Ridge Wider Kit

User Guide

Product description

The product is RidgeWider Kit consisting of dental implant procedural devices (drill, procedural tools) made of medical device materials such as stainless steel and titanium.

Intended use

The product is a dental procedural device developed for convenient and easy split and expansion with RidgeWider Kit including expander, safe disk, drill and chisel in narrow ridge case where implant placement is difficult

Preservation

Keep in a dry place at room temperature without direct sunlight.

How to Prepare Before Use

1. Practitioners should be completely aware of the product status, performance and function before using the product.
2. Make sure to clarify any ambiguity regarding the product by contacting the manufacturer before using the product.
3. Make sure to inspect patients' oral health status and establish operational plan based on precise diagnosis before procedure.
4. Prepare appropriate procedural devices according to each patient's status.

Components

1. Bone Trimmer

   Used to level the bone or set the position of fixture placement.
   Recommended rpm: 1,200-10,000rpm

Model no.	Specification
BTRI6010	Ø6.0

2 Ø1.5 Initial Drill

Used to set a precise hole position and direction in the previous stage before using the bone expander.
Recommended rpm: 1,200rpm

Model no.	Specification
SFDI5	Ø1.5

3 Safe Disk

Used for ridge cutting.
Recommended rpm: 1,200~2,000rpm

Model no.	Specification
SAWD0703N	Ø7 / 0.35T
SAWD1003N	Ø10 / 0.35T
SAWD1303N	Ø13 / 0.35T
SAWD0710N	Ø7 / 1.0T

4 Bone Chisel

Used for split after bone cutting with safe disk

Model no.	Specification
BCHI60	-

5 Bone Expander

Used for expansion before fixture placement.
Recommended rpm: 25~35rpm

Model no.	Specification
BEXP30	Ø3.0
BEXP35	Ø3.5
BEXP40	Ø4.0
BEXP45	Ø4.5
BEXP50	Ø5.0

6 Ratchet Connector

Used to change drill and expander to torque type.

Model no.	Specification
RC15	15mm

7 Drill Stopper
Used to adjust the drilling depth when using the initial drill.

Model no.	Specification
SFDS030	Ø3.0
SFDS050	Ø5.0
SFDS070	Ø7.0

How to use

1. Sterilize the components before use according to the recommended steam sterilization requirements by the Company
2. Remove the ridge bone with bone trimmer until the buccilingual thickness becomes 3mm at least.
3. Drill the fixture placement spot on leveled bone to the planned placement depth using the twist drill.
4. Cut the buccilingual center on the leveled bone using the safe disk. (Use the safe disk to cut the compact bone in the mesial surface part, distal surface part and lower part, if necessary.)
5. Split between the cut ridges using the bone chisel.
6. Expand the ridge by using the bone expander in a consecutive manner to fit into the fixture size.

Notices to use

1. In drilling, move the hand piece upward and downward vertically (pumping).
2. In using the bone trimmer, drill and safe disk, make sure to inject water to reduce the frictional heat with bone.
3. The recommended use of bone trimmer is 50 times.
4. The recommended use of drill is 50 times
5. The recommended use of safe disk is 50 times
6. In using the Ø13 safe disk, use Ø7 for areas close to adjacent teeth.
7. The recommended use of bone expander is 50 times and its tolerable torque limit is 80Ncm.
8. In using the bone chisel, be careful not to apply too much force and break the bone.

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 ℃ 270 °F	2 bars 28.5 psi	3 minutes	30 minutes
KIT, Instrument	Gravity[3]	121 ℃ 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.)

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. Paresthesia due to nerve damage or malocclusion, infection, edema, hypodermic bleeding.
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 Biotech
Satisfaction to Dentists

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