

Nobel Biocare Replacement Parts

Instructions for use



Important: Please read.

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, it is his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instructions for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

Replacement parts are defined as prosthetic components and instruments in the Nobel Biocare product range that are essential to maintain existing prosthetic constructions in patients with phased-out implants i.e. implants no longer placed on the market.

Nobel Biocare replacement parts and components are divided into the following categories based on their use.

NobelPerfect® System:

- Instruments for restorative procedures: impression copings, implant replicas.
- Final restorative components: abutments.
- Temporary restorative components: healing abutments.

Brånemark System® Novum:

- Instruments for restorative procedures: implant replicas.

Brånemark System®:

- Temporary prosthetic components: healing caps.
- Final restorative components: abutments, ball attachment housings (Plastic Caps with O-ring).

Steri-Oss™ and Replace™ External Hex:

- Temporary restorative components: temporary copings.
- Final restorative components: abutments.

Immediate Provisional Implant (IPI):

- Temporary components: copings and caps.

Intended use:

NobelPerfect® System:

- Impression copings are premanufactured devices to be directly connected to the implant and used to transfer the location and orientation of dental implants, via a closed or open tray impression technique from the patients upper or lower jaw to a working dental laboratory model (master cast) together with an implant replica.
- The laboratory components such as implant replicas are intended to be used in the dental laboratory on the master cast only. Laboratory screws are used for temporary fixation of the abutments on the implant replicas.
- Dental implant abutments are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.

- Healing abutments are intended to be used as temporary components to an endosseous implant to allow healing of the soft tissue.

Brånemark System® Novum:

- The laboratory components such as the implant replicas are intended to be used in the dental laboratory on the master cast only. Laboratory screws are used for temporary fixation of the abutments on the implant replicas.

Brånemark System®:

- Healing caps are intended to be used as a temporary component to allow healing of the soft tissue.
- Dental implant abutments are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.
- The Plastic Caps with O-ring are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

Steri-Oss™ and Replace™ External Hex:

- Temporary copings are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.
- Dental implant abutments are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.

Immediate Provisional Implant (IPI):

- The caps are intended to be used as a temporary component to allow healing of the soft tissue.
- The copings are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.

Indications:

NobelPerfect® System:

- The impression copings and laboratory components do not specify a disease, condition or population and therefore the Indication for Use is the same as the Intended Use.
- Dental implant abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacement in either jaw. Restorations range from replacing one single tooth to fixed partial and full dentures using cement-retained or screw-retained supra-constructions.
- The healing abutments are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for one single tooth to full arch denture procedures.

Brånemark System® Novum:

- Laboratory components such as implant replicas do not specify a disease, condition or population and therefore the Indication for Use is the same as the Intended Use.

Brånemark System®:

- Healing caps are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for single tooth to full arch denture procedures.
- Dental implant abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacement in either jaw. Restorations range from replacing one single tooth to full arch denture procedures.
- The Plastic Caps with O-ring are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for partial or full arch denture procedures.

Steri-Oss™ and Replace™ External Hex:

- Temporary copings in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacement in either jaw. Restorations range from

replacing one single tooth to fixed partial and full dentures using cement-retained or screw-retained supra-constructions.

- Dental implant abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacement in either jaw. Restorations range from replacing one single tooth to fixed partial and full dentures using cement-retained or screw-retained supra-constructions.

Immediate Provisional Implant (IPI):

- The caps are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for multiple teeth to full arch denture procedures.
- The copings are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for multiple teeth to full arch denture procedures.

Contraindications:

It is contraindicated placing the restorative components in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (titanium, aluminium, vanadium). It is contraindicated placing impression copings in:
- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (titanium, aluminium, vanadium), Polyoxymethylene (POM), PEEK (Polyetheretherketone), PBT (Polybutyleneterephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.

For laboratory components:

- None identified.

Cautions:

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment. It is strongly recommended that Nobel Biocare surgical instruments and prosthetic components are used only with Nobel Biocare implants, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue or unsatisfactory esthetic results.

It is strongly recommended that clinicians, new as well as experienced implant users, 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 info please visit www.nobelbiocare.com.

Working the first time with a colleague experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components. Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

Do not use temporary cement when cementing ceramic crowns due to increased risk of micro fractures. To secure the long term treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Handling instructions:

NobelPerfect System:

Impression coping and implant replica:

1. Insert the impression coping into the implant. Ensure that the connection is clean and free of any tissues. Use the Unigrip™ screwdriver and hand tighten the screw.
2. Take the radiograph to verify proper seating of the impression coping.
3. Block out the Unigrip™ screwdriver indentation on the impression coping.
4. Inject heavy body impression material (polyether material or polyvinylsiloxane) around the impression coping and into the tray. Record the impression.
5. Remove the block-out material from the Unigrip™ screwdriver indentation on the impression coping. Remove the impression coping.
6. Attach the impression coping onto the corresponding implant replica and reseal the assembly into the impression.
7. Send the impression to the dental laboratory.

Abutment:

Laboratory procedure:

1. Produce a working model with removable gingival material.
2. Connect the abutment to the implant replica and check for occlusal clearance.
3. Modify the abutment if necessary. Do not modify the abutment connection.
4. Fabricate the crown with NobelProcera® technique or with conventional casting technique, the implant replica can be used to protect the abutment interface.

Clinical procedure:

5. Remove temporary restoration if applicable.
6. Ensure the interface is clear from any foreign bodies before attaching the restoration.
7. Clean and disinfect the abutment prior to inserting it in the patient's mouth.
8. Tighten the abutment to **35Ncm** using the Unigrip™ screwdriver and Manual Torque Wrench Prosthetic.
9. Cement the final crown using conventional procedures after sealing of access hole.

Make sure there is no excess cement. Take x-ray to verify the correct seating.

Shall a replacement screw be needed for NobelPerfect® restoration, a corresponding NobelReplace® screw should be ordered (for NP: article no.36818, for RP and WVP: article no.29475).

Caution: Do not use temporary cement when cementing ceramic crowns due to increased risk of micro fractures.

Healing Abutment:

1. Select appropriate healing abutment and check occlusal clearance.
2. If required, clean the interface before placing the healing abutment. Connect and tighten it using Unigrip™ Screwdriver. It is recommended to verify the final abutment seating using radiographic imaging.

Brånemark System® Novum:

Laboratory procedure:

1. Attach the Novum Fixture Replicas to the respective impression copings.
2. Fabricate a gypsum model with removable soft tissue.
3. Follow the shipping instructions for NobelProcera® Scan and Design service.

Brånemark System®:

Healing cap:

Clinical procedure:

1. Select appropriate healing cap and check occlusal clearance.
2. Connect to implant and tighten using Unigrip™ Screwdriver.

Abutment Angulated:

1. Select appropriate Abutment and check occlusal clearance.
2. Connect to implant and tighten.

Abutment Complete EsthetiCone:

1. Select appropriate abutment and check occlusal clearance.
2. Connect to the implant and tighten the screw using the Screwdriver Multi-unit.

Plastic Cap with O-ring:

1. Connect the cap on the ball attachment.

2. Apply a small amount of light cure acrylic around each plastic cap and seat the denture over the caps.
3. Disengage the denture from the abutments, fill the voids with the light cure acrylic material and cure.
4. Finalize the denture.

Steri-Oss™ and Replace™ External Hex:

PME temporary coping:

Clinical procedure:

1. Connect the PME temporary coping to the PME abutment and check for occlusal clearance.
2. If required, modify the coping height extraorally.
3. Fabricate a bridge using conventional technique.

Direct Abutment:

Laboratory procedure:

1. Create a master model.
2. Connect the abutment to the implant replica in the master model and check for occlusal clearance.
3. Fabricate a crown using conventional technique.

Immediate Provisional Implant (IPI):

Immediate Provisional Implant Coping:

Place the copings onto the Immediate Provisional Implants:

1. Place autopolymerizing, tooth-colored acrylic into the processed acrylic shell and place over the copings.
2. After acrylic has hardened, remove the prosthesis with the copings secured in it.
3. Finalize the prosthesis and refine the occlusion.
4. Cement the restoration using temporary cement.

Immediate Provisional Implant Comfort Cap:

1. Snap the Immediate Provisional Implant Comfort Cap onto the Implant.

Materials:

NobelPerfect® System:

- Impression copings: Titanium alloy 90% Ti, 6% Al, 4% V.
- Implant replicas: Titanium alloy 90% Ti, 6% Al, 4% V.
- Abutments/healing abutments: Titanium alloy 90% Ti, 6% Al, 4% V.

Brånemark System® Novum:

- Implant replicas: Titanium alloy 90% Ti, 6% Al, 4% V.

Brånemark System®:

- Healing caps: Polybutyleneterephthalate (PBT) Pocan.
- Abutments Angulated: Unalloyed Titanium Grade 1 and 4; Screw: Titanium alloy 90% Ti, 6% Al, 4% V.
- Abutments Complete/EsthetiCone: Unalloyed Titanium Grade 1 and 4; Screw: Titanium alloy 90% Ti, 6% Al, 4% V.
- Ball attachment housings (Plastic Caps with O-ring): Rubber; O-ring: Buna-N-Nitril, Plastic cap: PEEK.

Steri-Oss™ and Replace™ External Hex:

- Temporary coping & screw: Titanium alloy 90% Ti, 6% Al, 4% V.
- Direct Abutment Plastic: Acetal (Delrin) Plastic; screw: Titanium alloy 90% Ti, 6% Al, 4% V.
- Direct Abutment Gold/Plastic: Acetal (Delrin) Plastic; screw: Titanium alloy 90% Ti, 6% Al, 4% V.
- Coping Gold/Plastic: Gold Alloy for Copings, Acetal (Delrin) Plastic, screw: Titanium alloy 90% Ti, 6% Al, 4% V.
- PME Coping Gold/Plastic: Gold Alloy for Copings, screw: Titanium alloy 90% Ti, 6% Al, 4% V.

Immediate Provisional Implant (IPI):

- Copings: Titanium alloy 90% Ti, 6% Al, 4% V.
- Caps: Polyethylene terephthalate white (PET).

Sterility and Reusability Information:

NobelPerfect® System:

The NobelPerfect® Impression Coping is delivered non-sterile and intended for re-use. Prior to re-use clean, disinfect and sterilize the product using the recommended parameters.

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

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

The NobelPerfect® Implant Replica is delivered non-sterile and intended for re-use.

Note: Implant replica is used only in the dental laboratory (no intraoral use) and has no cleaning and sterilization requirements.

The NobelPerfect® Abutment is delivered non-sterile for single use only. Prior to use clean, disinfect and sterilize the product using the recommended parameters.

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

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

Caution: This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross-contamination.

The NobelPerfect® Healing Abutment is delivered sterile for single use only prior to labeled expiration date.

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

Caution: This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross-contamination.

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

Brånemark System® Novum:

The Replica Fixture Novum is delivered non-sterile and intended for re-use. Note: implant replica is used only in the dental laboratory (no intraoral use) and has no cleaning and sterilization requirements.

Brånemark System®:

The following components for Brånemark System®: healing caps and Plastic Caps with O-ring are delivered non-sterile for single use only.

Prior to use clean, disinfect and sterilize the product using the recommended parameters.

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

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

Caution: The articles listed above are single use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross-contamination.

The following components for Brånemark System®: Angulated Abutments and Complete/EsthetiCone Abutments are delivered sterile for single use only prior to the labelled expiration date.

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

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

Caution: The articles listed above are single use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross-contamination.

Steri-Oss™ and Replace™ External Hex:

The following components for Steri-Oss™ and Replace™ External Hex:

PME temporary copings, PME Gold Copings, Direct Abutments, and Gold Copings, are delivered non-sterile for single use only.

Prior to use clean, disinfect and sterilize the product using the recommended parameters.

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

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

Caution: This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross-contamination.

Immediate Provisional Implant (IPI):

The following components for Immediate Provisional Implant:

IPI Coping and IPI Comfort Cap, are delivered non-sterile for single use only. Do not use after the labeled expiration date.

Prior to use clean, disinfect and sterilize the product using the recommended parameters.

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

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

Caution: This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross-contamination.

Cleaning and sterilization instructions:

If required (see section above): Clean the device using manual or automated cleaning, disinfect and dry the device following instructions in Cleaning and Sterilization Guidelines available at nobelbiocare.com/sterilization.

Inspect and seal the single device in a pouch and steam sterilize, both the gravity cycle (saturated steam) and pre-vacuum (forced air removal) cycle can be applied, using the following parameters:

For USA: Steam sterilization 270°F (132°C) for 4 minutes when using pre-vacuum method and 15 minutes when using the gravity method. Dry for 20 to 30 minutes when using pre-vacuum method and 15 to 30 minutes when using the gravity method.

For USA: FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

For outside USA: Temperature 132°C (270°F), max 137°C (279°F) for 3 minutes (up to 20 minutes). Dry for 10 minutes in chamber.

Alternative UK: Temperature 134°C (273°F), max 137°C (279°F) for 3 minutes (up to 20 minutes). Dry for 10 minutes in chamber.

Full set of recommended parameters are provided in "Cleaning & Sterilization Guidelines including Magnetic Resonance Imaging information of Nobel Biocare Products" available at nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

Magnetic Resonance (MR) safety information:

These articles have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

For additional information on Magnetic Resonance Imaging, please consult the "Cleaning & Sterilization Guidelines including Magnetic Resonance Imaging Information of Nobel Biocare Products" available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

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:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Prescription device: Rx only

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

CE 0086

Rx Only



Non-sterile



Do not re-sterilize



Caution



Consult instructions
for use



Do not re-use



Batch code



Do not use
if package is
damaged



Sterilized using
irradiation



Use-by date



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