

## INSTRUCTIONS FOR USE IMPLANT REMOVAL



**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 Implant Extractor is indicated for the removal of intact dental implants, implants resulting from malposition, those affected by infectious processes, those with mechanical damage (fractures), old implants without prosthetic resolution, or to meet other clinical needs. It uses the mechanical principle of counter-torque (counterclockwise) to promote rupture of the osseointegrated layer and remove the implant.

### DESCRIPTION

The DSP Implant Extractor is made of Stainless Steel, supplied non-sterile, has counterclockwise threads (in the opposite direction to the DSP Implant threads), an interface for connection with 4.0mm square wrenches and can be used on any DSP implant model with threads between 1.6mm and 2.5mm.

The key's mechanism of action is based on the principle of deformation of the Implant Extractor threads when tensioned through circular movements against the internal interface of the implant.

### NOTICE

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

Depending on the level of osseointegration of the implant, it is recommended to use trephine drills to remove the implant.

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

### 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.

### 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 instruments for implant removal parallel to the long axis of the implant to be removed.
- Excessive use of force can lead to fracture of the instrument, making the procedure unfeasible.
- Tilting surgical instruments to remove implants 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.

### **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. Users should always avoid touching instruments and parts without protection (sterile protective gloves and aprons should be worn).

The Implant 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 the 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 implant removal process:

1. Select the implant to be removed.

2. Remove any components that are connected to the implant.
3. Clean the internal cavity. For implants with an external hexagon or Morse Taper without a hexagonal cavity, the interior of the implant must be ground to enlarge the cavity and allow the active part of the implant extractor to deepen. Failure to perform ground or insufficient grounding may cause the active tip of the implant extractor to fracture.
4. Sometimes it is necessary to cut the active tip of the Implant Extractor to reach the implant's internal canal. Manually insert the remover into the implant until it locks in a counterclockwise direction, ensuring that the remover is parallel to the implant's long axis.
5. Attach a torque wrench and perform gentle counterclockwise movements. Apply apical pressure to the implant extractor, but do not allow any lever movement. Continue applying counter-torque in a gentle counterclockwise direction until the osseointegration ruptures and the implant is completely removed.
6. The maximum recommended torque is 30 Ncm. Excessive force can lead to instrument fracture, making the procedure impossible.
7. It is recommended that implant removal instruments always be used parallel to the long axis of the implant to be removed. Tilting surgical instruments during implant removal can result in damage or even fracture.

## **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 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.















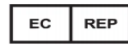









## **GUARANTEE**

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](mailto: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                       |
|  | Do not reuse  |  | FDA-mandated prescription notification for the United States market             |

## Products

| Description       | Code    |
|-------------------|---------|
| Implant Retriever | 28.0006 |

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