

IMPLANT REMOVAL KIT

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USER GUIDE



Instructions for Use

Includes instruments and tools
to remove an implant

Procedure

1. Expose the implant to be removed.
2. Select a Fixture Remover Screw that corresponds to the specific implant (see "Compatibility List" in this pamphlet) and thread it into the implant **clockwise** using the Hexed Screw Driver (Fig. 1).
3. Using the Hexed Screw Driver (Table 1, Fig. 2) and Torque Wrench (Fig. 3), tighten the Fixture Remover Screw in a clockwise direction to 50-60Ncm by pulling on the thin torsion bar to the recommended torque (Table 2).

Caution: Failure to tighten the Fixture Remover Screw to 50-60Ncm will damage the screw.

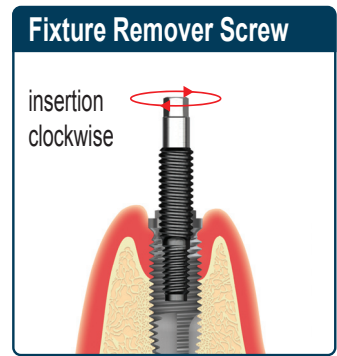


Fig. 1

Discard Fixture Remover Screw after use



Fig. 2

Hexed Screw Driver (Table 1)



Length (mm)	Product Name
7.0	HDF 1607
12.0	HDF 1612
17.0	HDF 1617



Fig. 3

Fixture Remover Screw (Table 2)



Note: Screws in Fixture CLOCKWISE



Fig. 4

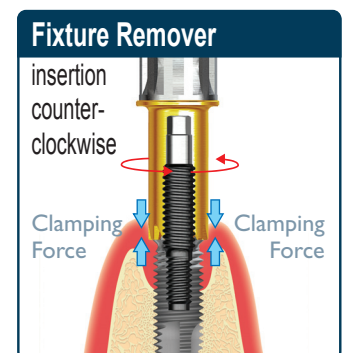


Fig. 5

Do not exceed maximum torque

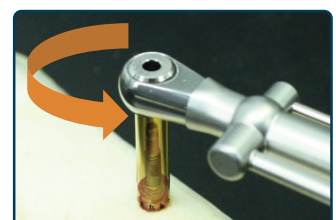


Fig. 6

Screw size	Product Name	Recommended Torque	Maximum Torque (Ncm)
M 1.4	FRS 14	50	60
M 1.54 (not included in kit)	FRS 154	50	60
M 1.6	FRS 16	60	80
M 1.8	FRS 18	60	100
No 1-72 UNF	FRS 172	60	100
M 2.0	FRS 20	60	100
M 2.5	FRS 25	60	100

- With the Fixture Remover Screw in place (Fig. 4), manually thread the Fixture Remover (Fig. 5) onto the Fixture Remover Screw in a **counterclockwise** direction.
- Using the Torque Wrench (Fig. 6), rotate the Fixture Remover **counterclockwise** until the implant rotates by pulling on the thick torsion bar to the recommended torque (Table 3). **Caution: Do not exceed maximum torque. Use irrigation during the implant removal process.**

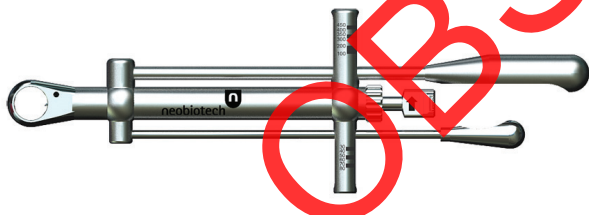
Fixture Remover (Table 3)



Note: Screws in **COUNTER-CLOCKWISE** over Fixture Remover Screw

Fixture Size	Length (mm)	Fixture Remover (Product Name)	Fixture Remover Screw	Recommended Removing Torque (Ncm)	Maximum Removing Torque (Ncm)
Narrow 3.5	15.0 20.0	FR 315 or FR 320	FRS 14	200	250
			FRS 16	250	300
			FRS 18 / FRS 172 FRS 20	300 350	350 400
Regular 3.5 4.0	15.0 20.0	FR 315 or FR 320	FRS 18 / FRS 172	300	350
			FRS 20	350	400
		FR 415 or FR 420	FRS 18 / FRS 172 FRS 20	300 350	350 400
Wide 5.0	15.0 20.0	FR 415 or FR 420	FRS 20	350	400
			FRS 25	400	450
		FR 515 or FR 520	FRS 20 FRS 25	350 400	400 450
Wide 6-8	15.0 20.0	FR 515 or FR 520	FRS 20	350	400
			FRS 25	400	450
		FR 615 or FR 620	FRS 20 FRS 25	350 400	400 450

Torque Indicating Ratchet Wrench



Description	Product Name
Ratchet Torque Control Device	FRCHT TW 80400

- If the implant does not turn at maximum torque, remove the Fixture Remover and relieve a minimum amount of coronal bone around the implant using a Round Bur. Repeat step 5.
- After removing the implant (Fig 7) with the Fixture Remover in place, grip the implant firmly in a vise, (Fig. 8) and rotate the Fixture Remover in a **clockwise** direction. Keep the Fixture Remover.
- Discard the implant and the attached disposable Fixture Remover Screw.

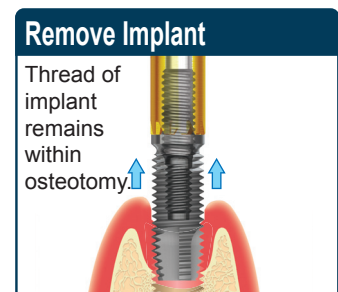
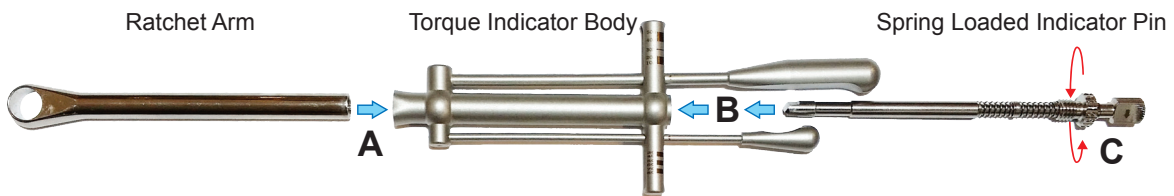


Fig. 7



Fig. 8

Torque Indicating Ratchet Wrench Assembly



- A. Insert the Ratchet Arm into the large barrel opening of the Torque Indicator Body
- B. Insert the narrow portion of the Spring Loaded Direction Indicator Pin into the opposite end of the Ratchet Arm of the Torque indicator
- C. Manually tighten the knurled knob clockwise to ensure the Ratchet Arm is secured to its maximum insertion

Note: Pulling and turning on the Spring Loaded Direction Indicator will provide desired clockwise or counter clockwise performance

Cleaning and Sterilization of the Implant Removal Kit and Instruments

Surgical instruments and instrument cases are susceptible to damage for a variety of reasons, including prolonged use, misuse, and rough or improper handling. Care must be taken to avoid compromising their performance. To maintain the quality of surgical instruments, a standardized cleaning and sterilization protocol should be adopted.

The recommended cleaning and sterilization procedures in this document apply to the *Implant Removal Kit* and the instruments housed within.

Warnings and Precautions

- DO NOT place used instruments back into the tray prior to proper cleaning per the following procedure (Steps 1-7).
- Unless otherwise indicated, instrument kits are NOT sterile and must be thoroughly cleaned and sterilized prior to use.
- Instruments should NOT be flash-autoclaved inside the instrument case. Flash-autoclaving of individual instruments should be avoided.
- Unwrapped instrument cases DO NOT maintain sterility.
- The following procedures DO NOT apply to powered instrumentation.
- For the Torque (TW80400 and FRCHT) Indicating Ratchet Wrench, disassembly is required.

Recommended Procedures for Cleaning and Sterilization of Implant Removal Instruments and Kit

Materials Required For Procedures

Solutions

- Neutral-pH detergent, or specialized cleaning solution
- Proteolytic enzyme detergent
- Ethyl alcohol (Ethanol); do not use rubbing alcohol (isopropyl alcohol)
- Tap water
- Distilled water

Tools

- PPE: Personal Protective Equipment (gloves, goggles, apron, etc.)
- Glass beakers
- Soft bristled brushes of various sizes
- Thin wire brush
- Autoclave-approved paper or bags

Equipment

- Ultrasonic cleaning unit
- Steam autoclave

Step-By-Step Instructions

Cleaning of Instruments

Note: *Individuals who clean surgical instruments need to wear appropriate personal protective equipment.*

1. Following completion of a clinical surgical procedure, gather all instruments, prepare a solution for soaking using tap water (tepid or lukewarm) and a neutral-pH detergent at a dilution recommended by the detergent manufacturer. Place instruments in a single layer at the bottom of a glass beaker containing the dilute solution. Soak the instruments for at least ten (10) minutes.

Note: It is important to clean instruments as soon as possible; if immediate cleaning is not possible, continue to soak the instruments to prevent blood from drying on the surfaces.

2. Rinse with running tap water for a minimum of two (2) minutes while brushing exteriors of items individually with a soft bristled brush to remove visible debris; clean interior lumens of specified instruments with small brushes.
3. Using a clean beaker, prepare a solution for ultrasonic cleaning using distilled water with a specialized enzymatic detergent per the detergent manufacturer's recommendations.
4. Place all instruments in a single layer into the beaker of solution. Place the beaker containing the instruments into the ultrasonic bath and turn on for five (5) minutes.
5. Remove each instrument and repeat the scrubbing procedure; ream lumens of instruments having interior canals.
6. Rinse by flushing instruments for one (1) minute with a steady stream of running tap water. Note: This step is important to prevent spotting.
7. Inspect each instrument visually and check for cleanliness, any remaining bone fragments, visible soil or residual debris, and for visible damage and/or wear. Repeat the scrubbing procedure as necessary. Set aside the instruments specific to the *Implant Removal Kit* for packaging.

Cleaning of Implant Removal Kit

8. Detach the insert from the Implant Removal Tray. Scrub all surfaces of the tray and the insert with mild soap using a soft bristled brush.
9. Rinse both pieces with running tap water for a minimum of two (2) minutes and inspect surfaces for cleanliness.
10. Re-assemble the kit by placing the insert back into the tray and replacing the cleansed instruments into specified grommets.

Packaging Kit for Sterilizer

11. Pour ethyl alcohol over the Implant Removal Tray, the lid, and onto the instruments to rinse and remove residual soap and water minerals. Allow the instruments to dry before wrapping.
12. Close the surgical kit and wrap it with autoclave paper twice, or place it within two (2) autoclave-approved bags.

Steam Sterilization per ANSI/AAMI ST79 Standard *

13. GRAVITY DISPLACEMENT STERILIZER (FULL CYCLE)

The exposure time is a minimum of fifteen (15) minutes at a temperature of 270 – 275°F (132-135°C).

– Or –

PRE-VACUUMED STERILIZER (HI-VAC)

The exposure time is a minimum of four (4) minutes, four (4) pulses at a temperature of 270 – 275°F (132-135°C).

14. Post-sterilization drying time is a minimum of thirty (30) minutes.

Storage

15. Instruments should be dried completely and stored in a moisture-free environment. Failure to do so may result in stainless steel corrosion or staining.

16. Prior to use, the exterior of each sterilized package should be inspected for integrity. If a package is suspect, it should not be used and should be reprocessed as per the above sterilization procedure.

17. 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. The probability of an occurrence of contamination increases over time, with handling, and based on the packaging method.

* The recommended sterilization procedures have been validated with the Implant Removal Kit.

BIOMET **3i** cannot control individual clinic handling procedures, cleaning methods, bioburden levels and other conditions, and therefore assumes no responsibility for sterilization of product by the user, even when the recommended guidelines above are followed.

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Compatibility List for IMPLANT REMOVAL KIT

Implant system

Recommended FRS screw size

Manufacturer: NOBEL BIO CARE®

Branemark System® MK III Groovy NP Ø3.3mm	M1.6
Branemark System MK III Groovy RP Ø3.75mm	M2.0
Branemark System MK III Groovy RP Ø4.0mm	M2.0
Branemark System MK III Groovy WP Ø5.0mm	M2.5
NobelSpeedy® System MK III Groovy NP Ø3.3mm	M1.6
NobelSpeedy System MK III Groovy RP Ø4.0mm	M2.0
NobelSpeedy System MK III Groovy WP Ø5.0mm	M2.5
NobelSpeedy System MK III Groovy WP Ø6.0mm	M2.5
NobelReplace® Straight Groovy NP Ø3.5mm	M1.8
NobelReplace Straight Groovy RP Ø4.0mm	M2.0
NobelReplace Straight Groovy WP Ø5.0mm	M2.0
NobelSpeedy Replace NP Ø3.5mm	M1.8
NobelSpeedy Replace RP Ø4.0mm	M2.0
NobelSpeedy Replace WP Ø5.0mm	M2.0
NobelSpeedy Replace 6.0 Ø6.0mm	M2.0
NobelReplace Tapered NP Ø3.5mm	M1.8
NobelReplace Tapered RP Ø4.3mm	M2.0
NobelReplace Tapered WP Ø5.0mm	M2.0
NobelReplace Tapered 6.0 Ø6.0mm	M2.0
NobelActive® 3.5 Ø3.5mm	M1.54

Manufacturer: STRAUMANN®

Standard Ø3.3 RN	M2.0
Standard Ø4.1 RN	M2.0
Standard Ø4.8 RN	M2.0
Standard Ø4.8 WN	M2.0
Standard Plus Ø3.3 NN	M1.6 or M1.8 TRY IN
Standard Plus Ø3.3 RN	M2.0
Standard Plus Ø4.1 RN	M2.0
Standard Plus Ø4.8 RN	M2.0
Standard Plus Ø4.8 WN	M2.0
Tapered Effect Ø3.3 RN	M2.0
Tapered Effect Ø4.1 RN	M2.0
Tapered Effect Ø4.8 RN	M2.0
Bone Level Implant Ø3.3 NC	M1.6 or M1.8 TRY IN
Bone Level Implant Ø4.1 NC	M1.6 or M1.8 TRY IN
Bone Level Implant Ø4.8 NC	M1.6 or M1.8 TRY IN

Implant system

Recommended FRS screw size

Manufacturer: BIOMET 3i

Certain® Internal Ø3.4	M1.6 or M1.8 TRY IN
Certain Internal Ø4.1	M1.6 or M1.8 TRY IN
Certain Internal Ø5.0	M1.6 or M1.8 TRY IN
Certain Internal Ø6.0	M1.6 or M1.8 TRY IN
External Ø3.4	M2.0
External Ø4.1	M2.0
External Ø5.0	M2.0
External Ø5.0	M2.0

Manufacturer: ASTRA TECH™

OsseoSpeed™ 3.0S	M1.4
OsseoSpeed 3.5S	M1.6
OsseoSpeed 4.0S	M1.6
OsseoSpeed 4.5	M2.0
OsseoSpeed 5.0	M2.0
OsseoSpeed 5.0S	M2.0

NOTE: For other Manufacturers not listed, the clinician is advised to complete a "try in" by selecting a corresponding analog or implant to thread into whereby sequentially starting with the widest diameter FRS screw M2.5 followed by, in descending order, the next available diameter. This will ensure compatibility.

OBSOLETE

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