USE INSTRUCTION

Figure 1: Zygomatic HIZ

Figure 2: Zygomatic HEZ

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

This device is intended to a specialized procedure, which shall be made by professionals qualified in Dental Implants. To achieve optimized results, use the product knowing the proper techniques. Always apply them in proper conditions in a surgical environment.

DESCRIPTIVE INFORMATION

INDICATION OF USE

The DSP ZYGOMATIC ANCHOR implants have the purpose of restoring the patient's aesthetics and the masticatory function. They are endosseous implants indicated to be inserted in the region of the zygoma for rehabilitation of atrophic maxilla where the osseous quantity and height are very limited or poor. They are also indicated to:

- Patients with sequels of resection procedures or face trauma.
- Adults patients submitted to several prior surgical procedures, where there is inadequate surgical bed for reconstruction procedures.
- Patients that were unsuccessful with reconstruction procedures or another technique.
- Patients with bilateral alveolar extension of the maxillary sinuses, which need a posterior anchoring point, since they present systemic impairment that contraindicates the reconstruction techniques.

DESCRIPTION OF THE DEVICE

ZYGOMATIC ANCHOR DSP is manufactured in ASTM F67 G4 titanium. It is self-threaded and presents a cylindrical format, straight or with angle of 45º of prosthetic interface, for compensation of the angle between the zygoma and the maxilla. It may be flat (with threads in the apex region only) or with threads in the region of the apex and platform. The diameter of the portion that anchors on the zygoma is 3.9 mm, and the diameter of the portion that anchors in the residual alveolar process of the maxilla is 4.4 mm. The pyramidal thread profile provides a better distribution of forces. In the apex, it presents chambers that optimize the secondary stability. This product is available with prosthetic interface of External Hexagon, Flexcone, and Internal Hexagon.

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

The installation of zygomatic implants is contraindicated in the following cases:

- In unit rehabilitations;
- Acute sinus inflammations (chronic sinusitis)
- Maxillary diseases or diseases in the zygomatic region;
- Patients with decompensated or malignant systemic diseases;
- Patients with parafunctional habits;
- In children, before the end of the growth and of the epiphyseal occlusion.

RISKS AND BENEFITS

As 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.

APPLICATION

Zygomatic HEZ

Patients with facial sequels or traumas.
• Adult patients with maxillary bone insufficiency.
• Patients that did not obtain positive results through procedures with other techniques.
• Patients that need an additional anchoring point beyond the maxillary region..

Zygomatic HIZ

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• Patients that need an additional anchoring point beyond the maxillary region..

WARNINGS AND PRECAUTIONS

• Do not use the product if the package is violated or with expired validity;
• The products shall be used with clean and sterilized surgical tools.
• Single-use sterile product - REPROCESSING IS FORBIDDEN;
• In case of reuse, there are risks, such as: infection, non-osseointegration, contamination of the patient with other chemical agents.
• Use sterile surgical field, and avoid the contact of the implant with other materials;
• The inadequate use, abuse, or excessive force may cause the stripping, breakage, or irreversible damages to the product;
• The use of these products requires knowledge of the technique of installation of zygomatic implants, therefore, the sale is restricted to qualified professionals.
• DSP is not responsible for technical errors of incorrect application of the product or inadequate handling by the professional.
• Attach the traceability label to the patient's registry sheet;
• It is recommended that the surgery for installation of zygomatic implants is made at hospital with follow-up of a professional of the medical area.
• Dental implants may cause interferences in magnetic resonance and computerized tomography exams (image distortion). It is important that the professional informs his/her patient about this risk. The DSP Implant System was not assessed in relation to safety, compatibility, heating, or migration in an environment of magnetic resonance.
• The patient shall not be given with guarantees in relation to the success of the implant(s) or of the prosthesis in the short and long term. The bone insufficiency, low quality of the bone, located infections, deficient oral hygiene, and health problems of the patient are some of the causes of the loss of the implant over the time.

IMPORTANCE OF THE NEED OF ADHESION TO A CARE REGIME

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.

OPERATION INSTRUCTIONS

DRILLS

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)
Zygomatic HEZ	800-1200
Zygomatic HIZ	400-800

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

SEQUENCE OF ZYGOMATIC HEZ TYPE I, II, III AND IV				
IMPLANT DIAMETER (MM)	INITIAL DRILL Ø2.0mm	CYLINDRICAL DRILL Ø2.7mm	PILOT DRILL Ø2.7/3.3	CYLINDRICAL DRILL Ø3.3mm
Ø 4.2	●	●	●	●

● Indicated

SEQUENCE OF ZYGOMATIC HIZ TYPE I, II, III AND IV				
IMPLANT DIAMETER (MM)	INITIAL DRILL Ø2.0mm	CYLINDRICAL DRILL Ø2.7mm	PILOT DRILL Ø2.7/3.3	CYLINDRICAL DRILL Ø4.3mm
Ø 4.2	●	●	●	●

● 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. Make the palatal incision at 45° of the soft tissue, and its detachment in the posterosuperior direction of the lateral surface of the zygomatic bone until reaching the zygomatic notch.
2. Make the osteotomy of the lateral wall of the maxillary sinus to allow detachment of the sinus membrane, make the drilling, and determine the length of the Zygomatic implant to be used.
3. Prepare the receiving bone bed considering the volume and quantity of the remaining bone, in addition to the geometry, height, and diameter of the implant to be installed. Use drills with progressive diameters, with good cutting state, and with plenty of irrigation.
4. Make the opening of the carton and the rupture of the sealing of the blister. Hold the tube, remove the sealing cap, and transport the implant until the surgical socket.
5. Insert the whole body of the zygomatic implant. The recommended maximum torque is from 35 to 80 Ncm. Remove the fitter from the implant and then dispose it according to the effective laws for disposal of products.
6. DSP recommends the Migliorança's Exteriorized Technique (Migliorança RM, Ilg JP, Serrano AS, Soua RP, Zamperlini MS. Exteriorização de fixações zigomáticas em relação ao seio maxilar: uma nova abordagem cirúrgica. Implant News. 2006; 3(1): 30-35.) for insertion of the DSP zygomatic implants.

7. After the surgical procedure, it is started the prosthetic procedures.

PROSTHETIC

To use the ZYGOMATIC HIZ and ZYGOMATIC HEZ in two-stage procedures, the prior preparation of the soft tissues may be made using a compatible Protection Cylinder.
For molding procedure, the coping is used properly fitting it on the implant head.
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) being able to 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 LABEL

This product is accompanied by three labels that allow its traceability and shall be attached to the following documents:
• patient's records;
• prosthetic records;
• Document to be delivered to the patient.
The identification and traceability are carried out through the REF and LOT number 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 Implant System was not assessed for safety and compatibility in the MR environment. Tests were not carried out regarding factors of heating, migration, or image artifact in the MR environment.
The safety of the DSP Implant System in the MR environment is unknown, submit a patient that has this device to magnetic resonance may result in injury to the patient.

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.

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.

DISPOSAL OF MATERIALS

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.

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.

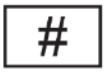
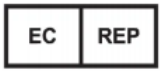
PRODUCT GUARANTEE

DSP Biomedical assures 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.

SYMBOLS

SYMBOLOGY	DESCRIPTION	SYMBOLOGY	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

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: 7908467800419HEBIOFITWZ

REF : Products

Device Name(s)	Code	Device Name(s)	Code
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 30.0	50.4230S	HEZ DOUBLE STRAIGHT IMPLANT Ø 4.4 X 37,5	17.4437D
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 32.5	50.4232S	HEZ DOUBLE STRAIGHT IMPLANT Ø 4.4 X 40	17.4440D
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 35.0	50.4235S	HEZ DOUBLE STRAIGHT IMPLANT Ø 4.4 X 42,5	17.4442D
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 37.5	50.4237S	HEZ DOUBLE STRAIGHT IMPLANT Ø 4.4 X 45	17.4445D
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 40.0	50.4240S	HEZ DOUBLE STRAIGHT IMPLANT Ø 4.4 X 47,5	17.4447D
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 42.5	50.4242S	HEZ DOUBLE STRAIGHT IMPLANT Ø 4.4 X 50	17.4450D
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 45.0	50.4245S	HEZ DOUBLE STRAIGHT IMPLANT Ø 4.4 X 52,5	17.4452D
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 47.5	50.4247S	HEZ DOUBLE STRAIGHT IMPLANT Ø 4.4 X 55	17.4455D
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 50.0	50.4250S	HEZ DOUBLE STRAIGHT IMPLANT Ø 4.4 X 57	17.4457D
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 52,5	50.4252S	HEZ SINGLE ANGLE IMPLANT Ø 4,4 X 13,0	17.4513S
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 55.0	50.4255S	HEZ SINGLE ANGLE IMPLANT Ø 4,4 X 15,0	17.4515S
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 57.5	50.4257S	HEZ SINGLE ANGLE IMPLANT Ø 4,4 X 17,0	17.4517S
HIZ SINGLE STRAIGHT IMPLANT Ø 4.2 X 60.0	50.4260S	HEZ SINGLE ANGLE IMPLANT Ø 4,4 X 19,0	17.4430S
HEZ DOUBLE ANGLE IMPLANT Ø 4,4 X 30,0	17.4530D	HEZ SINGLE ANGLE IMPLANT Ø 4,4 X 21,0	17.4432S
HEZ DOUBLE ANGLE IMPLANT Ø 4,4 X 32,5	17.4532D	HEZ SINGLE ANGLE IMPLANT Ø 4,4 X 23,0	17.4435S
HEZ DOUBLE ANGLE IMPLANT Ø 4,4 X 35,0	17.4535D	HEZ SINGLE STRAIGHT IMPLANT Ø 4.4 X 37,5	17.4437S
HEZ DOUBLE ANGLE IMPLANT Ø 4,4 X 37,5	17.4537D	HEZ SINGLE STRAIGHT IMPLANT Ø 4.4 X 40	17.4440S
HEZ DOUBLE ANGLE IMPLANT Ø 4,4 X 40,0	17.4540D	HEZ SINGLE STRAIGHT IMPLANT Ø 4.4 X 42,5	17.4442S
HEZ DOUBLE ANGLE IMPLANT Ø 4,4 X 42,5	17.4542D	HEZ SINGLE STRAIGHT IMPLANT Ø 4.4 X 45	17.4445S
HEZ DOUBLE ANGLE IMPLANT Ø 4.1 X 45.0	17.4545D	HEZ SINGLE STRAIGHT IMPLANT Ø 4.4 X 47,5	17.4447S
HEZ DOUBLE ANGLE IMPLANT Ø 4,4 X 47,5	17.4547D	HEZ SINGLE STRAIGHT IMPLANT Ø 4.4 X 50	17.4450S
HEZ DOUBLE ANGLE IMPLANT 3,9 X 50,0	17.4550D	HEZ SINGLE STRAIGHT IMPLANT Ø 4.4 X 52,5	17.4452S
HEZ DOUBLE ANGLE IMPLANT Ø 4,4 X 52,5	17.4552D	HEZ SINGLE STRAIGHT IMPLANT Ø 4.4 X 55	17.4455S
HEZ DOUBLE ANGLE IMPLANT Ø 4,4 X 55,0	17.4555D	HEZ SINGLE STRAIGHT IMPLANT Ø 4.4 X 57	17.4457S
HEZ DOUBLE ANGLE IMPLANT Ø 4,4 X 57,0	17.4557D	HEZM SINGLE ANGLE IMPLANT Ø 4,4 X 30	17.4430Z
FCZ SINGLE ANGLE IMPLANT Ø 4.4 X 30	18.4530S	HEZM SINGLE ANGLE IMPLANT Ø 4,4 X 32,5	17.4432Z
FCZ SINGLE ANGLE IMPLANT Ø 4.4 X 32,5	18.4532S	HEZM SINGLE ANGLE IMPLANT Ø 4,4 X 35	17.4435Z
FCZ SINGLE ANGLE IMPLANT Ø 4.4 X 35	18.4535S	HEZM SINGLE ANGLE IMPLANT Ø 4,4 X 37,5	17.4437Z
FCZ SINGLE ANGLE IMPLANT Ø 4.4 X 37,5	18.4537S	HEZM SINGLE ANGLE IMPLANT Ø 4,4 X 40	17.4440Z
FCZ SINGLE ANGLE IMPLANT Ø 4.4 X 40	18.4540S	HEZM SINGLE ANGLE IMPLANT Ø 4,4 X 42,5	17.4442Z
FCZ SINGLE ANGLE IMPLANT Ø 4.4 X 42,5	18.4542S	HEZM SINGLE ANGLE IMPLANT Ø 4,4 X 45	17.4445Z
FCZ SINGLE ANGLE IMPLANT Ø 4.4 X 45	18.4545S	HEZM SINGLE ANGLE IMPLANT Ø 4,4 X 47,5	17.4447Z
FCZ SINGLE ANGLE IMPLANT Ø 4.4 X 47,5	18.4547S	HEZM SINGLE ANGLE IMPLANT Ø 4,4 X 50	17.4450Z
FCZ SINGLE ANGLE IMPLANT Ø 4.4 X 50	18.4550S	HEZM SINGLE ANGLE IMPLANT Ø 4,4 X 52,5	17.4452Z
FCZ SINGLE ANGLE IMPLANT Ø 4.4 X 52,5	18.4552S	HEZM SINGLE ANGLE IMPLANT Ø 4,4 X 55	17.4455Z
FCZ SINGLE ANGLE SINGLE IMPLANT Ø 4.4 X 55	18.4555S	HEZM SINGLE ANGLE IMPLANT Ø 4,4 X 57,5	17.4457Z
FCZ SINGLE ANGLE IMPLANT Ø 4.4 X 57	18.4557S	HEZ SINGLE ANGLE IMPLANT Ø 4.4 X 30	17.4530S
FCZ SINGLE ANGLE DOUBLE IMPLANT Ø 4.4 X 30	18.4530D	HEZ SINGLE ANGLE IMPLANT Ø 4.4 X 32,5	17.4532S
FCZ DOUBLE ANGLE IMPLANT Ø 4.4 X 32,5	18.4532D	HEZ SINGLE ANGLE IMPLANT Ø 4.4 X 35	17.4535S
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FCZ DOUBLE ANGLE IMPLANT Ø 4.4 X 45	18.4545D	HEZ SINGLE ANGLE IMPLANT Ø 4.4 X 47,5	17.4547S
FCZ DOUBLE ANGLE IMPLANT Ø 4.4 X 47,5	18.4547D	HEZ SINGLE ANGLE IMPLANT Ø 4.4 X 50	17.4550S
FCZ DOUBLE ANGLE IMPLANT Ø 4.4 X 50	18.4550D	HEZ SINGLE ANGLE IMPLANT Ø 4.4 X 52,5	17.4552S
FCZ DOUBLE ANGLE IMPLANT Ø 4.4 X 52,5	18.4552D	HEZ SINGLE ANGLE IMPLANT Ø 4.4 X 55	17.4555S
FCZ DOUBLE ANGLE IMPLANT Ø 4.4 X 55	18.4555D	HEZ SINGLE ANGLE IMPLANT Ø 4.4 X 57	17.4557S
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HEZ DOUBLE STRAIGHT IMPLANT Ø 4.4 X 30	17.4430D		
HEZ DOUBLE STRAIGHT IMPLANT Ø 4.4 X 32,5	17.4432D		
HEZ DOUBLE STRAIGHT IMPLANT Ø 4.4 X 35	17.4435D		

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.