

INSTRUCTIONS FOR USE SPINDLE PULLER



ATTENTION: The figures are for illustrative purposes only. They do not represent actual dimensions or colors.

This device is indicated for specialized procedures, which must be performed by qualified implantology professionals. For best results, use the product with appropriate techniques. Always apply the product under appropriate conditions, in a surgical setting.

INDICATION FOR USE

The DSP Spindle Extractor is indicated for removing prosthetic screws with a broken head and the body inside the implant .

DESCRIPTION

The DSP Spindle Extractor is made of stainless steel and supplied non-sterile. Its active tip features claws that adapt to the screw head, facilitating removal. It features a guide to prevent the rotating part from damaging the sides of the implant thread. It can be used with any DSP implant model, depending on the screw thread size (1.4 to 2.5 mm). The driver's mechanism of action is based on the principle of deformation of the Spindle Extractor's threads when tensioned through circular movements against the implant's internal interface.

NOTICE

Failure to recognize the usage technique may cause the product to break.

This is a single-use product and should not be reusable.

CONTRAINDICATIONS

This product has no contraindications as long as it is used correctly for the indicated purposes.

RISKS AND BENEFITS

As with any surgery, there's no guarantee of full functionality, as achieving good performance involves several factors, including usability, the patient's clinical condition, and the product itself. Failure to follow the indicated usage limitations and work steps may result in failure.

Failure to recognize the usage technique may cause the product to break.

WARNING AND PRECAUTIONS

- Do not use descaling products.
- Avoid using enzymatic liquid in concentrations higher than 10% and drying parts that still contain cleaning solution residue, as these procedures encourage oxidation.

- The use of steel brushes is also not recommended.
- Drying the parts is extremely important before storage and sterilization, as the accumulation of moisture in the products is harmful and can cause oxidation.
- It is recommended to always use the instruments to remove the screw parallel to the long axis to be removed.
- Excessive use of force can lead to fracture of the instrument, making the procedure unfeasible.
- Tilting surgical instruments to remove screws during use can result in damage or even fracture of the part.
- Caution should be exercised in cases of patients who show signs of allergy or hypersensitivity to the chemical components of the material: stainless steel.
- This product is for single use only.
- Reusing this product may cause adverse biological effects resulting from product residues, microorganisms, and/or substances from previous use and/or reprocessing; and changes in the product's original physical, mechanical, and chemical, macro- and microstructural characteristics, which may impair its intended functionality. Reusing this product does not guarantee its safety and effectiveness and waives any warranty for related products.
- Do not use the product if the packaging is broken.
- Do not use the product after its expiration date.
- Before each procedure, make sure the pieces fit together perfectly.
- Ensure that the parts are not swallowed or aspirated by the patient.
- Always use the DSP product sequence. The use of instruments and/or prosthetic components from other manufacturers does not guarantee the perfect function of the DSP Implant System and voids any product warranty.

IMPORTANCE OF THE NEED FOR ADHERENCE TO A CARE REGIMEN

Products must be protected against aspiration when handled intraorally. Aspiration of products can lead to infection or unintended physical injury. If you want to protect yourself, use a rubber dam. If an implant or instrument is swallowed or aspirated, call a doctor immediately. In addition to mandatory precautions for any surgery, such as asepsis, when drilling the jawbone, damage to the inferior alveolar nerve and the facial, deep facial, upper and lower labial blood vessels must be avoided. Anatomical knowledge and preoperative medical imaging (e.g., X-rays) should be consulted.

Improper use of products leads to poor workmanship and increased risk. In particular, users of hand tools should be careful to use them gently and with consideration. The user should always avoid touching the instruments and parts without protection (sterile protective gloves and aprons should be worn). Thermal bone damage caused by rotating and oscillating tools should always be avoided (user training, working at low speeds, and with adequate cooling (see the "Cooling" section).

The Spindle Extractor is supplied under non-sterile conditions and must be reprocessed and sterilized before first use. Improper cleaning and sterilization of instruments can result in patient infection with harmful bacteria. To avoid damaging the instruments, they should be removed from the blister packaging individually. The shipping blister is not intended to be used as a container for steam sterilization of burs. They must be unpacked before first reprocessing. Do not use the device if the primary packaging has been damaged or previously opened. Instruments that are bent and/or inoperative should be discarded immediately. Damaged, corroded, or worn devices should not come into contact with intact instruments to avoid contact corrosion.

OPERATING INSTRUCTIONS

Follow the steps below for the screw removal process:

1. Position the guide on the implant or intermediate prosthetic component which has the damaged screw.

2. Adapt the drill to the contra-angle.
3. Apply slight pressure to the head of the contra-angle.
4. Pass the rod through the guide with an intermittent movement in the reverse direction and at low speed.
5. Remove the screw.

CLEANING INSTRUCTIONS

HYGIENE

1. Completely immerse the part in enzymatic detergent (diluted according to the manufacturer).
2. Wash in an ultrasonic washer for approximately 10 to 15 minutes.
3. Rinse with plenty of distilled water until all solution residue is removed.
4. The use of nylon brushes is permitted.
5. Dry with a clean, dry cloth or with compressed air.
6. Perform a visual inspection, checking for any flaws in the cleaning process. If there is still residue, repeat the process.
7. Select packaging according to the sterilization process. Preferably use self-sealing surgical-grade paper packaging with laminated film.

PRESENTATION AND STERILIZATION

This instrument is for single use only – REPROCESSING IS PROHIBITED.

They are supplied NON-sterile and must be properly sanitized and sterilized before use.

Sterilize the products the day before or on the day of the procedure.

It is recommended, preferably, to follow the steam autoclave sterilization method and, also, the parameters and procedures established in the ISO 17665-1 standard (Sterilization of health care products . Moist heat Requirements for the development, validation and routine control of a sterilization process for medical devices).

Recommended parameters: 121°C, 30 min, at 1 atm. Alternatively, you can proceed according to the autoclave manufacturer's instruction manual.

Sterilization validity: 7 to 15 days, provided the product is stored in a clean, dry environment away from sunlight.

MAINTENANCE DESCRIPTION

All products mentioned in these instructions are supplied non-sterile. They must be sanitized and sterilized before each use. It is the professional's responsibility to carry out this entire process.

STORAGE INSTRUCTIONS

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

INSTRUCTIONS ON HOW TO SAFELY DISPOSE OF THE DEVICE

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 adhere to current legislation .

ADDITIONAL INFORMATION

Instruct the patient on the need for professional medical monitoring after surgery and follow instructions on precautions, hygiene, and medication prescriptions. These guidelines are the responsibility of the attending physician.

USEFUL LIFE

This product is for single use only and cannot be reused.

VALIDITY PERIOD

See packaging.

ADVERSE EVENTS

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















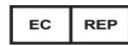







GUARANTEE


DSP Biomedical guarantees the owner of this product against any material or manufacturing defects. Any defect must be reported immediately to the manufacturer within the legal deadline. The warranty for products manufactured by DSP Biomedical is linked to compliance with the information described in the instructions for use. Improper use of the product, ignoring the instructions, exempts the manufacturer and/or distributor from any liability.

ASSISTANCE INFORMATION

If further information is required, or if the product presents any adverse effect, with potential risk to the patient, which generates or has the potential to cause injury or threaten public health, or if the customer is dissatisfied, contact DSP by calling 0800 600 88 66, or send an email to sac@dspbiomedical.com.br.

SYMBOLS

SYMBOLISM	DESCRIPTION	SYMBOLISM	DESCRIPTION
	Batch number		Consult the instructions for use or consult the electronic instructions for use
	Date of manufacture		Careful
	Produced by		Keep in a dry place
	Non-Sterile		Keep protected from sunlight
	Product code		Expiration date
	Temperature limit		Unique device identification number
	Upper and lower humidity limit		Do not use if packaging is broken and consult instructions for use.
	Authorized representative in the European community		Manufacturer Country
	Model number		Medical Device
	Fragile, handle with care		Importer
	CE Mark		CE marking with number of Notified body; SIQ, number 1304

SYMBOLISM	DESCRIPTION	SYMBOLISM	DESCRIPTION
	Do not reuse	Rx _{only}	FDA-mandated prescription notification for the United States market

REF : Products

Description	Code
Screw Extractor He 3.3/1.8mm	26.1018E
Screw Extractor He 4.1/2.0mm	26.1020E
Screw Extractor HE 5.0/2.5mm	26.1025E
Screw Extractor FCM/1.6mm	26.1016M
SCREW EXTRACTOR FC/1.8 MM	26.1018F
Screw Extractor CMI/1.8 mm	26.1018C
Screw Extractor HIM / 1.6 mm	26.1016I
SCREW EXTRACTOR CMH 3.3/1.8 MM	26.1018H
SCREW EXTRACTOR CMH 4.0/2.0 MM	26.1020H
Screw Extractor MPC/1.4 mm	26.1014
Screw Extractor His/1.8mm	26.1018s
Screw Extractor Hinges/ 2.0mm	26.1020t
Screw Extractor 1.4	26.1014/2
Screw Extractor 1.6	26.1016/2
Screw Extractor 1.8	26.1018/2
Screw Extractor 2.0	26.1020/2

MANUFACTURED BY

DSP INDUSTRIAL LTDA
Marechal Floriano Peixoto Street, 303 – Ouro Verde II
Campo Largo /PR – Brazil
CNPJ 03.960.018/0001-23
Phone: +55 41 3291-2200
www.dspsbiomedical.com
Responsible technician: CREA- PR 25412/D

REPRESENTATIVE IN THE EUROPEAN COMMUNITY

DSP BIOMEDICAL EUROPA UNIP LDA
Ocean Avenue, 142 Lt . 4.24 0H
Nations Park – Lisbon - Portugal
1990-502
Phone: (351) 962833592

ANVISA Registration: 80116980004