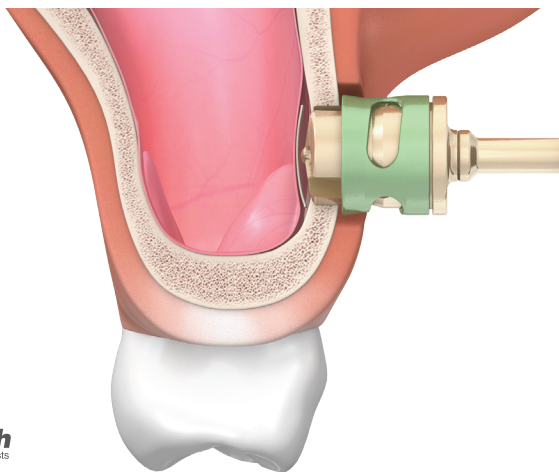


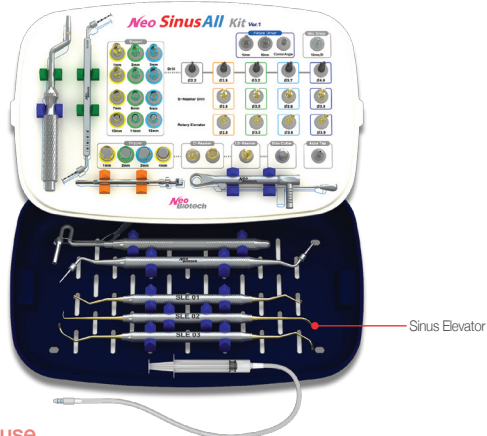
Neo SinusAll Kit

User Guide



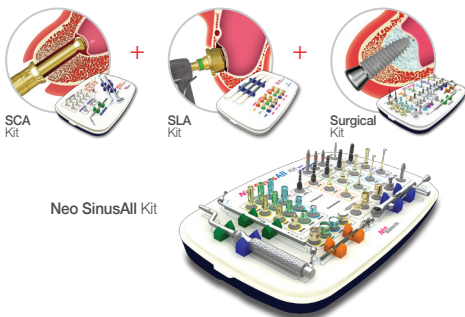
Product description

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



Intended use

The SinusAll Kit combines NeoBiotech's SCA (Sinus Crestal Approach) Kit, SLA (Sinus Lateral Approach) Kit, and the Surgical Kit into a single kit. The product allows maxillary sinus implant procedures to take place using a single kit, rather than having to prepare a sinus kit and a surgical kit separately.



Preservation

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

How to Prepare Before Use

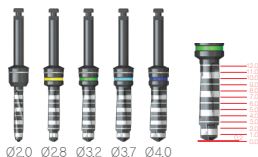
- 1 Prior to using this product, the clinician must completely understand the condition, performance, and function of the product.
- 2 Use only after raising any doubts and verifying any issues with the manufacturer.
- 3 For the procedure, a plan must be first established, based on checking the patient's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

Components

<Crestal Approach Tool Components>

1 Surgical Drill

- Consist of a total of five types :
Ø2.2 / Ø2.8 / Ø3.2 / Ø3.7 / Ø4.0
- Ensure safe drilling by attaching a stopper.
- Drill 1 mm shorter than the remaining maxillary sinus bone.

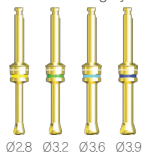


Diameter(Ø)	Product Name
Ø2.2	SAD22
Ø2.8	SAD28
Ø3.2	SAD32
Ø3.7	SAD37
Ø4.0	SAD40

* 1,200rpm

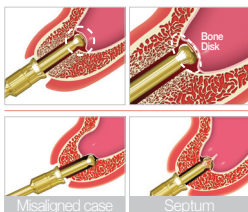
2 S-Reamer

- Consist of a total of four types :
Ø2.8 / Ø3.2 / Ø3.6 / Ø3.9
- Ensure safe drilling by attaching a stopper.



Diameter(Ø)	Product Name
Ø2.8	SAR28
Ø3.2	SAR32
Ø3.6	SAR36
Ø3.9	SAR39

* 1,200rpm

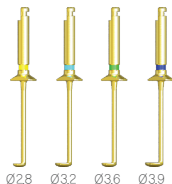


The reamer does not hurt the membrane because during drilling, the bone chip filled the reamer space so it makes more wide and safe side

- Creates a hole of the desired size in the sinus inferior cortical wall without damaging the sinus mucosa.
- Even direct contact with the tool does not cause the sinus membrane to rip. Accordingly, the membrane is safe even when drilling through the side or the septum.
- Bone chips are formed by the end of the S-Reamer's blade in a flat shape, meaning that the membrane will not rip, even if there is direct contact with the sinus membrane

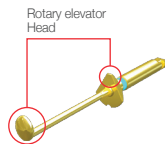
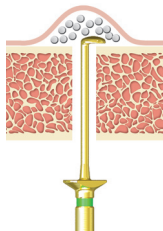
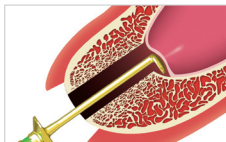
3 Rotary elevator

- This tool is used to initially remove the mesial and distal membranes immediately after a hole is formed.
- This tool is used to push the bone into the interior and the sides of the sinus after the bone is inserted into the hole.



Diameter(Ø)	Product Name
Ø2.8	SARE28
Ø3.2	SARE32
Ø3.6	SARE36
Ø3.9	SARE39

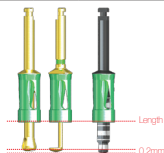
* 80rpm



4 Stopper

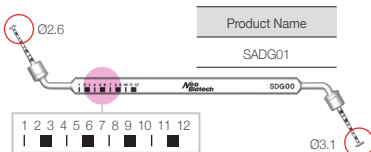
												
Length	1mm	2mm	3mm	4mm	5mm	6mm	7mm	8mm	9mm	10mm	11mm	12mm
Product Name	CDS010	CDS020	CDS030	CDS040	CDS050	CDS060	CDS070	CDS080	CDS090	CDS100	CDS110	CDS120

- Consist of a total of twelve types, from 1 to 12 mm
- Used by attaching to a Drill, S-Reamer, Depth gauge, Bone Condenser, or other tool.
- The various stoppers have different colors to prevent confusion.
- When a stopper is attached to a drill, the drill becomes 0.2 mm longer.



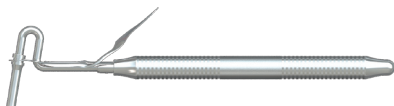
5 Depth gauge

- Tip sizes come in Ø2.6 and Ø3.1
- This tool is used to measure the thickness of the remaining bone.
- The depth can be safely verified when a stopper is attached.



- Insert slowly, hugging the wall closely with the tip part.
- With both sides of the tip flat, the tip is designed to hook inside the sinus wall.
- Care must be taken not to insert the depth gauge more than 1mm further than the length of the remaining bone.

6 Bone carrier



- This tool is used to transplant insert the bone inside a sinus hole.
- Volume inserted per use: 0.05 cc

Product Name
JUMB02

7 Bone condenser



8 Aqua system

- This is a system for detaching sinus membrane that uses water.
- Its design is based on a 3 cc syringe; the extent of detachment can be adjusted.

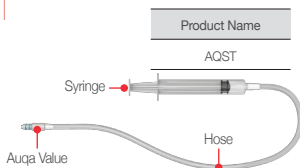
8-1) Aqua Tap

This tool is attached to the bone after a sinus hole has been formed in order to allow water to be safely injected into the sinus.



8-2) Aqua Valve, Hose, Syringe

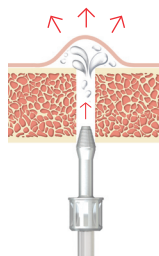
- This tool detaches sinus membrane using the water inside the syringe.
- A set of this tool consists of an aqua valve, a hose, and a syringe.



<How to Use>



1. After completing drilling towards the Crestal direction, self-tap the Aqua Tap using a Torque Ratchet for fixation to the bone.
2. Insert the blue rubber part of the Aqua System valve into the head hole of the Aqua Tap, fixing it.
3. Fill the syringe with the desired amount of physiological saline solution, then inject slowly.



9 Drill Handle

This tool is connected to contra angle type devices, such as a drill or Rotary Elevator, in order to allow the user to utilize them manually.



Product Name

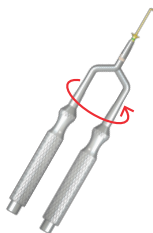
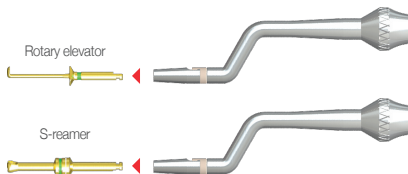
SADH01

9-1) Use as Osteotome

Possible to use as an osteotome, by connecting a surgical drill to the Drill Handle.



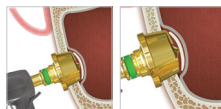
9-2) Use by connecting to a Rotary Elevator or S-Reamer



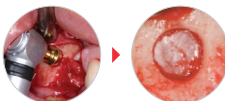
<Lateral Approach Tool Components>

1 LS-Reamer

- This tool forms a thin bone disk between the reamer and the membrane during lateral approach and penetrates the lateral wall.
- There is a single size—Ø6.5. This tool can be used to drill safely by connecting a Lateral Stopper.



* 2,000rpm(20:1) / 5,000rpm(1:1)



<Special Characteristics and How to Use>

1. With adequate irrigation, can be used to drill at 2,000 to 5,000 rpm.
2. When creating a lateral hole, prevents sinus membrane damage by forming a thin bone disk between the sinus membrane and the LS-Reamer.
3. Helps perform the procedure safely by allowing visual observation of the hole as it is formed, allowing visual identification of special anatomical features, such as blood vessels or the septum, in the course of drilling.

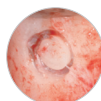
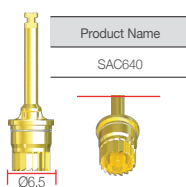
2 C-Guide & C-Reamer

- The C-Guide is a guide drill used to prevent slippage and to locate the position accurately before use of the C-Reamer.

C-guide



C-reamer



* 2,000rpm(20:1)
5,000rpm(1:1)

- The C-Reamer is a drill used to create a circular core while forming a bone window in the lateral wall.
- Can be used to drill safely by attaching a stopper.

<Special Characteristics and How to Use >

1. The circular core that is formed by drilling will be 1 mm smaller than the head size of the C-Reamer. This can be detached from the membrane and stored to be used as a cover after the procedure.
2. The cutting edges of the C-Reamer are formed on the front and the side, allowing fast drilling at 2,000 rpm or higher. Sinus membrane damage is minimized because bone chips are discharged around the cutting edges.
(Because the core tends to become wedged inside the head of the C-Reamer and spin in place, it is recommended that, after an appropriate amount of drilling, the user remove the core before it is completely formed, using an Elevator)

3 Sinus Elevator

This tool is used to initially remove the mesial and the distal membranes immediately after formation of the hole.

3-1) Elevator 1

This tool is used to initially remove the mesial and the distal membranes immediately after formation of the hole.



Product Name

SLE01

3-2) Elevator 2

- This tool is used after Elevator 1. The hook is used to detach the lower part of the lateral wall from the hole.
- The part with a gentle slant of approximately 30° is used to remove the membranes from the entire sinus floor and from the medial and posterior walls.



Product Name

SLE02

3-3) Elevator 3

This tool is used to detach any remaining tissue from the deep interior parts.



Product Name

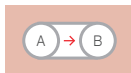
SLE03

4 Side cutter

- This tool is used laterally to widen a hole formed using the LS-Reamer or the C-Reamer.
- It comes in one size : Ø3.0



<Window extend>



* 1,200rpm

Product Name

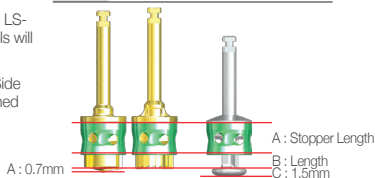
SCT30

5 Lateral stopper

- Consist of a total of four sizes: 1 to 4 mm
- Use after connecting to the LS-Reamer, C-Reamer, Side Cutter, or other components.
- When a stopper is connected to the LS-Reamer or the C-Reamer, those tools will be lengthened by 0.7 mm.
- When a stopper is attached to the Side Cutter, the latter tool will be lengthened by 1.5 mm.



Length	1mm	2mm	3mm	4mm
Product Name	LTS010	LTS020	LTS030	LTS040



<Implant Placement Tool Components>

1 Fixture driver

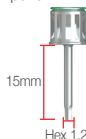
- This tool is used to implant the fixture
- It includes two types of ratchets and one type of contra angle.



Length	Product name
Ratchet (Short)	ISFD10R
Ratchet (Long)	ISFD15R
Contra Angle	ISFD05C

2 Hex driver

This tool is used to connect the cover screw, Healing Abutment, Abutment screw, and other components to the implant.



Product name
HD1215S

3 Torque wrench

This tool is used by connecting to a type of ratchet when implanting or applying torque to an implant.



Product name
TW60

I 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 ^②	132 °C	2 bars	3 minutes	30 minutes
		270 °F	28.5 psi		
KIT, Instrument	Gravity ^①	121 °C	1 bars	40 minutes	30 minutes
		250 °F	14.5 psi		

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.

I 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.

I Label Symbols

Symbol	Definition	Symbol	Definition
	Catalog Number	 CONSULT INSTRUCTIONS FOR USE	Consult instruction for use
	Batch Code	 STERILIZED USING IRRADIATION	Sterilized Using irradiation
	Date of manufacture	 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		

* This product is a non-sterilized medical device.

