



Figure 1. Definitive screw



Figure 2. Working screw

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 must be performed by qualified professionals in Dental Implants. For best results, use the product knowing the appropriate techniques. Always apply them in appropriate conditions, also in an operating room environment.

### INDICATIONS FOR USE

The DSP Implant System is intended to be surgically placed in the upper or lower jaw bone to provide support to prosthetic devices, such as artificial teeth, to restore chewing function. It can be used with single-stage or two-stage procedures, for single or multiple restorations, and can be loaded immediately when good primary stability is achieved and with adequate occlusal loading.

### DESCRIPTION

Prosthetic Screws are manufactured in titanium alloy according to ASTM F136. They are made up of two different parts: head and body. The head has a geometry for the Driver/Connection fitting that allows its use; and the body has a thread with geometry that allows its fixation. There are two types of Prosthetic Screws: square and hexagonal. Check the compatibility of the chosen screws and implant lines.

### INDICATION

Screws are components indicated for the fixation of screwed prosthetic components.

### CONTRAINDICATIONS

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

### INSTRUCTIONS FOR USE

The screws must be fastened with appropriate screwdrivers. During installation, make sure it is aligned with the insertion axis of the prosthesis. Make sure it is perfectly fitted to the pillar.

The installation torque of the screw is 10 N.cm.

### PRECAUTIONS

- Before installing the product, make sure it has the same prosthetic interface as the implant. Ensure that the stability of the implant is sufficient to support the installation torque of the prosthetic component and the functional load, according to the implant's instructions for use.
- Check passivity and perform occlusal and interproximal adjustment after the installation of the prosthesis, avoiding compromising 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 implant loss or fracture, loosening or fracture of prosthetic components and/or screws.
- The selection of the material for the prosthesis structure must consider general aspects of the patient.
- Do not use the product if the packaging is damaged.
- Do not use the expired product.
- The material to be used during the procedure must be sterile.
- This product should be used immediately after opening the package at the time of the procedure. If it is not used, discard it.
- This product is for single use only and cannot be re-sterilized.
- Reuse of this product may cause adverse biological effects of waste products, microorganisms and/or substances resulting from previous uses and/or reprocessing; Changes in the physical, mechanical and chemical properties of the products, macro and micro structural, which can jeopardize the desired functionality. The reuse of this product does not guarantee its safety and effectiveness and disclaims any warranty of the products.
- Misuse, abuse, or excessive force may cause stripping, breakage, or irreversible damage to the product;

- Write down the conditions of the intraoral tissue, bone quality and the quantity of the bed that receives the implant, through radiographic and/or tomographic examinations. Failure to perform the pre-surgical evaluation may compromise the success of the procedure.
- Before each procedure, make sure that the pieces are properly fitted.
- Make sure 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, excluded markings, compromised sharpness, warping, and 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 disclaims any product warranty.
- It is the responsibility of the practitioner to use DSP Biomedical products in accordance with the instructions for use.

#### **ADVERSE EFFECTS**

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

#### **ADDITIONAL INFORMATION FOR THE PROFESSIONAL**

Instruct the patient about the need for professional medical follow-up after surgery and obey the guidelines regarding care, hygiene and prescription of medications. 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 MR environment. It has not been tested for heating, migration, or image artifact in the MRI environment. The safety of the DSP implant system in the MR environment is unknown. Scanning a patient who has this device may result in injury to the patient.

#### **PRESENTATION AND STERILIZATION**

This product is indicated for single use, sterilized by gamma ray, individually packaged 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 must be attached to the following documents: • patient record;

- prosthetic records;
- implant card;

Identification and traceability are carried out through the REF and LOT codes.

#### **STORAGE CONDITIONS**

This product should 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 surgery to install dental implants can put the health of those who handle them at risk after use. Before disposing of them in the environment, it is recommended to observe current legislation and comply with it.

#### **LIFE TIME**

This product has an estimated life span of 5 years.

#### **EXPIRATION DATE**

See on label

#### **PRODUCT WARRANTY**



























DSP Biomedical provides product warranty against any manufacturing defect. The presence of any defect must be immediately reported to the manufacturer, respecting the legal deadline. The warranty of products manufactured by DSP Biomedical is strictly linked to following the information described in the instructions for use. Improper use of the product in disregard of the indications exempts the manufacturer and/or seller from any responsibility.

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

### SERVICE INFORMATION

If there is a need for more information, or the product presents any adverse effect, with potential risk to the patient, which generates or has the potential for injury or threat to public health, or any customer dissatisfaction, please contact DSP at 0800 600 88 66, or send an email to [sac@dspbiomedical.com.br](mailto:sac@dspbiomedical.com.br).

### SYMBOLOLOGY

SYMBOLOLOGY	DESCRIPTION	SYMBOLOLOGY	DESCRIPTION
	Batch number		Refer to the instructions for use or refer to the electronic instructions for use
	Date manufacturing		Do not re-sterilize
	Manufacturer		Keep dry
	Sterilized by Gamma Radiation		Keep out of sunlight
	Product Code		Unique sterile barrier system
	Model Number		Expiration date
	Do not reuse		Unique Device Identifier
	Maximum temperature limit		Country of manufacturer
	Authorised representative in the European Community		Do not use if packaging is damaged and refer to instructions for use
	Care		Humidity limits
	Importer		Medical Device
	Fragile, handle with care		FDA-Required Prescription Notification for the United States States Market
	CE Mark		CE marking with Notified Body number; SIQ, number 1304

**REF :Products**

<b>Device Description</b>	<b>Code</b>
DEFINITIVE SCREW M1.8 SQUARE	3.3310
DEFINITIVE SCREW M1.8 HEXAGONAL	3.3300
DEFINITIVE SCREW M2.0 SQUARE	3.4010
DEFINITIVE SCREW M2.0 HEXAGONAL	3.4000
DEFINITIVE SCREW M2.5 SQUARE	3.5010
DEFINITIVE SCREW M2.5 HEXAGONAL	3.5000
DEFINITIVE SCREW M1.8 HEXAGONAL	3.4011
DEFINITIVE SCREW M1.4 HEXAGONAL	6.4050
DEFINITIVE SCREW M1.4 SQUARE	6.4060
DEFINITIVE SCREW M1.8 HEXAGONAL	7.7050
DEFINITIVE SCREW M1.8 SQUARE	7.7060
DEFINITIVE SCREW M1.6 HEXAGONAL	53.4000R
DEFINITIVE SCREW M1.6 SQUARE	53.4010R
DEFINITIVE SCREW M1.6 HEXAGONAL	7.3050
DEFINITIVE SCREW M1.6 SQUARE	7.3060
DEFINITIVE SCREW M1.4 HEXAGONAL	7.4050
DEFINITIVE SCREW M1.4 SQUARE	7.4060
DEFINITIVE SCREW M1.8 HEXAGONAL	75.4111/2
DEFINITIVE SCREW M1.8 HEXAGONAL	75.4107/2
DEFINITIVE SCREW M1.8 HEXAGONAL	76.1741/2
WORK SCREW 1.8	3.3350
WORK SCREW 2.0	3.4050
WORK SCREW 2.5	3.5050
WORK SCREW 1.4	6.4055
WORK SCREW 1.8	7.4055
WORK SCREW 1.6	7.3055
WORK SCREW 1.8	7.7055
WORK SCREW 1.6	53.4000L
WORK SCREW 1.6 SHORT	72.3001
WORK SCREW 1.6 LONG	72.3002
WORK SCREW 1.8 SHORT	72.3701
WORK SCREW 1.8 LONG	72.3702
WORK SCREW 1.4	6.4031/2

**MANUFACTURER**

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