purchase of equipment/capital assets as per the provisions of GFR 2017. Subsequent release of grants under the project shall be considered only on receipt of the said documents.
8. *As per the GFR 2017 Rule 230 (8) the Grantee Institute should ensure that all the interests or other earnings against Grant-in-Aid or advances (other than reimbursement) released to any Grantee institution should be mandatorily remitted to the Consolidated Fund of India (through Non-Tax Receipt Portal (NTRP), i.e. [www.bharatkosh.gov.in](http://www.bharatkosh.gov.in)), immediately after finalization of accounts, as it shall not be adjusted towards future release of Grant. A certificate to this effect shall have to be submitted along with Statement of Expenditure / Utilization Certificate for considering subsequent release of Grant/ Closure of Project accounts.*
9. *GI should also follow Rule 230(17) of GFR, 2017 concerning reservation of SC/ST/OBC, if applicable.*
10. The grantee organization will maintain separate audited account for the project and the entire amount of grant will be kept in an interest bearing bank account. The interest earned/accrued should be reported to DST (financial year wise) while submitting the Statement of Expenditure/Utilization Certificate.
11. DST reserves sole rights on the assets created out of grants. Assets acquired wholly or substantially out of government grants (except those declared as obsolete and unserviceable or condemned in accordance with the procedure laid down in GRF 2017), shall not be disposed of without obtaining the prior approval of DST.



  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

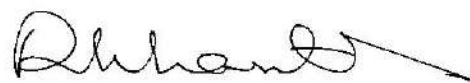
12. In case the scheme provides for payment of honorarium/remuneration/fellowships/scholarship to the PI, a para may suitably be incorporated in the DST to the effect that PI is not drawing any emoluments/salary/fellowship from any other project either supported by DST or by any other funding agency.
13. The account of the grantee organization shall be open to inspection by the sanctioning authority and audit (both by C&AG of India and Internal Audit by the Principal Accounts Office of the DST), whenever the organization is called upon to do so, as laid down under Rule 236(1) of General Financial Rules 2017.
14. Due acknowledgement of technical support/financial assistance resulting from this project grant should mandatorily be highlighted by the grantee organization in bold letters in all publications/media releases as well as in the opening paragraphs of their Annual Reports during and after completion of the project.
15. Failure to comply with the terms and conditions of the Bond will entail full refund with interest in terms of Rule 231 (2) of GFR 2017.
16. The expenditure involved is debitable to Demand No. 87, Department of Science & Technology for the year 2020-21:
- |          |   |                                                                   |
|----------|---|-------------------------------------------------------------------|
| 3425     | : | Other Scientific Research (Major Head)                            |
| 60       | : | Others                                                            |
| 60.200   | : | Assistance to Other Scientific Bodies (Minor Head)                |
| 70       | : | Technology Development and Deployment.                            |
| 70.00.31 | : | Grants for Creation of General Assets for the year 2020-21 (Plan) |
|          |   | (Previous: TDP -3425.60.200.26.01.31)                             |
17. The amount of **Rs. 33,95,859/-** (Rupees Thirty three lakh Ninety five Thousand Eight hundred Fifty nine Only) will be drawn by the Drawing and Disbursing Officer, DST and will be disbursed to the following institutions given below:
- A) Rs. 18,38,083/- (Rupees Eighteen Lakh Thirty Eight thousand Eighty Three only) is Disbursed to The Registrar of Periyar University and
- Name of the Account Holder** : The Registrar of Periyar University  
**Name of Bank** : CANARA BANK  
**Bank Account Number** : 8450101001640  
**IFSC Code** : CNRB0008450
- B) Rs. 15,57,776/- (Rupees Fifteen Lakh Fifty Seven Thousand Seven Hundred Seventy Six only) is Disbursed to the Sibar institute of Dental Sciences Department of Research
- Name of the Account Holder** : Sibar Institute Of Dental Sciences Department Of Research  
**Name of Bank** : State Bank of India  
**Bank Account Number** : 31819434144  
**IFSC Code** : SBIN0007168
18. As per Rule 234 of GFR 2017, this sanction has been entered at Sl.No. in the register of grants maintained in the Division for the scheme (Innovation, Technology Development and Deployment).



  
**Dr. L. KRISHNA PRASAD**  
 DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
 GUNTUR-522509, A.P., India.



19. This issues with the concurrence of IFD vide their Concurrence Dy. No. C/6095/IFD/2020-21 dated 23.03.2021.
20. It is certified that all the Utilization Certificate in regard of all schemes/programmes/projects, present and previous pertaining to the institute have been received and no UC is pending against the organization as per the details in the PFMS also.
21. Continuation of the scheme/ programme beyond 31st March, 2021 will be subject to appraisal and approval of the continuation of the Umbrella scheme "Innovation, Technology Development & Deployment " under which the project is funded
22. Grantee Institution (GI) is advised to start using EAT module as the next release will be made only after mapping and following of EAT module by the GI



**Dr. Krishna Kanth Pulicherla,**

Scientist-D

Tele:011-26590493

The Pay & Accounts Officer  
Department of Science & Technology  
New Delhi-110016

Copy for information and necessary action:

1. Cash Section (3 copies) for preparing the bill and remitting the amount to the above grantee.
2. Accounts Section, DST, New Delhi.
3. IFD, DST, New Delhi.
4. Director of audit (CW&M-II) AGCR Building, IP Estate, New Delhi.
5. Dr. E.K. Girija, Assistant Professor, Department of Physics, Periyar University, Salem
6. Dr. Vivekanand Kattimani, Professor, Department of Oral and Maxillofacial surgery, Sibar Institute of Dental Sciences, Guntur-09, Andhra Pradesh
7. Dr. V. Manju, Assistant Professor, Department of Biochemistry, Periyar University, Salem-636 011.
8. Dr. V. Viswabaskaran, VB Ceramic consultants, Chennai-600 041.
9. Sanction Folder



**Dr. Krishna Kanth Pulicherla,**

Scientist-D

Tele:011-26590493



**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

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**Reg: BIG-17 Due Diligence\_Final Documentation**

---

**Aryan Jaiswal Bioinnovation KIIT - TBI** <aryan@kiitincubator.in>

26 August 2021 at 13:57

To: drvivekanandsk@gmail.com

Cc: Namrata Misra &lt;namrata@kiitincubator.in&gt;, Arpan Ghosh &lt;arpan@kiitincubator.in&gt;, Ray Saisoubhagya &lt;sai@kiitincubator.in&gt;

Dear BIG Grantee,

Greetings from KIIT-TBI!

We have finalized all the documents that you've submitted for the due diligence process of the BIG-17 call, and have attached them herewith to this mail for your perusal.

The total budget allocated to you for the BIG project is **49.89 Lakhs**.

**Please use the exact budget distribution given in Annexure-1 (attached herewith) for your MoU agreement as your final budget.**

Some of the documents are modified as per the BIRAC guidelines, therefore we request you to kindly go through them thoroughly and let us know if you have any queries. (9348880168)

Kindly do all the necessary modifications and send all the updated agreement and no-lien bank account details by **30th August 2021, 01:00 PM** positively.

PFA

--

*Thanks & Regards,***Aryan Jaiswal**Program Associate-Bioinnovation  
KIIT-Technology Business Incubator

**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

E: [aryan@kiitincubator.in](mailto:aryan@kiitincubator.in)

M: +91-9348880168

A: KIIT-TBI, KIIT University, Bhubaneswar-24

W: <https://www.kiitincubator.in/>L: <https://www.linkedin.com/in/aryan-jaiswal-a2a485152/>

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**2 attachments****Annexure I -Budget justification Dr Vivekanand Kattimani 28 July 2021.xls**

84K

**Vivekananda Kattimani.zip**

6837K



**SRI DURGA MALLESWARA  
EDUCATION IMPROVING SOCIETY**  
JOJI NAGAR, BHAVANIPURAM, VIJAYAWADA - 520 012.  
VIJAYAWADA WEST, N.T.R. DISTRICT



Estd:1959

**Y.S.K.KISHORE**  
Secretary & Correspondent

Date : 28/07/2020

To  
Dr. A.J. Sai Sankar,  
Professor & HOD,  
Dept. of Pedodontics,  
Sibar Institute of Dental Sciences,  
Guntur.

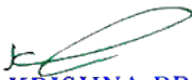
Dear Dr. A.J. Sai Sankar,

Sub:- Approval of Research Grant-Reg.

On behalf of the Sri Durga Malleswara Education Improving Society, I am pleased to inform you, that with the delegated authority from the Sri Durga Malleswara Education Improving Society board of directors, I have approved your application for a research grant of Rs. 25,000/- for the project on "Determining the effect of irrigating solutions on the calcium & phosphate content and Microhardness of root dentin".

Please note that at the end of the project, you are expected to submit a completion report to the Sri Durga Malleswara Education Improving Society office.

Regards,

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**For S.D.M.E.I. SOCIETY**  
  
Authorized Signatory  
**SECRETARY**





**SRI DURGA MALLESWARA  
EDUCATION IMPROVING SOCIETY**  
JOJI NAGAR, BHAVANIPURAM, VIJAYAWADA - 520 012.  
VIJAYAWADA WEST, N.T.R. DISTRICT



Estd:1959

**Y.S.K.KISHORE**  
Secretary & Correspondent

Date : 28/07/2020

To  
Dr. D. Ravindranath,  
Professor & HOD,  
Dept. of Periodontics  
Sibar Institute of Dental Sciences,  
Guntur.

Dear Dr. D. Ravindranath,

Sub:- Approval of Research Grant – Reg

On behalf of M/s Sri Durga Malleswara Education Improving Society, I am pleased to inform you that with the delegated authority from M/s Sri Durga Malleswara Education Improving Society board of directors, I have approved your application for a research grant of Rs. 25,000/- for the project on "A Comparative evaluation of soft tissue & crestal bone levels utilizing a diode laser and scalpel in implant surgery".

Please note that at the end of the project, you are expected to submit a completion report to the M/s Sri Durga Malleswara Education Improving Society office.

Regards,

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**For S.D.M.E.I. SOCIETY**  
  
Authorized Signatory **SECRETARY**



**SRI DURGA MALLESWARA  
EDUCATION IMPROVING SOCIETY**

JOJI NAGAR, BHAVANIPURAM, VIJAYAWADA - 520 012.  
VIJAYAWADA WEST, N.T.R. DISTRICT



Estd:1959

**Y.S.K.KISHORE**  
Secretary & Correspondent

Date: 19/09/2020

To  
Dr. K. Kiran Kumar,  
Professor,  
Dept. of Oral Pathology,  
Sibar Institute of Dental Sciences,  
Guntur.

Dear Dr. Kiran Kumar,

Congratulations! M/s Sri Durga Malleswara Education Improving Society has approved a grant of Rs. 20,000/- for your research project titled "Giving identity to undocumented children in India". Our offer of this grant is subject to your agreement to:

- 1) Use the grant funds only as specified in the grant proposal.
- 2) Maintain the records of accounts of the utilization of grant funds.
- 3) Acknowledge this project in scientific presentations and publications.

For S.D.M.E.I. SOCIETY

*Y.S.K. Kishore*  
Authorized Signatory  
SECRETARY

*L. Krishna Prasad*  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.



**SRI DURGA MALLESWARA  
EDUCATION IMPROVING SOCIETY**  
JOJI NAGAR, BHAVANIPURAM, VIJAYAWADA - 520 012.  
VIJAYAWADA WEST, N.T.R. DISTRICT



Estd:1959

**Y.S.K.KISHORE**  
Secretary & Correspondent

Date: 21/09/2020

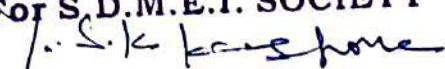
To  
Dr. M. Kalyani,  
Professor,  
Dept. of Orthodontics,  
Sibar Institute of Dental Sciences,  
Guntur.

Dear Dr. M. Kalyani,

Congratulations! M/s Sri Durga Malleswara Education Improving Society has approved a grant of Rs.25,000/- for your research project titled "A comparative evaluation of the shear bond strength of brackets bonded to pre-treated demineralised enamel treated with two different remineralising agents ". Our offer of this grant is subject to your agreement to:

- 1) Use the grant funds only as specified in the grant proposal.
- 2) Maintain the records of accounts of the utilization of grant funds.
- 3) Acknowledge this Project in scientific presentations and publications.

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**For S.D.M.E.I. SOCIETY**  
  
Authorized Signatory  
SECRETARY





**SRI DURGA MALLESWARA  
EDUCATION IMPROVING SOCIETY**  
JOJI NAGAR, BHAVANIPURAM, VIJAYAWADA - 520 012.  
VIJAYAWADA WEST, N.T.R. DISTRICT



Estd:1959

**Y.S.K.KISHORE**  
Secretary & Correspondent

Date :21/10/2020

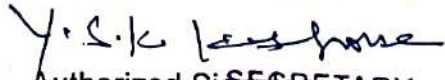
To  
Dr. Ch. Ram Sunil,  
Professor,  
Dept. of Conservative Dentistry & Endodontics,  
Sibar Institute of Dental Sciences,  
Guntur.

Dear Dr. Ch. Ram Sunil,

Congratulations! We, M/s Sri Durga Malleswara Education Improving Society has approved a grant of Rs. 25,000/- for your research project titled "The effect of various reinforcing materials on the fracture resistance endodontically treated teeth". Our offer of this grant is subject to your agreement to :

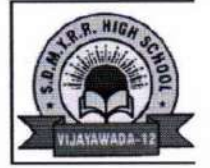
- 1) Use the grant funds only as specified in the grant proposal.
- 2) Maintain the records of accounts of the utilization of grant funds.
- 3) Acknowledge the project in scientific presentations and publications.

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**For S.D.M.E.I. SOCIETY**  
  
Authorized Signatory



**SRI DURGA MALLESWARA  
EDUCATION IMPROVING SOCIETY**  
JOJI NAGAR, BHAVANIPURAM, VIJAYAWADA - 520 012.  
VIJAYAWADA WEST, N.T.R. DISTRICT



Estd:1959

**Y.S.K.KISHORE**  
Secretary & Correspondent

Date: 28/07/2020

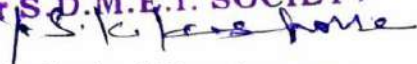
To  
Dr. K. Kishore Kumar,  
Professor,  
Dept. of Periodontics,  
Sibar Institute of Dental Sciences,  
Guntur.

Dear Dr. Kishore Kumar,

Congratulations! M/s Sri Durga Malleswara Education Improving Society has approved a grant of Rs. 25,000/- for your research project titled "Effect of non surgical periodontal therapy on salivary procalcitonin levels in chronic periodontitis patients with type II diabetic mellitus.". Our offer of this grant is subject to your agreement to:

- 1) Use the grant funds only as specified in the grant proposal.
- 2) Maintain the records of accounts of the utilization of grant funds.
- 3) Acknowledge this project in scientific presentations and publications.

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**For S.D.M.E.I. SOCIETY**  
  
Authorized Signatory  
SECRETARY



**SRI DURGA MALLESWARA  
EDUCATION IMPROVING SOCIETY**  
JOJI NAGAR, BHAVANIPURAM, VIJAYAWADA - 520 012.  
VIJAYAWADA WEST, N.T.R. DISTRICT



Estd:1959

**Y.S.K.KISHORE**  
Secretary & Correspondent

Date: 28/07/2020


To  
Dr. M. Sridhar,  
Professor,  
Dept. of Pedodontics,  
Sibar Institute of Dental Sciences,  
Guntur.

Dear Dr. M. Sridhar,

Congratulations! M/s Sri Durga Malleswara Education Improving Society has approved a grant of Rs. 25,000/- for your research project titled "Centralization ability and canal transportation of root canals prepared with three commercially available pediatric rotary files - a cone beam computerised tomography study". Our offer of this grant is subject to your agreement to:

- 1) Use the grant funds only as specified in the grant proposal.
- 2) Maintain the records of accounts of the utilization of grant funds.
- 3) Acknowledge this project in scientific presentations and publications.

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**FOR S.D.M.E.I. SOCIETY**  
  
Authorized Signatory  
SECRETARY





**SRI DURGA MALLESWARA  
EDUCATION IMPROVING SOCIETY**  
JOJI NAGAR, BHAVANIPURAM, VIJAYAWADA - 520 012.  
VIJAYAWADA WEST, N.T.R. DISTRICT



Estd:1959

**Y.S.K.KISHORE**  
Secretary & Correspondent

Date: 21/10/2020

To  
Dr. Varri Sujana,  
Professor,  
Dept. of Conservative Dentistry & Endodontics,  
Sibar Institute of Dental Sciences,  
Guntur.

Dear Dr. Varri Sujana,

Congratulations! M/s Sri Durga Malleswara Education Improving Society has approved a grant of Rs. 25,000/- for your research project titled " An In-vitro Assessment of Dentinal Shear Bond Strength after Pretreatment with Silver Nanoparticles and Nanochitosan with Different Adhesion Protocols".

Our offer of this grant is subject to your agreement to:

- 1) Use the grant funds only as specified in the grant proposal.
- 2) Maintain the records of accounts of the utilization of grant funds.
- 3) Acknowledge this project in scientific presentations and publications.

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**For S.D.M.E.I. SOCIETY**  
  
Authorized Signatory  
SECRETARY



**SRI DURGA MALLESWARA  
EDUCATION IMPROVING SOCIETY**  
JOJI NAGAR, BHAVANIPURAM, VIJAYAWADA - 520 012.  
VIJAYAWADA WEST, N.T.R. DISTRICT



Estd:1959

**Y.S.K.KISHORE**  
Secretary & Correspondent

Date: 21/09/2020

To  
Dr. P. Revathi,  
Professor & HOD,  
Dept. of Orthodontics,  
Sibar Institute of Dental Sciences,  
Guntur.

Dear Dr. P. Revathi,

Congratulations! M/s Sri Durga Malleswara Education Improving Society has approved a grant of Rs. 25,000/- for your research project titled "Assessment of frictional resistances of newly introduction poly crystalline ceramic brackets". Our offer of this grant is subject to your agreement to:

- 1) Use the grant funds only as specified in the grant proposal.
- 2) Maintain the records of accounts of the utilization of grant funds.
- 3) Acknowledge this project in scientific presentations and publications.

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**For S.D.M.E.I. SOCIETY**  
  
Authorized Signatory  
SECRETARY



**SRI DURGA MALLESWARA  
EDUCATION IMPROVING SOCIETY**  
JOJI NAGAR, BHAVANIPURAM, VIJAYAWADA - 520 012.  
VIJAYAWADA WEST, N.T.R. DISTRICT



Estd: 1959

**Y.S.K.KISHORE**  
**Secretary & Correspondent**

Date: 19/09/2020

To  
Dr. P. Chandra Sekhar,  
Professor,  
Dept. of Oral Pathology,  
Sibar Institute of Dental Sciences,  
Guntur.

Dear Dr. P. Chandra Sekhar,

Congratulations! M/s Sri Durga Malleswara Education Improving Society has approved a grant of Rs. 20,000/- for your research project titled "Quantitative analysis of CD133 as a prognostic marker in Oral squamous cell carcinoma". Our offer of this grant is subject to your agreement to:

- 1) Use the grant funds only as specified in the grant proposal.
- 2) Maintain the records of accounts of the utilization of grant funds.
- 3) Acknowledge this project in scientific presentations and publications.

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

**For S.D.M.E.I. SOCIETY**  
  
Authorized Signatory  
SECRETARY

**FELLOWSHIP AWARD LETTER/GRANT LETTER**  
**FROM THE FUNDING AGENCY**  
**(2019-2020)**



**DST/TDT/WM/2015/576**  
Government of India  
Ministry of Science & Technology  
Department of Science & Technology

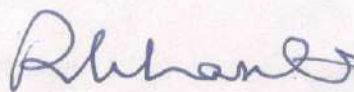
Technology Bhavan  
New Mehrauli Road  
New Delhi- 110 016  
Dated: 19.08.2019


**ORDER**

Sub: Financial assistance for the project entitled "**Pilot studies on microwave conversion of eggshell into nanostructured hydroxyapatite for biomedical applications and to design and fabricate continuous flow microwave reactor for scaling up the process**" sponsored to **Dr. E.K. Girija, Assistant Professor, Department of physics, Periyar University, Salem, Tamilnadu.**

In continuation of this Department's order of even number dated 05.05.2016, 29.08.2017 and 24.07.2018, sanction of the President is hereby accorded for the **upward revision** of the total project cost from Rs. 54,10,143/- (Rupees Fifty-four lakhs ten thousand one hundred forty-three only) to Rs. 72,75,143/- (Rupees Seventy-two lakhs seventy-five thousand one hundred forty-three only) for providing an additional grant of Rs. 18,65,000/- (Rupees Eighteen lakhs sixty-five thousand only) under the General budget head under the project as per the recommendation made by the EAC.

2. Sanction of the President is also accorded for the release of **Rs. 21,00,000 /- (Rupees Twenty-one lakhs only)** i.e. 4,00,000/- will be transferred to the Registrar, Periyar University, Salem, Tamilnadu and Rs. 17,00,000/- will be transferred to the Director, Sibar Institute of Dental Sciences Department of Research, Guntur, Andhra Pradesh.
3. It is also certified that this is the **Fourth sanction** for the project and as per the provision of GFR 212(1) relating to U.C. for the fund released under the project have been satisfied and the U.C. are being enclosed with the order to Pay & Accounts Officer of Department of Science & Technology, New Delhi.
4. Sanction of the President is also accorded to **carry forward** the unspent balance amount of **Rs. 62,153/-** under Recurring Budget from the last financial year 2018-19 to current financial year 2019-20 for being utilized in the expenses of the project
5. This sanction is subject to the condition that the grantee organization will furnish to the Department of Science & Technology, financial year wise Utilization Certificate (UC) in the pro forma prescribed as per GFR 2017 and audited Statement of Expenditure (SE) along with up to date progress report at the end of each financial year duly reflecting the interest earned/accrued on the grants received under the project. This is also subject to the condition of submission of the final statement of expenditure, utilization certificate and project completion report within one year from the scheduled date of completion of the project.
6. The grantee organization will have to enter and upload the Utilization Certificate in the PFMS portal besides sending it in physical form to this Division. The subsequent/final installment will be released only after confirmation of the acceptance of the UC by the division and entry of previous Utilization Certificate in the PFMS.
7. If the grant has been released under capital head through separate sanction order under the same project for purchase of equipment(s), separate SE/UC has to be furnished for the released Capital head grant.



  
**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.



8. The grant-in-aid being released is subject to the condition that:
  - a. A transparent procurement procedure in line with the Provisions of General Financial Rules 2017 will be followed by the Institute/organization under the appropriate rules of the grantee organization while procuring capital assets sanctioned for the above mentioned project and a certificate to this effect will be submitted by the Grantee organization immediately on receipt of the grant:
  - b. While submitting Utilization Certificate/Statement of Expenditure, the organization has to ensure submission of supporting documentary evidences with regard to purchase of equipment/capital assets as per the provisions of GFR 2017. Subsequent release of grants under the project shall be considered only on receipt of the said documents.
9. The grantee organization will maintain separate audited account for the project and the entire amount of grant will be kept in an interest bearing bank account. The interest earned/accrued should be reported to DST (financial year wise) while submitting the Statement of Expenditure/Utilization Certificate.
10. ***The grantee organization will maintain separate audited account for the project and the entire amount of grant will be kept in an interest bearing account. For Grants released during F.Y. 2017-18 and onwards, all interests and other earnings against released Grant shall be remitted to Consolidated Fund of India (through Non-Tax Receipt Portal (NTRP), i.e. [www.bharatkosh.gov.in](http://www.bharatkosh.gov.in)), immediately after finalization of accounts, as it shall not be adjusted towards future release of Grant. A certificate to this effect shall have to be submitted along with Statement of Expenditure / Utilization Certificate for considering subsequent release of Grant/ Closure of Project accounts.***
11. ***GI should also follow Rule 230(17) of GFR, 2017 concerning reservation of SC/ST/OBC, if applicable.***
12. DST reserves sole rights on the assets created out of grants. Assets acquired wholly or substantially out of government grants (except those declared as obsolete and unserviceable or condemned in accordance with the procedure laid down in GRF 2017), shall not be disposed of without obtaining the prior approval of DST.
13. In case the scheme provides for payment of honorarium/ remuneration/ fellowships/ scholarship to the PI, a para may suitably be incorporated in the DST to the effect that "PI is not drawing any emoluments/salary/fellowship from any other project either supported by DST or by any other funding agency.
14. The account of the grantee organization shall be open to inspection by the sanctioning authority and audit (both by C&AG of India and Internal Audit by the Principal Accounts Office of the DST), whenever the organization is called upon to do so, as laid down under Rule 236(1) of General Financial Rules 2017.
15. Due acknowledgement of technical support/financial assistance resulting from this project grant should mandatorily be highlighted by the grantee organization in bold letters in all publications/media releases as well as in the opening paragraphs of their Annual Reports during and after completion of the project.
16. Failure to comply with the terms and conditions of the Bond will entail full refund with interest in terms of Rule 231 (2) of GFR 2017.
17. The expenditure involved is debit to Demand No. 86, Department of Health and Family Welfare, Government of India for the year 2019-20:

**Dr. L. KRISHNA PRASAD**

DEAN

**SIBAR INSTITUTE OF DENTAL SCIENCES**

GUNTUR-522509, A.P., India



3425	:	Other Scientific Research (Major Head)
60	:	Others
60.200	:	Assistance to Other Scientific Bodies (Minor Head)
70	:	Innovation, Technology Development and Deployment.
70.00.31	:	Grants-in Aid General for the year 2019-20 (Plan)
(Previous: TDP-3425.60.200.26.01.31)		

18. The amount of **Rs. 21,00,000 /- (Rupees Twenty-one lakhs only)** to the i.e 4,00,000/- will be transferred to the Registrar, Periyar University, Salem, Tamilnadu and Rs. 17,00,000/- will be transferred to the Sibar Institute of Dental Sciences Department of Research, Guntur, Andhra Pradesh will be drawn by the Drawing and Disbursing Officer, DST and will be disbursed to the bank details for electronic transfer of funds through RTGS are given below:

**Periyar University**


**Name of the Account Holder** : Registrar, Periyar University  
**Name of the Bank** : Canara Bank  
**Bank Account Number** : 8450101001640  
**IFSC Code** : CNRB0008450

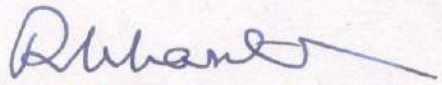
**SIBAR Institute**

**Name of the Account Holder** : Sibar Institute of Dental Sciences, Guntur  
**Name of the Bank** : State Bank of India  
**Bank Account Number** : 31819434144  
**IFSC Code** : SBIN0007168

**NGO Darpan ID : AP/2019/023/7167**

18. As per Rule 234 of GFR 2017, this sanction has been entered at S. No. **160** in the register of grants maintained in the Division for the scheme (Innovation, Technology Development and Deployment).
19. This issues with the concurrence of IFD vide their Concurrence Dy. No. C/2254/IFD/2019-20 dated 19.08.2019.
20. It is certified that all the Utilization Certificate in regard of all schemes/ programmes/ projects, present and previous pertaining to the institute have been received and no UC is pending against the organization as per the details in the PFMS also.
21. **As per the Rule of GFR 2017, it is mandatory for the grantee organization to purchase the equipment through the Government e-Marketplace (GeM), to the extant available there as the project involves government funding**

  
**Dr. L. KRISHNA PRASAD**  
 DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
 GUNTUR-522509, A.P., India.

  
 Dr. Krishna Kanth Pulicherla  
 Scientist D  
 011-26590493

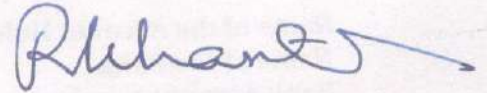
The Pay & Accounts Officer  
 Department of Science & Technology  
 New Delhi -110 016.

(P.T.O.)




Copy for information and necessary action to:

1. Cash Section (3 copies) for preparing the bill and remitting the amount to the above grantee.
2. Accounts Section, DST, New Delhi.
3. IFD, DST, New Delhi.
4. Director of audit (CW&M-II) AGCR Building, IP Estate, New Delhi.
5. The Registrar, Periyar University, Salem, Tamilnadu
6. Dr. E.K. Girija, Assistant Professor, Department of physics, Periyar University, Salem, Tamilnadu
7. Dr. Vivekanand S. Kattimani, Associate Professor, Department of Oral and Maxillofacial Surgery, SIBAR Institute of Dental Sciences, Guntur, Andhra Pradesh
8. Dr. V. Manju, Assistant Professor, Department of Biochemistry, Periyar University, Salem, Tamilnadu
9. Dr. L. Krishna Prasad, Dean, SIBAR Institute of Dental Sciences, Guntur, Andhra Pradesh
10. Dr. A. Thamizhavel, Associate Professor, Department of Condensed Matter Physics & Materials Sciences, Tata Institute of Fundamental Research, Mumbai
11. Sanction Folder



Dr. Krishna Kanth Pulicherla  
Scientist D  
011-26590493



**Dr. L. KRISHNA PRASAD**  
DEAN  
**SIBAR INSTITUTE OF DENTAL SCIENCES**  
GUNTUR-522509, A.P., India.

**FELLOWSHIP AWARD LETTER/GRANT LETTER**  
**FROM THE FUNDING AGENCY**  
**(2018-2019)**



# Academy of General Education

MANIPAL, Karnataka, India

*The Supreme Governing Body of the Academy of General*

*Education hereby makes known that*

*Dr. Pingili Shruthi*

*has been enrolled as a*

## FELLOW OF THE ACADEMY

*Given under the seal of the Academy this the*

*04<sup>th</sup>*

*day of*

*July*

*2018*

*Dr. L. KRISHNA PRASAD*  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.



No. *18760*

*Manjiv*  
REGISTRAR



Academy  
of  
Dentistry International

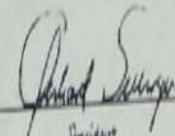
The Board of Regents confers upon

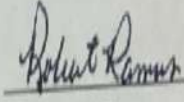
Dr. Revathi D.

the title of  
Fellow

in recognition of worthy contributions  
to the advancement of Dentistry worldwide on

6 October 2018

  
President

  
Executive Director

  
Dr. L. KRISHNA PRASAD  
DEAN

SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

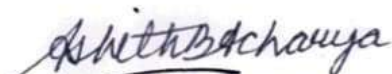


## Certificate of Attendance

This is to certify that **Dr. Kiran Kumar K** has completed a six-day contact module from 6–11 August 2018 as part of the one-year Fellowship of Forensic Odontology in which he is currently enrolled at S.D.M. College of Dental Sciences and Hospital, Dharwad, Karnataka.

As part of the contact module, **Dr. Kiran Kumar K** has gained experience in the methods of evidence collection and analysis in dental age estimation, odontometric sex assessment, population identification and forensic bite mark investigation.

Yours sincerely,



Dr. Ashith B. Acharya, B.D.S., G.D.F.O.

State Dental Council Reg. No. 7041-A

Government-certified Forensic Dentist

Associate Professor and Head

Department of Forensic Odontology

SDM College of Dental Sciences & Hospital

Sattur, Dharwad – 580009

Karnataka

Mobile: +91-9880192052

11 August 2018

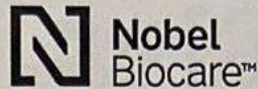


Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.



**FELLOWSHIP AWARD LETTER/GRANT LETTER**  
**FROM THE FUNDING AGENCY**  
**(2017-2018)**





## SUPPORT AGREEMENT MODIFICATION/AMENDMENT

**Study Title:** Evaluation of hard and soft tissue changes after immediate and delayed loading in parallel conical connection implants – A clinical study.  
**Study code:** 2016-1475

**Execution Date of the Original Agreement:** 2017-April-13<sup>th</sup>

**Modification Number:** No. 2

### Changes/Modifications in this Contract

- Appendix 2 The table timeline is **replaced** with the following:


Milestone	Date
Start of recruitment of patients	May 2017
Patients recruitment finalized	Feb 2022
All patients implant placement completion	March 2022
All patients final prosthesis delivered	Sep 2022

- Appendix 2: The term is **replaced** with the following:

**Term:** This agreement enters into force at signing and shall remain in force until finalization of the study or until **2023-12-31**

- All other terms and conditions remain the same.**
- 

(Signature page follows)

  
**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.





## SUPPORT AGREEMENT

BETWEEN

**Sibar Institute of dental sciences**

Department of Oral and maxillofacial Surgery, Department of Prosthodontics and crown,  
Bridge, Takkellapadu, Guntur, INDIA  
("Clinic")

AND

**Nobel Biocare Services AG**

Postfach, CH-8058 Zürich-Airport, SWITZERLAND  
VAT Reg. No. CHE-116.325.566 MWST  
("Nobel Biocare")

*WHEREAS*, the Clinic is engaged in education and research in the field of dental implants and dental prosthetics;

*WHEREAS*, Nobel Biocare is an entity within the Nobel Biocare group; the Nobel Biocare group is a world-leading supplier of aesthetic dental solutions; the Nobel Biocare group develops, produces and markets dental implants and IT-based industrialised dental prosthetics and treatments world-wide;

*WHEREAS*, the Clinic wishes to perform a study and has asked Nobel Biocare to support the Clinic in its efforts to perform said study;

*NOW THEREFORE*, the parties have agreed as follows:

### 1. Support

Nobel Biocare would be pleased to support the Clinic making the in-kind contributions of Nobel Biocare components as set forth in Appendix 1 ("**Support**"). The Support constitutes the maximum support of Nobel Biocare; the Clinic acknowledges that no further support will be granted by Nobel Biocare, unless expressly agreed in writing by the parties, and that the actual amount of Support will be determined according to actual consumption of Support (see clause 7).

Nobel Biocare is committed to an ethical, proactive and professional approach to clinician-industry relations. Therefore, Clinic acknowledges and agrees that information regarding the Support made and costs or expenses covered or reimbursed pursuant to this Agreement or other information relating to this Agreement may be disclosed by Nobel Biocare to third parties or governmental authorities pursuant to applicable laws (e.g. the US Patient Protection Affordable Care Act), regulations, or policies.

## 2. Purpose

The Clinic shall use the Support exclusively for the purpose of performing the study as set forth in Appendix 2 ("**Study**"). The Clinic represents and warrants that the study protocol attached as Appendix 2 is complete and accurate (in particular, no other products or group of products than those detailed in the study protocol are included in the Study).

The Clinic agrees to inform Nobel Biocare about any intended change in the study protocol and will implement such change only with Nobel Biocare's prior written approval. If the Clinic changes the study protocol without approval of Nobel Biocare, Nobel Biocare is entitled to stop any outstanding Support and to claim back or, at Nobel Biocare's sole discretion, invoice any already provided Support.

## 3. Responsibility

The Clinic shall have the sole responsibility and liability for the Study and all circumstances relating to the Study, including but not limited to obtaining relevant ethical approvals for performance of the Study. Nobel Biocare shall have the product liability for the Nobel Biocare standard products delivered to the Clinic under this agreement.

For the avoidance of doubt, the sponsor, as defined in ICH-GCP, ISO 14155 etc. for the Study is:

Name: Dr.T Krishna Mohan  
Address: Department of Prosthodontics Crown and Bridge  
Sibar Institute of dental sciences, Takkellapadu, Guntur, India

In case the sponsor leaves the Clinic or is not able to continue his/her work as sponsor for any other reason, the Clinic will ensure a suitable replacement of the sponsor. If Clinic does not nominate a suitable new sponsor within three (3) months from the date the Clinic becomes aware that the old sponsor is no longer able to continue his work as sponsor, Nobel Biocare is entitled to immediately terminate this agreement. The suitability of a new sponsor is determined by Nobel Biocare at its sole discretion.

Clinic ensures that all involved clinicians have sufficient training and experience on the products and procedures used in the Study (i.e. at least 10 patients treated with products and respective procedures of the Study) to prevent that the results of the Study are influenced by the learning curve of the clinicians. Furthermore, Clinic ensures that all involved personnel has received training on Good Clinical Practice, if applicable, and the sponsor has at least a two (2) year proven history in clinical investigations.

Clinic agrees to inform Nobel Biocare at least once per calendar quarter in detail on the status of the Study by communication means agreed with Nobel Biocare (e.g. email, phone).

## 4. Reports

Clinic provides Nobel Biocare with a report as a service in return for the Support ("**Final Report**"). The Final Report has to be submitted to Nobel Biocare no later than six (6) months after completion of the Study. In case of in vivo studies, "completion" shall mean "last patient out". For projects ongoing over 12 months, the Clinic will provide Nobel Biocare with an annual report no later than December 15 of each calendar year ("**Progress report**"). The Final Report must meet the standards as defined for

publications in a Peer-Review-Journal with Impact Factor (e.g., J Dent Res, J Clin Periodontol, Int J Oral Maxillofac Implants).

All reports must be submitted in English language. A publication or a thesis may be considered as a replacement for a report if Nobel Biocare gives its consent after having been provided with the manuscript. A poster, abstract, PowerPoint-presentation will not be considered as a replacement of a report.

Nobel Biocare reserves the right to refuse acceptance of a report within sixty (60) days after receipt if the submitted report does not meet the required standard as set out above and is allowed to ask for subsequent improvement, which is to be provided within sixty (60) days.

If the Final Report is not submitted in a timely manner, Nobel Biocare is entitled to invoice any in-kind support provided under this agreement at current list prices in the country of the Clinic. If a Progress Report is not submitted in a timely manner, Nobel Biocare may withhold the Support until the Progress Report is submitted.

#### **5. Publications**

Nobel Biocare recognises the Clinic's fundamental interest in publishing the study's general scientific findings and it will not unreasonably prevent such scientific publications. In recognition of Nobel Biocare's justified economic interests, the parties agree that the Clinic will keep the specific results of the Study confidential and will publish them only after having provided Nobel Biocare a copy of the proposed publication and given Nobel Biocare reasonable time, not below sixty (60) days, to give its comments on the proposed publication. Nobel Biocare's acceptance of the publication will not be unreasonably withheld.

#### **6. Recognition**

Recognition of this Support by the Clinic will be made in publications under "Acknowledgements". Such recognition shall read: "This work has been supported by Nobel Biocare with research grant 2016-1475".

#### **7. Statements on actual use and consumption of Support**

The Clinic agrees to provide to Nobel Biocare no later than December 15 of each calendar year a detailed written report on the actual use and consumption of any Support provided by Nobel Biocare under this agreement (the "**Yearly Statement**"). If a Yearly Statement is not submitted in time to Nobel Biocare, Nobel Biocare may, at its sole discretion, withhold any future parts of the Support until the Yearly Statement is submitted by the Clinic.

In addition, the Clinic agrees to provide to Nobel Biocare at the date of the termination or the completion of the Study a final detailed written report on the actual use and consumption of all Support provided by Nobel Biocare under this agreement (the "**Final Statement**"). In case the Final Statement shows that the Support or parts thereof were not consumed as of the termination date of this agreement or completion of the Study, Nobel Biocare may, at its sole discretion and unless expressly agreed otherwise by the parties in writing, claim back the not consumed parts of the Support or may invoice any

not consumed in-kind contribution from the Clinic at then current list prices in the country of the Clinic.

#### 8. **Confidentiality**

Subject to the publication rights set out below, the Clinic and Nobel Biocare agree to keep in confidence any written information expressly marked as "confidential" that is forwarded by Nobel Biocare to the Clinic, or such oral information which is clearly defined as confidential upon its disclosure provided it is followed by a written notice specifying the information so disclosed and its being confidential within 30 days of such disclosure.

#### 9. **Rights to results of the study**

All rights to results from Clinic's work on the study shall remain the property of the Clinic.

The Clinic shall promptly disclose in writing to Nobel Biocare any inventions that are made under the Study ("**Invention**"). Further, the Clinic shall inform Nobel Biocare whether or not the Clinic will file a patent application concerning the Invention. Nobel Biocare is entitled to file in its own name a patent application concerning the Invention (i) if the Clinic does not intend to file a patent application concerning the Invention; or (ii) if the Clinic within forty (40) days has not replied to Nobel Biocare's request if the Clinic intends to file a patent application concerning the Invention.

If the Clinic in its own (or any affiliate's) name files a patent application concerning the Invention the following shall apply. The Clinic hereby grants Nobel Biocare and all companies within the Nobel Biocare Group an exclusive, worldwide, royalty-free license to use and practice the Invention.

#### 10. **Assigned Contact persons**

The following individuals are assigned to settle all queries arising from this agreement:

- from Nobel Biocare: Nobel Biocare Services AG  
Clinical Research Department  
Attn: Alexandra Rieben  
Postfach  
CH-8058 Zurich Airport  
Switzerland
- from the Clinic: Dr. Vivekanand Kattimani  
Department of Oral and Maxillofacial Surgery  
Department of Prosthodontics Crown and Bridge  
Sibar Institute of dental sciences, Takkellapadu, Guntur  
India

#### 11. **Entire Agreement**

This agreement constitutes the entire understanding between the parties with respect to the subject matter hereof and supersedes all prior agreements, understandings and negotiations, both written and oral, between the parties.



**12. Term**

This agreement enters into force at signing and shall remain in force until finalization of the Study as set out in the time schedule in Appendix 2. Sections 4, 5, 7 and 8 of this agreement, however, shall survive the term. If the Clinic has not started the study and claimed the Support under this agreement within three (3) months from signing of this agreement, this agreement shall immediately terminate and all support and in-kind contributions paid to the Clinic shall immediately be repaid to Nobel Biocare.

**13. Termination**

Either party may terminate this agreement with immediate effect if the other party (i) has taken general measures to cease payment of its debts, initiated negotiations for a general agreement with its creditors, been subject to an application for bankruptcy proceedings or enters into composition, reorganisation or similar arrangements with its creditors or ceases to carry on business or is wound up or goes into liquidation or has a receiver appointed for all or any part of its assets; or (ii) fails to fulfil its obligations under this agreement, provided such failure is of fundamental importance for the other party and the failure has not been cured within thirty (30) days of receiving written notification from the party invoking this item. The notification shall be made without unreasonable delay, once the party becomes aware of the relevant circumstances.

In addition to the termination right set out above, each party may terminate this agreement with a three (3) months prior written notice to the other party.

Sections 4, 5, 7 and 9 of this agreement, however, shall survive the termination.

**14. Waiver**

Failure to insist upon strict compliance with any of the terms, covenants or conditions of this Agreement shall not be deemed a waiver of such terms, covenants or conditions, nor shall any waiver or relinquishment of any right or power hereunder at any one time or more times be deemed a waiver or relinquishment of such right or power at any other time or times.

**15. Severability**

The invalidity or unenforceability of any provision of this Agreement shall not affect the other provisions hereof, and the Agreement shall be construed in all respects as if such invalid or unenforceable provisions were omitted. Furthermore, upon the request of any Party hereto, the Parties to this Agreement shall add, in lieu of such invalid or unenforceable provisions, provisions as similar in terms to such invalid or unenforceable provisions as may be possible and legal, valid and enforceable.

**16. Applicable Law**

This Agreement shall be governed by and construed according to the substantive Laws of Switzerland.

**17. Dispute resolution**

In case of controversies arising out of this Agreement, which cannot be settled amicably, the exclusive place of jurisdiction shall be at the registered office of Nobel Biocare.

\_\_\_\_\_  
Signature page follows

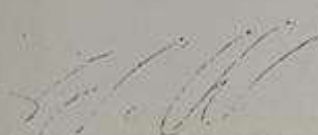



Kloten, 03. April 2017

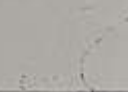
Place and date 13<sup>th</sup> APRIL 2017

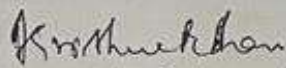
NOBEL BIOCARE SERVICES AG

THE CLINIC


  
\_\_\_\_\_  
Prof. Dr. Stefan Holst  
Vice President Implant Systems & Research

  
\_\_\_\_\_  
Name: Dr.L Krishna Prasad, Dean  
~~Sponsor Investigator~~

  
\_\_\_\_\_  
Adrian Schell  
Legal Counsel

  
Name: Dr. T. Krishna Mohan, Director  
Sponsor Investigator.

Read and understood

  
Dr. L. KRISHNA PRASAD  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.

\_\_\_\_\_

**APPENDIX 1****NOBEL BIOCARE SUPPORT AND IN-KIND CONTRIBUTIONS**

<b>SUPPORT DATE</b>	<b>IN-KIND CONTRIBUTION</b>	
Upon signing this agreement and after receipt of ethical approval	Max. 60	Nobel Parallel Conical Connection with Cover Screw
	Max. 30	Healing Abutment Conical Connection
	Max. 30	Temporary titanium abutments
	Max. 15	Impression coping
	Max. 1	Protection Analog Conical Connection NP 5/pkg
	Max. 60	Implant replica Conical Connection
	Max. 60	Universal Base (for screw retained prosthesis)

All in-kind contributions consist of components from Nobel Biocare's standard assortment. The value of the in-kind contributions will be based on the published Nobel Biocare price list in effect in India at the time of the contribution.

The abovementioned in-kind contributions constitute the maximum amount of support granted to the Clinic. The actual amount of support will be determined based on the actual consumption of support (see clauses 2 and 7). In no event will the Support exceed the abovementioned in-kind contributions. The Support is inclusive of all taxes, charges, fees, postage, etc., if any (i.e. Nobel Biocare will not reimburse Clinic for any taxes, charges, fees etc., unless expressly agreed otherwise in writing).

The ordering of the in-kind contribution components as mentioned above can be initiated after the signing of this Agreement by both Parties at the earliest and shall exclusively be made through the competent clinical research manager, not via commercial platforms such as Nobel Biocare customer service or the e-Shop or the NobelProcera software. The applicable ordering process will be communicated by the competent clinical research manager without delay after the signing of this Agreement by both Parties. In case of non-compliance with any of the above instructions, components will not be considered as in-kind contribution according to this Agreement and Nobel will not reimburse or revoke any invoices received for such orders.

**APPENDIX 2****DESCRIPTION OF THE STUDY****Study code:** 2016-1475**Study title:** Evaluation of Hard and soft tissue changes after immediate and delayed loading in parallel conical connection implants - A clinical study.**Title of the Topic:**

Evaluation of Hard and soft tissue changes after immediate and delayed loading in parallel conical connection implants - A clinical study.

**Background and Need for the study:**

Creating an aesthetic & functional restoration that is indistinguishable from natural teeth requires good bone density & thickness of soft tissue which surrounds the bone structure. These are important factors for the success of the implant. Bone density and type of bone is considered to determine the predictability of implant stability and successful implant treatment. Gingival biotype is also reported to influence the outcome of implant therapy. The thickness of buccal gingiva and alveolar bone at different apicocoronal level is of paramount importance to determine implant stability. This study evaluates and compares the bone density, implant stability and influence of soft tissue biotype on crestal bone level in immediate and delayed loading.

**Objectives of the study:**

- 1) Assessment of implant stability
- 2) Assessment of crestal bone level
- 3) Assessment of soft tissue biotype
- 4) Assessment of soft tissue adaptation around implant

**Hypothesis:**

Immediate loading also have similar result on hard and soft tissue changes as in delayed loading.

**Material and Methods:**

- 1) Implants (Nobel Biocare parallel conical connection implants.)
- 2) Intra oral periapical (IOPA) radiographs with grid
- 3) Cone beam computed tomography (CBCT)
- 4) DIGORA software
- 5) Provisional restoration (self-cure acrylic)
- 6) William's periodontal probe (coloruve probe-Hu-Friedy)

  
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 DEAN  
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 GUNTUR-522509, A.P., India.



- 7) Osstel (Resonance Frequency Analyzer)
- 8) Definitive prosthesis
- 9) Surgical template
- 10) Endodontic file no: 20 with rubber stopper
- 11) Pressure sensitive Probe (Hu- Friedy)
- 12) Digital callipers

**Source of data:**

Study population will be selected according to the following criteria:

- Study will be conducted on 60 patients between the age group of 20-50yrs with partial edentulous condition requiring fixed implant supported prosthesis presenting to outpatient department of Sibar Institute of Dental Sciences. Guntur.
- The patients will be divided into two groups (30 patients each).
- In Group I implants will be loaded immediately and Group II – will receive delayed loading (3-6 months after placement of implant) randomised using lottery method.

**Inclusion criteria:**

- i) Patients aged between 20-50yrs, irrespective of their gender.
- ii) Patients with Edentulous area.
- iii) Patients with adequate bone height (>13 mm )and width (>6 mm buccolingually and mesiodistally )
- iv) Patients who are systematically healthy (ASA I and II).
- v) Patients who are cooperative, motivated and hygiene conscious.

**Exclusion criteria:**

- i) Medically compromised patients and patients with adverse oral habits like smoking, para-functional habits, hypertension, pregnancy.
- ii) Patients who need restorative treatment of adjacent teeth and any form of bone augmentation before or in conjunction with implant surgery.

**Pre-operative protocol:**

- Pre-operative photographs, radiographs and impressions will be obtained for initial screening and evaluation.
- Initial therapy consists of thorough scaling with proper oral hygiene instructions.

- Impressions will be taken and diagnostic casts will be prepared.
- A surgical guide will be prepared on the diagnostic casts.

**Post-operative protocol:**

- After surgery all patients will be prescribed, antibiotics Cap.Amoxicillin / Tab. Erythromycin 500mg three times a day for five days and Tab.Metronidazole 400mg three times a day for five days are used. Chlorhexidine oral rinse of 0.2% prescribed for 60 seconds 3-4 times a day for 14 days.
- During healing period, patients will not be allowed to use any removable prosthesis and encouraged to maintain good oral hygiene.

**Surgical procedure:**

**Immediate Loading Protocol**

Standard operating protocol will be followed under Local Anesthesia using conventional surgical stent for Implant Placement. The implant platform will be positioned slightly below the alveolar crest level in the esthetic area. After placement of implant RFA will be checked. Implant level impression will be taken for crown preparation and temporary prosthesis will be prepared using temporary titanium abutment and fixed using screw. After 3 months, temporary prosthesis will be removed and permanent screw retained prosthesis will be fixed using universal base titanium (UBT) abutment.

**Delayed Loading Protocol**

Standard operating protocol will be followed under Local Anesthesia using conventional surgical stent for Implant Placement. After the placement of implant RFA will be checked. Implant screw will be placed and sutures will be given. Tissue punch will be used to expose implant screw and will be removed after 3 months in mandible and 6 months in Maxillae. Healing cap will be placed for 10 days. After 10 days healing cap will be removed and Implant level Impression will be taken for crown preparation and screw retained prosthesis will be fixed using universal base titanium (UBT) abutment.

**Follow up protocol:**

1. All the parameters (Bone density, Stability of the implant, bone level, Sulcus probing depth, Soft tissue biotype or Mucosal Thickness, Bleeding on probing) will be recorded at baseline, 3 month, 6 month and later at 12, 24 months postoperatively.

**Method of collection of data:**

**The following parameters will be measured for hard and soft tissue assessment:**

- 1) **Bone Density values:** Density will be measured using cone beam computed tomography (CBCT) assessed preoperatively and at 24month interval. Intra oral periapical (IOPA) radiographs will be taken and with help of Digora software density will be measured at baseline, 6, 12 and 24 month intervals.
- 2) **Stability of the implant:** Stability will be assessed using Osstel- Resonance Frequency Analyzer on the day of Implant placement and 3 months in mandible and 6 months in maxilla after implant placement and post operatively at 12 & 24 months; it will be measured in implant stability quotient (ISQ).
- 3) **Crestal bone level:** Bone level will be measured using standard IOPA radiographs with the help of grids. The distance between implant shoulder and alveolar crest (at the bone to implant contact point) will be recorded at the mesial and distal areas of implants assessed at base line, 6, 12 and 24 month post operatively.
- 4) **Sulcus probing depth (PD):** Probing depth will be measured using William's probe (Coloruve probe-Hu-Friedy) in the mesial, distal line angle and middle of buccal /lingual areas and will be recoded as the probing depth around the implant at base line, 6, 12 and 24 months post operatively.
- 5) **Soft tissue biotype or Mucosal Thickness (MT):** Thickness will be measured using endodontic file number 20 with rubber stopper. The file will be inserted at predetermined reference point to assess the mucosal thickness. The reference point will be taken at the midpoint of the distance between free gingival margin and mucogingival junction. The distance between the tip of file and rubber stopper will be recorded as the mucosal thickness using a digital calliper (to the nearest 0.1mm) at base line, 6, 12 and 24 months post operatively.
- 6) **Bleeding on probing (BOP):** Bleeding will be measured using pressure sensitive probe at base line, 6, 12 and 24 months post operatively; pass it along with gingival sulcus with force of 0.25 N/cm wait for 30 seconds to assess modified sulcular bleeding index by Muhlemann and son. (No bleeding - 0, Pinpoint bleeding - 1, Thin linear rim of bleeding -2, Profuse bleeding-3).

#### Statistical Procedure for Evaluation-

Observational data will be processed for comparison between the techniques of implant insertion using mean and percentage. Bleeding on probing at different time intervals will be explained with descriptive analysis. Interval scale data like probing depth will be explained. Standard deviation, Paired t-test used for comparison of each point, Non parametric Wilcoxon signed rank test, and Mann Whitney U -test will be used for assessment with 0.05 level of significance.

**Requirement for the study in addition to previous approval-**

1) As the study involves immediate loading protocol, we require temporary titanium abutment for temporization. So, the study requires 30 temporary titanium abutments (36663) in addition to previous requirements.

2) Requirement of Protection analog 60 (36730) in no for Universal base abutment as mentioned in work flowchart.

**Query-**

1) Regarding the use of UBT abutment as per brochure (Universal workflow chart point no:4) after casting the final restoration, it will be cemented using cement/Adhesive to Titanium base and then screwed to implant. So in last proposal, it has been mentioned as cement and screw retained. But considering the concerns of global team the changes have been carried out in the draft of planned study proposal as the only screw retained solution.

**Milestones and estimated timeline**

Milestone	Date
Start of Recruitment of Patients	May -2017.
All patients implant placement completion	April-2019
All patients Final prosthesis delivered	October 2019

**Term:** This agreement enters into force at signing and shall remain in force until finalization of the study or until 2020-12-31.

  
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 DEAN  
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 GUNTUR-522509, A.P., India.





**INSTITUTIONAL ETHICS COMMITTEE**

**Sibar Institute of Dental Sciences**

Takkellapadu, Guntur - 522 509, Andhra Pradesh

Date: 09.01.2021

To,  
Dr. T. Krishna Mohan  
Principal Investigator

Sir,

Subject: Regarding extension of study "Evaluation of hard and soft tissue changes after immediate and delayed loading in parallel conical connection implants – A clinical study"

With reference to your letter dated 2/01/2021, regarding extension of study period of your research project titled "Evaluation of hard and soft tissue changes after immediate and delayed loading in parallel conical connection implants – A clinical study" till 31<sup>st</sup> December 2022 and the same has been unanimously accepted by the review committee of IEC – Sibar in its meeting held on 06. 01.2021.



**Dr. L. KRISHNA PRASAD**  
DEAN  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR-522509, A.P., India.



Member Secretary,  
**MEMBER SECRETARY**  
Institutional Ethics Committee  
SIBAR INSTITUTE OF DENTAL SCIENCES  
GUNTUR

**APPENDIX 1****NOBEL BIOCARE SUPPORT AND IN-KIND CONTRIBUTIONS**

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All in-kind contributions consist of components from Nobel Biocare's standard assortment. The value of the in-kind contributions will be based on the published Nobel Biocare price list in effect in India at the time of the contribution.

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The ordering of the in-kind contribution components as mentioned above can be initiated after the signing of this Agreement by both Parties at the earliest and shall exclusively be made through the competent clinical research manager, not via commercial platforms such as Nobel Biocare customer service or the e-Shop or the NobelProcera software. The applicable ordering process will be communicated by the competent clinical research manager without delay after the signing of this Agreement by both Parties. In case of non-compliance with any of the above instructions, components will not be considered as in-kind contribution according to this Agreement and Nobel will not reimburse or revoke any invoices received for such orders.

  
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