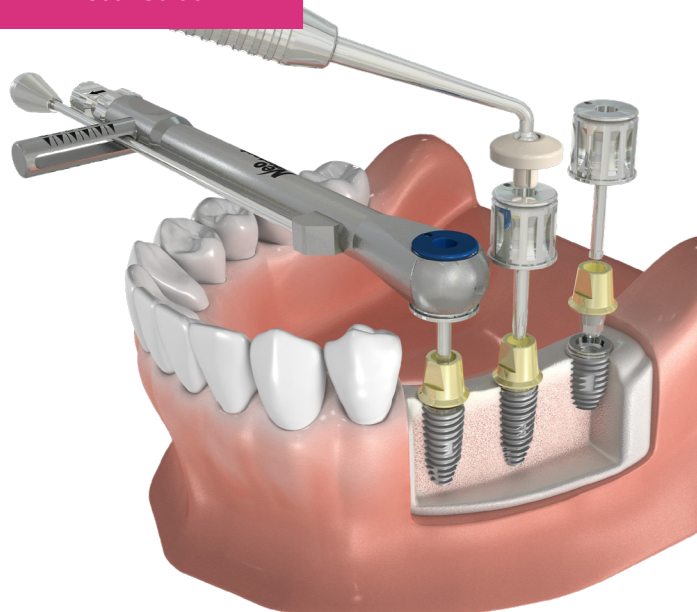


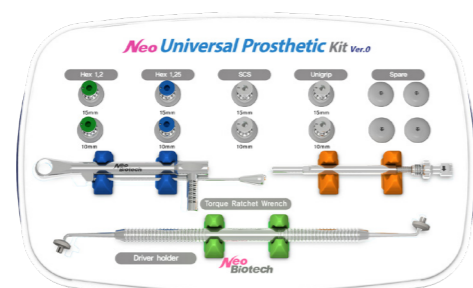
Universal Prosthetic Kit

User Guide



I Product description

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



I Intended use

This Universal 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.

I Preservation

Hermetically sealed packages should be stored in a dry location away from direct light at room temperature. (1~30°C)

I How to Prepare Before Use

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

I Components

• Driver

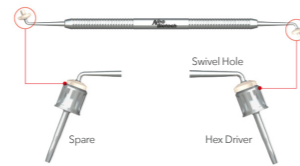
This tool is used to tighten an abutment or abutment screw. 1.2 Hex short, long / 1.25 Hex short, long / SCS short, long / Unigrip short, long driver.



[Figure 1]

• Driver Holder

Holding a hex driver, this tool is used when tightening an abutment or abutment screw Intraorally.



[Figure 2]

• Torque Ratchet

Tightening hex driver and measuring torque as changing Tip direction, Tightening and loosening can be controlled.



[Figure3]

I Compatibility List [Table 1]

| Name | Image | COMPATIBLE IMPLANT OR COMPANY | Code | |
|-----------------------|-------|--|--------------|------------|
| | | | Product Name | Length(mm) |
| 1.2 Hex Driver (0.5') | | Neobiotech Biomet 3i Dentsply-Friadent, Xive Osstem, DICO Megagen | HD1210S | 10mm |
| | | | HD1215S | 15mm |

| Name | Image | COMPATIBLE IMPLANT OR COMPANY | Code | |
|------------------------|-------|---|--------------|------------|
| | | | Product Name | Length(mm) |
| 1.25 Hex Driver (0.5') | | Biohorizons Zimmer, Astra Implant Direct Legacy Camlog, MIS Dentis, Dentium | HD12510S | 10mm |
| | | | HD12515S | 15mm |
| SCS Driver | | Straumann Implant Direct Replant | SCSD10S | 10mm |
| | | | SCSD15S | 15mm |
| Unigrip Driver | | Nobel Biocare Implant Direct Swishplait Southern Implants Neocas | UGD10S | 10mm |
| | | | UGD15S | 15mm |

I How to sterilize

- Because the product is a non-sterilized medical device, select a pre-vacuum autoclave. (Plastic products must not be sterilized at or above 170°C (338°F))
- Before sterilization, the inner wrapper must be removed from the tray. Assembled components must be separated in order to improve the efficiency of sterilization.
- Using surgical wrap, wrap the tray, seal with autoclave tape, and sterilize.

<Recommended steam sterilization conditions>

| Cycle Time | Temperature | Exposure Time | Dry Time |
|------------|---------------|---------------|------------|
| Pre-Vacuum | 132°C (270°F) | 4 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.

I 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.
- 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 distilled water and, after ten minutes of ultrasound washing, rinse using distilled water for three minutes.
- Completely 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.
- Following the instructions of the cleaner manufacturer, dilute the enzyme cleaner using distilled water and soak for one minute. Afterwards, using a soft brush, remove any foreign objects remaining on any part.
- After washing, rinse for three minutes using distilled water to remove the remaining enzyme cleaner.
- 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.)

I 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.
- Do not store in a soiled area or where there is a risk of infection.
- 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)

I Precautions

- Implants with bigger than 5mm in diameter, and shorter than 7mm are limited to be used only in the posteriors, and they should be splinted with other restorations during prosthetic treatment.
- All Neobiotech's instruments are only for use on Neo CMI Implant System.

I Contraindication

- Uncontrolled chronic medical disorder (Diabetes, Hypertension, etc.)
- High dose irradiation, Radiotherapy in maxillofacial and neck areas

- Traumatic occlusion, Large vertical gaps in jaw rims
- Recurring mucosal diseases of the mouth, Poor oral hygiene, Periodontal disease, Oral bisphosphonate, Bruxism, Xerostomia
- Pregnancy, Drug abuse, Smokers/tobacco chewers, Psychiatric disorder, Alcoholism
- Anti-coagulant treatment, Cardiovascular diseases
- Titanium allergic diathesis
- Therapy-resistant parodontopathies, Uncontrolled systemic conditions, Crippling disease

I Side effects

Complications such as malocclusion, Paresthesia caused by neurological damage, Infections, Injury or damage to other teeth or blood vessels, Bleeding, Discomfort and pain, Bruising, Swelling, etc.

I Storage and maintenance method after use.

- Disposable dental implant. Must not reuse.
- Must discard opened products, even unused.
- Discard the packaging of used products.
- Surgical instruments must be cleaned, sterilized, and properly dried with cleaning products, alcohol, and distilled water.

I Warnings

Implantation must be performed by a dentist who has completed surgical training and gained hands-on practice. The implantologist must only use the product after gaining complete knowledge of the surgical methods and precautions, and choose suitable products for the treatment plan. Selecting unsuitable patients or operations can cause the failure of the implant or occurrence of bone loss surrounding the implant. Patients with excessive occlusal force can have osseointegration failure or fracture of the implant; the implantologist must use the proper implant diameter, length, and quantity.

Neobiotech
Satisfaction to Dentists

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