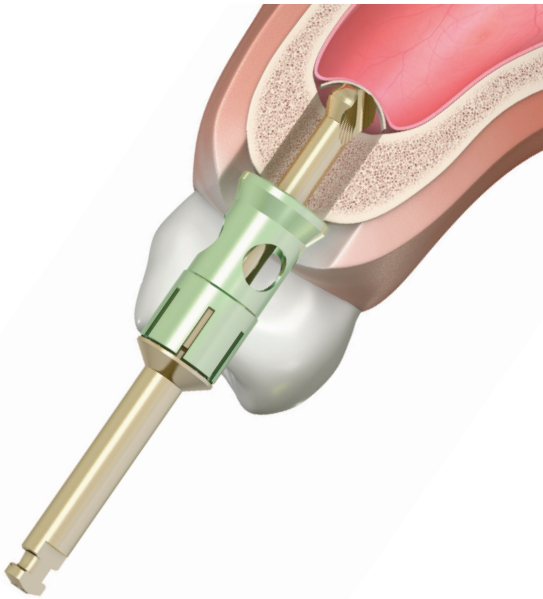
Rev.4 08/2015 -E

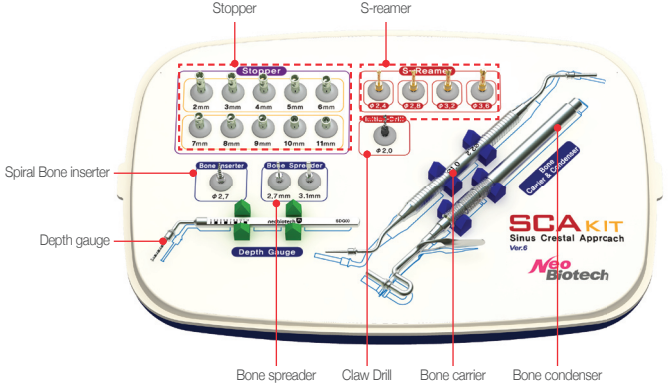
Neo SCA Kit
User Guide



Neo Biotech
Satisfaction to Dentists

Product description

This product is a Sinus Crestal Kit, consisting of dental implant surgical tools (drills, surgical tools, and drivers) made out of medical grade materials, including stainless steel.



Intended use

SCA Kit is a drilling tool on the inferior cortical bone without tearing of membrane and make a perforation on the inferior cortical bone without malleting osteotome technique Therefore User can get CMI fixation(Initial fixation in Crestal cortical bone, Middle cancellous bone and inferior cortical bone)

'3S' of SCA Kit

Speedy
It can provide fast drilling procedure typically operated at 800~1,200RPM

Safer
The operation is simpler and much comfortable process for patient and dentist

Simpler
Using general drilling method

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. Initial Drill

Drill for creating guide hole upon designating the precise point before using S-reamer

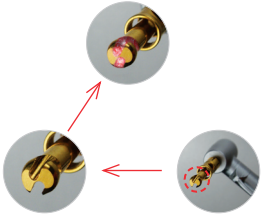
Diameter(Ø)	Product Name
Ø2.0	SSD20

* 1,200rpm

2. S-Reamer

Diameter(Ø)	Product Name
Ø2.4	ICR24
Ø2.8	ICR28
Ø3.2	ICR32
Ø3.6	ICR36

* 1,200rpm



* The reamer does not hurt the membrane because during drilling, the bone chip filled the reamer space so it makes more wide and safe side

- S-reamer is the main instrument of SCA kit that creates desired size hole on the sinus inferior cortical wall without damaging Schneiderian membrane.
- Even if reamer touched sinus membrane, membrane dosen't tear and perforate and S-reamer can be applicable to even in the misaligned septum, cases.
  *S-reamer filled with bone chip and bone chip makes smooth surface.
- S-reamer is named after 'S' shaped blade design and drill for sinus elevation
- S-reamer provide high speed drilling at 800~1,200 rpm there it can remove the bone effectively.
- Bone chip makes flat blade surface and S-reamer doesn't tear sinus membrane Further more It is very safe in case of misaligned and septum case
- User can safely perforate the inferior cortical bone with Stopper.
- S-reamer's diameter is Ø2.4, Ø2.8, Ø3.2, Ø3.6 Choice of diameter is very important to CMI fixation So, user have to choose diameter carefully.

3 Stopper

- The stopper is composed of 10pieces, 2mm~11mm.
  Each 1mm step make the S-reamer stop to insert maximum 1mm in sinus. To prevent membrane rupture by physical pressure.
- Stopper is compatibility with S-reamer, bone spread and bone condenser.
  When bone spreading or condensing, User have to use it for prevention of the mem brane tearing

< image 1 >

Length	2mm	3mm	4mm	5mm	6mm	7mm	8mm	9mm	10mm	11mm
Product Name	SKS02	SKS03	SKS04	SKS05	SKS06	SKS07	SKS08	SKS09	SKS10	SKS11

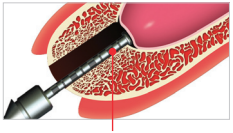
< image 2 >

* The written length is not length of stopper body but depth of drilling (image 1, 2)

4 Depth gauge

Depth gauge is an instrument for measuring the depth of the remaining bone upon perforating with S-reamer

* Caution : Do not insert the depth gauge maximum 1mm than residual bone height



Insert and drag the depth guage along the wall carefully

Product Name
SDG00

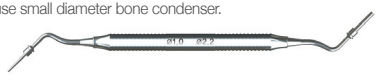
5 Bone Carrier

- Bone carrier is used to carry the bone grafting materials into osteotome site
- One time insertion 0.05CC

Product Name
JUMBO2

6 Bone Condenser

- Bone condenser is used to keep the graft materials in place on the floor of the sinus through the osteotome site
- The appropriate size of sopper mounted on the bone condenser should be selected same as the residual bone height
- When inserting hard or big particle bone, user would be better to use small diameter bone condenser.



Product Name
SBC01

7 Bone Inserter

Spiral Bone Inserter is an instrument which is for bone graft to push the bone into sinus after inserting the bone into a hole with bone carrier Bone inserter can be safely used without any damages at membrane after combination with 1mm long Stopper

Product Name
SBI27

* 80rpm

8 Bone Spreader

The bone inserted in the sinus floor can be spread out to a lateral direction(left and right side) by this tool thereafter the sinus membrane at the inferior aspect of the osteotomy its naturally detached from the floor of the maxillary sinus and elevated upward to create more space in the floor of the sinus for the bone-graft material. The minimum 0.3cc amounts of(height 3mm) bone grafting material are recommended to be inserted into the space before use the bone spreader in sinus and then mount the same size stopper in length as residual bone height, Whenever insert the bone grafting material, 0.2~0.3cc, change the 1mm larger size stopper continuously

Diameter(Ø)	Product Name
Ø2.7	SBS20
Ø3.1	SBS30

* 80rpm

Using Method & Precaution for use

1. Get accurate X-ray image of the posterior maxillary region to assess the residual bone height.
2. After checking the residual bone height, make your osteotomy starting with a point(guide) drill then choose a proper S-reamer drill in diameter and 1mm shorter than the estimated bone height. Decide the final drilling diameter based on bone density
3. For safety, drill only 1mm more in each step using 1mm longer stopper.
4. Select S-reamer diameter considering the fixture diameter and insertion depth in sinus. Diameter Selection(Based on implant insertion depth in sinus)

	CMI Implant Regular fixture	CMI Implant Wide fixture
1mm~3mm insertion	Ø2.4	Ø3.2
More than 4mm insertion	Ø2.8	Ø3.6

* S-reamer must be chosen right diameter because it is very related with Neo CMI Implant diameter

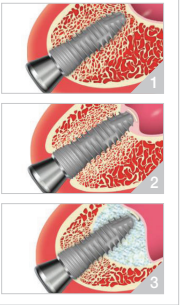
CMI Fixation

CMI Fixation is a new implantation technique which is presented by Dr. Young Ku, Heo It is for effective initial fixation at mixed bone's each part such as hard-soft bone and an abbreviation for crest cortical, Middle cancellous and Inferior cortical fixation, especially it is an important concept for effective fixation at Middle cancellous bone and inferior cortical bone.

C fixation is method which removes enough Crest cortical bone and then makes a final implantation, the fixture can be fixed passively without over-compression.

M fixation is method which is clean and best getting the best fixation from soft bone.

I fixation is method of gaining strong fixation inner sinus inferior cortical wall by making a small hole.



5. If the sinus inferior cortical wall does not perforate until the stopper reaches to the crestal bone, change 1mm longer size stopper and drilling continuously.
6. Yon can feel perforating in inferior cortical wall and then measure the residual bone height with depth gauge. When you hang on the end of depth gauge in sinus wall inside, you can check the detailed residual bone height.
   (caution: Do not insert the depth gauge maximum 1mm in sinus)
7. When the inferior wall is perforated, close the patients nose and then make them blow out to check the membrane status. The soft bone(such as DFDBA bone) should be inserted first. If a lot of bone insertion is required, yon may use the hard bone as well as the soft bone.
8. Insert the bone with bone carrier and stopper mounted bone condenser.
9. Insert the bone volume based on membrane elevation height, if you want to elevate the membrane about 1mm, you may need 0.1cc volume of bone grafting material. However, if Depends on how effectively you can transfer the graft to the osteotomy.
10. To elevate the membrane more laterally, after inserting at least 0.3cc volume of bone, start the bone spreading with stopper mounted bone spreader, Narrow one is for 2.4 X 2.8mm S-reamers and wide one is for 3.2X3.6mm S-reamers.
11. Spread out the bone with stopper at every 0.2cc~0.3cc volume of bone insertion It is not necessary to increase the stopper size even if additional bone is inserted.
12. When finish the insertion the bone in sinus, you can refresh the hole with a larger diameter drill.
13. Based on the crest cortical bone density, the countersink could be needed depending on the patients the crest cortical bone density(except, IT type) The conuntersink should be used for the D1 and D2 bone.
14. Finally, place the fixture at the prepared hole.

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
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