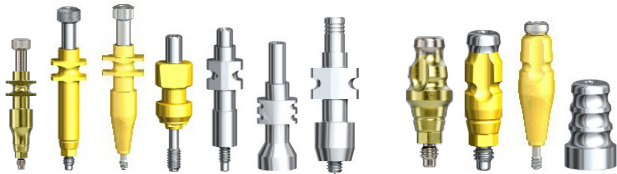


# Impression Copings



Impression Copings Open Tray

Impression Copings Closed Tray

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 implant systems featuring an internal conical connection. 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 implant systems featuring a Tri-oval conical connection (TCC).
- Impression Copings Open Tray NobelReplace NP/RP/WP/6.0 feature an internal tri-channel connection and can be used with Nobel Biocare implant systems featuring an internal tri-channel connection.
- 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 implant systems featuring an external hex connection.
- 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.

## 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.

- 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.

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](http://ifu.nobelbiocare.com).

## Intended Use/Intended Purpose

### Impression Copings

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

## Indications

### 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 implants (excl. Brånemark System) : titanium alloy Ti-6Al-4V (90 wt.% titanium, 6 wt.% aluminum, 4 wt.% vanadium) according to ASTM F136 and ISO 5832-3.
- Guide pins (for impression copings intended for use with Nobel Biocare's implants, excl. Brånemark System): titanium alloy Ti-6Al-4V (90 wt.% titanium, 6 wt.% aluminum, 4 wt.% vanadium) according to ASTM F136 and ISO 5832-3.
- Impression copings for Nobel Biocare's Brånemark System implants: Unalloyed Titanium Grade 1 according to ASTM F67.

- Guide pins (for impression copings intended for use with Nobel Biocare's Brånemark System implants and with the Multi-unit Abutment): stainless steel AISI 303/420F Mod according to ASTM F899.
- Impression copings for Nobel Biocare's Multi-unit Abutments: stainless steel AISI 303 according to ASTM F899.
- O-ring: silicone.

## 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.

## Intended Users and Patient Groups

Impression copings are intended to be used by dental health care professionals.

Impression copings are intended to be used in patients subject to dental implant treatment.

## Clinical Benefits and Undesirable Side Effects

### Clinical Benefits Associated with Impression Copings

Impression copings are a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

### Undesirable Side Effects Associated with Impression Copings

The placement of these devices is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, and swelling. During abutment placement or removal, the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Impression copings are part of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to those associated with teeth, such as retained cement, calculus, mucositis, ulcers, soft tissue hyperplasia, soft and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area such as graying.

### Notice regarding serious incidents

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB  
[www.nobelbiocare.com/complaint-form](http://www.nobelbiocare.com/complaint-form)

## Handling Procedure

### Open Tray Impression Technique

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

**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.
2. Connect the impression coping to the implant or abutment and hand-tighten the screw using the applicable manual screwdriver. 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 cleaned and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to [ifu.nobelbiocare.com](http://ifu.nobelbiocare.com).

## Performance Requirements and Limitations

To achieve the desired performance, the devices must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with the devices, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

## Facilities and Training

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit [www.nobelbiocare.com](http://www.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

<b>Manufacturer</b> 	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden <a href="http://www.nobelbiocare.com">www.nobelbiocare.com</a>
<b>UK Responsible Person</b> <div>UK RP</div>	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
<b>Distributed in Turkey by</b>	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytaç Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
<b>CE Mark for Class II Devices</b>	
<b>UKCA Mark for Class I Devices</b>	

**Note** Refer to the product label to determine the applicable conformity marking for each device.

**Note** Regarding Canadian device licensure, not all products described in the IFU may have a device licence according to Canadian law.

## Basic UDI-DI Information

Product	Basic UDI-DI Number
Impression Copings Open Tray Conical Connection 3.0/NP/RP/WP	733274700000013674
Impression Copings Open Tray Conical Connection NP/RP/ WP Bridge	
Impression Copings Closed Tray Conical Connection 3.0/NP/RP/ WP	
Impression Copings Open Tray Nobel Biocare N1™ TCC NP/RP	
Impression Copings Closed Tray Nobel Biocare N1™ TCC NP/RP	
Impression Copings Open Tray NobelReplace NP/RP/ WP/6.0	
Impression Copings Open Tray Brånemark System NP/RP/ WP/6.0 Impression Copings Open Tray Multi-unit	
Impression Copings Open Tray Multi-unit Brånemark Syst WP	
Impression Copings Closed Tray Multi-unit Plus	
Impression Copings Closed Tray Multi-unit Brånemark Syst WP	
Brånemark System Zygoma Impression Copings Open Tray	

## Legal Statements

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## 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](https://ifu.nobelbiocare.com).