
Figure 1: HE


Figure 2: HIM


Figure 3: HIL


Figure 3: HIS


Figure 4: CMI


Figure 5: CMH

ATTENTION: Images are for illustrative purposes only. They do not correspond to the actual dimensions of the product.

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.

DESCRIPTION

The Oring Abutment is a straight prosthetic component made of commercially pure titanium conforming to ASTM F67. One of its ends presents a fitting to the recommended driver/ connection for its installation and its other end has an interface compatible with the implant lines HE, HIM, HIL, HIS, CMI, FC, FCM. It presents a ball-shaped head design.

IMPLANT LINES	DIAMETER (MM)	GINGIVAL HEIGHT (MM)
HE	4.1	1, 2, 3, 4, 5
HIM	4.1	0, 1, 2, 3, 4, 5, 6
HIL	4.1	0, 1, 2, 3, 4, 5, 6
HIS	4.1	0, 1, 2, 3, 4, 5, 6
CMI	4.1	1.5, 2.5, 3.5, 4.5
FC	2.15	N.A.
FCM	2.15	N.A.

The Capsule is a prosthetic component having a specific function to link the removable prosthesis to the Oring Abutment, allowing the prosthesis to be removed for maintenance and cleaning. The Capsule has a pod-shaped cylindrical geometry with a polymer rubber ring conditioned inside the Capsule. The Capsule is made of commercially pure titanium conforming to ASTM F67 and is to remain fixed at the overdenture.

APPLICATIONS

The Oring Abutment is indicated to stabilize implant-mucosa supported removable full prostheses (retained on the implant and supported on the mucosa), on implants installed on the maxilla or mandibula. It can be used in immediate or conventional rehabilitation procedures for multi-unit restorations.

Check the compatibility between the prosthetic interfaces chosen. This product is indicated depending on the interocclusal space available, existing transmucosal height, and three-dimensional position of the Implant.

CONTRAINDICATIONS

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

HANDLING

Select the Oring Abutment according to the prosthetic planning and install it on the implant with proper driver to the recommended torque as specified in the table below.

LINES	INSTALLATION TORQUE (N.cm)
HE, HIM, HIL, HIS, CMI	30
FC/FCM	20

Fit the Plastic Capsule (2.4094) over the O-ring Abutment to correct the parallel alignment between the dental implants or roots and determine the correct distance between the Oring Abutment and Plastic Capsule. Position the Spacer Ring (2.4094) between the Oring Abutment and Capsule. In mouth, capture the Capsule position with acrylic resin, one at a time, keeping the prosthesis in occlusion until the resin completely cures. After, remove the Spacer Ring and perform the finishing on the prosthesis. The Oring Abutment will remain in the mouth and the Capsule and its inner Oring Rubber will remain on the prosthesis.

PRECAUTIONS

• Before installing the product, ensure that it has the same prosthetic interface as the implant. 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.
• The misuse, abuse or excessive force can cause stripping, breakage or irreversible damage to the product;
• 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.

ORING ABUTMENT
0.1146-IFU

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PRESENTATION AND STERILIZATION

This product is indicated for single use, sterilized by gamma ray, unitarily packed in a packaging that offers double protection: blister-type and cardboard.

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.

LIFETIME

This product has an estimated lifetime of 5 years.

DATE OF EXPIRATION

Written on the label.

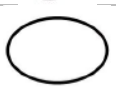
PRODUCT GUARANTEE

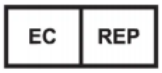
DSP Biomedical assures to the owner of this product guarantee against any material or manufacturing defect, the presence of any defect shall be immediately informed to the manufacturer, respecting the legal term. The guarantee of the products manufactured by DSP Biomedical is strictly connected to following 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. BASIC UDI: 79084678TIBASE2W

REF : Products

Device Description	Code
HE SLIM ORING ABUTMENT H1	2.3341
HE SLIM ORING ABUTMENT H2	2.3342
HE SLIM ORING ABUTMENT H3	2.3343
HE SLIM ORING ABUTMENT H4	2.3344
HE SLIM ORING ABUTMENT H5	2.3345
HE ORING ABUTMENT H1	2.4041
HE ORING ABUTMENT H2	2.4042
HE ORING ABUTMENT H3	2.4043
HE ORING ABUTMENT H4	2.4044
HE ORING ABUTMENT H5	2.4045
HIM ORING ABUTMENT H0	52.4040R
HIM ORING ABUTMENT H1	52.4041R
HIM ORING ABUTMENT H2	52.4042R
HIM ORING ABUTMENT H3	52.4043R
HIM ORING ABUTMENT H4	52.4044R
HIL ORING ABUTMENT H0	52.4040T
HIL ORING ABUTMENT H1	52.4041T
HIL ORING ABUTMENT H2	52.4042T
HIL ORING ABUTMENT H3	52.4043T
HIL ORING ABUTMENT H4	52.4044T
HIL ORING ABUTMENT H5	52.4045T
HIL ORING ABUTMENT H6	52.4046T
ORING ABUTMENT HIS H0	52.4040S
ORING ABUTMENT HIS H1	52.4041S
ORING ABUTMENT HIS H2	52.4042S
ORING ABUTMENT HIS H3	52.4043S
ORING ABUTMENT HIS H4	52.4044S
CMI ORING ABUTMENT H1.5	72.4041
CMI ORING ABUTMENT H2.5	72.4042
CMI ORING ABUTMENT H3.5	72.4043
CMI ORING ABUTMENT H4.5	72.4044
CMH SLIM ORING ABUTMENT H1	62.3341
CMH SLIM ORING ABUTMENT H2	62.3342

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Device Description	Code
CMH SLIM ORING ABUTMENT H3	62.3343
CMH SLIM ORING ABUTMENT H4	62.3344
CMH SLIM ORING ABUTMENT H5	62.3345
FCM ORING ABUTMENT	72.3004
FC ORING ABUTMENT	72.3704

MANUFACTURED BY

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