

USE INSTRUCTIONS



Figure 1 HIM IMPLANT

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

This device is intended for a specialized procedure, which shall be made by professionals qualified in Dental Implants. To achieve optimized results, use the product only if you are trained in the appropriate techniques. Always apply them in proper conditions in a surgical environment.

DEVICE INFORMATION

INDICATION OF USE

The HIM Implant System is intended to be surgically installed on the human upper and lower jawbone, serving as support for prosthetic devices, such as artificial teeth, with the purpose of restoring the masticatory function and the aesthetics of the patient. The DSP Implant System may be used in one- or two-stage procedures, for unit or multiple restorations, enabling performance of immediate loading, when achieving good primary stability and the proper occlusal loading.

INTENDED PURPOSE

The DSP Implant System is an implantable endosseous medical device system intended to replace missing tooth roots in the human maxillary and mandibular jawbone, providing mechanical anchorage to support dental prosthetic restorations, with the therapeutic purpose of restoring long-term masticatory function, dentofacial esthetics, and oral rehabilitation through osseointegration-based stability.

DESCRIPTION OF THE DEVICE

The Morse Internal Hexagon Implants (HIM) are dental implants made of commercially pure titanium (Grade 4), their external surfaces are treated with mechanical attack and chemical attack. The implants may be installed using a surgical motor or a torque wrench (manual).

They are available according to the table below:

IMPLANT	DIAMETER (mm)	HEIGHTS (mm)	PLATFORM (mm)
HIM IMPLANT	3.5	7.0, 8.5, 10, 11.5, 13, 15	4.1
	3.75	7.0, 8.5, 10, 11.5, 13, 15	4.1
	4.0	7.0, 8.5, 10, 11.5, 13, 15	4.1
	4.5	7.0, 8.5, 10, 11.5, 13, 15	4.1
	5.0	7.0, 8.5, 10, 11.5, 13, 15	4.1

HIM has a cylindrical format, conical apex, self-cutting trapezoidal thread, and micro-threads in the upper portion.

WARNING

The non-recognition of the real lengths in relation to the radiographic measures may result in permanent injury to the nerves and other vital structures. The drilling beyond the depth intended to the surgery of the lower jaw may result in permanent numbness on the lower lip and chin or lead to bleeding on the lower part of the mouth.

Follow the mandatory procedures of any surgery, such as: asepsis during the bone drilling, avoid damages in blood vessels and nerves, using the pre-surgery anatomical and radiographic knowledge.

CONTRAINDICATIONS

This product is contraindicated for patients that present signs of allergy or hypersensitivity to the composition of the material: titanium.

In the presence of acute inflammatory or infectious processes, inadequate bone volume or quality, serious clinical problems, such as: disorders of the bone metabolism, disorders of blood coagulation, inadequate capacity of regeneration, insufficient oral hygiene, incomplete growth of the jaw, non-collaborative and non-motivated patient, undue use of drugs or alcohol, psychosis, extended functional disorders that resist to any treatment with medicines, xerostomia, weakened immune system, diseases requiring the use of steroids, endocrine diseases, pregnancy.

RISKS AND BENEFITS

The clinical evaluation confirmed a high implant survival rate of 98.8%, demonstrating that the benefits of oral rehabilitation outweigh the residual risks.

As with any surgery, there is no total guarantee of operation, because achieving a good performance involves several factors, being them usability, clinical conditions of the patient, and the product itself. Non-observance of the indicated limitations of use and work stages may result in failure.

The non-recognition of the real lengths of the risks in relation to the radiographic measures may result in permanent injury to the nerves and other vital structures. The drilling beyond the depth intended to the surgery of the lower jaw may result in permanent numbness on the lower lip and chin or lead to bleeding on the lower part of the mouth.

CLINICAL APPLICATION

The HIM implants are indicated for intraoral installation through surgical procedures in bones with density I, II, III, or IV, according to Lekholm & Zarb's jawbone quality classification (1985), they are used as temporary or definitive support, for unit or multiple restorations, including conventional protocols with immediate loading, provided that the required primary stability is achieved.

The HIM implants may be installed immediately after the dental extraction.

The HIM implants have cylindrical body and self-cutting trapezoidal threads, in the region of the cervical third, the threads become double-way micro threads that assist in the primary stability, and increase the osseointegration area.

WARNINGS AND PRECAUTIONS

- Do not use the product if the package is violated.
- Do not use the product if the validity is expired.
- The material to be used during the procedure shall be sterile.
- This product shall be used immediately after the opening of the package at the surgery time, if it is not used, dispose it.
- This product is of single use and may not be re-sterilized.
- Reprocessing is Forbidden.
- The reuse of this product may cause adverse biological effects due to microorganisms and/or substances resulting of previous uses and/or reprocessing, being able to generate changes in the physical, mechanical, and chemical properties of the products, macro- and micro-structural, which may put the function desired at risk.
- The reuse of this product does not guarantee its safety and efficacy and exempts any guarantee of the product.
- Observe the conditions of the intraoral tissue, the bone quality, and the quantity of the bone bed, through radiographic exams and/or tomography. The absence of the pre-surgery assessment may compromise the success of the procedure.
- The inadequate surgical and/or prosthetic planning may compromise the performance of the implant/prosthesis set, resulting in failure in the system, such as loss or fracture of the implant, loosening, or fracture of prosthetic components and/or screws.
- The maximum installation torque suggested is 55 N.cm. The insertion torque higher than the recommended one may make the system inoperative.
- Before each procedure, certify that the parts are duly laid down.
- Certify that the parts are not swallowed or aspirated by the patient.
- Check the passivity and make the occlusal and interproximal adjustments after the installation of the prosthesis, avoiding the impairment of the implant/prosthesis set.
- Before each procedure, check the conditions of DSP Biomedical surgical instruments, always respecting their service life. Replace the instruments if there are damages, marks removed, sharpening compromised, deformation, or wear and tear.
- Always use the sequence of DSP Biomedical products, the use of prosthetic components and/or instruments of other manufacturers does not guarantee the perfect function of the DSP Implant System, and exempts any guarantee of the product.

- It is the professional's responsibility to use the DSP Biomedical products according to the instructions of use.

GENERAL PRECAUTIONS AND SAFETY INFORMATION

The products shall be protected against aspiration when handled through intraoral way. The aspiration of products may lead to infection or physical injury not planned. If you want to protect it, use a rubber barrier. If an implant or an instrument is swallowed or aspirated, immediately call a doctor. In addition to the mandatory precautions to each surgery, such as asepsis, during the drilling in the jawbone, it shall be avoided damages to the inferior alveolar nerve and to the facial, deep facial, superior and inferior lip blood vessels. The anatomic knowledge and the pre-surgery medical images (for example, radiographies) shall be referred to.

The non-recognition of the real duration in relation to the radiographic measures may result in permanent injury of the nerves and other vital structures. The drilling beyond the depth intended to the surgery of the lower jaw may potentially result in permanent numbness on the inferior lip and chin or lead to bleeding on the floor of the mouth.

The inadequate use of the products lead to a work poorly performed, and increase of the risk. In particular, the users of manual tools shall take care of gently using them and with attention. The user shall always avoid touching on the instruments and pieces with no protection (sterile protective gloves and aprons shall be used). The thermal bone damages caused by rotary and oscillating tools shall always be avoided (user's training, work at low speed and with sufficient cooling. During the intraoral application, it shall pay attention to the fact that the products are protected against aspiration or dropping on the floor. The rotary instruments need to be fixed as further as possible with their speed set before the application. Do not exceed the recommended drilling speeds, since it may cause bone necrosis or fracture of components of the system. The inadequate cleaning and sterilization of the instruments may result in the patient's infection with harmful bacteria. To avoid damaging the instruments, they shall be individually taken out of the blister package.

Do not use the device if the primary package had been damaged or previously opened.

Do not use damaged or forceful instruments for drilling. The broken land lips of the instruments cause vibrations and high pressure forces, which, on their turn, leads to broken preparation corners and rough surfaces. Instruments that are folded and/or do not work shall be immediately disposed of. Damaged, corroded, or worn devices shall not contact intact instruments to avoid contact corrosion.

RESIDUAL RISKS AND GENERAL RESIDUAL RISKS

Despite the implemented risk control measures, residual risks inherent to dental implant therapy and to the surgical/prosthetic procedure may remain. The residual risk information is communicated in this IFU through the sections "Warnings and Precautions" and "Adverse Effects", including guidance on proper planning and use of the defined surgical/prosthetic protocol, limitations regarding maximum installation torque, handling and use conditions (including storage and transportation requirements), compatibility of components and instruments, single-use status (do not reuse/reprocess/resterilize), disposal information, and MRI (MR) safety limitations. Users shall follow all warnings and instructions provided in this IFU to minimize residual risks and ensure safe and effective use of the device.

OPERATION INSTRUCTIONS

DRILLING

Under abundant irrigation, make the drilling using drills in good cutting conditions and with proper rotation speed, as indicated in table:

IMPLANT	DRILLING ROTATION (rpm)
HIM	800-1200

Select the sequence of drills according to the model of implant to be installed, according to the indications in the tables below:

IMPLANT DIAMETER (MM)	INITIAL DRILL 2.0mm	CYLINDRICAL DRILL Ø2.8mm	PILOT DRILL Ø2.0/ Ø3.0mm	CYLINDRICAL DRILL Ø3.0mm	PILOT DRILL 3.0/ Ø3.0mm	CYLINDRICAL DRILL Ø3.15mm	CYLINDRICAL DRILL Ø3.3mm	CYLINDRICAL DRILL Ø3.5mm	CYLINDRICAL DRILL Ø3.8mm	CYLINDRICAL DRILL Ø4.3mm	COUNTERSINK Ø5.0mm
Ø3.5	●	●				▲					
Ø3.75	●		●	●			▲				
Ø4.0	●		●	●			●	▲			
Ø4.5	●		●	●	●		●		●	▲	
Ø5.0			●	●	●		●		●	●	▲

▲ Drill to a depth of 3.5 mm to seat the implant's micro threads. ● Indicated

IMPLANT DIAMETER (MM)	INITIAL DRILL Ø2.0mm	CYLINDRICAL DRILL Ø2.5mm	CYLINDRICAL DRILL Ø2.8mm	PILOT DRILL 2.0/ Ø3.0mm	CYLINDRICAL DRILL Ø3.0mm	PILOT DRILL 3.0/ Ø3.0mm	CYLINDRICAL DRILL Ø3.15mm	CYLINDRICAL DRILL Ø3.3mm	CYLINDRICAL DRILL Ø3.8mm	CYLINDRICAL DRILL Ø4.3mm
Ø3.5	●	●			▲					
Ø3.75	●		●				▲			
Ø4.0	●			●	●			▲		
Ø4.5	●			●	●			●	▲	
Ø5.0	●			●	●	●			●	▲

▲ Drill to a depth of 3.5 mm to seat the implant's micro threads.
● Indicated

The drilling depth of the drills, as well as their size, shall be in compliance with the model of Implant selected during the planning, considering measures of the Implant, installation level, three-dimension spacing, among other factors (short, regular, or long drills).

SEQUENCE OF IMPLANT HANDLING

1. The box of the Implant shall be manually opened, with no sterile gloves.
2. Break the seal of the box and remove the Blister. Open the Blister and the implant driver / insertion driver on the sterile surgical field.
3. Using sterile surgical gloves, hold the tube with the non-dominant hand, and remove the cap (tube cap) with the dominant hand.
4. For installation using a surgical motor, capture the implant with the proper connection driver. Take the implant to the surgical cavity. In the surgical motor, use maximum torque of 35 Ncm and insertion rotation of 20-30 rpm.
5. Complete the installation of the implant with the Torque Wrench. The maximum installation torque suggested is 55 N.cm.

The indication of application of loads in relation to the torque is described in the table as follows:

LOAD APPLICATION	MIN. TORQUE (N.cm)	MAX. TORQUE (N.cm)
Delayed Loading	10	55

LOAD APPLICATION	MIN. TORQUE (N.cm)	MAX. TORQUE (N.cm)
Immediate Loading	35	55

PROSTHETIC AND INSTRUMENT COMPATIBILITY

The HIM implants are intended to be used only with compatible DSP Biomedical prosthetic components and installation instruments designed for the HIM prosthetic interface. Depending on the prosthetic technique, the compatible workflow may include cover screw, healing abutment, protection cylinder, transfer, coping (temporary metal coping, calcinable coping or definitive coping), definitive prosthetic component and Abutment O-ring, when applicable. The implant shall be installed only with the corresponding compatible driver/connection adapter and torque instruments intended for the HIM implant line. Components and instruments that do not correspond to the HIM prosthetic interface shall not be used, since incompatibility may compromise fit, passivity, mechanical stability and intended performance of the implant/prosthesis assembly. Prosthetic components and instruments intended for other implant interfaces shall not be used with the HIM implant line.

For two-stage surgical protocols using the HIM, soft-tissue management may be performed beforehand using a compatible protective cylinder.

For the procedure of modeling the head in a pillar form of the implant.

1. Fit the corresponding transfer, assure the proper fitting, and make the molding with proper materials.
2. Prepare the cast model.
3. Prepare the prosthesis using the corresponding coping. (Temporary metal coping, calcinable coping, definitive coping). It may be cemented or screwed, or use Abutment Oring, according to the proper laboratory techniques.
4. The tests shall be made on the passivity and the adjustment of the structure of the prosthesis.
5. Cement or screw the final prosthesis on the implant head, use its indexer, and check the perfect fitting between prosthesis and implant.

TRACEABILITY LABELS

This product is supplied with three traceability labels. The labels shall be affixed to:

- the patient's records;
- the prosthetic records;
- the International Implant Card (attach the label and deliver the completed card to the patient after the procedure; the card provides key implant identification and traceability information, including manufacturer details, UDI, REF, and LOT).

Device identification and traceability are ensured through the REF and LOT codes.

PRESENTATION AND STERILIZATION

This product is indicated for single use and is provided sterile by gamma radiation, packed unit by unit in packages that offer quadruple protection: clear tube, capsule, blister, and box.

MAGNETIC RESONANCE (MR) - SAFETY INFORMATION

The DSP Dental Implant System is manufactured from commercially pure titanium Grade 4 (ASTM F67 / ISO 5832-2). Titanium is generally considered paramagnetic and therefore interacts weakly with magnetic fields. The DSP Dental Implant System has not been evaluated for safety and compatibility in the MR environment, and no non-clinical testing has been performed to assess MR-related heating, displacement/force (migration), torque, or image artifacts. As MR safety has not been established, MR examinations should be performed only after a case-by-case clinical assessment by the responsible physician and the MR facility, considering the potential risks and benefits. The presence of the implant may affect image quality in the region of interest.

STORAGE INSTRUCTIONS

This product shall be stored in its original package, in clean and ventilated place, at maximum temperature of 45°C, and protected against direct sunlight.

INSTRUCTIONS ON HOW TO SAFELY DISPOSE THE DEVICE

Every product and consumable used during the surgery for installation of dental implants may put at risk the health of those who handle them, after the use. Before disposing of them in the environment, it is recommended to observe the effective legislation and adhere thereto.

FURTHER INFORMATION

Instruct the Patient regarding the need of professional medical follow-up after the surgery, and follow the guidelines relative to the precautions, hygiene, and prescription of medicines. Such guidelines are responsibility of the professional in charge.

SERVICE LIFE

This product is of single use; it may not be reused.

EXPIRATION DATE

See package.

ADVERSE EFFECTS

The installation of dental implants, as well as any other surgical procedure, may cause a slight discomfort and localized edema. More persistent symptoms may occur, such as: chronic pain related to the dental implant, permanent paresthesia, dysesthesia, maxillary/mandibular bone reabsorption, localized systemic infection, oroantral or oronasal fistula, adjacent teeth unfavorably affected, irreversible damages to the adjacent teeth, fracture of the implant, jaw, bone, or prosthesis, aesthetic problems, injury to the nerves, exfoliation, hyperplasia.

Failure in the osseointegration and loss of the prosthesis during the treatment may be caused by:

Inadequate osteotomy, infections, diseases, or systemic problems, low quality or insufficient volume of bone, absence or failure of irrigation, use of instruments and/or non-specific instruments with no power of cutting, poor oral hygiene, occlusal trauma, lack of prosthetic passivity, and lack of specific training.









PRODUCT GUARANTEE




















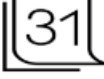


DSP Biomedical assures the owner of this product guarantee against any material or manufacturing defect, the presence of any defect shall be immediately informed to the manufacturer, respecting the legal term. The guarantee of the products manufactured by DSP Biomedical is strictly connected to following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

INFORMATION OF TECHNICAL ASSISTANCE

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.

SYMBOLS

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 with protective packaging inside
	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
	Patient name or ID		Date of Implementation
	Name and address of the Health Institution or Health Professional		Patient information website

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: 7908467800450HIMZW

REF : Products

Device Description	Code
HIM IMPLANT Ø 3.5 X 7.0	50.3507R
HIM IMPLANT Ø 3.5 X 8.5	50.3508R
HIM IMPLANT Ø 3.5 X 10.0	50.3510R
HIM IMPLANT Ø 3.5 X 11.5	50.3511R
HIM IMPLANT Ø 3.5 X 13.0	50.3513R
HIM IMPLANT Ø 3.5 X 15.0	50.3515R
HIM IMPLANT Ø 3.75 X 7.0	50.3707R
HIM IMPLANT Ø 3.75 X 8.5	50.3708R

Device Description	Code
HIM IMPLANT Ø 3.75 X 10.0	50.3710R
HIM IMPLANT Ø 3.75 X 11.5	50.3711R
HIM IMPLANT Ø 3.75 X 13.0	50.3713R
HIM IMPLANT Ø 3.75 X 15.0	50.3715R
HIM IMPLANT Ø 4.0 X 7.0	50.4007R
HIM IMPLANT Ø 4.0 X 8.5	50.4008R
HIM IMPLANT Ø 4.0 X 10.0	50.4010R
HIM IMPLANT Ø 4.0 X 11.5	50.4011R
HIM IMPLANT Ø 4.0 X 13.0	50.4013R
HIM IMPLANT Ø 4.0 X 15.0	50.4015R
HIM IMPLANT Ø 4.5 X 7.0	50.4507R
HIM IMPLANT Ø 4.5 X 8.5	50.4508R
HIM IMPLANT Ø 4.5 X 10.0	50.4510R
HIM IMPLANT Ø 4.5 X 11.5	50.4511R
HIM IMPLANT Ø 4.5 X 13.0	50.4513R
HIM IMPLANT Ø 4.5 X 15.0	50.4515R
HIM IMPLANT Ø 5.0 X 7.0	50.5007R
HIM IMPLANT Ø 5.0 X 8.5	50.5008R
HIM IMPLANT Ø 5.0 X 10.0	50.5010R
HIM IMPLANT Ø 5.0 X 11.5	50.5011R
HIM IMPLANT Ø 5.0 X 13.0	50.5013R
HIM IMPLANT Ø 5.0 X 15.0	50.5015R

MANUFACTURED BY

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Reference

1-Lekholm U, Zarb G. Patient selection and preparations. Branemark, PI, Zarb,G & Albrektsson, T, eds Tissue-Integrated Prostheses: Osseointegration in Clinical Dentistry. Chigado: Quintessence; 1985. p. 233-40.