

For proper use of our products is recommended that practitioner is trained. Implant System Microdent S.L. organizes periodic training courses, which reports on the particularities of each of the components of surgical instruments and their proper use.

These instructions for use are available in pdf format at the following web address: www.microdentsystem.com/instructions-for-use

To open pdf files you need the free Adobe Acrobat Reader.

INTENDED USE

Implant Microdent System S.L. 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 Microdent Implant System SL.
- Drill FEX100.
- Steel tip ref. PM100.
- Punch ref. CP1010.
- Thread cleaner LRI180, 200,220 or 250 according to metric (optional).

Products are made of stainless steel with the exception of drill and punch made of easily oxidable material.

MICRODENT BROKEN SCREW EXTRACTOR SYSTEM PRESENTATION

Packaging

Implant Microdent System S.L. 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.

Instrument supply state.

Surgical instruments are **not sterile**. Before using, product 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.
- Place the product in FDA- cleared sterilization accessories, such as bag or containers, are to be used for the recommended sterilization parameters. We recommend steam sterilize (autoclave) using a pre-vacuum cycle. Please observe the characteristics of equipment you have. The parameters recommended by ANSI / AAMI ST79 are:
 - Temperature: 270°F/132°C
 - Exposure time: 4 minutes.
 - Drying time: 20 minutes.

LABELLING SYMBOLS

Product label shows the following indications:



Non-sterile



Consult Instructions for use

CONTRAINDICATIONS

None Known.

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 SL.

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 System Microdent S.L. 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.**



BROKEN SCREW EXTRACTOR SYSTEM (Non sterile)

1st 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).

2nd 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).

-If the breakage of the screw is not accessible from the level of the implant platform.

1st Position the center guide, according to the implant on which are working, on the connection implant platform, hold it in that position and drill with FEX100 (diameter 1mm) a mark in the center of the screw.

The cutting direction of this drill is left (counterclockwise usual).

2nd 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

3th 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 (countee 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.

LIABILITY, SAFETY AND WARRANTY

If due to transportation, packaging and product content was damaged, Implant Microdent System S.L. shall return it at no charge.

Evidence of product handling disclaims liability indicated above.

The guarantee will apply to Implant Microdent System S.L. products provided they have been used following the instructions indicated.

For a refund of the products that mention these instructions should follow the guidelines established in our conditions of sale and delivery.

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Made in Spain.