

1. Application:

1.1. Explantation set

The Osseous atraumatic explant set is compatible with the platforms Osseous Mini (OssMn), Osseous Standard (OssSt) and Osseous Maxi (OssMx).

The Osseous atraumatic explant set allows the extraction of an endosseous implant in any of the clinical situations in which this procedure is necessary in a simple way, and in all cases minimizing the level of trauma suffered by the tissues attached to the implant.

1.2. Set for extracting broken screws

The broken screw removal set is compatible with the platforms Osseous Mini (OssMn), Osseous Standard (OssSt) and Osseous (OssMx) Maxi. The broken screw removal set is used to extract a fractured screw from the inside of an implant. As a general rule, the extraction of the screw will be possible provided that no type of cement or fixative has been used, or if the screw or the thread of the implant is severely damaged due to previous attempts to extract it.

2. Instructions for use:

2.1. Explantation set

The set should be used exclusively by trained personnel specialized in dentistry.

2.1.1 Case 1: Direct extraction by removing.

Whenever possible, it is recommended to start with this case, since it is the simplest and most protective option with tissues. The conditions to apply this technique are:

- Cone and hexagon of the internal connection in good condition.

Step 1: Detect the implant (\*1).

Step 2: Check that the implant connection is intact and usable. To do this, insert the corresponding remover until it rests on the implant platform (\*2, \*3).

Step 3: Place the high-torque ratchet on the remover in the extraction position (counterclockwise) and apply the removal torque progressively. It is necessary to monitor that the removal is aligned with the implant, and also to place pressure towards the implant to keep the remover in place. To preserve the integrity of the remover and prevent the implant from fracturing, it is recommended not to exceed the following explant torques according to the implant platforms:

Osseous Mini <100 Ncm Osseous STD <150 Ncm Osseous Maxi <200 Ncm

Step 4: In case of not achieving explantation, go to Case 2.



Fig. 1 Case 1: Direct extraction by removing.

2.1.2 Case 2: Extraction by extraction key.

This method allows an atraumatic explantation in cases of strong osseointegration of the implant. The conditions to apply this technique are:

- Cone of the internal connection and implant thread in good condition.

Step 5: Detect the implant (\*1).

Step 6: Select the corresponding explant screw and tighten it to about 50 Ncm with the help of the explant screw key, clockwise (\*3).

Step 7: Place the explant key on the explant screw by screwing it counterclockwise (\*3).

Step 8: Place the high-torque ratchet on the explant key in the extraction position (counterclockwise) and apply the removal torque in a progressive manner.

It is necessary to try to apply the torque without exerting a bending movement that can break the fastening screw of the extraction key.

It is recommended to use aspiration frequently to remove the titanium chips that may be produced.

To prevent the implant from fracturing, it is recommended not to exceed the following explant torques according to the type of implant:

Osseous Mini <200 Ncm

Osseous STD <250 Ncm

Osseous Maxi <300 Ncm

\*In the event that the explant key is loosened before getting the explantation and before reaching the maximum torque, repeat the process from step 6.

\*In the case of reaching the maximum torque and not getting the explantation, proceed to step 9.

Step 9: Remove the explant key by turning it clockwise with the aid of the ratchet, and remove the explant screw by turning it counterclockwise with the help of the explant screw key.

Step 10: Draw around the implant to a depth of 1-2 mm with the appropriate trephine drill and repeat the procedure from Step 6 until the explantation is achieved (\*3).



Fig. 2 Case 2: Extraction with extraction key.

2.1.3 Case 3: Extraction with counter thread.

This alternative explantation is only recommended for cases in which the implant connection and the implant thread are unusable.

Warning: This method of explantation is less likely to succeed and is potentially less protective of the tissues attached to the implant. It is recommended to proceed with Cases 1 and 2 whenever possible before resorting to case 3, since it will not be possible to return to alternatives 1 and 2 once 3 has begun.

Step 11: Detect the implant (\*1).

Step 12: Use the titanium drills sequentially to enlarge the connection hole. Drilling until reaching a diameter of 2 mm and depth marked.

Warning: This is a delicate operation that will largely determine the success of the explantation. It is recommended to take into account the following recommendations:

-Use drills in good condition with abundant irrigation, and frequent pumping to avoid excessive heating of the implant and surrounding tissues.

-Let the area cool down for a few minutes after every 15-20 seconds of work.

-Try to maintain a constant direction in the drilling and monitor the pitch of the tool.

-Use aspiration frequently to remove the titanium chips that may be produced.

Step 13: Insert the counter-thread key into the implant by turning it in the direction of removal (counterclockwise) and simultaneously applying pressure in the direction of the implant.

Step 14: Place the high-torque ratchet on the counter-thread key in the extraction position (counterclockwise) and apply the removal torque in a progressive manner.

You have to look to achieve maximum friction between the counter-thread key and the implant, and it is necessary to apply pressure to the implant to keep the tool in place. To prevent the implant from fracturing, it is recommended not to exceed the following explant torques according to the implant platforms:

Osseous Mini <150 Ncm

Osseous STD <200 Ncm

Osseous Maxi <300 Ncm

\*In the case of reaching the maximum torque and not getting the explantation, proceed to step 15.

\*Once the counter-thread key has been used, it must be discarded.

Step 15: Remove the counter-thread key by turning it clockwise with the help of the ratchet.

Step 16: Draw around the implant to a depth of 1-2 mm with the appropriate trephine drill and repeat the procedure from step 13 until the explantation is achieved (\*3).

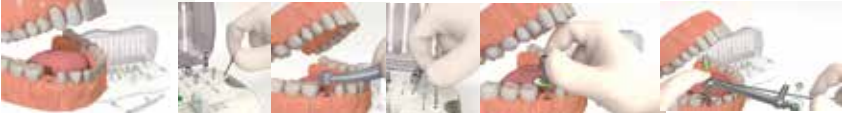


Fig. 3 Case 3: Extraction with counter thread

(\*1) Remove the soft tissues, the closing or healing screw, the prosthesis and the retaining screw, the remover, the key and explant screw or any other element that may be previously found on the connection or the remains of the implant as the case may be.

(\*2) Check that the screw is not broken. If the screw is fractured and prevents the correct placement of the extraction tool on the implant, use the TICARE Osseous broken screw removal set that is in this same set or jump to Case 3.

(\*3) See identification and marking code of each of the elements of the set for an appropriate selection according to the platform of the implant.

2.2. Set for extracting broken screws

The set should be used exclusively by trained personnel specialized in dentistry.

Step 1: Choose the appropriate ratchet spanner to the implant platform (see spanner marking code according to platform).

Step 2: Choose the appropriate reamer to the implant platform according to the code marked on it.

Step 3: Attach the reamer to the multiconverter (multiconverter not included in the set), or to the C/A, as desired.

Step 4: Place the ratchet spanner on the implant and insert the reamer-multiconverter assembly (or reamer on C/A) through it until resting on the fractured screw.

Step 5: Press the reamer-multiconverter assembly (or reamer in C/A at 15 rpm counter-clockwise) simultaneously, anti-clockwise, trying to extract the screw. It may take several attempts to get the screw removed. If the screw is loosened, go to step 7.

Step 6a: Only in the case that reamer extraction fails, the corresponding left-hand drill will be used to roughen the screw section and improve reamer grip. To do this, select the appropriate left-hand drill according to the color code (\*1).

Step 6b: Place the drill in the contra angle and select reverse direction of rotation (to the left), at about 700-800 rpm.

Step 6c: Drill over the screw through the ratchet spanner only enough to increase the roughness of the screw section, and go back to Step 4. It is recommended to insert and remove the drill periodically to evacuate any chips that may be generated and that could obstruct the thread of the implant.

It is also advisable, as far as possible, to aspirate or blow the implant thread to eliminate these chips.

Step 7: When the screw is almost out, remove it with pliers if possible. In cases where it is difficult to access the screw with pliers, the ratchet spanner and/or the drill can be used turning left and at low revolutions (200-300 rpm) making lateral and circular movements until the screw is completely released.

Step 8: Once the screw is removed it is recommended to clean the implant thread by aspirating or blowing (\*2).

(\*1) It is recommended to minimize the use of the drilling cutter to avoid generating chips that are susceptible to clogging the screw.

(\*2) In the event that once the screw is removed there is a remnant that prevents inserting a new screw freely, you can use the tap thread implant of the appropriate metric to eliminate these remnants, introducing it manually or at a maximum of 15 rpm.

For an appropriate selection according to the implant platform.

3. Preparation:

3.1 Treatment instructions / warnings

To avoid damage, do not use metal brushes or cleaning sponges.

Use only cleaning solutions and disinfectants with a pH value between 4.5 and 10. The set and the elements of the set are supplied non-sterile and must be cleaned and sterilized before use.

Do not exchange the loose parts of different ratchets if more than one torque ratchet is used. Each piece has to be mounted on the corresponding instrument.

3.2 Restriction of subsequent processing

The end of the useful life of the product is marked, normally, by the wear and tear resulting from use and incorrect handling.

3.3 Cleaning preparations

Remove all visible dirt from the parts with cold running water and a soft brush. Be sure to rinse all holes and cavities thoroughly. Do not let blood or other impurities dry.

The torque ratchet can be disassembled into its individual components without the need for tools. For this, the adjusting nut must be completely unscrewed.



Fig. 4 Stripping the key of the ratchet

3.4 Cleaning and disinfection: manual

Ultrasound bath: Place the pieces in a wire basket, taking care that they do not touch each other to avoid acoustic shadows. Clean them for 3 minutes in an ultrasonic bath (35-40 kHz) at a temperature of 40-50 °C with an enzymatic cleaning solution. Ensure that the pieces are completely submerged and that no bubbles form in the water. Rinse with clear cold water. If possible, use deionized water.

Dry the parts with a lint-free cloth and compressed air.

3.5 Cleaning and disinfection: automatic cleaning and disinfection apparatus:

Place the pre-cleaned parts securely in the supports. Do not overload the supports. Start the program. After the rinse, chemical cleaning is carried out at 40-60 °C. The residues of the cleaning process must be removed consistently in the subsequent rinsing phase. Damage to the material caused by neutralizing reagents should be avoided. Disinfection is achieved with a temperature of 90-95 °C. After the final treatment with deionized water, adequate drying must be carried out. Remove the parts from the set immediately after the end of the program.

3.6 Maintenance, inspection and testing

Allow the pieces to cool to room temperature and visually check for the absence of protein residues and other impurities. If necessary, repeat the preparation steps.

- Lightly lubricate the areas of the torque ratchet marked with maintenance oil for elbow pieces. Mount the ratchet and check operation before sterilization.

3.7 Sterilization packaging

Place the set or the elements of the set separately in a suitable packaging for sterilization in accordance with the standards ISO 11607 and EN 868.

The bag must be large enough for the set or the elements. The closures should not be forced.

3.8 Sterilization

Method: fractionated pre-vacuum procedure according to ISO 17665

Temperature: heating at 134 °C, max. 137 °C

Pressure: 3 phases pre-vacuum with at least 60 millibars pressure

Duration: 5 minutes; Drying time: at least 10 minutes.

After sterilization, make sure that the sterilization packaging is not damaged and check the sterilization indicators.

4. Storage and packaging

Store the set at a moderate temperature in a dry, dust-free and ventilated place where no corrosive vapors are produced.

All the product information is on the label. Products are individually packed.

No special storage conditions are required since the raw materials used are stable under normal pressure and temperature conditions. It is recommended to store at temperatures between 18 °C and 50 °C and with a humidity limit below 70%.

5. Calibration

It is recommended to calibrate the ratchet annually. The ratchet has to be cleaned and sterilized before shipment; otherwise, it will be returned to the sender.

6. Additional information

You can find more information about the preparation of medical devices at www.rki.de or www.a-k-l.org

7.Element markings

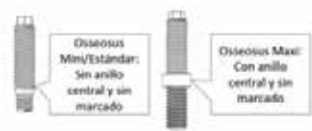
7.1.Marking of the removers:



7.2 Marking the explantation keys:



7.3. Marking of explantation screws:



7.4. Marking of ratchet spanners



- Ratchet Spanner Osseous Mini (OssMn)
- Ratchet Spanner Osseous Standard (OssSt)
- Ratchet Spanner Osseous Maxi (OssMx)

7.5. Marking of reamers:



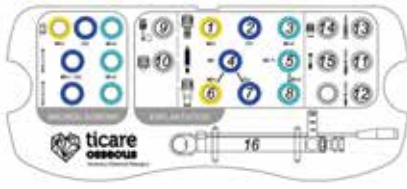
- Reamer Osseous Mini (OssMn)
- Reamer Osseous Standard (OssSt)
- Reamer Osseous Maxi (OssMx)

7.6. Marking of left drills:

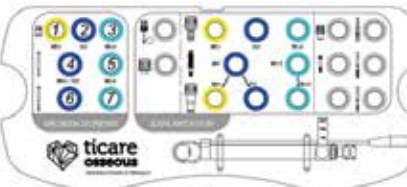


- Drill Osseous Mini (OssMn) / Standard (OssSt)
- Drill Osseous Maxi (OssMx)

8. Kit components



1. Remover Osseous Mini
2. Remover Osseous Standard
3. Remover Osseous Maxi
4. Explantation screw Osseous Mini
5. Explantation screw Osseous Standard
6. Explantation screw Osseous Maxi
7. Explantation key Osseous Mini
8. Explantation key Osseous Standard
9. Explantation key Osseous Standard
10. Explantation key Osseous Maxi
- 11.Explantation screw tightening wrench
12. Tungsten drill diameter 1.6 mm
13. Tungsten drill diameter 2 mm
14. Trephine drill 4.3-5.0 mm
15. Hexagonal expander for ratchet
16. Counter-thread key
17. High-torque ratchet key



1. Ratchet spanner Osseous Mini
2. Ratchet spanner Osseous Standard
3. Ratchet spanner Osseous Maxi
4. Reamer Osseous Mini/Standard
5. Reamer Osseous Maxi
6. Left drills Osseous Mini/Standard
7. Left drills Osseous Maxi

Fig. 4 Distribution of the set and item breakdown

9. Warnings and precautions

For the safety and effectiveness of the instruments, it is strongly suggested that only qualified personnel use the product. THESE INSTRUCTIONS ARE NOT INTENDED TO BE A SUBSTITUTE FOR ADEQUATE TRAINING. All the products are supplied NON-STERILE, and should be used under aseptic conditions.

10. Cleaning and sterilization

The products must be cleaned, disinfected and sterilized before each use; this must be done before the first use after delivery since the products are supplied non-sterile. Correct cleaning and disinfection are prerequisites for proper sterilization.

Please remember that the disinfectant used in the pretreatment is only for personal protection and does not replace the sterilization operation that must be performed after the cleaning has been carried out. Sterilization method:

- Insert the product in sterilization bags.
- Place the product inside the autoclave. Do not sterilize materials of different types in contact with each other.
- Autoclave moist heat sterilization 134 °C (273 °F) - 5 minutes. Make sure that the elements inside the autoclave are not oxidized.
- Exposure temperature of products and sterilization trays should not exceed 137 °C.
- When the autoclave is finished, remove the product from inside the autoclave.

11. Contraindications

Products that have varied their properties with use should not be used, as they are not safe for the functions that are indicated.

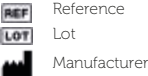
12. Product composition

All the components of the set are made of stainless steel.

13. Manufacturer



10. Labeling symbols



EU Marking



See instructions for use