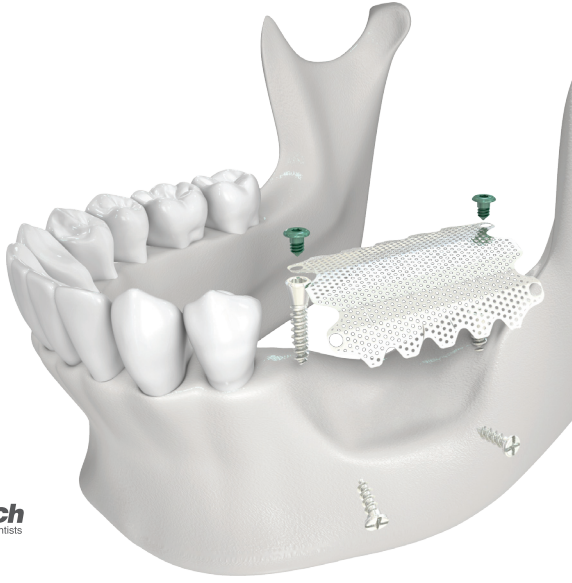
Rev.1 12/2015-E

Neo GBR Kit
User Guide



Neo Biotech
Satisfaction to Dentists

Product description

This product is a GBR Kit consisting of dental implant surgical tools (drill, surgical tool, driver) made from medical grade material such as stainless steel.

Intended use

This product is a surgical tool used for oral bone grafting onto areas in which there are defects in autogenous bones. It consists of surgical tool components that can affix collagen membranes.

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

<Basic Components of GBR KIT >

1 Screw Fixation Drill

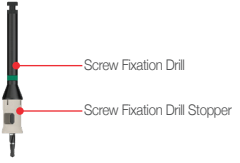
This is used form a hole in D1 to D3 bone before implanting the Tent Screw and the Fixing Screw.

Product Name	Diameter(Ø)
SFD10	Ø1.0
SFD13	Ø1.3
SFD13	Ø1.5

2 Screw Fixation Drill Stopper

After it is connected to the Screw Fixation Drill, this is used to drill safely to the desired depth.

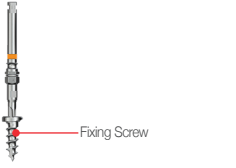
Product Name	Drilling Depth
SFDS030	3mm
SFDS050	5mm
SFDS070	7mm



3 Philips Head Screw Driver

This is a cross-head (+) driver used when implanting Fixing Screws.

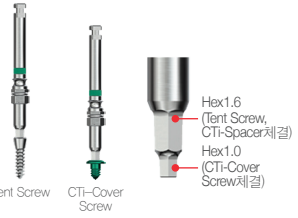
Product Name	Length(L)
PHSD05	5mm
PHSD10	10mm
PHSD20	20mm



4 Philips Head Screw Driver

This is a double stage hex. It is used to fasten or remove Tent Screws and CTi-cover Screws

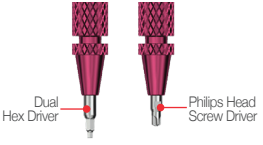
Type	Product Name	Length(L)
Contra Angle	DHDC10	10mm
	DHDC20	20mm
Ratchet	DHDR15S	15mm



5 Driver Handle

This is used to tighten or remove drivers for Contra Angle by hand.

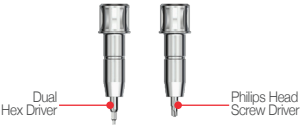
Product Name
DRH



6 GBR Ratchet Connector

This is used to connect with drivers for Contra Angle to change them to Ratchet types.

Product Name	Length(L)
GRC15	15mm



7 Hex Hand Driver

This is used to tighten/remove our company's Abutment screws, Cover screws, Healing abutments and the like, using a hand-type driver of Hex 1.2 size

Product Name	Hex Size	Length(L)
HDH1215S	Hex 1.2	15mm
* HDH1220S		20mm
* HDH12520S	Hex 1.25	20mm

* Optional

<GBR Components> *Optional

1 Tent Screw

This is a screw for GBR use developed to make it easier to maintain the specs for bone formation and to attach a membrane when a wide-scale or horizontal/vertical strengthening is necessary. It is implanted using the Dual Hex Driver.

Consists of 2 each per Length, total 8 ea/1SET

Product Name	Length(L)
CTS2007	7mm
CTS2010	10mm
CTS2013	13mm
CTS2015	15mm

x 2ea

Product Name
CTSSET02

2 Fixing Screw

This is a membrane Fixation Screw for secondary attachment of a membrane. It is attached using the Philips Head Screw Driver

x 4ea

Consists of 4 each per Length, total 12ea/1SET

Product Name	Length(L)
MFS1603	3mm
MFS1605	5mm
MFS1607	7mm
MFSSET01	3mm, 5mm, 7mm

3 CTi-Cove Screw

This is a product used to submerge the Tent Screw or CTi-Spacer after attaching them to the membrane. It is tightened or removed using the Dual Hex Driver

Product Name
CTCS30

4 CTi-Spacer

This is used to attach a membrane using the CTi-Cover Screw after it is connected to the Fixture. A compatible model must be used.

▪ IS CTi-Spacer

A CTi-Spacer that is compatible with IS Fixtures

Product Name	Length(L)
ISCSP3505	0.5mm
ISCSP3510	1.0mm
ISCSP3515	1.5mm
ISCSP3520	2.0mm

▪ Universal Spacer

A CTi-Spacer that is compatible with numerous implant systems.

Product Name	Diameter	Screw Size	Cuff	compatible and Implant List
UVCSP1410	Ø1.0	M 1.4	1.0mm	Astra X-Small
UVCSP1415			1.5mm	
UVCSP1420			2.0mm	
UVCSP1605	Ø3.5	M 1.6	0.5mm	Megagen EZ Plus NP Astra Small Straumann (bone level) NP, RP Nobel Active NP
UVCSP1610			1.0mm	
UVCSP1615			1.5mm	
UVCSP1620			2.0mm	
UVCSP2005	Ø4.0	M 2.0	0.5mm	Neobiotech IS Megagen EZ Plus RP Warantec One plant Astra Large Nobel Active RP Dio SM Regular
UVCSP2010			1.0mm	
UVCSP2015			1.5mm	
UVCSP2020			2.0mm	

Instruction for use

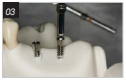
1 Disinfection

Before using the surgical tools, sterilize and disinfect the components based on our recommended steam sterilization conditions.

2 Surgical procedure

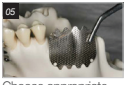
Connect Stopper to Drill

Drill at least 3mm depending on the Bone Density



Insert Tent Screw leaving space for augmentation (15~25Ncm)

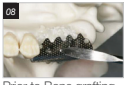
Decorticated surroundings after Tent Screw insertion



Choose appropriate CTi-mem

Tighten Fixing Screw in to Fixing Hole

Create matching hole for Cover Screw on CTi-mem with tweezers



Prior to Bone grafting, to avoid bone material from entering Tent Screw, insert material after tightening Cover Screw. Check for correspondence with Cover Screw Hole

After removing Cover Screw apply CTi-mem, fixate Tent Screw on CTi-mem with Cover Screw(10~15Ncm)

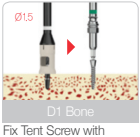
Adapt the remaining part of CTi-mem to the tissue and cover up

3 Drilling Guide for Tent screw & Fixing screw

3-1) While fastening Tent Screw

Neo GBR kit's Tent Screw is a Temporary Screw that works as a prop to get space to enable vertical and horizontal bone formation on large defected area

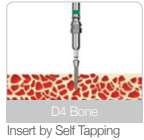
- Insert 3mm or more into the bone and needs primary stability of 15~25Ncm
- Tent Screw could break when 30Ncm is exceeded
- Insert to the level of bone grafting



Fix Tent Screw with Dual Hex Driver after drilling with 1.5

Fix Tent Screw with Dual Hex Driver after drilling with 1.3

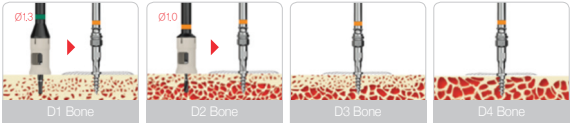
Fix Tent Screw with Dual Hex Driver after drilling with 1.0



Insert by Self Tapping

3-2) While fastening Fixing Screw

Neo GBR kit's Fixing Screw secondarily stations Membrane and maintains the desirable volume of bone formation



Fixate Fixing Screw with Phillips Driver after drilling with 1.3	Fixate Fixing Screw with Phillips Driver after drilling with 1.0	Self Tapping	Self Tapping with 5~7mm Screw

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.

Neo GBR Kit

Neo Guided Bone Regeneration Kit

Manufacturer /Distributor : Neobiotech Co., Ltd. www.neobiotech.co.kr
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