

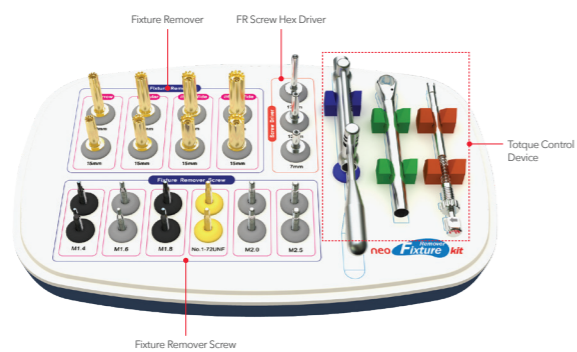
# FR Kit

## User Guide



### I Product description

This product is a fixture remover kit consisting of dental implant surgical tools (drills, surgical tools, drivers) manufactured from medical device materials such as stainless steel.



### I Intended use

This product is a surgical tool designed to remove implants that were stopped during the implantation due to excessive torque or implants whose surrounding bones have been damaged. After removing the implant, a new implant with the same diameter can be immediately implanted.

### I Preservation

Hermetically sealed packages must be stored in cool and dry place at ambient temperature (1-30°C), away from direct sunlight.

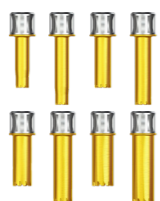
### I How to Prepare Before Use

- Prior to using this product, the clinician must completely understand the condition, performance, and function of the product.
- Use only after raising any doubts and verifying any issues with the manufacturer.
- For the procedure, a plan must be first established, based on checking the patient's oral condition and accurate judgments.
- After taking into consideration the condition of the patient, tools appropriate for the procedure must be prepared.

### I Components

#### • Fixture Remover

This is used in combination with a fixture remover screw, and is used to remove the implant by directly applying removing torque



[Figure 1]

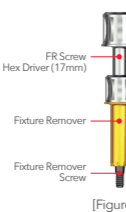
Product Name	Product Name	Length
Narrow	FR315	15mm
	FR320	20mm
Regular	FR415	15mm
	FR420	20mm
Wide (Ø5)	FR515	15mm
	FR520	20mm
Wide (Ø6~8)	FR615	15mm
	FR620	20mm

#### • FR Screw Hex Driver

This is used when the fixture remover screw needs to be affixed to, or removed from, the implant.



[Figure 2]



[Figure 3]

Product Name	Length
HDF1607	7mm
HDF1612	12mm
HDF1617	17mm

<HDF1617 is used when removing the FR screw from the fixture remover>

#### • Fixture Remover Screw

This is connected to the screw hole inside the implant to be removed. It is connected to the implant and the fixture remover to allow the implant to be removed.



[Figure 4]

Product Name	Screw size
FRS14	M1.4
FRS16	M1.6
FRS18	M1.8
FRS172	1-72UNF
FRS20	M2.0
FRS25	M2.5

\* "M" means a metric screw, and the number stands for the size of the external diameter of the screw

#### • Torque Control Device

This can be used by connecting the fixture remover or the FR screw hex driver. It is used to apply to, or measure from, the connected surgical tool an exact amount of torque.



[Figure 5]

Product Name	Screw size
TW80400	80Ncm / 400Ncm

### I Instruction for use

- Before using the surgical tool, sterilize and disinfect the components based on our recommended steam sterilization conditions.
- Completely remove the prosthesis connected to the implant that needs to be removed.
- After selecting the fixture remover screw that is the appropriate size for the size of the screw hole inside the implant that needs to be removed, connect it to the FR screw hex driver and apply a torque of 40~80Ncm to the implant. (Figures 6-1, 6-2)

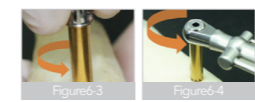


\* Recommended tightening torque according to the Fixture remover screw size is as follows

<Fixture remover screw Guide Torque> [Table 1]

Screw	Spec.	Recommended Torque (N-cm)
FRS14	M1.4	60
FRS16	M1.6	80
FRS18	M1.8	80
FRS172	1-72UNF	80
FRS20	M2.0	80
FRS25	M2.5	80

- Rotate the fixture remover connected to the fixture remover screw attached to the implant in a counterclockwise direction as far as possible then, using the torque control device, apply torque in the removal direction (counterclockwise) until the implant rotates. (Figures 6-3, 6-4)



\* The maximum torque based on the fixture size is as follows

<Fixture removing Torque> [Table 2]

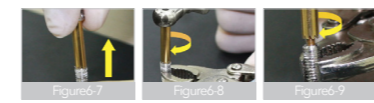
Fixture Size	Remover	Screw	Recommended Torque (N-cm)
Narrow	FR315 or FR320	FRS14	200
		FRS16	250
		FRS18 / FRS172	300
		FRS20	350
Regular	FR315 or FR320	FRS18 / FRS172	300
		FRS20	350
		FRS18 / FRS172	300
		FRS20	350
Wide (Ø5)	FR415 or FR420	FRS20	350
		FRS25	400
		FRS20	350
		FRS25	400

#### • Optional procedure

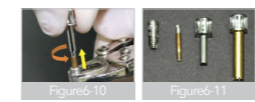
If the implant cannot be removed even after the fixture removing torque has been applied, remove the fixture remover from the implant and, using the round bur, remove a minimum amount of the bone surrounding the upper part of the implant. Then retry the step "number 4." (Figures 6-5, 6-6)



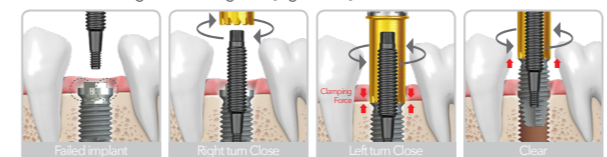
- Attach a vise to the lower part of the removed implant (Figure 6-7). After connecting the torque control device to the fixture remover, rotate clockwise in order to separate from the implant. (Figures 6-7, 6-8, 6-9)



- Separate all of the fixture remover screws connected to the removed implant by rotating them counterclockwise, using the FR screw hex driver. (Figures 6-10, 6-11)



<Fixture Removing Mimetic Diagram> [Figure 6-12]



### I Precaution for use

- The product must be used only after the user becomes completely familiar with the proper methods of use.
- When selecting the size of the fixture remover screw, the precise size of the screw hole inside the implant that needs to be removed must be verified. If not, incomplete fixation of the fixture remover screw to the implant may cause the screw to become damaged or fractured before the implant can be removed (If a fixture remover screw is used that is too small for the size of the screw hole inside the implant, connection can be forced. Accordingly, when the proper size is unknown, start from the largest size fixture remover screw and go down until the proper size fixture remover screw to connect is selected.)
- When selecting the size of the fixture remover, it is recommended that a size bigger than the diameter of the upper part of the implant be selected. If a smaller size is used, it may not be able to properly receive the removing torque, making it difficult to remove the implant.
- When affixing the fixture remover screw, it must be affixed using the recommended amount of torque. If not, the fixture remover screw may fracture, bend, or it may simply rotate between the implant and the fixture remover.
- A fixture remover screw and fixture remover must be used one time only as the fixture remover screw and fixture remover may bend or fracture if reused. Accordingly, reuse is prohibited.
- When the maximum removing torque is exceeded in the course of using the fixture remover, there is a risk that the surgical tool will be damaged, or the implant will be shattered or bone fractured. Accordingly, caution should be taken not to exceed the maximum removing torque. If 60 Ncm or a higher amount of torque is applied when removing the implant, the implant must be removed with adequate irrigation in order to prevent any overheating.
- When using the torque control device together with surgical tools, if torque is applied before they are completely connected, the product performance may be reduced or the product may be damaged. Accordingly, use only after they are properly connected. (Such as a fixture remover, or FR Screw hex driver)

### I How to Sterilize

- Because the product is a non-sterilized medical device, select a pre-vacuum autoclave. (Plastic products must not be sterilized at or above 170°C (338°F))
- Before sterilization, the inner wrapper must be removed from the tray. Assembled components must be separated in order to improve the efficiency of sterilization.
- Using surgical wrap, wrap the tray, seal with autoclave tape, and sterilize.

<Recommended steam sterilization conditions>

Cycle Time	Temperature	Exposure Time	Dry Time
Pre-Vacuum	132°C (270°F)	4 minutes	30 minutes

In order to effectively carry out high-pressure steam sterilization, the use of biological indicators at a regular interval must be considered. (Dry heat sterilization or chemical sterilization is not recommended.)

- ① Minimum time and temperature conditions for steam sterilization to reach the sterilization guarantee level of 10<sup>6</sup>
- ② If regional or national sterilization requirements are stricter than the conditions provided above, they must be followed.

If the above sterilization conditions are exceeded, it is possible that the plastic and components may be damaged. The sterilization device must be adjusted to ensure that the recommended temperatures are not exceeded.

### I How to Wash after Use

<Surgical tools>

- After the procedure ends, detach all surgical tools from the tray, soak them in alcohol, and rinse them using conventional means.
  - After washing by using distilled water or flowing water and rinsing, remove any traces of blood or foreign objects remaining. Use a syringe or pipe cleaner for areas that are difficult to wash.
  - Following the instructions of the cleaner manufacturer, dilute the enzyme cleaner using distilled water and, after fifteen minutes of ultrasound washing, rinse using distilled water for three minutes.
  - Completely remove the moisture using a dry cloth or a warm-air circulator.
- <KIT Tray>
- Remove all visible foreign objects using distilled water or flowing water and a soft brush. For areas that are difficult to clean, use a syringe or pipe cleaner.
  - Following the instructions of the cleaner manufacturer, dilute the enzyme cleaner using distilled water and soak for one minute. Afterwards, using a soft brush, remove any foreign objects remaining on any part.
  - After washing, rinse for three minutes using distilled water to remove the remaining enzyme cleaner.
  - Completely remove the moisture using a dry cloth or a warm-air circulator.
  - Organize the dry surgical tools in the kit case and sterilize, following the sterilization procedure.
  - (At this time, refer to the colors to make the setup easy.)

### I How to Store and Maintain after Use

- All surgical tools that were used must be immediately detached, washed, and dried, after the procedure, then stored at room temperature.
- Do not store in a soiled area or where there is a risk of infection.
- This product is a non-sterilized medical device. Accordingly, it may be used only after sterilizing in an autoclave before and after any procedure. (See How to Sterilize)



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