



Figure 1: HE Figure 2: HIM Figure 3: HIL Figure 4: HIS Figure 5: CMI Figure 6: CMH Figure 7: HEZ

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 Mini Conical Abutment is an intermediary prosthetic component to be installed between the implant and the prosthesis. It is made of commercially pure titanium conforming to ASTM F67 and is available in straight or angled versions. They are available for HE, HIM, HIL, HIS, CMI and CMH prosthetic interface with different gingival heights options to match the variations in mucosal thickness as shown in the table below:

PROSTHETIC INTERFACE	ANGLE (°)	DIAMETER (MM)	GINGIVAL HEIGHT (MM)
HE	0	4.1	1, 2, 3, 4, 5,5
	15	4.1	1, 2, 3
	25	4.1	1, 2
HIM	0	4.1	1, 2, 3
	17	4.1	1, 2, 3
	30	4.1	1, 2
HIL	0	4.1	1, 2, 3, 4,5
	17	4.1	1, 2, 3
	30	4.1	1, 2
HIS	0	4.1	1, 2, 3, 4,5
	17	4.1	1, 2, 3
	30	4.1	1,2
CMI	0	4.1	0.30, 0.75, 1.5, 2.5, 3.5, 4.5, 5.5, 6.5
	17	4.1	1.5, 2.5, 3.5
	30	4.1	1.5, 2.5
CMH	0	3.3	1,2,3

Mini Conical Abutments in straight version are available in one piece version only. Mini Conical Abutments in angled versions are available in two pieces version only.

APPLICATIONS

The Mini Conical Abutments are indicated for multi-unit restorations only. They are to be used exclusively with a coping extending the abutment portion to a minimum of 2 mm.

The Mini Conical Abutments can be used in immediate or conventional rehabilitation procedures on the maxilla or mandible. Check the compatibility between the prosthetic interface chosen.

The prosthesis is screw-retained over Mini Conical Abutment.

This product is indicated depending on the interocclusal space available, existing gingival 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 and Titanium alloy Ti6Al4V.

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

HANDLING

For use of the Mini Conical Abutment in two-stage procedures, prior preparation of the soft tissues can be done with use of a healing abutment.

Select the Mini Conical Abutment according to the prosthetic planning and install it over the implant using the recommended torque (see table below). Make sure of the correct fit between the abutment and the implant. Protect the access for the screw (with teflon and resin compound). It is recommended to make up a provisional prosthesis for gingival conditioning.

For the impression procedure, fit the corresponding Impression Coping, ensure the right fitting and take the impression using appropriate materials. Prepare the plaster model. Prepare the prosthesis according to appropriate laboratory techniques. Tests should be performed on passivity and the fit of the structure of the prosthesis. Screw the final prosthesis on the abutment.

TYPE	INSTALLATION TORQUE (N.CM)
Straight	30
Angled	15

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



MINI CONICAL ABUTMENT

0.1147-IFU

Revision 01 – 2025/04/17

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, sterile 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.



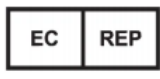









Note: the guarantee does not cover wear and tear from using the product.

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.

SYMBOLGY

SYMBOLGY	DESCRIPTION	SYMBOLGY	DESCRIPTION
	Batch number		Consult instructions for use or consult electronic instructions for use
	Date of manufacture		Do not resterilize
	Manufactured by		Keep dry
	Sterilized using irradiation		Keep away from sunlight
	Product Code		Single sterile barrier system
	Model Number		Used by-date
	Do not reuse		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 MINI CONICAL ABUTMENT H1	6.3401
HE SLIM MINI CONICAL ABUTMENT H2	6.3402
HE SLIM MINI CONICAL ABUTMENT H3	6.3403
HE MINI CONICAL ABUTMENT H1	6.4101
HE MINI CONICAL ABUTMENT H2	6.4102
HE MINI CONICAL ABUTMENT H3	6.4103
HE MINI CONICAL ABUTMENT H4	6.4104
HE MINI CONICAL ABUTMENT H5	6.4105
HIM MINI CONICAL ABUTMENT H1	56.4101M
HIM MINI CONICAL ABUTMENT H2	56.4102M
HIM MINI CONICAL ABUTMENT H3	56.4103M
HIL MINI CONICAL ABUTMENT H1 MULT.	56.4101T
HIL MINI CONICAL ABUTMENT H2 MULT.	56.4102T
HIL MINI CONICAL ABUTMENT H3 MULT.	56.4103T
HIL MINI CONICAL ABUTMENT H4 MULT.	56.4104T
HIL MINI CONICAL ABUTMENT H5 MULT.	56.4105T
HIS MINI CONICAL ABUTMENT H1 MULT.	56.4101S
HIS MINI CONICAL ABUTMENT H2 MULT.	56.4102S
HIS MINI CONICAL ABUTMENT H3 MULT.	56.4103S
HIS MINI CONICAL ABUTMENT H4 MULT.	56.4104S
HIS MINI CONICAL ABUTMENT H5 MULT.	56.4105S
CMI MINI CONICAL ABUTMENT H0.3	76.4100
CMI MINI CONICAL ABUTMENT H0.75	76.4000
CMI MINI CONICAL ABUTMENT H1.5	76.4001
CMI MINI CONICAL ABUTMENT H2.5	76.4002
CMI MINI CONICAL ABUTMENT H3.5	76.4003
CMI MINI CONICAL ABUTMENT H4.5	76.4004
CMI MINI CONICAL ABUTMENT H5.5	76.4005
CMI MINI CONICAL ABUTMENT H6.5	76.4006
CMH SLIM MINI CONICAL ABUTMENT H1 MULT.	66.3401

CMH SLIM MINI CONICAL ABUTMENT H2 MULT.	66.3402
CMH SLIM MINI CONICAL ABUTMENT H3 MULT.	66.3403
HEZ MINI CONICAL ABUTMENT H1	6.4101Z
HEZ MINI CONICAL ABUTMENT H2	6.4102Z
HEZ MINI CONICAL ABUTMENT H3	6.4103Z
HEZ MINI CONICAL ABUTMENT H4	6.4104Z
HEZ MINI CONICAL ABUTMENT H5	6.4105Z
CMH MINI CONICAL ABUTMENT H1 MULT.	66.4101
CMH MINI CONICAL ABUTMENT H2 MULT.	66.4102
CMH MINI CONICAL ABUTMENT H3 MULT.	66.4103
CMH MINI CONICAL ABUTMENT H4 MULT.	66.4104
CMH MINI CONICAL ABUTMENT H5 MULT.	66.4105
HE MINI CONICAL ABUTMENT 15° H1 UNIT.	6.1541
HE MINI CONICAL ABUTMENT 15° H2 UNIT.	6.1542
HE MINI CONICAL ABUTMENT 15° H3 UNIT.	6.1543
HE MINI CONICAL ABUTMENT 25° H1 UNIT.	6.2541
HE MINI CONICAL ABUTMENT 25° H2 UNIT.	6.2542
HIM MINI CONICAL ABUTMENT 17° H1	56.1741R
HIM MINI CONICAL ABUTMENT 17° H2	56.1742R
HIM MINI CONICAL ABUTMENT 17° H3	56.1743R
HIM MINI CONICAL ABUTMENT 30° H1	56.3041R
HIM MINI CONICAL ABUTMENT 30° H2	56.3042R
HIL MINI CONICAL ABUTMENT 17° H1	56.1741T
HIL MINI CONICAL ABUTMENT 17° H2	56.1742T
HIL MINI CONICAL ABUTMENT 17° H3	56.1743T
HIL MINI CONICAL ABUTMENT 30° H1	56.3041T
HIL MINI CONICAL ABUTMENT 30° H2	56.3042T
HIS MINI CONICAL ABUTMENT 17° H1	56.1741S
HIS MINI CONICAL ABUTMENT 17° H2	56.1742S
HIS MINI CONICAL ABUTMENT 17° H3	56.1743S
HIS MINI CONICAL ABUTMENT 30° H1	56.3041S
HIS MINI CONICAL ABUTMENT 30° H2	56.3042S
CMI INDEX MINI CONICAL ABUTMENT 17° H1.5	76.1741I
CMI INDEX MINI CONICAL ABUTMENT 17° H2.5	76.1742I
CMI INDEX MINI CONICAL ABUTMENT 17° H3.5	76.1743I
CMI INDEX MINI CONICAL ABUTMENT 30° H1.5	76.3041I
CMI INDEX MINI CONICAL ABUTMENT 30° H2.5	76.3042I
HEZ MINI CONICAL ABUTMENT 15° H1	6.1541Z
HEZ MINI CONICAL ABUTMENT 15° H2	6.1542Z
HEZ MINI CONICAL ABUTMENT 15° H3	6.1543Z
HEZ MINI CONICAL ABUTMENT 25° H1	6.2541Z
HEZ MINI CONICAL ABUTMENT 25° H2	6.2542Z
HIS MINI CONICAL ABUTMENT 17° H4	56.1744S
HIS MINI CONICAL ABUTMENT 17° H5	56.1745S
HIZ MINI CONICAL ABUTMENT 30° H3	56.3043S
HIZ MINI CONICAL ABUTMENT 30° H4	56.3044S
HIZ MINI CONICAL ABUTMENT 30° H5	56.3045S
HIZ MINI CONICAL ABUTMENT 45° H2	56.4542S
HIZ MINI CONICAL ABUTMENT 45° H3	56.4543S
HIZ MINI CONICAL ABUTMENT 45° H4	56.4544S
HIZ MINI CONICAL ABUTMENT 45° H5	56.4545S
HIZ MINI CONICAL ABUTMENT 52° H2	56.5242S
HE CONICAL ABUTMENT 15° H1 UNIT.	7.1541
HE CONICAL ABUTMENT 15° H2 UNIT.	7.1542
HE CONICAL ABUTMENT 15° H3 UNIT.	7.1543

HE CONICAL ABUTMENT 25° H1 UNIT.	7.2541
HE CONICAL ABUTMENT 25° H2 UNIT.	7.2542
CMH MINI CONICAL ABUTMENT 15° H1	66.1541
CMH MINI CONICAL ABUTMENT 15° H2	66.1542
CMH MINI CONICAL ABUTMENT 15° H3	66.1543
CMH MINI CONICAL ABUTMENT 25° H1	66.2541
CMH MINI CONICAL ABUTMENT 25° H2	66.2542

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