

INSTRUCTIONS FOR USE



Figure 1. UCLA



Figure 2. Coping

ATTENTION: The figures are merely illustrative. They do not represent the real dimensions.

This device is intended for a specialized procedure, which should be performed by professionals qualified in Dental Implants. For optimum results, use the product knowing the appropriate techniques. Always apply them under appropriate conditions, also in an operating room atmosphere. They are prosthetic components indicated for making prostheses, used in laboratory, for casting of the basis of the elements which will be used in intraoral rehabilitation.

INDICATIONS FOR USE

The DSP Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

DESCRIPTION

Coping: prosthetic component made of castable polymer material for laboratory use in the phases of waxing and casting of infrastructure of prosthesis screwed or cemented on dental implants. It features external retentions. It has cylinder format with external retentions for the execution of the closing. In one of the ends there is fitting for the installation over the respective implant/component.

UCLA: prosthetic component made of castable polymer material for laboratory use in the phases of waxing and casting of infrastructure of prostheses screwed or cemented on dental implants. Available in rotational and antirotational versions.

APPLICATIONS

Cylinder: Suitable for manufacturing infrastructures of multiple or single prostheses (table) screwed or cemented on the Prosthetic Component or Implant. They can be used in immediate or conventional rehabilitation procedures on the maxilla or mandible. Check the compatibility between the prosthetic interface chosen. This product is indicated depending on the interocclusal space available, existing gingival height, and three-dimensional position of the implant.

CONTRAINDICATIONS

This product is contraindicated for insufficient interocclusal space and unsatisfactory three dimensional position of the implant.

HANDLING

For the use of the Cylinder or UCLA, in procedures in two stages, prior preparation can be executed of the soft tissue using the healing abutment. After the installation of the Implant or intermediary item in the mouth, transfer its position by means of molding with the aid of the corresponding transfer, as per suitable techniques. Screw the Cylinder or UCLA on the Analog and customize in accordance with the interocclusal space available. Execute the wax-up. The standard obtained must be included in cover compatible with the alloy which will be used in the casting process. Thus, one obtains the structure which will be the basis for the acrylization or porcelain application. Tests must be made of passivity and adaptation of the prosthesis structure. Torques recommended:

CALCINABLE UCLA	20 Ncm
CALCINABLE COPING	10 Ncm

PRECAUTIONS

- It is advisable that the end prosthesis is hygienized before the installation in the mouth.
- Before installing the product, ensure that it has the same prosthetic interface as the prosthetic component/implant. Check that the stability of the implant is sufficient to withstand the installation torque of the prosthetic component and functional load, in accordance with the instructions for use of the implant.
- The selection of the material of the prosthesis structure must take into account local aspects of the patient.
- Do not use the product with the validity expired.
- For application of immediate load check the indication of torque of the implant installed.
- Check the torque to be given on the prosthetic component to be used. The excess or lack of torque can lead to undesirable results.
- Before each procedure, ensure that there is a perfect fit between the parts.
- Ensure that the parts are not swallowed or inhaled by the patient.
- During the installation, make sure to align it with the implant insertion axis. Ensure that it is perfectly seated in the Implant. To do so, periapical radiographs are recommended with the parallelism technique.
- Ensure that you use a prosthetic screw compatible with the prosthetic interface and the prosthetic component.
- Check passivity and execute occlusal and interproximal adjustment after the installation of the prosthesis, avoiding the impairment of the implant/prosthesis unit.
- Before each procedure check the condition of the DSP Biomedical instruments, always respecting their useful life. Replace the instruments if there is damage, markings deleted, sharpness jeopardized, deformation and wear.
- It is the dentist's responsibility to use the DSP Biomedical products in compliance with the instructions for use.
- This product is of single use.
- Reuse of this product may cause:
 - adverse biological effects of residual products, microorganisms and / or substances resulting from previous uses and / or reprocessing;
 - changes in physical, mechanical and chemical properties of products, macro and micro structural, that can put in risk the desired functionality. The reuse of this product does not guarantee its safety and efficacy and disclaims any warranty of products.
- Do not use the product if the package has been violated.
- This product should not be used as a plastic temporary element.
- The metal choice should be done by a dentist in order to minimize the possible adverse events for each patient.
- An insertion torque higher than that recommended and improper Drivers may cause damages to the material and make the system unusable.
- Better results are achieved with the utilization of the DSP Biomedical products sequence. The utilization of instrumentations and/or Prosthetic Components from other manufacturers does not assure the perfect function of the DSP Biomedical Implant System and voids any product guarantee.
- A special precaution should be taken during the closure so that the interocclusal space is not insufficient or excessive. • Improper planning can compromise the performance of all the teeth or Implants/Prosthesis resulting in system failures, such as the loss or breakage of a tooth/Implant, the loosening or fracture of a Prosthetic Screw.

ADVERSE EFFECTS

Adverse effects are not expected as long as the product is used in accordance with its instructions for use.

ADDITIONAL INFORMATION TO THE PROFESSIONAL

Instruct the patient as to the need of a professional medical monitoring after the surgery and to obey the guidelines regarding the precautions, hygiene and prescription of drugs. These guidelines are the responsibility of the professional in charge.

MAGNETIC RESONANCE IMAGING (MRI) - SAFETY INFORMATION

The DSP Implant System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the DSP Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PRESENTATION AND STERILIZATION

This product is indicated for single use and supplied non-sterile, packaged unitarily.

SANITATION

This product must be correctly sanitized and sterilized before its use.

For cleaning the DSP Abutments use the following manual cleaning process only. Automated cleaning has not been validated. Do not use automated cleaning for DSP Abutments.

1. Disassemble the abutment and screw (if applicable).

2. Prepare Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner per manufacturer's recommendation of 1ml/L of lukewarm tap water.
3. Immerse the articles into the prepared detergent solution and allow them to soak for a minimum of 1 minute. While soaking, brush the articles with a soft bristled brush.
4. Prepare Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner per manufacturer's recommendation of 1mL/L in lukewarm tap water in a sonication unit.
5. Immerse the articles into the prepared detergent solution and allow them to sonicate for 10 minutes.
6. Visually inspect each test article for visible soil. If any visible soil remains, repeat the cleaning process (steps 4-8) until no visible soil remains.

STERILIZATION

Sterilize the products the day before or on the day of the procedure.

ATTENTION: It is not recommended to autoclave these products in their original packaging. The product must be wrapped with a legislation-cleared wrap.

Please use for sterilization only the steam sterilization according to the following parameters:

VACUUM FRATIONATED/DYNAMIC AIR REMOVAL PARAMETERS¹	
Sterilization time	4 minutes
Temperature	132°C
Drying Time	20 minutes ²

¹ At least three vacuum steps.

² The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

TRACEABILITY LABEL

This product is accompanied by three labels that allow its traceability and should be attached to the following documents: • Medical record; • Collection tax document; • Document to be delivered to the patient (ask your advisor). The identification and traceability are performed through numeric codes REF and LOT.

STORAGE CONDITIONS

This product should be stored, in its original packaging, in a clean and dry location, in a maximum temperature of 45°C and protected from direct sunlight.

DISPOSAL OF MATERIAL

Every product and consumable used during the surgery for the installation of dental implants may endanger the health of those who handle them after use. Before discarding them into the environment, it is recommended to observe the current legislation and adhere to it.

DATE OF EXPIRATION

Written on the label.

PRODUCT GUARANTEE


























DSP Biomedical assures to the owner of this product guarantee against any material or manufacturing defect, the presence of any defect shall be immediately informed to the manufacturer, respecting the legal term. The guarantee of the products manufactured by DSP Biomedical is strictly connected to following the information described in the instruction of use. The inadequate use of the product disregarding the indications releases the manufacturer and/or vendor of any responsibility.

Note: the guarantee does not cover wear and tear from using the product.

ASSISTANCE INFORMATION

If there is need of further information, or the product presents any adverse effect, with potential of risk to the patient, which generates or has potential of injury or threat to public health, or any dissatisfaction of the client, contact DSP through the phone numbers 0800 600 88 66, or send an e-mail to sac@dspbiomedical.com.br.

SYMBOLOLOGY

SYMBOLOLOGY	DESCRIPTION	SYMBOLOLOGY	DESCRIPTION
	Batch number		Consult instructions for use or consult electronic instructions for use
	Date of manufacture		Manufactured by
	Non Sterile		Keep dry
	Product Code		Keep away from sunlight
	Model Number		Single sterile barrier system
	Do not reuse		Used by-date
	Limit of temperature		Unique Device Identifier
	Authorized representative in the European Community		Country of manufacturer
	Caution		Do not use if package is damaged and consult instructions for use
	Importer		Humidity limitation
	Fragile, handle with care		Medical device
	CE Mark		Mandatory medical prescription Notification required by FDA for United States market
	CE marking with number of Notified body; SIQ, number 1304		

The SSCP is available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI. Please see Eudamed public website: <https://ec.europa.eu/tools/eudamed>. BASIC UDI: 79084678POMBASEBL

REF : Products

Device Description	Code
FCM SHORT CEMENTABLE CALCINABLE UCLA UNIT.	72.3008
FCM SHORT CEMENTABLE CALCINABLE UCLA MULT.	72.3005
FCM LONG CEMENTABLE CALCINABLE UCLA UNIT.	72.3010
FCM LONG CEMENTABLE CALCINABLE UCLA MULT.	72.3007
FC SHORT CEMENTABLE CANCELINABLE UCLA UNIT.	72.3708
FC LONG CEMENTABLE CALCINABLE UCLA UNIT.	72.3710
HE SLIM CALCINABLE UCLA UNIT.	3.3301
HE SLIM CALCINABLE UCLA MULT.	3.3302
MPC CALCINABLE UCLA MULT.	6.4012
CONICAL ABUT SLIM CALCINABLE UCLA UNIT.	7.3311
CONICAL ABUT CALCINABLE UCLA UNIT	7.4011
HE CALCINABLE UCLA UNIT.	3.4001
HE CALCINABLE UCLA MULT.	3.4002

Device Description	Code
FCM CALCINABLE UCLA UNIT	77.3011
FCM CALCINABLE UCLA MULT.	77.3012
FC CALCINABLE UCLA UNIT.	77.3311
FC CALCINABLE UCLA MULT	77.3312
CMH SLIM CALCINABLE UCLA UNIT	63.3301
CMH SLIM CALCINABLE UCLA MULT	63.3302
CMH CALCINABLE UCLA UNIT.	63.4001
CMH CALCINABLE UCLA MULT	63.4002
MPC CASTABLE COPING	6.4031
FCM CASTABLE COPING	77.3085
FC CASTABLE COPING	77.3385
TI-BASE SLIM CALCINABLE UCLA	4.5410I
TI-BASE STANDARD CALCINABLE UCLA	4.6410I
ANATOMICAL ABUTMENT CALCINABLE UCLA H4	4.4410I
ANATOMICAL ABUTMENT CALCINABLE UCLA H4	4.4410M
ANATOMICAL ABUTMENT CALCINABLE UCLA H6	4.4010I
ANATOMICAL ABUTMENT CALCINABLE UCLA H6	4.4010M

MANUFACTURED BY

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Reference

1-Lekholm U, Zarb G. Patient selection and preparations. Branemark, PI, Zarb,G & Albrektsson, T, eds Tissue-Integrated Prostheses: Osseointegration in Clinical Dentistry. Chigado: Quintessence; 1985. p. 233-40.