Figure 1. Support Copping

Figure 2. Castable Coping

Figure 3. Titanium Coping

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

INSTRUCTIONS FOR USE

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.

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. Implants with lengths less than 7 mm are intended for delayed loading only.

DESCRIPTION

Four exclusive prosthetic components are required for performing the One Step Hybrid Technique.
Support Coping: it is a prosthetic component made of Stainless-Steel ASTM F138 intended for prosthesis laboratory use, that presents in the outer part a tapered geometry for fitting the Castable Coping. Its inner part is compatible to the planned definitive Implant or abutment.
Castable Coping: it is a castable cylindrical prosthetic component made of POM. Its inner part is compatible to the planned definitive Coping.
One Step Hybrid Abutment/Coping: it is a prosthetic component made of commercially pure titanium (ASTM F67) that presents a tapered geometry with grooves and treated surface (Zirconia blasting) for cement retention. It is the definitive abutment/coping-type prosthetic device of the One Step Hybrid technique. The metallic infrastructure is cement-retained over the One Step Hybrid Abutment/ Coping, which is screw-retained over the coronal portion of the planned implant or Abutment.
Laboratory Screw: It is a screw made of Stainless-Steel ASTM F138 intended for laboratory use only in order to facilitate the handling. It presents thread compatible to the definitive abutment and can be installed or removed with hand or with a screwdriver.

APPLICATIONS

The One Step Hybrid Technique is indicated for multiple screwed prostheses when there is a need to obtain passivity in the metallic infrastructure fitting without using weld and regardless of the metal dimensional change after the casting process. The components for One Step hybrid technic are available for FC implants/ abutments, FCM implants/ abutments and Mini Conical abutments. Check the compatibility between the prosthetic interfaces chosen.

CONTRAINDICATIONS

These products are contraindicated for patients exhibiting signs of allergy or hypersensitivity to the chemical ingredients of the material: Titanium and Titanium alloy Ti6Al4V.
This product is contraindicated for insufficient interocclusal space and unsatisfactory three-dimensional position of the implant.

HANDLING

Whenever the Prosthetic Components for the One Step Hybrid Technique are used in procedures of two stages, a previous preparation of soft tissues with a Protection Cylinder is recommended. After installing the implants/ abutments in the mouth, transfer their position through molding with the corresponding Impression Coping, according to appropriate techniques.
Metallic structure casting process: Place the Support Copings over Analogs that correspond to the planned definitive Implants/abutments. Place the Castable Copings over the Support Copings, screw them with Laboratory Screws. After that, connect with acrylic resin the Castable Copings that are parallelly connected. Perform the infrastructure waxing and, once it is concluded, remove the Laboratory Screws, submitting the infrastructure to the casting process with specific metallic alloy. Place the casted infrastructure over the Support Copings in order to check the assembly passivity. If necessary, provide internal wear in the regions corresponding to the Castable Copings, which are now casted in metal, in order to achieve infrastructure passivity on Support Copings. Once the infrastructure passivity is achieved, perform internal retentions in the casted Copings in order to create mechanical retentions for the cement. Apply a thin layer of primer specific for metal (alloy primer) on this area. Substitute the Support Copings,

which present a slightly greater dimension (0.10 mm), for One Step Hybrid Copings, screw them over the corresponding Analogs with their corresponding Screws. Apply the primer specific for metal (alloy primer) on the external portion of One Step Hybrid Copings, obliterating the input hole with wax to avoid the entry of resinous cement. Apply a dual resinous cement on the outer surface of the One Step Hybrid Copings and on the internal portion of the metallic infrastructure that corresponds to the Castable Copings positions. Still with fresh cement, press the infrastructure over the One Step Hybrid Copings, immediately removing any overflown excess from the orifice. After cementing it, unscrew the infrastructure from the analogs and remove all the excess of remaining cement from the One Step Hybrid Copings edge. NOTE: For the cementation, it is recommended to use dual resinous cement Panavia F (Kuraray Co Ltd Tokyo-Japan) and the primer specific for metal Alloy Primer (Kuraray Co Ltd Tokyo-Japan). Proof and tests of passivity and adaptation of the prosthesis structure must be performed. Use the proper screwdrivers for handling of Prosthetic components for the One Step Hybrid Technique.
The One Step Hybrid Coping installation torque is 10 N.cm.

PRECAUTIONS

• It is recommended that the final prosthesis is cleaned before installation in the mouth, according to laboratory instructions.
• Before installing the product, ensure that it has the same prosthetic interface to the implant/ Abutment. Ensure 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.
• Check passivity and perform occlusal and interproximal adjustment after installation of the prosthesis, avoiding impairment of the implant/prosthesis assembly.
• Inadequate surgical and/or prosthetic planning can compromise the performance of the implant / prosthesis assembly, resulting in system failure, such as loss or fracture of the implant, loosening or fracture of components and/or prosthetic screws.
• The material selection of the prosthesis structure must consider general aspects of the patient.
• Do not use the product if the packaging is damaged.
• Do not use the product with the validity expired.
• The material to be used during the procedure must be sterile.
• This product must be used immediately after opening the packaging, at the moment of procedure. If it Is not used, discard it.
• This product is of single use and cannot be resterilized.
• 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.
• Note the conditions of the intra-oral tissue, the bone quality and quantity of the bed receiving the implant, by means of radiographic and/or tomography examinations. Nonperformance of the pre-surgical assessment may compromise the success of the procedure.
• Before each procedure, make sure the pieces are properly seated.
• Ensure that the parts are not swallowed or aspirated by the patient.
• Before each procedure check the conditions of the DSP Biomedical surgical instruments, always respecting their useful life. Replace the instruments if there is damage, markings deleted, sharpening compromised, deformation and wear.
• Always use the DSP Biomedical product sequence. The use of prosthetic components and/or instruments of other manufacturers does not ensure the perfect function of the DSP Implant System and exempts any product warranty.
• It is the professional's responsibility to use the DSP Biomedical products according to the instructions for use.

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, packaged individually in a package that offers double protection: blister and cardboard. The final cylinder is sterile using gamma radiation.

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

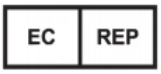
DSP Biomedical assures to the owner of this product guarantee against any material or manufacturing defect, the presence of any defect shall be immediately informed to the manufacturer, respecting the legal term. The guarantee of the products manufactured by DSP Biomedical is strictly connected to following 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.

SYMBOLOGY

SYMBOLOGY	DESCRIPTION	SYMBOLOGY	DESCRIPTION
LOT	Batch number		Consult instructions for use or consult electronic instructions for use
	Date of manufacture		Do not resterilize
	Manufactured by		Keep dry
STERILE R	Sterilized using irradiation		Keep away from sunlight
REF	Product Code		Single sterile barrier system
#	Model Number		Used by-date
	Do not reuse	UDI	Unique Device Identifier

	Limit of temperature		Country of manufacturer
	Authorized representative in the European Community		Do not use if package is damaged and consult instructions for use
	Caution		Humidity limitation
	Importer		Medical device
	Fragile, handle with care		Mandatory medical prescription Notification required by FDA for United States market
	CE Mark		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.

Support Coping: BASIC UDI: 79084678TIBASE2W
Castable Coping: BASIC UDI: 79084678POMBASEBL
One Step Hybrid Abutment/Coping: BASIC UDI: 79084678TIBASE2W

REF : Products

Device Description	Code
MPC SUPPORT COPING	6.4022
FCM SUPPORT COPING	77.3084
FLEXCONE SUPPORT COPING	77.3384
MPC CASTABLE COPING	6.4031
FCM CASTABLE COPING	77.3085
FC CASTABLE COPING	77.3385
MPC TITANIUM CYLINDER	6.4062
FCM TITANIUM CYLINDER	77.3081
FCM INDEXED DEFINITIVE CYLINDER	77.3081I
FC TITANIUM CYLINDER	77.3381
FC INDEXED DEFINITIVE CYLINDER	77.3381I

MANUFACTURED BY

DSP INDUSTRIAL LTDA
Rua Marechal Floriano Peixoto, 303 – Ouro Verde II
Campo Largo /PR – Brazil
CNPJ 03.960.018/0001-23
Phone: +55 41 3291-2200
www.dspbiomedical.com
Technician in charge: CREA- PR 25412/D

AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

DSP BIOMEDICAL EUROPA UNIP LDA
Alameda dos Oceanos, 142 Lt. 4.24 0H
Parque das Nações – Lisboa - Portugal
1990-502
Phone: (351) 962833592