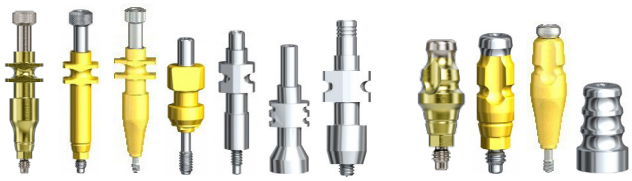
Impression Copings



Impression Copings Open Tray

Impression Copings Closed Tray

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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 3.0/NP/RP/WP, Impression Copings Closed Tray Conical Connection 3.0/NP/RP/WP and Impression Copings Open Tray Conical Connection NP/RP Bridge feature an internal conical connection (CC) and can be used with Nobel Biocare's NobelActive™, NobelParallel™ CC and NobelReplace CC implant systems. The impression copings are available with different emergence profiles.
- 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) and can be used with Nobel Biocare's Nobel Biocare N1™ implant system.
- Impression Copings Open Tray NobelReplace NP/RP/WP/6.0 feature an internal tri-channel connection and 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 and 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 and 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	none	Unigrip™
		NP	●	
		RP	●	
		WP	●	
	Closed tray	3.0	none	
		NP	●	
		RP	●	
		WP	●	
Tri-oval conical connection (TCC)	Open tray	NP	●	Omnigrip™ mini
		RP	●	
	Closed tray	NP	●	
		RP	●	
Tri-channel	Open tray	NP	●	Unigrip™
		RP	●	
		WP	●	
		6.0	●	
External Hex	Open tray	NP	none	Unigrip™
		RP		
		WP		
Multi-unit Abutment	Open tray	NP	none	Unigrip™
		RP		
		WP		
	Closed tray	NP	none	
		RP		
		WP		
Brånemark System Zygoma	Open tray	RP	none	Unigrip™

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

Intended Use

Impression Copings

Intended 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.

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.

Warnings

Warning Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

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

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 Nobel Biocare's 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, a dental dam or a 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).
3. 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.
4. 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.
5. Inject impression material around the impression coping and into the tray.
6. Seat the impression tray fully, so that the tip of the guide pin is identified.
7. 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.

8. 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.
9. Attach the implant replica or abutment replica to the embedded impression coping using the applicable manual screwdriver.
10. 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.

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 as the device sterility and/or integrity may be compromised.

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

These products are intended to be cleanded and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.nobelbiocare.com.

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 PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 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 licensed physician or dentist.

Legal Statements

Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.