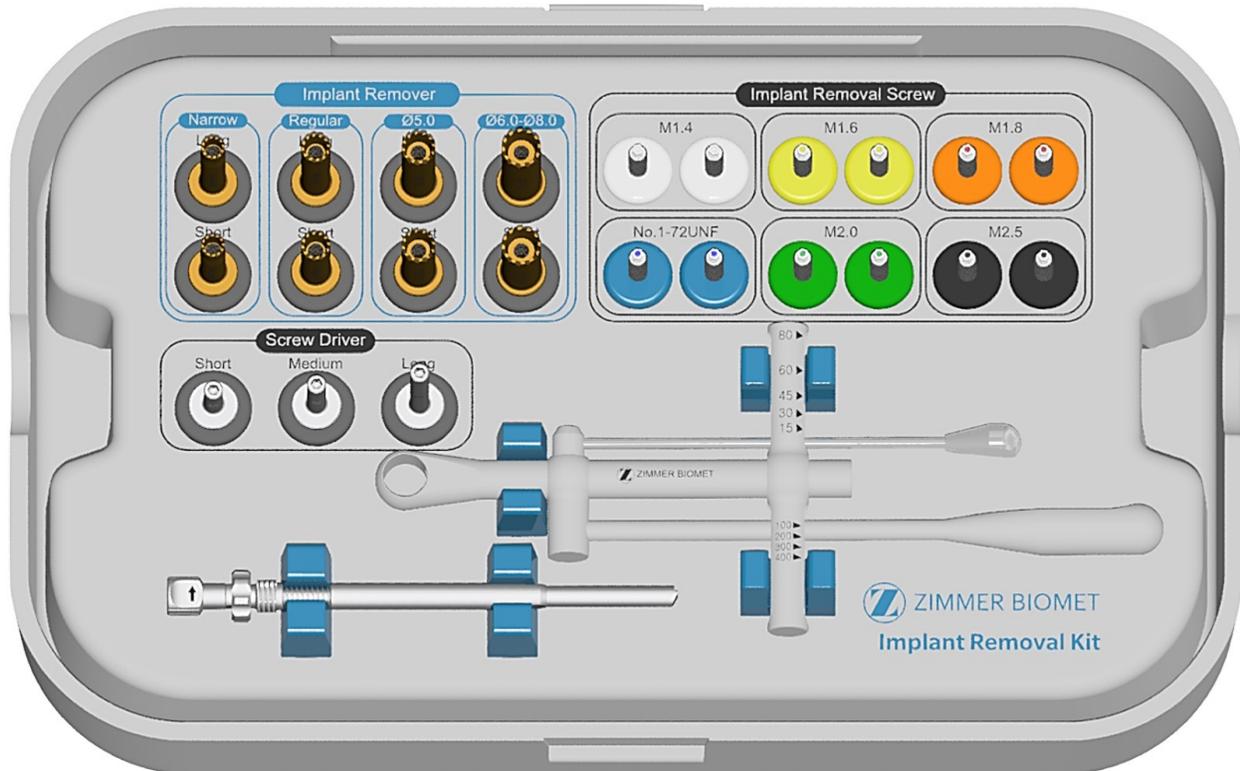


Zimmer Biomet Implant Removal Kit Instructions for Use

Description:

The Implant Removal Kit is designed for atraumatic removal of dental implants. The Implant Removal Kit is sold non-sterile and is compatible with most dental implant systems. The kit must be sterilized prior to use.



Intended Use:

The Implant Removal Kit is intended for atraumatic removal of failed implants.

Preparations for Use:

- Before using the Implant Removal Kit and its components, the clinician performing the procedure should carefully study these instructions and fully comply with them.
- This product is provided non-sterile. It should be used only after cleaning and sterilizing in an autoclave before and after each procedure. (Refer to cleaning and sterilization instructions).

Sterilization Instructions:

1. This product is provided non-sterile and must be sterilized prior to use by a pre-vacuum or a gravity autoclave.
2. Assembled components must be organized in the tray in order to improve the effectiveness of the sterilization.
3. Using a surgical wrap, wrap the tray, seal it with autoclave tape and sterilize using the below parameters.

Recommended Steam Sterilization Conditions

Cycle Type	Temperature	Exposure Time
Gravity Steam Sterilization	132°C	15 minutes
Pre-Vacuum (Steam)	132°C	4 minutes, 4 pulse

If regional or national sterilization requirements are stricter than the conditions provided above, the stricter requirements must be followed.

- In order to effectively carry out high-pressure steam sterilization, the use of biological indicators at regular intervals must be considered. (Dry heat sterilization or chemical sterilization is not recommended.)
- If the above sterilization conditions are exceeded, it is possible that the plastic and metal components may be damaged. The sterilization device must be adjusted to ensure that the recommended temperatures are not exceeded.

Methods for Use:

1. Expose the implant to be removed.
2. Select an Implant Removal Screw that corresponds to the specific implant (see compatibility chart on the Zimmer Biomet Dental website) and thread it into the implant clockwise using the Screw Driver. The Screw Drivers are available in three different lengths:
 - 7 mm (short)
 - 12 mm (medium)
 - 17 mm (long)
3. Use the Screw Driver and Implant Removal Ratchet Wrench to tighten the Implant Removal Screw clockwise while pulling on the thin torsion bar to the recommended torque (see Table 1).

Table 1. Recommended Torque Values – Implant Removal Screw

Screw Size	Recommended Torque (Ncm)	Maximum Torque (Ncm)
M1.4	15	25
M1.6	30	40
M1.8	45	60
No. 1-72 UNF	45	60
M2.0	60	80
M2.5	60	80

****Caution: Tightening the screw beyond the maximum torque will damage the screw.***

4. Remove the Implant Removal Ratchet Wrench and Screw Driver from the Implant Removal Screw when the recommended torque is reached.
5. Thread the Implant Remover counter-clockwise into the Implant Removal Screw.

6. Use the Implant Removal Ratchet Wrench to rotate the Implant Remover counter-clockwise until the implant rotates while pulling on the thick torsion bar to the recommended torque (see Table 2).

Table 2. Recommended Torque Values – Implant Remover

Implant Remover Size	Implant Remover Length	Corresponding Implant Removal Screw	Recommended Removing Torque (Ncm)	Maximum Removing Torque (Ncm)
Narrow 3.5	15 mm 20 mm	M1.4	200	250
		M1.6	250	300
Regular 3.5 4.0	15 mm 20 mm	M1.8 / No. 1-72 UNF	300	350
		M2.0	350	400
Wide 5.0	15 mm 20 mm	M2.0	350	400
		M2.5	400	450
Wide 6.0	15 mm 20 mm	M2.0	350	400
		M2.5	400	450

***Caution: Do not exceed maximum torque (see Table 2). Use irrigation during the implant removal process.**

7. If the implant does not rotate at maximum torque, remove the Implant Remover and relieve a minimum amount of coronal bone around the implant using a round bur. Repeat step 5.

8. Turn the Implant Remover clockwise to remove it from the implant.

9. Keep the Implant Remover. Discard the implant and Implant Removal Screw.

Cleaning Instructions:

Surgical Instruments

1. After completion of the procedure, detach all surgical instruments from the tray, soak them in alcohol or a cleaner and rinse using conventional means.
2. After washing with distilled or tap water, remove any remaining traces of blood or foreign material. Use a syringe or pipe cleaner for difficult to wash areas.
3. Following the instructions provided by the enzyme cleaner manufacturer, dilute the enzyme cleaner using tap water and after ten minutes of ultrasonic washing, rinse using tap water for three minutes.
4. Completely remove the moisture by using a dry cloth or a warm-air circulator.

Kit Tray

1. Remove all visible foreign material using distilled or tap water and a soft brush. For areas that are hard to clean, use a syringe or pipe cleaner.
2. Following the instructions provided by the enzyme cleaner manufacturer, dilute the enzyme cleaner using tap water and soak for one minute. Afterwards, remove any remaining foreign material on all parts with a soft brush.
3. After washing, rinse for three minutes using tap water to remove the remaining enzyme cleaner.
4. Completely remove the moisture by using a dry cloth or a warm-air circulator.
5. Organize the dry surgical tools in the kit case and sterilize using the sterilization instructions.

Maintenance and Storage:

- Dry and store instruments in a moisture-free environment. Failure to do so may result in corrosion or staining.
- Shelf-life and sterility of wrapped instrument cases are dependent on storage in a manner to avoid extreme temperature, moisture and/or other contamination.
- Care must be exercised in the handling of wrapped cases to prevent damage to the sterile barrier.
- Inspect the exterior of sterilized package before use. If a package is compromise, it should not be used, and should be reprocessed per the sterilization procedure.

Precautions:

- The Implant Removal Kit and related instruments must only be used by healthcare professionals with training and experience as dental professionals.
- A procedure plan must be established for each patient after testing and analyzing for ailments, infectious disease, possible treatment for other ailments and presence of oral lesions.
- The healthcare professional must use the product only after becoming completely familiar with the instructions for use and the relevant warnings, and must select the products that fit the treatment plan.
- Kit must be thoroughly cleaned and sterilized prior to use.
- Examine instruments for wear and tear before each procedure.
- DO NOT place used instruments back into the tray without proper cleaning.
- DO NOT flash-autoclave instruments.
- Hydrogen peroxide is prohibited for disinfection and washing as it could damage the TiN coating, laser markings and/or anodizing.
- Implant Removal Ratchet Wrench must be disassembled for thorough cleaning.

Contraindications:

- Patients with serious internal ailments: endocrinal ailments such as diabetes or hypertension, circulatory ailments, and ailments related to blood, organ, or immune systems
- Patients receiving high-level radiation treatment for malignant tumors or other reasons
- Patients who have unsuitable jaw relations or problematic occlusions

- Patients with dry mouths
- Patients with unrestored teeth who maintain poor oral health conditions
- Patients with acute inflammatory ailments and patients who are at risk of infection
- Pregnant patients
- Smokers
- Patients with blood clotting conditions or with severe cardiac ailments
- Children aged 16 years or younger
- Patients who are allergic to titanium or stainless steel
- Patients without ordinary wound-healing
- Zimmer Biomet Trabecular Metal implants

Side Effects:

- Using surgical techniques in a skillful manner minimizes the risk of complications.
- Paresthesia due to nerve damage or malocclusion, infection, edema, hypodermic bleeding, pain, opening of the sutures, soft tissue ulcer and other localized adverse reactions may occur.
- Localized and general allergic reactions may occur.

Labeling Symbols:

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Symbol	Definition	Symbol	Definition
	Catalog Number		Consult instructions for use ifu.biomet3i.com
	Batch Code		Non-Sterile
	Date of manufacture		Prescription Only
	Manufacturer	 Do not reuse	Do Not Reuse

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