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 phasoused 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.

Bränemark System Novelum:
- Instruments for restorative procedures: implant replicas.

Bränemark System:
- Temporary prosthetic components: healing caps.
- Healing abutments are intended to be used as temporary components to an endosseous implant to allow healing of the soft tissue.
- Healing caps are intended to be used as a temporary component to allow healing of the soft tissue.
- Healing abutments are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.
- Healing caps 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.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
- 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 (Polybutylene terephthalate) Stainless steel, Acetal plastic, Polyethylene terephthalate white (PET) or Gold alloy.
Plastic Cap with O-ring:
1. Connect to the implant and tighten the screw using the Screwdriver Multi-unit.

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.

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 coping: Titanium alloy 90% Ti, 6% Al, 4% V.
- Abutment healing abutments: Titanium alloy 90% Ti, 6% Al, 4% V.

Brånemark System® Novum:
- Implant replica: Titanium alloy 90% Ti, 6% Al, 4% V.

Steri-Oss™ and Replace™ External Hex:
Temporary coping & screw:
- 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.

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.

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.

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.

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: 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.

The following components for Steri-Oss™ and Replace™ External Hex:
PEM temporary copings, PEM 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: 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.

The following components for Immediate Provisional Implant: IMMEDIATE PROVISIONAL IMPLANT COPING AND IMPRESSION COPING AND IMPLANT REPLICAS: 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.

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.

**Manufacturer:** Nobel Biocare AB, Box 5190, 402 26 Västra Hamngatan 1, 411 17 Göteborg, Sweden.
Phone: +46 31 81 88 00. Fax: +46 31 16 31 52. www.nobelbiocare.com

**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.