Impression Copings

Instructions for use

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. 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 reserves the right to discontinue or change any product, 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 does not assume any liability whatsoever for damage arising therefrom. 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. 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-sensitve gagging reflex. Impression copings open tray are co-packaged with a guide pin. Impression copings closed tray are co-packaged 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 impression material.

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

- Impression Copings Open Tray Conical Connection (NP/RP)
- Impression Copings Closed Tray Conical Connection CC 3.0
- Impression Copings Bridge CC 3.0
- Impression Copings Open Tray Conical Connection (NP/RP), Impression Copings Closed Tray Conical Connection CC 3.0
- Impression Copings Open Tray Bridge CC 3.0
- Impression Copings Open Tray CC WP
- Impression Copings Open Tray CC WP
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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.

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.

Care and Maintenance of Sterile Instruments:

- 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.

Undesirable Side Effects Associated with Impression Copings:

- Patients may experience discoloration in the mucosal area such as graying.
- Some patients may experience side effects similar to those associated with teeth, such as retained cement, calculus, mucositis, ulcer, soft tissue hyperplasia, soft and/or hard tissue recessions. Some patients may experience discolouration in the mucosal area such as graying.
Impression copings for 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.

Caution:

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. 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 into 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 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 material (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).
7. Remove the block-out material from the screw, if applicable.
8. If the impression coping does not seat accurately or has a loose fit in the implant, the base, or the respective replica.
9. If with light pressure the screwdriver does not engage or slips in the receptacle of the screw or guide pin.
10. If the guide pin is no longer retained in the impression coping, which indicates that the O-ring for the guide pin has 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.

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Visual Inspection:

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.
3. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Mediclean). After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discolored/pitted or cracked surfaces, or if dental debris remains on the device. Properly discard any devices that fail the inspection.

First Anonymous cleaning and drying: After cleaning and drying, the device for unacceptable deterioration such as corrosion, discoloration, pitting or cracked surfaces, 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 the 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 maximum 40°C (104°F)/maximum 45°C (113°F).
2. Label the sterilization pouch with information necessary to identify the device (for example, TPL 410098 000 04 IFU1086 000 00 Page 3 of 4 Date of issue: 31/01/2020)

3. Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.

4. Separate, re-cycling or disposal of packaging material shall follow local country and government legislation or policy.

5. Clinical waste in accordance with local healthcare guidelines, country and government legislation or policy.

Performance Requirements and Limitations:
To achieve the desired performance, Impression Copings 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 impression coping, 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 both new and experienced users of dental implants, prosthetics, and associated software always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

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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.