

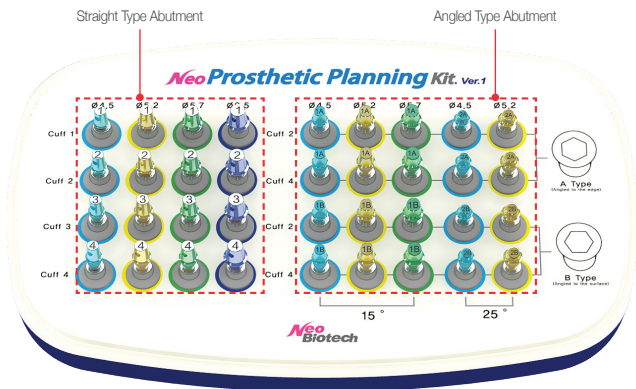
Neo Prosthetic Planning Kit

User Guide



Product description

This product is a Prosthetic Planning Kit for dental implant procedures made of medical grade materials, including titanium and stainless steel.



Intended use

The Prosthetic Planning Kit is used before the fixture is implanted in an area with a missing tooth in order to select the correct abutment by verifying the abutment diameter, cuff height, and the angle. It can be used by connecting it to the intraoral fixture or to the lab model analog.

Preservation

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

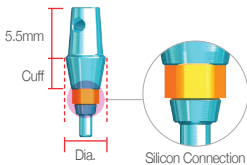
How to Prepare Before Use

















- 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 Straight Type Abutment

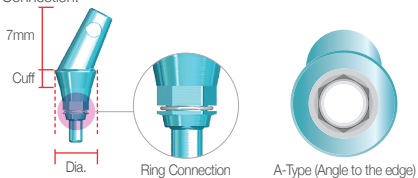
This product is used by connecting to the fixture or the analog with the one-touch method via a Silicon Connection.



		Diameter(Ø)			
		Ø4.5	Ø5.2	Ø5.7	Ø6.5
Cuff (mm)	1.0	 PISAH415	 PISAH515	 PISAH615	 PISAH715
	2.0	 PISAH425	 PISAH525	 PISAH625	 PISAH725
	3.0	 PISAH435	 PISAH535	 PISAH635	 PISAH735
	4.0	 PISAH445	 PISAH545	 PISAH645	 PISAH745

2 A-Type Angled Abutment

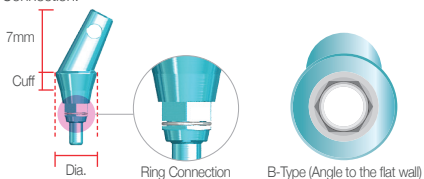
This product is used by connecting to the fixture or the analog with the one-touch method via a Ring Connection.



		Diameter (a) / Angle				
		Ø4.5		Ø5.2		Ø5.7
		15°	25°	15°	25°	15°
Cuff (mm)	2.0	PISAH-A1427	PISAH-A2427	PISAH-A1527	PISAH-A2527	PISAH-A1627
	4.0	PISAH-A1447	PISAH-A2447	PISAH-A1547	PISAH-A2547	PISAH-A1647

3 B-Type Angled Abutment

This product is used by connecting to the fixture or the analog with the one-touch method via a Ring Connection.



		Diameter (a) / Angle				
		Ø4.5		Ø5.2		Ø5.7
		15°	25°	15°	25°	15°
Cuff (mm)	2.0	PISAH-B1427	PISAH-B2427	PISAH-B1527	PISAH-B2527	PISAH-B1627
	4.0	PISAH-B1447	PISAH-B2447	PISAH-B1547	PISAH-B2547	PISAH-B1647

Precaution for Use

- 1 Verify whether the attachment is properly established when connecting using the one-touch method.
- 2 The maximum recommended number of uses is 50.

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 addiction, 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.



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