



Figure 1: HE



Figure 2: HIM



Figure 3: HIL



Figure 4: HIS



Figure 5: CMI



Figure 6: 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. Implants with lengths less than 7 mm are intended for delayed loading only.

**DESCRIPTION**

The Anatomical Abutments are intermediary prosthetic components to be installed between the implant and the prosthesis. They are made of commercially pure titanium conforming to ASTM F67, supplied with a removable abutment screw made of titanium alloy conforming ASTM F136. They are provided in the prosthetic interface and in different gingival heights to match the variations in mucosal thickness as shown in the table below:

| PROSTHETIC INTERFACE | ANGULATION (°) | DIAMETER (MM) | 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                       |
|                      | 15             | 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                         |
|                      | 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                         |
| HIS                  | 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 |
| 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 to 4 mm is allowed. The Anatomical Abutments are available in anti-rotational version only.

### APPLICATIONS

The Anatomical Abutments is indicated for single-unit restorations in immediate or conventional rehabilitation procedures on the maxilla or mandible.

Check the compatibility between the prosthetic interface chosen.

The prosthesis is cement-retained over the Anatomical Abutments.

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 Anatomical Abutments in two-stage procedures, prior preparation of the soft tissues can be done with use of a Healing Abutment.

Select the Anatomical Abutments according to the prosthetic planning. Install it on the implant with a torque of 30 N.cm using the proper screwdriver suitable for the selected abutment diameter and height. All Anatomical Abutments have 6 mm cementable height and allow chairside customization to 4 mm. Chairside customization means that the device preparation must be done in a controlled environment in the operating room, in the context of the prosthetic placement, in a surgical site's aseptic environment using sterilized tools. Make sure of the correct fit between the abutment and the implant. Protect the access for the screw (with teflon and resin compound), if applicable. It is recommended to make up a provisional prosthesis for gingival conditioning.

For the impression procedure, fit the corresponding Transfer, ensure the proper fit, and take the impression using appropriate materials. Prepare the plaster model. Prepare the prosthesis using the corresponding Calcinable Coping and cement it according to appropriate laboratory techniques. Tests should be performed on passivity and the fit of the structure of the prosthesis. Cement the final prosthesis on the Anatomical Abutment. Considering cementation is done in the mouth, follow the instructions from the cement manufacturer. In this case, it is worth remembering that it is necessary to take note of the technique to prevent excess cement and chemical burns on 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 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.
- It is clinically advisable to maintain the minimum height of 4 mm above the gingiva height.
- 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 and is supplied sterilized by gamma radiation method, 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](mailto:sac@dspbiomedical.com.br).

**SYMBOLOLOGY**

| SYMBOLOLOGY   | DESCRIPTION   | SYMBOLOLOGY  | DESCRIPTION  |
|---|---|--|--|
|              | Batch number  |     | Consult instructions for use or consult electronic instructions for use              |
|              | Date of manufacture                                 |     | Do not re-sterilize  |
|              | 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    |
|--------------------------------------|---------|
| TI-BASE SLIM HE SLIM Ø3,8 4,7 1,0    | 4.15011 |
| TI-BASE SLIM HE SLIM Ø3,8 4,7 2,0    | 4.15021 |
| TI-BASE SLIM HE SLIM Ø3,8 4,7 3,0    | 4.15031 |
| TI-BASE SLIM HE SLIM 17 Ø4,5 4,7 1,0 | 4.17011 |
| TI-BASE SLIM HE SLIM 17 Ø4,5 4,7 2,0 | 4.17021 |

|                                      |           |
|--------------------------------------|-----------|
| 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        | 54.3502RD |
| 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 | 54.1752RD |
| 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 | 54.3052RD |
| 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 |
| TI-BASE SLIM CMI Ø3,8 4,7 0,75        | 74.3500D  |
| TI-BASE SLIM CMI Ø3,8 4,7 1,5         | 74.3501D  |
| TI-BASE SLIM CMI Ø3,8 4,7 2,5         | 74.3502D  |
| TI-BASE SLIM CMI Ø3,8 4,7 3,5         | 74.3503D  |
| TI-BASE SLIM CMI Ø3,8 4,7 4,5         | 74.3504D  |
| TI-BASE SLIM CMI Ø3,8 4,7 5,5         | 74.3505D  |
| TI-BASE STANDARD CMI Ø5,0 4,7 0,75    | 74.5500D  |
| TI-BASE STANDARD CMI Ø5,0 4,7 1,5     | 74.5501D  |
| 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  |
| TI-BASE STANDARD CMI Ø5,0 4,7 5,5     | 74.5505D  |
| TI-BASE SLIM CMI 17° Ø4,5 4,7 1,5     | 74.1731D  |
| TI-BASE SLIM CMI 17° Ø4,5 4,7 2,5     | 74.1732D  |
| TI-BASE SLIM CMI 17° Ø4,5 4,7 3,5     | 74.1733D  |
| TI-BASE SLIM CMI 25° Ø4,5 4,7 1,5     | 74.3031D  |
| TI-BASE SLIM CMI 25° Ø4,5 4,7 2,5     | 74.3032D  |
| TI-BASE SLIM CMI 25° Ø4,5 4,7 3,5     | 74.3033D  |
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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  |
| TI-BASE SLIM CMH SLIM 17 Ø4,5 4,7 2,0 | 64.1702D  |
| TI-BASE SLIM CMH SLIM 17 Ø4,5 4,7 3,0 | 64.1703D  |
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| TI-BASE SLIM CMH SLIM 25 Ø4,5 4,7 2,0 | 64.3002D  |
| TI-BASE SLIM CMH SLIM 25 Ø4,5 4,7 3,0 | 64.3003D  |
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| TI-BASE SLIM CMH Ø3,8 4,7 2,0         | 64.3502D  |
| TI-BASE SLIM CMH Ø3,8 4,7 3,0         | 64.3503D  |
| TI-BASE STANDARD CMH Ø5,0 4,7 1,0     | 64.5501D  |
| 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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