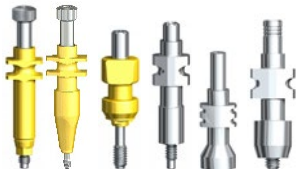
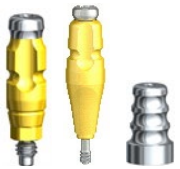
Impression Copings
Instructions for use



Impression Copings Open Tray



Impression Copings Closed Tray

Important – Disclaimer of Liability:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

Impression copings are pre-manufactured components which facilitate the transfer of an intra-oral location of an implant or abutment from the patient's jaw to the relative position on a master cast in the dental laboratory, to support creation of an implant restoration in the dental laboratory.

Impression copings are available for both open-tray and closed-tray impression techniques. The open-tray technique is recommended in cases with multiple implants, and must be used in cases with multiple implants that diverge more than 25°. The closed-tray technique is recommended in patients with less mouth opening, in limited access areas and with patients with a highly-sensitive gagging reflex.

Impression copings open tray are co-packed with a guide pin. Impression copings closed tray are co-packed with a screw.

The apical part of the impression coping is fixed to the implant or the abutment connection with a screw or guide pin. The coronal part of the impression coping is designed to retain the impression copings in the dental impression material.

Impression copings are designed to be used with different Nobel Biocare implant and abutment systems as follows:

- Impression Copings Open Tray Conical Connection NP/RP, Impression Copings Closed Tray Conical Connection NP/RP, Impression Copings Open Tray CC 3.0, Impression Copings Closed Tray CC 3.0, Impression Copings Open Tray Conical Connection NP/RP Bridge, Impression Copings Closed Tray CC WP, and Impression Copings Open Tray CC WP feature an internal conical connection (CC) can be used with Nobel Biocare's NobelActive™, NobelParallel™ CC and NobelReplace CC implant systems.
- Impression Copings Open Tray Nobel Biocare N1™ TCC NP/RP and Impression Copings Closed Tray Nobel Biocare N1™ TCC NP/RP feature a Tri-oval conical connection (TCC) can be used with Nobel Biocare's Nobel Biocare N1™ implant system.
- Impression Copings Open Tray NobelReplace NP/WP/6.0 feature an internal tri-channel connection can be used with Nobel Biocare's NobelReplace, Replace Select and NobelSpeedy Replace implant systems.
- Impression Copings Open Tray Brånemark System NP/RP/WP/6.0, Impression Copings Open Tray Multi-unit Brånemark Syst WP, and Impression Copings Closed Tray Multi-unit Brånemark Syst WP feature an external hex connection can be used with Nobel Biocare's Brånemark System and NobelSpeedy Groovy implant systems.
- Impression Copings Open Tray Multi-unit and Impression Copings Closed Tray Multi-unit Plus feature a multi-unit abutment connection and can be used with Nobel Biocare's multi-unit abutments.
- Brånemark System Zygoma Impression Copings Open Tray feature a Zygoma implant connection can be used with Nobel Biocare's NobelZygoma 45° and Brånemark System® Zygoma implant systems.

Table 1 presents a summary of the available impression copings, the compatible platforms and connection types, including the specifications for required screwdrivers, the associated color coding, and whether they are intended for open or closed tray techniques. Note that the specific impression coping used must have the same platform size as the implant or abutment.

Table 1: Nobel Biocare Impression Copings – Compatible Implant Platforms and Screwdrivers

Impression Coping for	Technique	Available platforms	Color coding	Screwdriver
Conical connection (CC)	Open tray	3.0 NP RP WP	none O O O	Unigrip
	Closed tray	3.0 NP RP WP	none O O O	
Tri-oval conical connection (TCC)	Open tray	NP RP	O O	Omnigrip mini
	Closed tray	NP RP	O O	
Tri-channel	Open tray	NP RP WP 6.0	O O O O	Unigrip
External Hex	Open tray	NP RP WP	none	Unigrip
Multi-unit Abutment	Open tray	NP RP WP	none	Unigrip
	Closed tray	NP RP WP	none	
Brånemark System Zygoma	Open tray	RP	none	Unigrip

Intended Use:

Impression Copings:

IIntended for use to transfer the direction, position, or orientation of a dental implant to a working cast or model.

Indications for Use:

Impression Copings Open Tray:

Impression copings open tray are indicated to be connected directly to a dental implant or implant abutment to be used to transfer the location and orientation of the dental implant or the abutment from the patient's edentulous or partially edentulous jaw to a master cast in the dental laboratory, using an open tray impression technique.

Impression Copings Closed Tray:

Impression copings closed tray are indicated to be connected directly to a dental implant or implant abutment to be used to transfer the location and orientation of the dental implant or the abutment from the patient's edentulous or partially edentulous jaw to a master cast in the dental laboratory, using a closed impression technique.

Contraindications:

It is contraindicated to use impression copings in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are contraindicated for treatment with Nobel Biocare implants or restorative components.
- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium), stainless steel, silicone.

For contraindications specific to the implant or abutment, refer to the Nobel Biocare IFU for the respective component.

Cautions:

General:

One hundred percent implant success cannot be guaranteed. In particular, non-observance of the product's indications for use and the surgical/handling procedure(s) may result in failure.

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

Impression copings must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with Impression Copings can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

Before Surgery:

All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery:

Care and maintenance of sterile instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. gauze, dental dam, or throat shield).

Accurate impressions form the basis for the fabrication of well-fitting restorations. Insufficient accuracy during the impression procedure or instability of the impression copings within the impression can lead to poor-fitting restorations, loose screws, screw and/or implant fractures, and occlusal discrepancies.

Handling Procedure:

Open Tray Impression Technique:

1. Select the appropriate impression coping according to the implant or abutment connection (see Table 1).
2. Connect the impression coping to the implant or abutment and hand-tighten the guide pin using the applicable manual screwdriver (see Table 1).

   Check that the impression coping is not in contact with adjacent teeth. A radiograph may be taken to verify proper seating of the impression coping.
3. Relieve and perforate the impression tray to allow full seating of the tray and protrusion of the guide pin. If there is a large opening in the tray, it may be closed off with wax to prevent impression material from escaping.
4. Inject impression material around the impression coping and into the tray.
5. Seat the impression tray fully, so that the tip of the guide pin is identified.
6. After the impression material has set, unscrew the guide pin until it is disengaged from the implant or abutment using the applicable manual screwdriver (see Table 1).

Caution: Do not remove the guide pin from the embedded impression coping, this might cause loss of the O-ring from the guide pin.

7. Remove the impression, keeping the impression coping and the guide pin embedded in the impression material, and check the impression for any irregularities or bubbles.
8. Attach the implant replica or abutment replica to the embedded impression coping using the applicable manual screwdriver.
9. Send the impression to the dental laboratory.

Closed Tray Impression Technique – Implant or Abutment Level:

1. Select the appropriate impression coping according to the implant or abutment connection (see Table 1).
2. Connect the impression coping to the implant or abutment and hand-tighten the screw using the applicable manual screwdriver (see Table 1). A radiograph may be taken to verify proper seating of the impression coping.
3. Block out the receptacle for the screwdriver on top of the impression coping (if present) to prevent impression material from entering. This facilitates re-seating the impression coping in to the impression for producing the laboratory model.
4. Inject a medium or heavy body impression material around the impression coping and into the tray.
5. Seat the tray and record the impression.
6. After the impression material has set, remove the impression, and check the impression for any irregularities or bubbles.
7. Remove the block-out material from the screw, if applicable.
8. Disconnect the impression coping from the implant or abutment using the applicable manual screwdriver.
9. Attach the implant replica or abutment replica to the impression coping using the applicable manual screwdriver.
10. Reposition the assembly of the impression coping and replica into its corresponding location in the impression.
11. Send the impression to the dental laboratory.

Materials:

- Impression copings for Nobel Biocare's Conical Connection, Nobel Biocare N1™, NobelReplace, Brånemark System, and Brånemark System Zygoma implant systems: titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- Impression copings for Nobel Biocare's Multi-unit Abutments: stainless steel 420F Mod according to ASTM F899.
- Guide pins (for open-tray impression copings intended for use with Nobel Biocare's Conical Connection, Nobel Biocare N1™, NobelReplace, and Brånemark System Zygoma implant systems): titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3; O-ring: silicone.
- Screws (for closed-tray impression copings intended for use with Nobel Biocare's Conical Connection, Nobel Biocare N1™, NobelReplace, and Brånemark System Zygoma implant systems): titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- Screws and guide pins (for impression copings intended for use with Nobel Biocare's Brånemark System implant system and with the Multi-unit Abutment): stainless steel 420F Mod according to ASTM F899.

Sterility and Reusability Information:

Impression copings are delivered non-sterile and are intended for reuse. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.

Warning: Do not use device if the packaging has been damaged or previously opened.

Impression copings are reusable devices which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. Impression copings shall be discarded if any of the following criteria are met:

- If any wear, abrasion of the anodization, deformations or corrosion is visible on the component.
- If the impression coping does not seat accurately or has a loose fit in the implant, the base, or the respective replica.
- If with light pressure the screwdriver does not engage or slips in the receptacle of the screw or guide pin.
- If the guide pin is no longer retained in the impression coping, which indicates that the O-ring for the guide pin has been stripped off or has deteriorated.

Cleaning and Sterilization Instructions:

Impression Copings are delivered non-sterile by Nobel Biocare and are intended for reuse. Prior to each use, the devices must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual and Automated Cleaning: AAMI TIR 12.
- Sterilization: AAMI ST79 and ISO 17665-1.

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note: The manufacturer's instructions for use for any detergent/cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note: The impression copings been validated to withstand these cleaning and sterilization procedures.

Initial Treatment at Point of Use Prior to Reprocessing:

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes. Use a dental probe for soil and debris in cavities.

Caution: All dental debris adhering to the impression copings (such as impression material) must be cleaned away after use. It may not be possible to remove the dried debris later in the process. Impression copings shall be discarded if dental debris cannot be removed.

3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area:

1. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
2. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Note: Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Automated Cleaning and Drying (Including Pre-cleaning):

Pre-cleaning:

1. Disassemble Impression Copings prior to cleaning by removing the screw or guide pin from the coping.
2. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
3. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 20 seconds until all visible soil is removed.
5. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 20 seconds until all visible soil is removed.
6. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
7. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying:

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

Note: It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum 5 minutes cleaning with minimum 55°C (131°F) tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum 3 minutes neutralization with cold desalinated water.
   - Draining.
   - Minimum 2 minutes rinsing with cold desalinated water.
   - Draining.
4. Run drying cycle at minimum 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Note: FDA-cleared washer-disinfectors are to be used for the recommended cleaning parameters.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting or cracked seals, or if dental debris remains on the device. Properly discard any devices that fail the inspection.

Manual Cleaning and Drying:

1. Disassemble the Impression Coping prior to cleaning by removing the screw or guide pin from the coping.
2. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP or Neodisher Medizym; maximum 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
5. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
6. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
7. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP or Neodisher Medizym) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/ maximum 45°C (113°F).
8. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
9. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
10. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting or cracked seals, or if dental debris remains on the device. Properly discard any devices that fail the inspection.

Sterilization:

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 and Selectomat PL/669-2CL (pre-vacuum cycle); Amsco Century Sterilizer and Selectomat PL/669-2CL (gravity cycle).

Note: It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.

1. Reassemble any multi-piece devices (where applicable) and seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - EN ISO 11607 and/or DIN 58953-7.
   - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 2 presents examples of suitable sterilization pouches.

Table 2: Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch Steriking pouch (Wipak)
Pre-vacuum Cycle	SteriCLIN® pouch Steriking pouch (Wipak)

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number if applicable).
3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters:
   - Gravity Cycle: Steam sterilization at 132°C (270°F) for 15 minutes at saturated steam pressure, followed by drying 15-30 minutes in chamber.
   - Pre-Vacuum Cycle: Steam sterilization at 132°C (270°F) for 4 minutes at saturated steam pressure, followed by drying 20-30 minutes in chamber.

Note: FDA-cleared sterilization equipment and accessories are to be used for the recommended sterilization parameters.

Note: Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to SN EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance:
After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/Shipping to Point of Use:
The container and/or outer packaging used to transport or ship the reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process.

Storage, Handling and Transportation:

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

Disposal:

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information:

Manufacturer:
Nobel Biocare AB
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

Distributed in USA by:
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, CA, 92887
USA

Caution: Federal law restricts this device to sale by or on the order of a dentist or physician.

Symbols Glossary:

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

Batch code

Catalogue number

Date


Date of manufacture


Manufacturer

Serial number

Unique Device Identifier

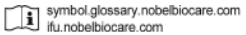

Health care centre or doctor


Patient identification


Patient number


Tooth number


Consult instructions for use



Link to Online Symbols Glossary and IFU Portal


Patient information website


Caution

Do not resterilize


Do not re-use


Do not use if package is damaged and consult instructions for use


Use-by date


Temperature limit


Upper limit of temperature


Keep away from sunlight


Keep dry

Contains biological material of animal origin


Contains hazardous substances

Contains or presence of DEHP phthalate

Contains or presence of natural rubber latex

Contains or presence of phthalate


Non-pyrogenic

Magnetic resonance conditional

Magnetic resonance safe

Non-sterile

Sterilized using Ethylene Oxide

Sterilized using irradiation

Sterilized using steam or dry heat


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside


Double sterile barrier system

Authorised Representative in Switzerland

Authorized representative in the European Community / European Union

UK Responsible Person

CE mark

CE mark with Notified Body number

EU Importer

Swiss Importer

UKCA mark

UKCA mark with Approved Body number

Medical device

Rx only

For prescription use only