



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

ATTENTION: The images are for illustrative purposes only. They do not reflect the actual dimensions of the product.

INSTRUCTIONS FOR USE

This device is intended for a specialized procedure, which must be performed by qualified dental implant professionals. For best results, use the product with knowledge of the appropriate techniques. Always apply it under appropriate conditions, including in an operating room setting.

INDICATIONS FOR USE

The DSP Implant System is intended for surgical placement in the upper or lower jawbone to support prosthetic devices, such as artificial teeth, to restore chewing function. It can be used in single- or two-stage procedures, for single- or multiple-tooth restorations, and can be loaded immediately once good primary stability and adequate occlusal loading are achieved. Implants shorter than 7 mm are intended for loading only.

DESCRIPTION

Ti-Base Anatomic Abutments are intermediate prosthetic components to be installed between the implant and the prosthesis. HIMs are made of commercially pure titanium in accordance with ASTM F67, supplied with a removable screw made of titanium alloy in accordance with ASTM F136. HIMs are supplied at the prosthetic interface and at different gingival heights to accommodate variations in mucosal thickness, as shown in the table below:

PROSTHETIC INTERFACE	ANGLE (°)	DIAMETER (MILLIMETER)	PROSTHETIC HEIGHT * (MM)	GINGIVAL HEIGHT (MM)
HE	0	3.3	6	1,2,3
	17	3.3	6	1,2,3
	25	3.3	6	1,2,3
	0	4.1	6	1, 2, 3
	17	4.1	6	1, 2, 3
	25	4.1	6	1, 2, 3
CMI	0	4.1	6	0.75, 1.5, 2.5, 3.5, 4.5, 5.5
	17	4.1	6	1.5, 2.5, 3.5
	25	4.1	6	1.5, 2.5, 3.5
	0	4.8	6	0.75, 1.5, 2.5, 3.5, 4.5, 5.5
	17	4.8	6	1.5, 2.5, 3.5
	25	4.8	6	1.5, 2.5, 3.5
HIM	0	4.1	6	1,2,3
	17	4.1	6	1,2,3
	25	4.1	6	1,2,3
	0	5.0	6	1,2,3
	17	5.0	6	1,2,3
	25	5.0	6	1,2,3
HIL	0	4.1	6	1,2,3
	15	4.1	6	1,2,3
	25	4.1	6	1,2,3
	0	5.0	6	1,2,3
	15	5.0	6	1,2,3
	25	5.0	6	1,2,3
HIS	0	4.1	6	1,2,3
	15	4.1	6	1,2,3
	25	4.1	6	1,2,3
	0	5.0	6	1,2,3

	15	5.0	6	1,2,3
	25	5.0	6	1,2,3
CMH	0	3.3	6	1,2,3
	17	3.3	6	1,2,3
	25	3.3	6	1,2,3

*For this cementable height, chairside customization up to 4 mm is permitted. The Ti-Base Anatomical Abutment is only available in the anti-rotational version.

INDICATION

The Ti-Base Anatomical Abutment is indicated for single restorations in immediate or conventional rehabilitation procedures in the maxilla or mandible.

Check compatibility between the chosen prosthetic interface.

The prosthesis is cemented onto the Ti-Base Anatomical Abutment .

This product is indicated depending on the available interocclusal space, the existing gingival height and the three-dimensional position of the implant.

CONTRAINDICATIONS

These products are contraindicated for patients who show signs of allergy or hypersensitivity to the chemical ingredients of the material: Titanium and titanium alloy Ti6Al4V.

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

HOW TO USE

For use of the Ti-Base Anatomical Abutment in two-step procedures, prior preparation of the soft tissues can be done with the use of a healing abutment.

SHIMcione the Ti-Base Anatomical Abutment according to the prosthetic plan. Install it in the implant with a torque of 30 N.cm using the appropriate connection wrench for the diameter and height of the sHIMcione abutment. All Ti-Base Anatomical Abutments have a cementable height of 6 mm and allow for in-office customization up to 4 mm. In-office customization means that the device preparation must be performed in a controlled environment in the operating room, during prosthetic placement, in the aseptic environment of a surgical site using sterile tools. Ensure proper fit between the abutment and the implant. Protect the screw access (with Teflon compound and resin), if applicable. Fabricating a temporary prosthesis for gingival conditioning is recommended.

For the impression procedure, adjust the corresponding transfer, ensure proper fit, and make the impression using appropriate materials. Prepare the plaster model. Prepare the prosthesis using the corresponding Castable Coping and cement it according to appropriate laboratory techniques. Passivity and fit tests of the prosthesis structure should be performed. Cement the final prosthesis to the Ti-Base Anatomical Abutment. Considering that cementation is performed in the mouth, follow the cement manufacturer's instructions. In this case, it is important to observe the technique to avoid excess cement and chemical burns in the tissues adjacent to the implant.

PRECAUTIONS

- Before installing the product, ensure that it has the same prosthetic interface as the implant. Ensure that the implant's stability is sufficient to support the prosthetic component's installation torque and functional load, according to the implant's instructions for use.
- Check passivity and perform occlusal and interproximal adjustment after installation of the prosthesis, avoiding compromising the implant/prosthesis assembly.
- Inadequate surgical and/or prosthetic planning may compromise the performance of the implant/prosthesis assembly, resulting in system failure, such as loss or fracture of the implant, loosening or fracture of prosthetic components and/or screws.
- It is clinically advisable to maintain a minimum height of 4 mm above the gum height.
- The selection of the prosthesis structure material must consider general aspects of the patient.
- Do not use the product if the packaging is damaged.
- Do not use the product after its expiration date.
- The material to be used during the procedure must be sterile.
- This product must be used immediately after opening the package, at the time of the procedure. If not used, discard it.
- This product is for single use only and cannot be resterilized.

- Reuse of this product may cause adverse biological effects from residual products, microorganisms, and/or substances resulting from previous use and/or reprocessing; Changes in the physical, mechanical, and chemical properties of the products, both macro- and microstructural, which may jeopardize the intended functionality. Reuse of this product does not guarantee its safety and effectiveness and disclaims any product warranty.
- Record the condition of the intraoral tissue, bone quality, and the amount of implant space available through radiographic and/or tomographic examinations. Failure to perform a pre-surgical evaluation may compromise the success of the procedure.
- Before each procedure, make sure that the parts are properly fitted.
- Ensure that the parts are not swallowed or aspirated by the patient.
- Before each procedure, check the condition of DSP Biomedical surgical instruments, always respecting their useful life. Replace instruments if there is damage, missing markings, compromised sharpness, deformation, or wear.
- Always use the DSP Biomedical product sequence. The use of prosthetic components and/or instruments from other manufacturers does not guarantee the perfect functioning of the DSP Implant System and waives any product warranty.
- It is the professional's responsibility to use DSP Biomedical products in accordance with the instructions for use.

ADVERSE EFFECTS

No adverse effects are expected, provided the product is used according to its instructions for use.

ADDITIONAL INFORMATION FOR THE PROFESSIONAL

Instruct the patient on the need for professional medical monitoring after surgery and follow instructions regarding care, hygiene, and medication prescription. These guidelines are the responsibility of the responsible professional.

MAGNETIC RESONANCE IMAGING (MRI) - SAFETY INFORMATION

The DSP implant system has not been evaluated for safety and compatibility in the MRI environment. It has not been tested for heating, migration, or image artifacts in the MRI environment. The safety of the DSP implant system in the MRI environment is unknown. Scanning a patient with this device may result in patient injury.

PRESENTATION AND STERILIZATION

This product is indicated for single use, sterile by gamma ray, packaged individually in packaging that offers double protection: blister and cardboard type.

TRACEABILITY LABEL

This product is accompanied by three labels that allow its traceability and must be attached to the following documents: • patient's medical records;

- prosthetic records;
- implant card;

Identification and traceability are carried out using REF and LOT codes.

STORAGE CONDITIONS

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

MATERIAL DISPOSAL

All products and consumables used during dental implant surgery can pose a health risk to those who handle them after use. Before disposing of them in the environment, it is recommended to observe and comply with current legislation.

LIFESTYLE

This product has an estimated lifespan of 5 years.

EXPIRATION DATE

See on label

PRODUCT WARRANTY



























DSP Biomedical provides a product warranty against any manufacturing defects. Any defect must be reported to the manufacturer immediately, within the legal timeframe. The warranty for products manufactured by DSP Biomedical is strictly linked to compliance with the information described in the instructions for use. Improper use of the product, disregarding the instructions, exempts the manufacturer and/or seller from any liability.

Note: The warranty does not cover wear and tear resulting from use of the product.

ASSISTANCE INFORMATION

If you need more information, or if the product presents any adverse effect, with potential risk to the patient, which generates or has the potential to cause injury or threat to public health, or if you experience any customer dissatisfaction, please contact DSP by calling 0800 600 88 66, or send an email to sac@dspbiomedical.com.br.

SYMBOLISM

SYMBOLISM	DESCRIPTION	SYMBOLISM	DESCRIPTION
	Batch number		Consult the instructions for use or consult the HIMtronics instructions for use
	Date manufacturing		Do not resterilize
	Manufacturer		Keep dry
	Sterilized by Gamma Radiation		Keep away from sunlight
	Product code		Unique sterile barrier system
	Model number		Expiration date
	Do not reuse		Unique Device Identifier
	Maximum temperature limit		Manufacturer's country
	Authorized representative in the European Community		Do not use if packaging is damaged and consult instructions for use.
	Careful		Humidity limits
	Importer		Medical device
	Fragile, handle with care		FDA-mandated prescription notification for the United States States Market
	CE Mark		CE marking with Notified Body number; SIQ, number 1304

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

BASIC UDI: 79084678TIBASE2W

REF :Products

Device Description	Code
TI-BASE SLIM HE SLIM Ø3.8 4.7 1.0	4.15011

TI-BASE SLIM HE SLIM Ø3.8 4.7 2.0	4.1502I
TI-BASE SLIM HE SLIM Ø3.8 4.7 3.0	4.1503I
TI-BASE SLIM HE SLIM 17 Ø4.5 4.7 1.0	4.1701I
TI-BASE SLIM HE SLIM 17 Ø4.5 4.7 2.0	4.1702I
TI-BASE SLIM HE SLIM 17 Ø4.5 4.7 3.0	4.1703I
TI-BASE SLIM HE SLIM 25 Ø4.5 4.7 1.0	4.3001I
TI-BASE SLIM HE SLIM 25 Ø4.5 4.7 2.0	4.3002I
TI-BASE SLIM HE SLIM 25 Ø4.5 4.7 3.0	4.3003I
TI-BASE STANDARD HE Ø5.0 4.7 1.0	4.5501I
TI-BASE STANDARD HE Ø5.0 4.7 2.0	4.5502I
TI-BASE STANDARD HE Ø5.0 4.7 3.0	4.5503I
TI-BASE STANDARD HE 17 Ø5.0 4.7 1.0	4.1751I
TI-BASE STANDARD HE 17 Ø5.0 4.7 2.0	4.1752I
TI-BASE STANDARD HE 17 Ø5.0 4.7 3.0	4.1753I
TI-BASE STANDARD HE 25 Ø5.0 4.7 1.0	4.3051I
TI-BASE STANDARD HE 25 Ø5.0 4.7 2.0	4.3052I
TI-BASE SLIM HIM Ø3.8 4.7 1.0	54.3501RD
TI-BASE SLIM HIM Ø3.8 4.7 2.0	54.3502
TI-BASE SLIM HIM Ø3.8 4.7 3.0	54.3503RD
TI-BASE STANDARD HIM Ø5.0 4.7 1.0	54.5501RD
TI-BASE STANDARD HIM Ø5.0 4.7 2.0	54.5502RD
TI-BASE STANDARD HIM Ø5.0 4.7 3.0	54.5503RD
TI-BASE SLIM HIM 17 Ø4.5 4.7 1.0	54.1731RD
TI-BASE SLIM HIM 17 Ø4.5 4.7 2.0	54.1732RD
TI-BASE SLIM HIM 17 Ø4.5 4.7 3.0	54.1733RD
TI-BASE SLIM HIM 25 Ø4.5 4.7 1.0	54.3031RD
TI-BASE SLIM HIM 25 Ø4.5 4.7 2.0	54.3032RD
TI-BASE SLIM HIM 25 Ø4.5 4.7 3.0	54.3033RD
TI-BASE STANDARD HIM 17 Ø5.0 4.7 1.0	54.1751RD
TI-BASE STANDARD HIM 17 Ø5.0 4.7 2.0	54.1752
TI-BASE STANDARD HIM 17 Ø5.0 4.7 3.0	54.1753RD
TI-BASE STANDARD HIM 25 Ø5.0 4.7 1.0	54.3051RD
TI-BASE STANDARD HIM 25 Ø5.0 4.7 2.0	54.3052nd
TI-BASE STANDARD HIM 25 Ø5.0 4.7 3.0	54.3053RD
TI-BASE SLIM HIL Ø3.8 4.7 1.0	54.3501TD
TI-BASE SLIM HIL Ø3.8 4.7 2.0	54.3502TD
TI-BASE SLIM HIL Ø3.8 4.7 3.0	54.3503TD
TI-BASE STANDARD HIL Ø5.0 4.7 1.0	54.5501TD
TI-BASE STANDARD HIL Ø5.0 4.7 2.0	54.5502TD
TI-BASE STANDARD HIL Ø5.0 4.7 3.0	54.5503TD
TI-BASE SLIM HIL 17° Ø4.5 4.7 1.0	54.1731TD
TI-BASE SLIM HIL 17 Ø4.5 4.7 2.0	54.1732TD
TI-BASE SLIM HIL 17 Ø4.5 4.7 3.0	54.1733TD
TI-BASE SLIM HIL 25 Ø4.5 4.7 1.0	54.3031TD
TI-BASE SLIM HIL 25 Ø4.5 4.7 2.0	54.3032TD
TI-BASE SLIM HIL 25 Ø4.5 4.7 3.0	54.3033TD
TI-BASE STANDARD HIL 17 Ø5.0 4.7 1.0	54.1751TD
TI-BASE STANDARD HIL 17 Ø5.0 4.7 2.0	54.1752TD
TI-BASE STANDARD HIL 17 Ø5.0 4.7 3.0	54.1753TD
TI-BASE STANDARD HIL 25 Ø5.0 4.7 1.0	54.3051TD
TI-BASE STANDARD HIL 25 Ø5.0 4.7 2.0	54.3052TD
TI-BASE STANDARD HIL 25 Ø5.0 4.7 3.0	54.3053TD
TI-BASE SLIM HIS Ø3.8 4.7 1.0	54.3501SD
TI-BASE SLIM HIS Ø3.8 4.7 2.0	54.3502SD

TI-BASE SLIM HIS Ø3.8 4.7 3.0	54.3503SD
TI-BASE STANDARD HIS Ø5.0 4.7 1.0	54.5501SD
TI-BASE STANDARD HIS Ø5.0 4.7 2.0	54.5502SD
TI-BASE STANDARD HIS Ø5.0 4.7 3.0	54.5503SD
TI-BASE SLIM HIS 17 Ø4.5 4.7 1.0	54.1731SD
TI-BASE SLIM HIS 17 Ø4.5 4.7 2.0	54.1732SD
TI-BASE SLIM HIS 17 Ø4.5 4.7 3.0	54.1733SD
TI-BASE SLIM HIS 25 Ø4.5 4.7 1.0	54.3031SD
TI-BASE SLIM HIS 25 Ø4.5 4.7 2.0	54.3032SD
TI-BASE SLIM HIS 25 Ø4.5 4.7 3.0	54.3033SD
TI-BASE STANDARD HIS 17 Ø5.0 4.7 1.0	54.1751SD
TI-BASE STANDARD HIS 17 Ø5.0 4.7 2.0	54.1752SD
TI-BASE STANDARD HIS 17 Ø5.0 4.7 3.0	54.1753SD
TI-BASE STANDARD HIS 25 Ø5.0 4.7 1.0	54.3051SD
TI-BASE STANDARD HIS 25 Ø5.0 4.7 2.0	54.3052SD
TI-BASE STANDARD HIS 25 Ø5.0 4.7 3.0	54.3053SD
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TI-BASE SLIM CMI Ø3.8 4.7 1.5	74.3501D
TI-BASE SLIM CMI Ø3.8 4.7 2.5	74.3502D
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TI-BASE STANDARD CMI Ø5.0 4.7 2.5	74.5502D
TI-BASE STANDARD CMI Ø5.0 4.7 3.5	74.5503D
TI-BASE STANDARD CMI Ø5.0 4.7 4.5	74.5504D
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TI-BASE SLIM CMI 25° Ø4.5 4.7 2.5	74.3032D
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TI-BASE STANDARD CMI 17 Ø5.0 4.7 2.5	74.1752D
TI-BASE STANDARD CMI 17 Ø5.0 4.7 3.5	74.1753D
TI-BASE STANDARD CMI 25 Ø5.0 4.7 1.5	74.3051D
TI-BASE STANDARD CMI 25 Ø5.0 4.7 2.5	74.3052D
TI-BASE STANDARD CMI 25 Ø5.0 4.7 3.5	74.3053D
TI-BASE SLIM CMH SLIM Ø3.8 4.7 1.0	64.1501D
TI-BASE SLIM CMH SLIM Ø3.8 4.7 2.0	64.1502D
TI-BASE SLIM CMH SLIM Ø3.8 4.7 3.0	64.1503D
TI-BASE SLIM CMH SLIM 17 Ø4.5 4.7 1.0	64.1701D
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TI-BASE STANDARD CMH Ø5.0 4.7 2.0	64.5502D

TI-BASE STANDARD CMH Ø5.0 4.7 3.0

64.5503D

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