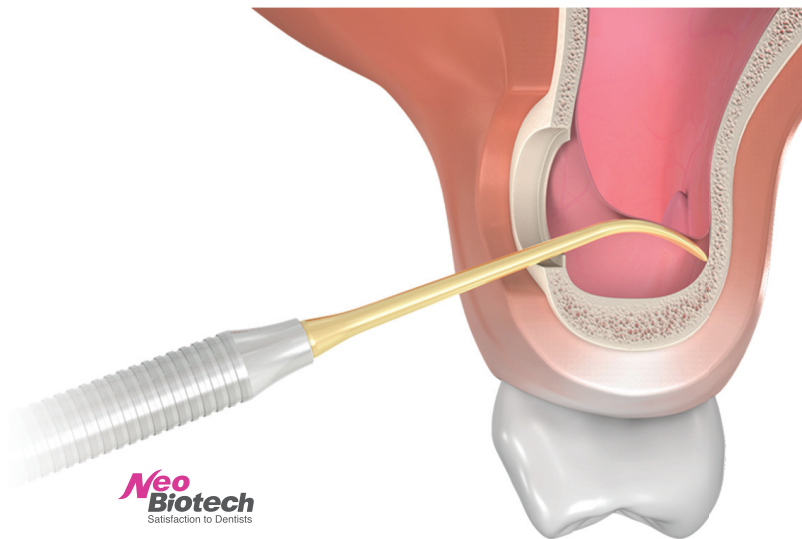


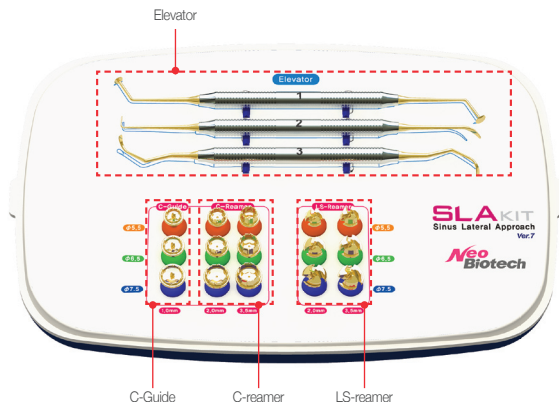
Neo SLA Kit

User Guide



Product description

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



Intended use

Lateral window technique is the formation of the access to the maxillary sinus through its lateral wall. The process using this tool is simpler and much comfortable than any other techniques. Above all, this surgical kit provides ultimate solutions for the cases of only having with a thin residual bone height which is difficult to approach with a crestal technique, membrane rupture by a sinus crestal approach or placing a multiple implants. In addition, SLA reamers can be easily adapted for the case of formation of minimum flap size on the inferior wall.

| | | | | |
|--|---|---|---|---|
|  LS-reamer |  |  |  | <p>SLA Kit has "3S" advantages!</p> <p><i>Speedy</i> Using SLA, We can make Ø4-6hole at once</p> <p><i>Safer</i> There is little possibility of tearing membrane by mistake</p> <p><i>Simpler</i> It is a very simple tool for everyone to operate on lateral wall</p> |
|  C-reamer |  |  |  | |

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 LS-reamer

LS-Reamer is a kind of drill which drills lateral wall. It makes thin bone disk between reamer and sinus membrane. There are 6 types as shown in the table below.



| Length | Product Name |
|--------|--------------|
| 2.0mm | LS520 |
| 2.0mm | LS620 |
| 2.0mm | LS720 |
| 3.5mm | LS535 |
| 3.5mm | LS635 |
| 3.5mm | LS735 |

* SPEED : 1:1 contra angle -5,000RPM
1:20 contra angle-2,000RPM

<LS-reamer's Merits & Features>

1. It is very safe, because the tapered trunk of LS-reamer is designed to control the drilling depth without stopper.
2. The LS-reamer mounted on a handpiece can be operated with high speed at 2,000~5,000 rpm under the sufficient irrigation
3. It protects sinus membrane, because LS-Reamer makes thin bone disk between reamer and sinus membrane
4. The reamer filled with bone chip protects the membrane from tearing
5. It provides the safe surgery because it is able to check an artery or septum etc, during the drilling through the lateral hole

2 C-guide & C-reamer

It is a guide drill to make a position to use C-reamer.

The hollow spaced and tapered C-reamer can save the circular bone core disk from the lateral wall and to limit any abrupt movement of the reamer to forward direction, respectively. It is designed to provide a safe, speedy recovery, fast surgery and quick bone formation in the lateral hole.



| Length | Product Name |
|--------|--------------|
| 2.0mm | LC520 |
| 2.0mm | LC620 |
| 2.0mm | LC720 |
| 3.5mm | LC535 |
| 3.5mm | LC635 |
| 3.5mm | LC735 |
| 1.0mm | SCG510 |
| 1.0mm | SCG610 |
| 1.0mm | SCG710 |

* SPEED : 1:1 contra angle - 5,000RPM
1:20 contra angle - 2,000RPM

<C-reamer's Merits & Features>

1. The bone core disk can be saved after drilling being used as the window cover before suturing.
2. With the tapered trunk of the C-reamer, the drilling depth can be controlled without using stopper.
3. The C-reamer cutting edges are positioned on the head and side of the C-reamer, therefore, it provides the high drilling efficiency. Typically, C-reamer can be operated a speed at 2,000 rpm. It is recommended that the bone core disk should be removed using elevators not to be excessively stuck to the C-reamer hollow space.
4. The four holes formed on the side of C-reamer are to provide irrigation line not to overheat during the drilling process.

3 Sinus Membrane Elevator

The three elevators provided are designed to obtain a best angle and length for membrane elevation in buccal. These tools are used one after another in number.

3-1) Elevator 1

The elevator #1 is designed as the initial membrane elevation of mesial and distal, after making a lateral hole.



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|--------------|
| Product Name |
|--------------|

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| SLE05 |
|-------|

3-2) Elevator 2

The elevator #2 has two functions. At the one end, the "L" shape is used to detach the sinus membrane from a lower part of lateral wall. At the other end, another shape is used to elevate the sinus membrane from sinus floor, medial wall and posterior wall.



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| Product Name |
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| SLE02 |
|-------|

3-3) Elevator 3

This is designed to detach the membrane from the remaining part and deep site in sinus.



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| Product Name |
|--------------|

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|-------|
| SLE03 |
|-------|

<Simultaneous applications with LS-reamer and C-reamer>

As the LS & C-reamer was designed for maximum 3.5mm drilling depth of the lateral wall, the required drilling depth may have been thicker than the reamer's length. In this case, it is required to remove a 2-3mm thickness bone core disk with C-reamer with Ø7.5 in diameter first. After removing the bone core disk by the chisel or periosteal elevator, then LS-reamer with Ø5.5 in diameter can be used to make a lateral hole to all the way to the sinus

I Using Method & Precaution for use

- 1 Radiography : Get an accurate X-ray image of the residual bone height of the maxillary posterior area. It is necessary to get a CT image to obtain the detailed structure, artery status, and lateral wall thickness.
- 2 Choice of SLA : The SLA Kit is easily adapted to the cases of only 3~4mm of residual bone height, membrane tearing by the crestal approach, convex sinus floor or a number of implants placement.
- 3 Flap formation : It is often required to make only limited size of the lateral flap and vertical incision without forming a large flap. When approach the flapless surgery, a semilunar incision is good enough to form a lateral hole.
- 4 Choice of LS-Reamer : The LS-reamer can be used when it is required to care for the artery bleeding, septum existence on the drilling path or to make a lateral hole in the overlapped region of inferior cortical wall and cancellous bone layer. After bone grafting, the additional membrane may be needed to cover the hole
- 5 Choice of C-reamer : The C-reamer's main purpose is to get the bone core disk from the lateral wall and to use as a cover of the lateral hole. If the bone core disk is not needed, you may select the LS-reamer to drill on the lateral wall.
- 6 Position of Lateral hole : A formation of lateral hole is preferred to be positioned on the most anterior and inferior site as possible to prevent the membrane tearing and to elevate the membrane effectively. If there is no possibility to reduce the residual bone strength caused by drilling, it is recommended to make a lateral hole on the spot containing about 1mm inferior cortical wall.
- 7 Rotation Speed : To take an initial drilling position on the lateral wall, the drilling speed with 5,000rpm is required by the 1:1 contra-angle. If the reamer is mounted on 20: 1 contra angle, drilling should be performed with a firm grip and vertical force on a handpiece to get a good stability.
- 8 Hole formation with LS-reamer : The LS-reamer is requested to drill until the lateral wall is completely perforated. At this moment, the remaining thin bone layer, called Residual bone Shield, will be formed, which may prevent the membrane tearing, When the artery appears during drilling in sinus, the other lateral approach at the lower site is recommended to make another lateral hole.
- 9 Hole formation with LS-reamer : The C-reamer is designed to be safe when it is in contact with sinus membrane. However, since C-reamer has the blade on the head of the reamer, it is relatively less safe than the LS-reamer. Therefore, when the thickness of the perforated lateral wall is more than 3mm, the bone core can be removed by chisel or periosteal elevator through lever action. Then the remained portion of the lateral wall can be finished by the LS-reamer. No attempt should be made to remove the bone core disk by C-reamer all the way to the sinus. Keep the bone core in the wet gauze or saline solution and cover the hole after finishing the graft.
- 10 Sinus Membrane Elevator: As mentioned on the above, use the elevator #1 ~ 3 in order to achieve membrane elevation
- 11 Graft material insertion & implant insertion : Graft the bone material and place implant into the 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 | 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.

| 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.

