



## PRECAUTIONS AND INSTRUCTIONS FOR USE SURGICAL INSTRUMENTS

### Broken screw extractor system

These usage instructions should be read before using the implants and materials supplied by IMPLANT MICRODENT SYSTEM S.L.U. as they contain essential information to avoid misuse.

The descriptions below have been written for implant professionals. Therefore, we recommend they receive instructions from an expert professional in the fields, who has received adequate information. Implant Microdent System S.L.U. offers regular training courses on the use of their products.

The user must ensure that the selected product is suitable for the planned purposes and procedures.

#### INTENDED USE

Implant Microdent System S.L.U. has developed a surgical instrument for the extraction of broken screws.

#### MICRODENT BROKEN SCREW EXTRACTOR SYSTEM DESCRIPTION

System for extraction of broken screws is composed of the following components:

- Center Guides particularized for each type of connection of different implant systems manufactured and marketed by Implant Microdent System S.L.U..
- Wrench for centering guide ref. LLGDC
- Drill FEX100.
- Steel tip ref. PM100.
- Punch ref. CP1010
- Thread cleaner LRI180, 200,220 or 250 according to metric (optional).

The material previously related is made of stainless steel with the exception of the drill the most easily oxidizable material. The square punch is treated to improve its oxidation resistance.

#### MICRODENT BROKEN SCREW EXTRACTOR SYSTEM PRESENTATION

##### Packaging

Implant Microdent System S.L.U. ensures that all extractor kit components follow a manufacturing process, control and extreme cleaning before being packaged.

Extractor kit components are packed in blister. The product contained will be identified in two identical labels, one in the back of the blister and the other in the box housing the blister.

##### Extractor kit supply state.

Extraction kit components **are not sterile**. Before use then, components must be sterilized, at customer sites.

For the correct sterilization of the product you should follow the following steps:

- Removing the product from the packaging supplied. This package does not allow the proper sterilization of the product contained.
  - Enter the product in a container or bag suitable for sterilization and to ensure no contamination until its use.
- We recommend the process of steam sterilization by autoclaving. Please observe the peculiarities of computer you have. The parameters recommended by UNE-EN ISO 17665-1 and EN ISO 17665-2 are:
- Temperature: 134 °C
  - Cycle of sterile: 3'

#### WARNINGS AND PRECAUTIONS

Several causes can cause fracture of the prosthesis retention screws or any other part. However, in both situations is very important to remember to avoid fracture of the screws should faithfully follow the following recommendations:

- The first and perhaps most often result from the calculation of load distribution of the prosthesis, its effect on the distribution of forces accompanied by a deficient passive adjustment.
- The other cause is linked to excessive torque exerted on the retention screw, is essential for this purpose to use a torque wrench to ensure control effort, not to exceed the recommended tightening torque Microdent Implant System for its different threaded elements.

Extraction kit components are part of an overall design concept, having adequate use with products manufactured by Implant Microdent System S.L.U. When the components have come into contact with pollutants, especially blood and saliva, must be cleaned and sterilized before use on another patient. Products should be used only for the purpose for which they were specified.

For proper cleaning of components should follow the following instructions:

- Do not use cleaning or disinfection with chlorine or acids.
- Avoid all products containing an aldehyde, given the ability to attach these proteins.
- Remove carefully all post-operative waste left on the surface or inside the components. For this work use a nylon bristle brush.
- In the case of components with cutting edges, to avoid as much as possible the contact bumps and other instruments that may damage the surface and / or the cutting edges thereof.
- Immediately after proceeding to the cleaning process, rinse with distilled water and dry thoroughly.
- **Improper drying can cause occurrence of oxidation points in the products.**

Before proceeding with surgery, it is the user's responsibility to check the product, the container and to make sure it is the right product for the patient.

Extraction kit components, is subject to wear and use, remain the responsibility of the user the periodic renewal of these products.

Implant Microdent System S.L.U. advised that the availability of substitutes.

In general, during the oral use of our products the user must take precautions to prevent aspiration by the patient.

#### USE PROTOCOL

- **If you see the screw fractured at the implant platform.**
1. Clean thoroughly the area of metal impurities and debris, especially in the spaces between the internal threads of the implant and the external thread of the broken screw. (Do not use any motorized rotary instrument prior to attempting to remove the screw).
  2. With the aid of the reference steel tip PM100 gently pressing the periphery of the broken screw by turning the steel tip in counter clockwise direction. This rotation will cause the output of the screw, once it is able to extract a few tenths of a millimeter is sufficient to proceed through a pincer remove the remaining fractured. (The use of steel tip must be accompanied by the security bracelet intraoral).



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- **If the breakage of the screw is not accessible from the level of the implant platform.**
- 1. Place the centering guide, according to the implant in which we are working on the prosthetic connection of the same. Keep it firmly and securely using the centering guide wrench and make with the diameter 1 mm drill., ref. FEX100, a mark in the center of the screw to be drilled. **The cutting direction of this drill is to left (counterclockwise).**
- 2. Remove guide and drill (about 1 millimeter in depth) the center of the screw in two or three steps and eliminating the accumulated shaving, we recommend maximum irrigation on the workspace. **Recommended speed should not exceed 1000 rpm**
- 3. After re-clean the work area, enter and press with a small impact the punch reference CP1010 in perforated shank, keeping some pressure unscrew the screw (counter clockwise direction). The rotation must be performed in a smooth and progressive.
- **Extracted screw**

After removal of screw portion housed in the implant proceed to a thorough cleaning of the threaded hole with compressed air to remove all traces of metal particles. Then introduce the thread cleaner according to the dimensions of the thread of the implant to achieve cleaning of the thread flanks (optional). Once we are done with this cleaning process will proceed to the introduction of a new screw to check that the implant thread has not been damaged in the operations described above.

#### LABELLING SYMBOLS

The product label will give the following information:

	Single use only.		Do not use if the package is damaged.
	Reference number.		Use before expiration date.
	Please follow the instructions for use.		Sterilized by irradiation.
	Batch number.		Manufacturer.
	Precaution consult the warnings.		Global trade item number.

#### LIABILITIES, SAFETY AND GUARANTEE

If the sterility packaging of the implant is damaged during delivery, Implant Microdent System S.L.U. will replace it free of charge. This will not be the case if there is evidence of product manipulation.

The guarantee applies to Implant Microdent System S.L.U. implants as long as they have been used in accordance with the indicated instructions of use. To proceed with returns of products mentioned in these instructions for use, please follow the regulations of our sales and supply conditions.



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