PRECAUTIONS AND INSTRUCTIONS FOR USE OF SURGICAL INSTRUMENTS (Class I)
Implant extraction system

To ensure correct and safe use of Microdent products, it is recommended that practitioners are trained in the particularities of its usage. Implant Microdent System S.L.U. organizes periodic training courses to inform about the particularities of each surgical instrument and its proper use.
These instructions for use are available in pdf format at the following web address: www.microdentsystem.com/instrucciones-uso
To open pdf files you need the free Adobe Acrobat Reader.

INTENDED USE
Implant System Microdent S.LU. placed on the market the surgical instruments required to enable the application and use of its implant systems.

IMPLANT EXTRACTION INSTRUMENTS DESCRIPTION

Definition
The implant extractor is designed to remove fully or partly osseointegrated implants due to loss of functionality or any other circumstance deemed appropriate by the physician.

Material
Device made on template stainless steel.

PRESENTATION OF MICRODENT SURGICAL INSTRUMENTS

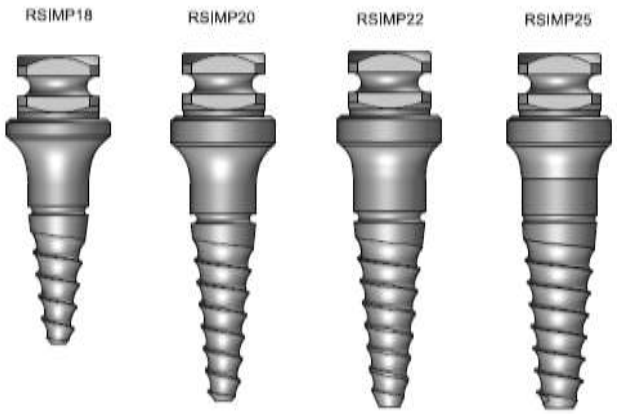
Packaging

Implant Microdent System S.L.U. ensures that all surgical instruments follow a manufacturing, control and extreme cleaning process before being packaged. Surgical instruments are packed in blister, bag or box. The product contains an identifying label with the batch number, size and model of product.

Instrument supply state.
Surgical instruments are delivered **non-sterile**. Before using, product must be sterilized, at customer sites.
For a correct product sterilization, the following steps must be taken:

- Remove 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.
  A steam sterilization process by autoclaving is recommended. Please observe the peculiarities of equipment to be sterilized. In accordance with UNE-EN ISO 17665-1 and EN ISO 17665-2, the recommended parameters are:
  - Temperature: 134 ° C
  - Cycle of sterile: 3 '

Models:
Implant Microdent System SL markets four different types of implant extractors in order to solve its entire range of implants.
Available references are:
1. RSIMP18, for implants: TRL3.8, MS and MST
2. RSIMP20, for implants: SU4.1/5.1, M 4.2/5.1, GN and EK
3. RSIMP22, for implants: TRL5.6
4. RSIMP25, for implants: MK



RECOMMENDED USE PROTOCOL

Use
After being removed from its packaging, transport the extractor to the implant using an LC44 key or an LLEO extra-oral key

Position this tool in the implant thread and, gently, screw it in in counter-clockwise direction (figure 1). The extractor should fit without problems to the internal thread.

Once the two pieces are properly tightened, applying a maximum force of 100 to 150 Ncm, unscrew the implant from the bone (figure 2).

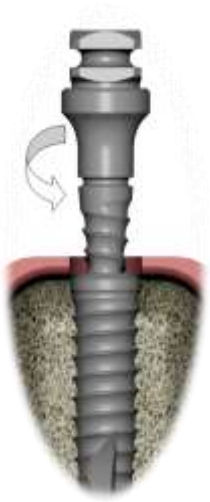


Figure 1

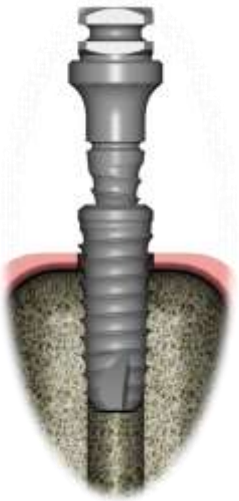


Figure 2

In case that a higher force than the previously mentioned is required, it is recommended to drill with trephines between 2 and 3 mm deep around the implant in order to avoid the extractor being broken.

A list of trephines to use with each implant system is detailed below:

- Implant MS/MST - Trephine TF50
- Implant M plat 4.2 - Trephine TF60
- Implans M plat 5.1 - Trephine TF70
- Implant MK plat 5.6 - Trephine TF70
- Implant SU plat 4.1 - Trephine TF60
- Implant SU plat 5.1 - Trephine TF70
- Implant TRL plat 3.8 - Trephine TF50
- Implant TRL plat 4.3 - Trephine TF60
- Implant TRL plat 5.1 - Trephine TF70
- Implant TRL plat 5.6 - Trephine TF70
- Implant GN plat 3.0 - Trephine TF50
- Implant GN plat 3.5 - Trephine TF50
- Implant GN plat 4 - Trephine TF50 or TF60
- Implant GN plat 4.5 - Trephine TF60
- Implant GN plat 5 - Trephine TF70
- Implant EK plat 3.7 - Trephine TF50
- Implant EK plat 3.7, core. 4.2 - Trephine TF60
- Implant EK plat 4.5 - Trephine TF60
- Implant EK plat 5.7 - Trephine TF70

Recommended torque
Depending on the tool used, the maximum recommended torque is:
- For the RSIMP18 model, it is recommended not to exceed a maximum torque of 150 Ncm.
- For the RSIMP20/22/25models, it is recommended not to exceed a maximum torque of 150 Ncm.

CONTRAINDICATIONS
The contraindications for this implant extraction system are the same as for any implant treatment:
serious problems of internal medicine, bone metabolism disorders, uncontrolled coagulation disorders, uncooperative or unmotivated patients, alcoholism or drug addiction, psychosis, functional disorders resistant to treatment present for some time, xerostomia, weakened immune system, diseases related to regular steroid use, titanium allergy, uncontrollable endocrine diseases.
Relative contraindications
Previously irradiated bone, diabetes, anticoagulant medication / haemorrhagic diabetes, bruxism, parafunctional habits, unfavourable bone anatomy, smoking, uncontrolled periodontitis, maxillary diseases and disorders of the oral mucosa susceptible of treatment, pregnancy, inadequate oral hygiene.
Local contraindications
Insufficient available bone or inadequate bone quality, local radicular remains.

WARNINGS AND PRECAUTIONS
This product is part of an overall concept, its design having been adapted to the products manufactured by Implant Microdent System S.L.U and may only be used in conjunction with the associated original products according to the instructions and recommendation of Implant Microdent System S.L.U.. The use of foreign brand surgical instruments can cause sub-optimal performance of Microdent products.
When a surgical instrument comes in contact with contaminant agents, especially blood and saliva, it must be cleaned and sterilized before being used on another patient.
Products must be used only for the purpose for which they were specified.
Be aware of possible risks of toxicity and allergenicity for those patients sensitive to the materials described in "MATERIAL" section.
Before surgery, it is the responsibility of the professionals to check:
- the condition of the instrument packaging and whether it matches the required product for the patient.
- the condition of the instrument itself and whether it is optimal.

Implant Microdent System S.L.U advises to have in stock some spare product.

LABELLING SYMBOLS
Product label shows the following indications:

REF	Reference Number.
	Please follow the instructions for use.
LOT	Lot number.
	Precaution consult the warnings.
	Manufacturer.
GTIN	Global trade ítem number.

LIABILITY, SAFETY AND WARRANTY
If the protective packaging of the product 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. Evidence of product manipulation excludes Implant Microdent System S.L.U. from the aforementioned responsibility. Any return of items that have been opened, tampered with or not in their original condition will not be accepted.
The guarantee will apply to products manufactured by Implant Microdent System S.L.U. provided they have been used following the indicated instructions.
In order to return the products mentioned in this document, the conditions set out in our terms of sale and delivery must be followed.

Implant Microdent System S.L.U.
Pol. Ind. Can Magre C/. Carles Buïgas, 1
08187 Sta. Eulalia de Ronçana, Barcelona (Spain)

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