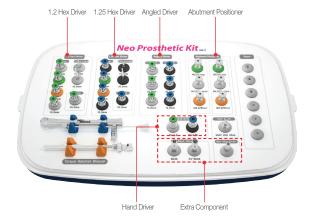
# **Neo Prosthetic Kit** User Guide





# | Product description

This product is a Prosthetic Kit consisting of dental implant procedure tools and drivers made of medical grade materials, including titanium and stainless steel.



# Intended use

This Prosthetic Kit is used when implanting a fixture in a place where a tooth is missing, or when connecting or detaching a Cover screw or other upper structures.

# | Preservation

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

# How to Prepare Before Use

- 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.
- 8 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

#### 1.2 Hex Driver

This tool is used by itself or in combination with the Abutment Positioner. It is used to tighten an Abutment or Abutment Screw.



	Product Name	Length(L)
Ratchet	HD1210S	10mm
	HD1215S	15mm
	HD1220S	20mm
	HD1225S	25mm
Rescue	HD1220RCS	20mm
Contra angle	HDC1210	10mm
	HDC1215	15mm

#### 2 1.25 Hex Driver

This tool is used by itself or in combination with the Abutment Positioner. It is used to tighten an Abutment or Abutment Screw.



	Product Name	Length(L)	
Ratchet	HD12510S	10mm	
	HD12515S	15mm	
	HD12520S	20mm	
	HD12525S	25mm	
Rescue	HD12520RCS	20mm	
Contra angle	HDC12510	10mm	
	HDC12515	15mm	

#### 3 Angled Driver

This tool is used to tighten an abutment screw in front teeth that require angular compensation.



Hex 1.2

Hex 1.25

Angle Max 25 Maximum Degrees Torque 38 Ncm

#### 4 Abutment Positioner

This tool is attached to an Abutment via friction. It is used to attach the Abutment to a Fixture easily.

	and the second se		Product Name	Length	Туре	Set Product Name	
			AP202N	2mm	M2.0/Short		
			AP205N	5mm	M2.0/Medium	-	
M2.0			M2.0	AP207N	7mm	M2.0/Long	_
/Short			AP252N	2mm	M2.5/Short		
			AP255N	5mm	M2.5/Medium	APSET (10as (ast)	
inna			AP257N	7mm	M2.5/Long	(10ea/set)	
			HD1215S	15mm	Hex1.2	_	
M2.5	M2.5 M2	M2.5	HD1220S	20mm	Hex1.2	_	
/Short	/Medium	/Long	HD12515S	15mm	Hex1.25	_	
			HD12520S	20mm	Hex1.25		



# Abutment Positioner can make Abutment Connection with only one hand, two fingers!





6 Hand Driver

This tool is used when attaching an Abutment or Abutment Screws intraorally.



Product Name	Length
HDH1220S	20mm
HDH12520S	20mm

#### 6 IT Abutment Driver

This tool is used when attaching an IT Solid or Exellent [sic]-Solid Abutment intraorally.



Product Name	Туре		
* ITADOL	Solid		
* ITESD00	Ex-Solid		
* Ontional			

#### Multi Unit Abutment Driver

This tool is used when attaching a Multi-Unit Abutment (Straight Type) intraorally.





8 Ball Abutment Driver

This tool is used when attaching a Ball Abutment intraorally.



## | Precaution for use

The maximum recommended number of uses of the Hex Drivers is 50. The maximum torque of the 0.9 Hex Driver is 20 Ncm. The maximum torque for the 1.2 and 1.25 Hex Drivers, as well as other Abutment Drivers, is 35 Ncm.

2 The maximum angle for the Angled Driver is 25° and its maximum torque is 25 Ncm. Although torque of up to 30 Ncm may be applied, because its tip area is softer than that of other drivers, use of excessive force may cause the tip to bend or break. (If the torque applied for tightening is 38 Ncm or higher, the driver will snap in order to protect the abutment)

8 Because the Abutment Positioner is attached by friction, if excessive force is used for tightening, it may separate. Care must be taken to ensure it is used with compatible models.

O The maximum recommended number of uses of the IT Abutment Driver is 50, and the maximum torque is 35 Ncm.

(5) The maximum recommended number of uses of the Multi-Unit Abutment Driver is 50, and the maximum torque is 35 Ncm.

6 The maximum recommended number of uses of the Ball Abutment Driver is 50, and the maximum torque is 50 Ncm.

# How to Sterilize

- 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.

	Cycle Type	Temperature	Pressure	Exposure Time	Dry Time
KIT, F Instrument	Pre-vacuum <sup>12</sup>	132 °C	2 bars	3 minutes	00
	Pre-vacuum**	270 °F	28.5 psi		30 minutes
KIT, Instrument	0.01	121 °C	1 bars	40 minutes	
	Gravity <sup>1</sup>	250 °F	14.5 psi		30 minutes

<Recommended Steam Sterilization Conditions >

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.)

() Minimum time and temperature conditions for steam sterilization to reach the sterilization guarantee level of  $10^6\,$ 

 $\oslash$  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

- 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.
- 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.

Ocmpletely remove the moisture using a dry cloth or a warm-air circulator.

KIT Tray

- 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.
- O 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.
- G Completely remove the moisture using a dry cloth or a warm-air circulator.
- 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

- 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

- Only dentists who have completed implant procedure education and training courses can use this product.
- Por each patient, a procedure plan must be established, based on a treatment plan after testing and analyzing for whole-body allments, infectious disease, whether they are receiving treatment for other ailments, and whether there is any oral lesion.
- 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.
- Before each procedure, the tools must be examined for wear and tear.
- 6 Any external contact with the surfaces is prohibited.
- Improper selection of the patient or procedure may cause failure of the implant or postsurgical bone loss around the implant.
- Hydrogen peroxide is prohibited for disinfection and washing, as it could damage or discolor the TiN Coating, Laser Markings, or Colors.

## **Contraindication**

- 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.
- 6 Patients with unrestored teeth who maintain bad oral health conditions.
- 6 Patients with acute inflammatory ailments and patients who are at risk of infection.
- Pregnant patients.
- 8 Smokers.
- Patients with blood clotting conditions or with severe cardiac ailments.
- 10 Children aged 16 years or younger.
- Patients who are allergic to titanium or stainless steel.
- Patients without ordinary wound-healing function.
- 13 Patients who are taking other drugs.
- Patients who are vulnerable to physical and mental stress due to temporary use of a specific medication.
- Patients who are emotionally unstable, such as due to alcohol addition, drug abuse, neurological ailments, or mental ailments.
- 18 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, pain, or opening of the sutures, ulcer in the soft tissues, and other localized adverse reactions may occur.

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 STERILZED USING IRRADIATION	Sterilized Using irradiation
	Date of manufacture	${f R}$ 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 DAWAGED	Do not use if package is damaged
NON	Non-Sterile		

\* This product is a non-sterilized medical device.

# Neo Prosthetic Kit

