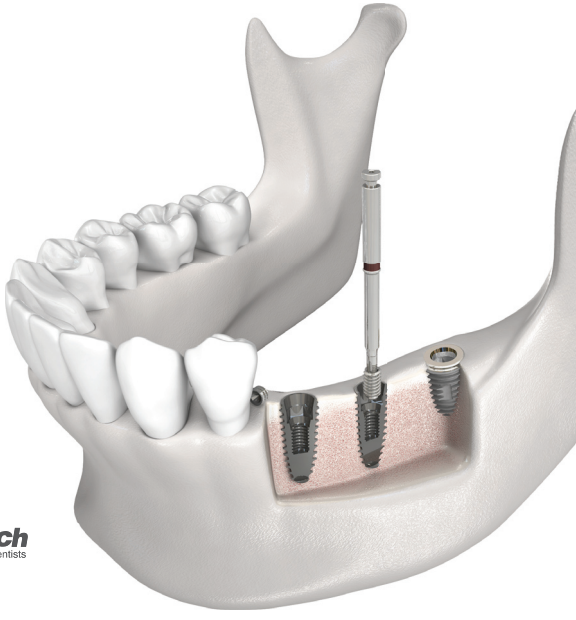
Rev.5 09/2015-E

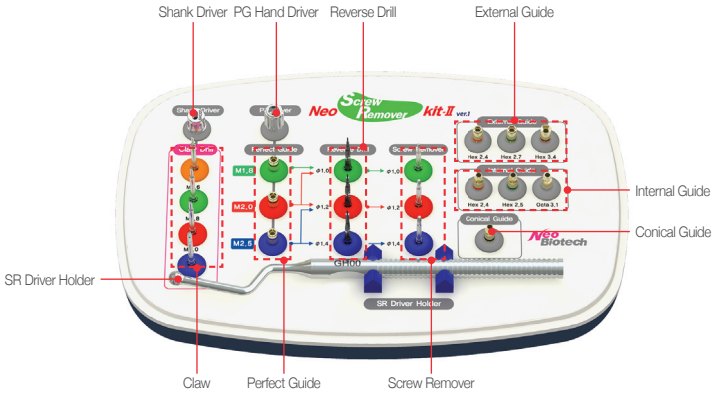
Neo SR Kit-II
User Guide



Neo Biotech
Satisfaction to Dentists

Product description

This product is a Screw Remover Kit consisting of dental implant Surgical tools (Drill, Surgical tools, and Drivers) made from medical grade materials, such as stainless steel



Intended use

This product is a surgical tool developed in order safely and quickly to remove screws that have become fractured inside an implanted Fixture for various reasons. After removing the Screw, a new Abutment may be connected to the Fixture

Preservation

Store at room temperature in a dry location away from direct light

How to Prepare Before Use

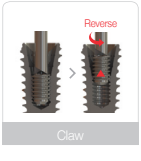
1. Prior to using this product, the clinician must completely understand the condition, performance, and function of the product.
2. Use only after raising any doubts and verifying any issues with the manufacturer.
3. For the procedure, a plan must be first established, based on checking the patient's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

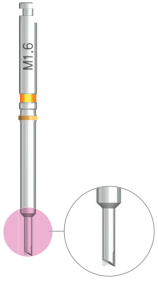
Components

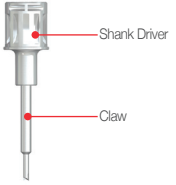
1 Claw

This is a surgical tool that removes a screw that has become fractured inside the Fixture. After selecting the size that is appropriate for the size of the screw that is to be removed, it must be used by connecting a guide to the Fixture (Conical/Internal/External Guide). Then it is connected to the Shank Driver, and the fractured screw can be removed by rotating by hand in the reverse direction. If the fractured screw cannot be removed using the Claw, it must be removed using the Reverse Drill and the Screw Remover.

Product Name	Fractured Screw size	Product Name	Fractured Screw size
CD16	M1.6	CD20	M2.0
CD18	M1.8	CD25	M2.5

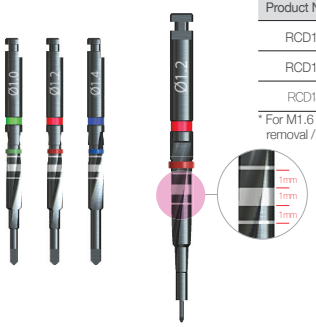






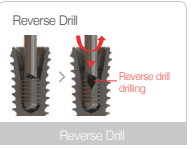
2 Reverse Drill

- This is a tool that creates a hole on the fractured face of the Screw that will be used by the Screw Remover.
- After selecting the appropriate Reverse Drill for the size of the screw that needs to be removed, it must be used by connecting a guide for the fixture (Perfect/ Conical/Internal/ External Guide). The depth of the drill can be adjusted from 1 mm to 3 mm, because the Drill body has markings.



Product Name	Diameter(Ø)	Fractured Screw size
RCD10	Ø1.0	M1.8
RCD12	Ø1.2	M2.0
RCD14	Ø1.4	M2.5

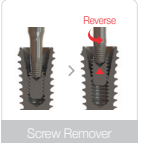
* For M1.6 Size Screw, use the claw for removal / 2,000 rpm



- The removal of an M1.6 size Screw Should utilize the Claw.
- Although different manufacturers produce different sizes of abutment screws, except in rare cases, typically they utilize screws of Size M1.6, M1.8, M2.0, or M2.5. ('M' stands for a metric screw. The number indicates the external size of the screw. For example, "M1.6 Screw" indicates that it is a metric screw the external diameter of which is 1.6 mm).

3 Screw Remover

- This is a device that removes a fractured screw. Insert a Screw Remover that is appropriate for the size of the hole that has been formed using the Reverse Drill and rotate at a low speed (at or below 80 rpm) in the reverse direction.
- The Screw Remover was designed in a tapered shape so as to increase, as it turns, the amount of friction, which is necessary to loosen the Screw.



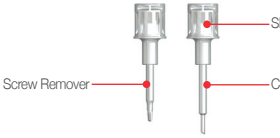
Product Name	Diameter(Ø)	Fractured Screw size
SR10	Ø1.0	M1.8
SR12	Ø1.2	M2.0
SR14	Ø1.4	M2.5

* At or below 80 rpm

4 Shank Driver

This is a surgical tool that was designed to be connected to the Screw Remover to allow the use of the hand, Torque Wrench, or Ratchet.

Product Name	Standard	Applicable Products
SHD00	for Hand or Ratchet	Screw Remover (SR10, SR12, SR14)



5 Perfect Guide & PG Hand Driver

- The Perfect Guide acts as a Guide for the Reverse Drill. It is used when the screw is fractured at the lower part of the female screw inside the Fixture. It is connected to PG Hand Driver and is directly applied to the Fixture female Screw.
- The Perfect Guide can be safely used because it has a stop structure inside that prevents the Reverse Drill from drilling more than 2 mm.

〈Perfect Guide〉

Product Name	Diameter(Ø)	Fractured Screw size	Applicable Revers Drill
PG1018	Ø1.0	M1.8	RCD10
PG1220	Ø1.2	M1.8, M2.0	RCD10,RCD12
PG1425	Ø1.4	M2.0, M2.5	RCD12,RCD14

〈PG Hand Driver〉

Product Name	Standard	Applicable Products
PGHD25SS	2.5Hex	Screw Remover (PG1018, PG1220, PG1425)

The Perfect Guide that is appropriate for the size of the screw to be removed must be selected.

6 Conical, Internal, External Guide

- They act as the Guide when using the Reverse Drill. They are used when the Perfect Guide cannot be used, or if the screw was fractured at a location deeper than 2 mm into the lower part of the female screw inside the Fixture.
- The Guide appropriate for connecting to the Fixture must be selecte

<Conical Guide>

Product Name	Standard	Applicable Fixture
CG00	11° / 8°	Having 11° / 8° Internal Fixture

<Internal Guide>

Product Name	Standard	Applicable fixture
IHG24	2.4Hex	Having 2.4Hex Internal Connection Fixture
IHG25	2.5Hex	Having 2.5Hex Internal Connection Fixture
IOG31	3.1Octa	Having 3.1Octa Internal Connection Fixture

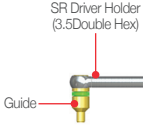
<External Guide>

Product Name	Standard	Applicable Fixture
EHG24	2.4Hex	Having 2.4Hex External Connection Fixture
EHG27	2.7Hex	Having 2.7Hex External Connection Fixture
EHG34	3.4Hex	Having 3.4Hex External Connection Fixture

7 SR Driver Holder

This can be easily affixed to the Fixture by connecting it to the 3.5 Double Hex part of the Conical, Internal, or External Guide.

Product Name	Standard	Applicable Fixture
GH00	2.4Hex	Conical Guide : CG00 Internal Guide : IHG24, IHG25, IOG31 External Guide : EHG24, EHG27, EHG34



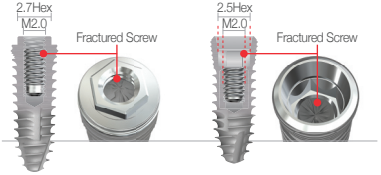
Instruction for use

1 Disinfection

Before using the surgical tools, the components should be sterilized and disinfected, based on our recommended steam sterilization conditions

2 Verifying the Size of the Fixture and the Screw (Figure 1)

In order to select the appropriate tool for removing the screw, verify the connection to the Fixture and the size of the screw to be removed, or the size of the female screw inside the Fixture.
(If the above information is unknown, the size must be verified by asking the manufacturer or the seller, then the appropriate tool selected, based on the verification.)



Fixture Connection

External : 2.4Hex, 2.7Hex, 3.3Hex, 3.4Hex
Internal : 2.4Hex, 2.5Hex, 3.1Octa

Screw Standard

In general M1.6, M2.0, M2.5 are Mostly fitted

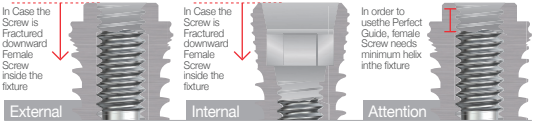
(Figure 1)

3 Selection and Connection of the Guide

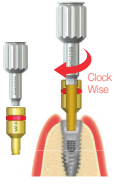
A Guide that is appropriate for the Fixture connection and screw size should be selected and connected to the Fixture.

- When Using the Perfect Guide (Figure 2, 3)

This is used if the screw was fractured inside the female screw inside the Fixture. Using the PG Hand Driver, connect the Perfect Guide inside the female screw of the Fixture using 15 Ncm of Torque (approximately the torque generated by hand tightening).

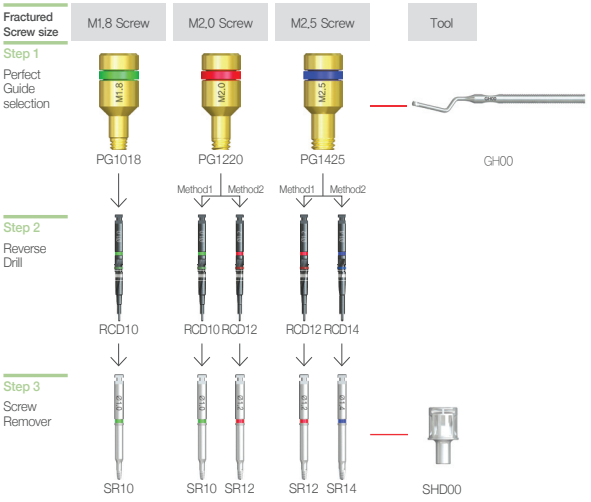


(Figure 2)



(Figure 3)

<How to Use Based on the Size of the Screw to be Removed >

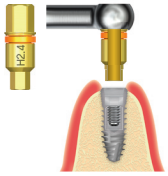


- If screw removal fails after trying the Method 1 sequence, a second attempt can be made using Method 2
- If the size of the female screw inside the Fixture is unknown, try to connect the largest size Perfect Guide (model name : PG1425). If a connection cannot be established, go down to the next smaller size until the correct size is found (PG1220 → PG1018)

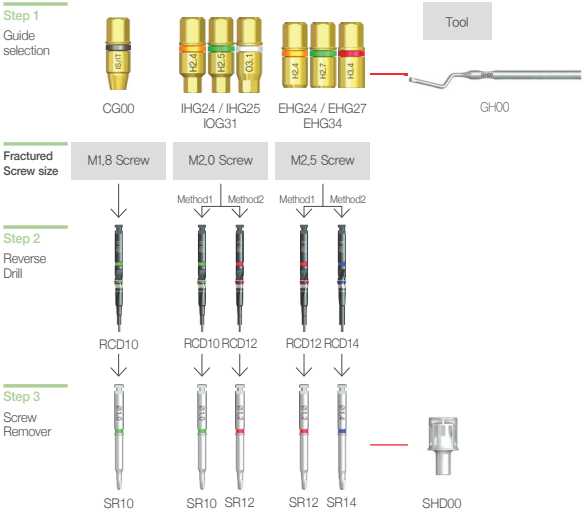
▪ If a Conical, Internal, or External Guide Is Used (Figure 4)

They can be used if the Perfect Guide cannot be used, or if the screw was fractured at a location deeper than 2 mminto the lower part of the female screw inside the Fixture. Select an appropriate guide based on the connection to the Fixture after attaching

(Figure 4)

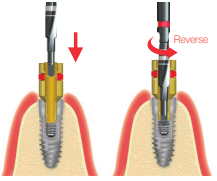


<How to Use Based on the Size of the Screw to be Removed >



4 Use of Reverse Drill (Figure 5)

Select the Reverse Drill appropriate for the size of the screw to be removed and connect to the contra angle of the Surgical engine. Then insert into the guide attached to the fixture and drill in the Reverse direction at approximately 2000 rpm to form a hole that is approximately 1 to 2 mm large in the face of the fractured screw.
While verifying the marking lines on the Drill body (lines are 1 mm apart), carry out the drilling with adequate irrigation.



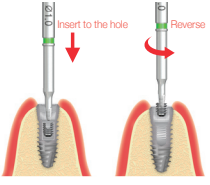
(Figure 5)

A drill stop is designed inside the Perfect Guide, which stops the Reverse Drill from drilling more than 2 mm. However, there is no drill stop inside the Conical, Internal, or External Guides. Accordingly, when using the Reverse Drill with those guides, the marking lines on the Drill body must be checked when drilling. (The marking lines are 1 mm apart.)

5 Use of Screw Remover (Figure 6)

After removing the Guide connected to the Fixture, select the Screw Remover that is appropriate for the hole created with the Reverse Drill. Connect to the contra angle of the Surgical engine and apply a proper amount of pressure and drill in the reverse direction at a low speed (80 rpm or less), in order to loosen the fractured Screw.

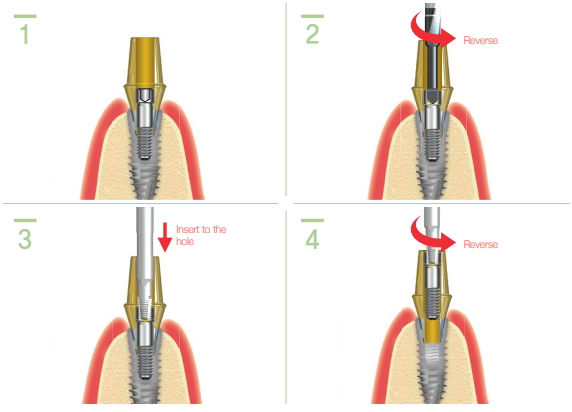
Connecting the shank driver to the Screw Remover enables the user to loosen by hand, Torque Wrench, or Ratchet. In particular, if the screw cannot be removed because the Surgical engine torque is too weak, the Screw can be removed by using a Ratchet



(Figure 6)

If the Screw Hex of the Abutment Screw Has Been Damaged (Figure 7)

The hex part of the screw head can be damaged if over-torque is applied when connecting the Fixture and the Abutment, or when the screw is tightened without the Hex Driver being firmly connected. In these situations, the Reverse Drill and the Screw Remover can be used to loosen the screw.



(Figure 7)

1) Use of Reverse Drill

Insert the Φ1.4 Reverse Drill (Model: RCD14) into the damaged area of the Hex and drill in the reverse direction at 2,000 rpm to form a hole that is approximately 1 to 1.5 mm deep. (Depending on the situation, the screw may be loosened simply by using the Reverse Drill.)

2) Use of Screw Remover

Insert the Φ1.4 Screw Remover (Model: SR14) into the hole created using the Reverse Drill and drill in the reverse direction at or below 80 rpm in order to loosen the Screw.

Precaution for use

1. The product may be used only after the user completely understands the proper methods of use.
2. The Fixture may be damaged if the size of the surgical tool is incorrectly selected. Accordingly, the size of the screw to be removed and the connection to the fixture, among others, must be verified and the appropriate Guide, Reverse Drill, and Screw Remover must be selected.
3. If the Perfect Guide does not connect easily, a Conical, Internal, or External Guide that is appropriate for the Fixture connection must be used. If use of the Perfect Guide is forced, the fixture may become damaged. (Perfect Guide recommended connection torque: 15 Ncm)
4. The Conical, Internal, or External Guide must be affixed to the SR Driver Holder tightly before use.
5. After attaching a guide, it is possible that the Screw can be removed just by reverse drilling. Accordingly, drilling must be conducted with care.
6. The Reverse Drill and the Screw Remover must use the appropriate rotation speed (rpm). (Reverse Drill = 2,000 rpm, Screw Remover = 80 rpm or lower)
7. The Reverse Drill is a single-use item, it cannot be reused.

How to Sterilize

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

<Recommended Steam Sterilization Conditions >

	Cycle Type	Temperature	Pressure	Exposure Time	Dry Time
KIT, Instrument	Pre-vacuum[1][2]	132 °C 270 °F	2 bars 28.5 psi	3 minutes	30 minutes
KIT, Instrument	Gravity[1]	121 °C 250 °F	1 bars 14.5 psi	40 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^{-6}

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.

How to Wash after Use

Surgical Tools

1. After the procedure ends, detach all surgical tools from the tray, soak them in alcohol, and rinse them using conventional means.
2. 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.
3. Following the instructions of the cleaner manufacturer, dilute the enzyme cleaner using tap water and, after ten minutes of ultrasound washing, rinse using tap water for three minutes.
4. Completely remove the moisture using a dry cloth or a warm-air circulator.

KIT Tray

1. 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.
2. Following the instructions of the cleaner manufacturer, dilute the enzyme cleaner using tap water and soak for one minute. Afterwards, using a soft brush, remove any foreign objects remaining on any part.
3. After washing, rinse for three minutes using tap water to remove the remaining enzyme cleaner.
4. Completely remove the moisture using a dry cloth or a warm-air circulator.
5. 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.)

How to Store and Maintain after Use

1. All surgical tools that were used must be immediately detached, washed, and dried, after the procedure, then stored at room temperature.
2. Do not store in a soiled area or where there is a risk of infection.
3. 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)

Precaution

1. Only dentists who have completed implant procedure education and training courses can use this product.
2. For each patient, a procedure plan must be established, based on a treatment plan after testing and analyzing for whole-body ailments, infectious disease, whether they are receiving treatment for other ailments, and whether there is any oral lesion.
3. The surgeon must use the product only after becoming completely familiar with how to use the product and the relevant warnings, and must select products that fit the treatment plan.
4. Before each procedure, the tools must be examined for wear and tear.
5. Any external contact with the surfaces is prohibited.
6. Improper selection of the patient or procedure may cause failure of the implant or post-surgical bone loss around the implant.
7. Hydrogen peroxide is prohibited for disinfection and washing, as it could damage or discolor the TiN Coating, Laser Markings, or Colors.

Contraindication

1. Patients with serious internal ailments: endocrinal ailments such as diabetes or hypertension, circulatory ailments, and ailments related to the blood, organ, or immune systems.
2. Patients receiving high-level radiation treatment for malignant tumors or other reasons.
3. Patients who have unsuitable jaw relations or problematic occlusions.
4. Patients with dry mouths.
5. Patients with unrestored teeth who maintain bad oral health conditions.
6. Patients with acute inflammatory ailments and patients who are at risk of infection.
7. Pregnant patients.
8. Smokers.
9. Patients with blood clotting conditions or with severe cardiac ailments.
10. Children aged 16 years or younger.
11. Patients who are allergic to titanium or stainless steel.
12. Patients without ordinary wound-healing function.
13. Patients who are taking other drugs.
14. Patients who are vulnerable to physical and mental stress due to temporary use of a specific medication.
15. Patients who are emotionally unstable, such as due to alcohol addition, drug abuse, neurological ailments, or mental ailments.
16. Patients who have unrealistic expectations regarding the treatment.

Side effect

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

Label Symbols

Symbol	Definition	Symbol	Definition
REF	Catalog Number	CONSULT INSTRUCTIONS FOR USE	Consult instruction for use
LOT	Batch Code	STERILE R STERILIZED USING IRRADIATION	Sterilized Using irradiation
	Date of manufacture	Rx only Prescription only	Prescription Only
	Manufacturer	DO NOT REUSE	Do not re-use
CAUTION,CONSULT ACCOMPANYING DOCUMENTS	Caution, consult accompanying documents	DO NOT USE IF PACKAGE IS DAMAGED	Do not use if package is damaged
NON STERILE	Non-Sterile		

* This product is a non-sterilized medical device.

Manufacturer /Distributor : Neobiotech Co., Ltd. www.neobiotech.co.kr
104, 24 / 102, 103, 104-1, 104-2, 105, 106, 205, 212, 312, 509, 510, 511, 10F
36 Digital-ro 27-Gil, Guro-Gu, Seoul, Korea Tel. +82 2 582 2885 Fax. +82 2 582 2883