Nobel Biocare Replacement Parts

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. 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:

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 and/or abutments i.e. devices no longer placed on the market.

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

The tables below summarize the available replacement parts and the compatible Nobel Biocare implant systems and/or abutments, screwdrivers and any other relevant information.

Replacement Parts Portfolio for Brånemark System:

The replacement parts portfolio for the Brånemark System is comprised of the following instruments and components (Table 1):

Table 1: Brånemark System Replacement Parts Portfolio

Original Abutment	Replacement Screw	Tightening Torque	Replacement/Screwdriver
Standard Abutment RP	Abutment Screw	20 Ncm	Multi-unit Screwdriver*
EsthetiCone Abutment	Abutment Screw EsthetiCone		
Standard Abutment RP or EsthetiCone Abutment + Gold Cylinder	Prosthetic screw internal hexagon	10 Ncm	Screwdriver Hexagon Machine screwdriver hex
	Prosthetic screw slot		Screwdriver Medium Screwdriver Slot Machine Screwdriver Slot
Low Profile Healing Screw	N/A	Hand-tightening	Screwdriver Hex 0.030"

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the Multi-unit Screwdriver. This IFU is available for download at ifu.nobelbiocare.com.

Replacement Parts Portfolio for Brånemark System Novum:

The replacement parts portfolio for the Brånemark System Novum is comprised of the following components (Table 2):

Table 2: Brånemark System Novum Replacement Parts Portfolio

Original Implant	Replacement Screw	Tightening Torque	Screwdriver	Replacement Impression Coping	Replacement Implant Replica
Brånemark System Novum	Lower bar screw UniGrip Prosthetic screw UniGrip	35 Ncm	Unigrip Screwdriver*	Impression Coping to Fixture Novum	Replica Fixture Novum

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the Unigrip screwdriver. This IFU is available for download at ifu.nobelbiocare.com.

Replacement Parts Portfolio for NobelPerfect System:

The replacement parts portfolio for the NobelPerfect System is comprised of the following components (Table 3):

Table 3: NobelPerfect System Replacement Parts Portfolio

Original Implant	Replacement Healing Abutment	Replacement Final Abutment	Final Abutment Tightening Torque	Screwdriver	Replacement Impression Coping	Replacement Implant Replica
NobelPerfect	Healing Abutment NobelPerfect	Abutment NobelPerfect	35 Ncm	Unigrip Screwdriver*	Implant Level Impression Coping NobelPerfect	Implant Replica NobelPerfect

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the screwdrivers. This IFU is available for download at ifu.nobelbiocare.com.

Replacement Parts Portfolio for SteriOss and Replace External Hex:

The replacement parts portfolio for SteriOss and Replace External Hex is comprised of the following components (Tables 4 – 7):

Table 4: SteriOss and Replace External Hex Replacement Parts Portfolio – Implant Level

Original Implant	Replacement Healing Abutment	Replacement Final Abutment	Replacement Screw	Tightening Torque	Screwdriver	Replacement Impression Coping	Replacement Implant Replica
SteriOss External Hex Replace External Hex	Healing Abutment	Direct Abutment Engaging Gold/Plastic Direct Abutment Non-Engaging Gold/Plastic	Abutment Screw TorqTite	35 Ncm	Unigrip Screwdriver*	Transfer Assy Hex Open Tray	Implant Analog

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the Unigrip screwdriver. This IFU is available for download at ifu.nobelbiocare.com.

Table 5: SteriOss and Replace External Hex Replacement Parts Portfolio – Abutment Level

Original Abutment	Replacement Copings	Replacement Screw	Tightening Torque	Replacement Screwdriver	Replacement Impression Coping	Replacement Abutment Replica	Replacement Wrench/ Wrench Insert
PME Abutment	PME Temporary Coping PME Coping Gold/Plastic	Coping Screw Slot	10 Ncm	Screwdriver Medium Screwdriver Slot Machine Screwdriver Slot	PME impression coping open tray	PME Abutment Analog	Transmucosal Abutment Wrench Torque Wrench Insert Transmucosal Abutment

Table 6: SteriOss and Replace External Hex Replacement Parts Portfolio – Abutment Level

Original Abutment	Replacement Prosthetic Screw	Prosthetic Screw tightening torque	Replacement Screwdriver	Replacement Torque Wrench Insert
Conical Abutment	Coping Screw Hex	10 Ncm	Screwdriver Hex 0.050"	Torque Wrench Insert Hex 0.050"

Table 7: SteriOss and Replace External Hex Replacement Parts Portfolio – O-Ring Abutment

Original Abutment	Replacement Retainer Ring	Replacement O-Ring	Replacement Abutment Replica
O-Ring Abutment	Retainer Ring	O-Ring Clinical White	O-Ring Abutment Analog with Spacer

Replacement Parts Portfolio for SteriOss Non-hex:

The replacement parts portfolio for SteriOss Non-hex is comprised of the following components (Table 8):

Table 8: SteriOss Non-hex Replacement Parts Portfolio

Original Implant	Replacement Abutment	Tightening Torque	Replacement Screwdriver	Replacement Torque Wrench Insert	Replacement Impression Coping	Replacement Implant Replica
SteriOss Non-hexed	Coronal screw set	35 Ncm	Screwdriver Hex 0.050"	Torque Wrench Insert Hex 0.050"	Thread Timed Transfer Pin	Implant Analog Non-Hex

Replacement Parts Portfolio for NobelReplace:

The replacement parts portfolio for NobelReplace is comprised of the following components (Table 9):

Table 9: NobelReplace Replacement Parts Portfolio

Original Implant/ Abutment	Replacement Abutment Screw	Tightening Torque	Screwdriver
Easy Abutment	Abutment Screw Easy Abutment	35 Ncm	Unigrip Screwdriver*
NobelReplace implant	Abutment Screw PS RP-NP		

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the Unigrip screwdriver. This IFU is available for download at ifu.nobelbiocare.com.

Replacement Parts Portfolio for the Ball Abutment:

The replacement parts portfolio for the Ball Abutment is comprised of the following components (Table 10):

Table 10: Ball Abutment Replacement Parts Portfolio

Original Abutment	Replacement Screwdrivers
Ball Abutment	Screwdriver Machine Ball Abutment Screwdriver Manual Ball Abutment Screwdriver/Activator

Other Replacement Parts Portfolio:

The remaining replacement parts portfolio is comprised of the following components (Table 11):

Table 11: Other Replacement Parts:

Original Restoration	Replacement Screws	Tightening Torque	Replacement/Screwdriver
NobelProcera Implant Bar Overdenture	Clinical Screw for Ti Straumann Abutment screw Octagon Ti	Per implant manufacturer	Unigrip Screwdriver*
N/A	Converter Screw Ti UniGrip Fit	20 Ncm	Unigrip screwdriver
N/A	Prosthetic screw conical	10 Ncm	Screwdriver Slot Machine Screwdriver Slot

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the Unigrip screwdriver. This IFU is available for download at ifu.nobelbiocare.com.

Intended Use/Intended Purpose:

Clinical/Abutment/Prosthetic Screws:

Intended for use to fasten dental implant system components to a dental implant or to another component.

Screwdrivers:

Intended for use to tighten and/or loosen screws used to connect dental implant system components.

Impression Copings:
Intended for use to transfer the direction, position, or orientation of a dental implant to a patient model.

Implant Replicas and O-ring Abutment Analog with Spacer:
Intended for use in the dental laboratory to facilitate the manufacture of dental prostheses.

Healing Abutments:
Intended to be temporarily connected to an endosseous dental implant or implant abutment to support healing of the surrounding soft tissue.

Final Abutments:
Intended to be finalized into a single-unit or multiple-unit dental prosthesis, which is connected to an endosseous dental implant to restore chewing function.

Temporary Copings:
Intended to be connected to an endosseous dental implant to support the placement of a temporary dental prosthesis.

Torque Wrench:
Intended for use to tighten and/or loosen dental implant system components with a measurable amount of torque.

Torque Wrench Insert:
Intended for use as an interface between a wrench and the instrument used to tighten or loosen dental implant system components.

Retainer Ring and O-ring Clinical White:
Intended for use as a component of a dental implant-supported bar overdenture system for the fabrication and/or placement of a final dental prosthesis.

Indications for Use:

Clinical/Abutment/Prosthetic Screws:
Clinical and Abutment screws are indicated for use to secure a dental abutment or framework to a dental implant in the maxilla or mandible for supporting tooth replacements to restore chewing function.

Screwdrivers:
Same as Intended Use/Intended Purpose.

Impression Copings:
Impression copings 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 or closed tray impression technique.

Implant Replicas and O-ring Abutment Analog with Spacer:
Same as Intended Use/Intended Purpose.

Healing Abutments:
Healing abutments are indicated for use with endosseous dental implants or implant abutments in the maxilla or mandible for supporting single tooth to full arch denture procedures.

Final Abutments:
Dental implant abutments are indicated to support the placement of prosthetic restorations in the maxilla or mandible.

Temporary Copings:
Temporary copings are indicated for use with screw-retained multiple-unit temporary dental prostheses which are placed on Nobel Biocare's abutments in the maxilla and mandible.

Torque Wrench:
Manual torque wrenches are indicated for use with Nobel Biocare abutments and abutment screws to ensure that the desired torque is achieved during placement of the abutment or screw. Manual torque wrenches can be used as an alternative to machine torque wrenches.

Torque Wrench Insert:
Torque wrench inserts are indicated for use to connect implant drivers and screwdrivers to manual torque wrenches.

Retainer Ring and O-ring Clinical White:
Dental implant abutments and retainer rings are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

Contraindications:

It is contraindicated to use Nobel Biocare replacement parts in:

- Patients who are medically unfit for an oral surgical procedure
- Patients in whom adequate sizes, numbers and desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to any of the materials which are included in the device. Refer to Materials section of this IFU for the material composition specific to each device.

Warnings:

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

Cautions:

General:
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

It is strongly recommended that Nobel Biocare replacement parts are used only with compatible Nobel Biocare instruments and components. Use of instruments or components that are not intended to be used in combination with Nobel Biocare replacement parts 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 surgical 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:
Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient.

After Surgery:
To help ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform the patient about appropriate oral hygiene.

Intended Users and Patient Groups:

Nobel Biocare replacement parts are intended to be used by dental health care professionals.

Nobel Biocare replacement parts are intended to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with Nobel Biocare replacement parts:
Nobel Biocare replacement parts 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 Nobel Biocare replacement parts:
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 reflex (gag reflex) may be triggered in patients with sensitive gag reflex.

Implant abutments 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, ulcera, 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

https://www.nobelbiocare.com/complaint-form

Handling Procedure:

Brånemark System:
Clinical Procedure:
- Select the appropriate screw for the abutment or framework.
- Following conventional procedures, insert the screw into the abutment or framework and place the assembly onto the implant or abutment.
- Tighten the screw using dedicated screwdriver and Manual Torque Wrench Prosthetic. Refer to Nobel Biocare IFU1046 for information regarding the Manual Torque Wrench Prosthetic. See Table 1 for compatible screwdrivers and tightening torques.

Caution: Never exceed recommended maximum tightening torque for the screw. Overtightening of abutment may lead to a screw fracture.

Brånemark System Novum:
Clinical Procedure:
- Connect the impression coping to the implant. Ensure that the connection is clean and free of any tissues. Use the Unigrip screwdriver and hand-tighten the pin.
- It is recommended to verify the proper seating using radiographic imaging.
- Block out the screwdriver indentation on the impression coping pin.
- Inject appropriate impression material around the impression coping and into the tray. Record the impression.
- Unscrew the impression coping pin, remove the tray and send it to the dental laboratory.

Laboratory Procedure:
- Attach the implant replica (Replica Fixture Novum) to the impression coping.
- Fabricate a master cast with removable soft tissue.
- Follow the shipping instructions for NobelProcera® Scan and Design service.

Clinical Procedure:
- Upon receiving the finalized restoration, connect it using Prosthetic screw UniGrip Novum. Tighten the screw to 35 Ncm using Unigrip screwdriver and Manual Torque Wrench prosthetic.
- If replacement of the bar screw is required, use the Lower bar screw Unigrip Novum and tighten it to 35 Ncm using Unigrip screwdriver and Manual Torque Wrench prosthetic.

Caution: Never exceed recommended maximum tightening torque for the screw. Overtightening of abutment may lead to a screw fracture.

NobelPerfect System:
Clinical Procedure:
- Connect the impression coping into the implant and hand-tighten it using the Unigrip screwdriver.
- It is recommended to verify the proper seating using radiographic imaging.
- Block out the screwdriver indentation on the impression coping pin.
- Inject appropriate impression material around the impression coping and into the tray. Record the impression.
- Remove the impression tray and unscrew the impression coping from the implant. Reseat the impression coping into the impression.
- Send the impression to the dental laboratory.

Laboratory Procedure:
- Upon receiving the impression, connect the corresponding implant replica to the impression coping. Fabricate a master cast with removable soft tissue.
- Connect the abutment to the implant replica and check for occlusal clearance. Use NobelReplace laboratory screw for processing the abutment in the laboratory.
- Modify the abutment if necessary. Do not modify the abutment connection. Implant replica can be used to protect the abutment interface.
- Fabricate the crown with NobelProcera® technique or with conventional casting technique.

Clinical Procedure:
- Clean and disinfect the abutment and crown upon receiving it from the dental laboratory.
- Connect the abutment to the implant and tighten it to 35 Ncm using Unigrip screwdriver and Manual Torque Wrench prosthetic.

Caution: Never exceed recommended maximum tightening torque for the screw. Overtightening of abutment may lead to a screw fracture.

- It is recommended to verify the proper seating using radiographic imaging.
- Block the clinical screw head using Teflon tape.
- Cement the final crown using conventional procedures. Remove excess cement.
- If a replacement screw is needed for NobelPerfect restoration, a corresponding NobelReplace screw should be used (for NP: article no.36818, for RP and WP: article no. 29475).

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

NobelPerfect - Healing Abutments:
Clinical Procedure:
- Select an appropriate healing abutment and check the occlusal clearance.
- Hand-tighten the healing abutment using Unigrip screwdriver.

Caution: Never exceed recommended maximum tightening torque for the screw. Overtightening of abutment may lead to a screw fracture.

- It is recommended to verify the final abutment seating using radiographic imaging.

SteriOss and Replace External Hex – PME Abutment:
Clinical Procedure:
- Connect the impression coping to the abutment and hand-tighten it using the dedicated screwdriver as per Table 5.
- It is recommended to verify the proper seating using radiographic imaging.
- Block out the screwdriver indentation on the impression coping pin.
- Inject appropriate impression material around the impression coping and into the tray.

Record the impression.

- Unscrew the impression coping pin and remove the impression tray.
- Send the impression to the dental laboratory.

Laboratory Procedure:

- Upon receiving the impression, connect the corresponding implant replica to the impression coping. Fabricate a master cast with removable soft tissue.
- Connect the gold coping to the replica and fabricate the final restoration with conventional casting technique.

Clinical Procedure:

- If necessary, re-tighten the PME abutment to 20 Ncm using dedicated abutment wrench and torque wrench insert as per Table 5.
- Upon receiving the restoration clean and disinfect it following the restorative material manufacturer's guidelines.
- Connect and tighten the final restoration to 10 Ncm using dedicated screwdriver as per Table 5.

Caution: Never exceed recommended maximum tightening torque for the screw. Overtightening of abutment may lead to a screw fracture.

- Shall an exchange of the prosthetic screw be required, select the appropriate screw for the abutment.
- Following conventional procedures insert the screw into the abutment or framework and place the assembly into the implant or abutment.
- Tighten the screw using dedicated screwdriver and wrench as per Table 5.

Caution: Never exceed recommended maximum tightening torque for the screw. Overtightening of the screw may lead to a screw fracture and/or damage of the component.

SteriOss and Replace External Hex – O-Ring Abutment:
To exchange the the O-ring or retainer ring, remove the old part and position a new O-ring or retainer ring in its place.

SteriOss and Replace External Hex – Implant-level Restorations:
Clinical Procedure:

- Connect the impression coping into the implant and hand-tighten it using the dedicated screwdriver as per Table 4.
- It is recommended to verify the proper seating of the impression coping using radiographic imaging.
- Block out the screwdriver indentation on the impression coping pin.
- Inject appropriate impression material around the impression coping and into the tray. Record the impression.
- Unscrew the impression coping pin and remove the impression tray.
- Send the impression to the dental laboratory.

Laboratory Procedure:

- Upon receiving the impression, connect the corresponding implant replica to the impression coping. Fabricate a master cast with removable soft tissue.
- Connect the gold coping to the replica and fabricate the final restoration with conventional casting technique.
- Finalize the restoration following the restorative material manufacturer's guidelines.

Clinical Procedure:

- Upon receiving the restoration clean and disinfect it following the restorative material manufacturer's guidelines.
- Connect the restoration to the implant with clinical screws using dedicated screwdriver as per Table 4.

Caution: Never exceed recommended maximum tightening torque for the screw. Overtightening of abutment may lead to a screw fracture.

- It is recommended to verify the proper seating using radiographic imaging.
- Block the clinical screw head using Teflon tape and close the screw access hole using composite.

SteriOss Non-hex:
Clinical Procedure:

- Connect the impression coping into the implant and hand-tighten it using the dedicated screwdriver as per Table 8.
- It is recommended to verify the proper seating of the impression coping using radiographic imaging.
- Block out the screwdriver indentation on the impression coping pin.
- Inject appropriate impression material around the impression coping and into the tray. Record the impression.
- Unscrew the impression coping pin and remove the impression tray.
- Send the impression to the dental laboratory.

Laboratory Procedure:

- Upon receiving the impression, connect the corresponding implant replica to the impression coping. Fabricate a master cast with removable soft tissue.
- Connect and hand-tighten the Coronal screw set to the replicas using dedicated screwdriver as per Table 8.
- Create a cast alloy bar following conventional procedures.
- Process the attachments into the overdenture.
- Complete and finish the restoration.

Clinical Procedure:

- Tighten the framework to 20 Ncm using Manual Torque Wrench prosthetic and dedicated screwdriver as per Table 8.

Caution: Never exceed recommended maximum tightening torque for the screw. Overtightening of the screw may lead to a screw fracture and/or damage of the component.

NobelReplace:
Clinical Procedure:

- If exchange of the clinical screw is required, select the appropriate screw for the Easy Abutment or PS Adapter.
- Following conventional procedures insert the screw into the abutment and place the assembly into the implant.
- Tighten the screw using dedicated screwdriver and wrench as per Table 9.

Caution: Never exceed recommended maximum tightening torque for the screw. Overtightening of the screw may lead to a screw fracture and/or damage of the component.

Ball Abutment:
Clinical Procedure using Manual Screwdriver:

- Engage the Screwdriver Manual Ball Abutment with light pressure to the Ball Abutment.
- Tighten the Abutment by hand.

Clinical Procedure using Machine Screwdriver:

- Connect the screwdriver to the Manual Torque Wrench prosthetic.
- Engage the screwdriver with light pressure to the Ball Abutment and tighten it to 15 Ncm.

For further instructions, refer to IFU 1024 for Ball Abutment. This IFU is available for download at ifu.nobelbiocare.com.

- To adjust the retention of the Gold Caps within the overdenture, turn the lamellae retention insert clockwise (increasing) or counter-clockwise (decreasing) using the Screwdriver/Activator.

Note: Do not turn the Screwdriver/Activator more than one turn.

Other Replacement Parts/Screws:

- Shall an exchange of the clinical screw be required, select the appropriate screw for the framework.
- Following conventional procedures insert the screw into the framework and place the assembly into the implant.
- Tighten the screw using Unigrip screwdriver and Manual Torque Wrench prosthetic as per implant manufacturer instructions.

Caution: Never exceed recommended maximum tightening torque for the screw. Overtightening of abutment may lead to a screw fracture.

Materials:

Brånemark System:

- Clinical screws: Titanium alloy Ti (90%), Al (6%), V (4%) according to ASTM F136 and ISO 5832-3.
- Prosthetic screws: Gold Alloy.

Brånemark System Novum:

- Brånemark System Novum impression coping and replica: Titanium alloy Ti (90%), Al (6%), V (4%) according to ASTM F136 and ISO 5832-3.
- Screws: Titanium alloy Ti (90%), Al (6%), V (4%) %) according to ASTM F136 and ISO 5832-3.

NobelPerfect:

- Impression Copings, Implant replicas, Final Abutments and Healing Abutments: Titanium alloy Ti (90%), Al (6%), V (4%).

SteriOss and NobelReplace External Hex:

- Healing Abutments, Implant Analogs, Impression Copings (Transfer Assy Hex), PME Temporary Copings, PME Abutment Analogs, PME Impression Copings, Coping Screws: Titanium alloy Ti (90%), Al (6%), V (4%) %) according to ASTM F136 and ISO 5832-3.
- Direct Abutment Engaging/Non-Engaging: Base and Sleeve: Acetal (Delrin) Plastic according to ASTM D6778-12, Screw: Titanium alloy Ti6Al4V ELI according to ASTM F136 and ISO 5832-3.
- PME Coping Gold/Plastic: Base: Gold Alloy for Copings, sleeve: Acetal (Delrin) Plastic according to ASTM D6778, Screw: Titanium alloy Ti (90%), Al (6%), V (4%) according to ASTM F136 and ISO 5832-3.
- O-Ring for Tools: 70 Dur Red silicone: Dow Corning Silastic Q7-4765 biomedical grade ETR Elastomer, 65 SHORE A.
- O-Ring Clinical White: 80 Shore White Silicon.
- O-Ring Abutment Analog: Brass.
- Torque Wrench Insert Hex: stainless steel 455 SST according to UNS S45500 and ASTM F899, O-Ring: Silicon Q7-4765 Biomedical Grade ETR Elastomer 65 shore A Color red, DT color K-74580, Pantone 1935C.
- Coronal Screw Set: Screw Titanium alloy Ti (90%), Al (6%), V (4%) according to ASTM F136 and ISO 5832-3, Sleeve: White Delrin.
- Implant Analog & Thread Timed Transfer Pin: Titanium alloy Ti (90%), Al (6%), V (4%) %) according to ASTM F136 and ISO 5832-3.

NobelReplace:

- Screws: Titanium alloy Ti (90%), Al (6%), V (4%) %) according to ASTM F136 and ISO 5832-3.

Other Replacement Parts:

- Screws: Titanium alloy Ti (90%), Al (6%), V (4%) %) according to ASTM F136 and ISO 5832-3.

All Screwdrivers: Stainless steel.

Sterility and Reusability Information:

Healing Abutments have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

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

Caution: Healing Abutments are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

Abutments NobelPerfect, Abutment Screws, Coping Screws, Converter Screws, Lower Bar Screws, Prosthetic Screws, Copings Conical Abutment Gold, PME Copings Gold/Plastic, PME Temporary Copings, Direct Abutments Coronal Screw Sets, O-Ring Clinical White, Retainer Rings are delivered non-sterile for single use only. 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.

Caution: Abutments NobelPerfect, Abutment Screws, Coping Screws, Converter Screws, Lower Bar Screws, Prosthetic Screws, Copings Conical Abutment Gold, PME Copings Gold/Plastic, PME Temporary Copings, Direct Abutments Coronal Screw Sets are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

Impression Copings, Transfer Assemblies, Screwdrivers Manual, Screwdrivers Machine, Torque Wrenches, Transmucosal Abutment Wrenches and O-Ring for Tools are delivered non-sterile and 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.

Prior to each use, Nobel Biocare reusable instruments and components must be inspected for signs of degradation that may limit the useful life or performance of the device, such as the following:

- Visible corrosion.
- Mechanical wear, abrasion, damage, or deformation.

Discard the device if any of these signs of degradation are evident.

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

Abutment Analogs, Implant Analogs and Replica Fixture Novum used in the dental laboratory only (not intended for intraoral use) and have no cleaning and/or sterilization requirements.

Cleaning and Sterilization Instructions:

Abutments NobelPerfect, Abutment Screws, Coping Screws, Converter Screws, Lower Bar Screws, Prosthetic Screws, Copings Conical Abutment Gold, PME Copings Gold/Plastic, PME Temporary Copings, Direct Abutments Coronal Screw Sets, O-Ring Clinical White, Retainer Rings are delivered non-sterile by Nobel Biocare and are intended for single use. Prior to use, the devices must be cleaned and sterilized by the user.

Impression Copings, Transfer Assemblies, Screwdrivers Manual, Screwdrivers Machine, Torque Wrenches, Transmucosal Abutment Wrenches and O-Ring for Tools are delivered non-sterile by Nobel Biocare and are intended for multiple use. 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.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual and Automated Cleaning: AAMI TIR 12.
- Sterilization: AAMI ST79 and ISO 17665-1.

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suiTable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note: The manufacturer's instructions for use for any detergent/cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note: The Abutments NobelPerfect, Abutment Screws, Coping Screws, Converter Screws, Lower Bar Screws, Prosthetic Screws, Copings Conical Abutment Gold, PME Copings Gold/Plastic, PME Temporary Copings, Direct Abutments Coronal Screw Sets, O-Ring Clinical White, Retainer Rings , Impression Copings, Transfer Assemblies, Screwdrivers Manual, Screwdrivers Machine, Torque Wrenches, Transmucosal Abutment Wrenches and O-Ring for Tools have been validated to withstand these cleaning and sterilization procedures.

Initial Treatment at Point of Use Prior to Reprocessing:

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.
3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area:

1. After removal of excess soil and debris, store the devices in a container which is suiTable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
2. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Note: Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suiTable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Automated Cleaning and Drying (Including Pre-cleaning):

Pre-cleaning:

1. Disassemble the Impression Copings prior to cleaning by removing the screw or guide pin from the coping.
2. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
3. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 20 seconds until all visible soil is removed.
5. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 20 seconds until all visible soil is removed.
6. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
7. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying:

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

Note: It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suiTable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum 5 minutes cleaning with minimum 55°C (131°F) tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum 3 minutes neutralization with cold desalinated water.
   - Draining.
   - Minimum 2 minutes rinsing with cold desalinated water.
   - Draining.
4. Run drying cycle at minimum 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection:

After cleaning and drying, inspect the device for unaccepTable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying:

1. Disassemble the Impression Copings prior to cleaning by removing the screw or guide pin from the coping.
2. Immerse 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; 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; Neodisher Medizym) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/ maximum 45°C (113°F).
8. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.

Note: The inner surfaces, lumina and cavities of Torque Wrenches should be flushed for a minimum of 15 seconds using a water jet pistol.

9. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
10. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:

After cleaning and drying, inspect the device for unaccepTable deterioration such as corrosion, discoloration, pitting, cracked seals and properly dispose any devices that fail the inspection.

Sterilization:

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 and Selectomat PL/669-2CL (pre-vacuum cycle); Amsco Century Sterilizer and Selectomat PL/669-2CL (gravity cycle).

Note: It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.

1. Reassemble any multi-piece devices (where applicable), and seal each device in a suiTable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - EN ISO 11607 and/or DIN 58953-7.
   - SuiTable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 12 presents examples of suiTable sterilization containers, pouches, and wraps.

Table 12: Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch Steriking pouch (Wipak)
Pre-vacuum Cycle	SteriCLIN® pouch Steriking pouch (Wipak)

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).
3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (Table 13):

Table 13: Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)	Minimum Pressure
Gravity Cycle[1]	132°C (270°F)	10 minutes	10 minutes	≥2868.2 mbar[4]
Pre-Vacuum Cycle[1]	132°C (270°F)	3 minutes		
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes		≥3042 mbar[5]
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		

[1] Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance to EN ISO 17665-1.

[2] Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.

[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] Saturated steam pressure at 132°C as per required by EN ISO 17665-2.

[5] Saturated steam pressure at 134°C as per required by EN ISO 17665-2.

Note: Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to SN EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance:

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/Shipping to Point of Use:

The container and/or outer packaging used to transport or ship the reprocessed device back to the point of use must be suiTable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Magnetic Resonance (MR) Safety Information:

The Replacement Parts such as clinical/abutment/prosthetic screws, abutments, temporary copings, gold copings, impression copings and healing abutments contain metallic materials which can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that the Replacement Parts such as screws, abutments, temporary copings, gold copings, impression copings and healing abutments are unlikely to impact patient safety under the following MRI conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only.
- Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode).

Note: Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

Under the conditions defined above, these devices are expected to produce a maximum temperature rise of 4.1°C (39.4°F) after 15 minutes of continuous scanning.

In the non-clinical testing, the image artifact caused by the devices extends approximately 30 mm from the devices when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Note: Although the non-clinical testing demonstrates that the Replacement Parts such as screws, abutments, temporary copings, gold copings, impression copings and healing abutments are unlikely to interfere with patient safety under the conditions defined above, this testing is insufficient to support a claim of MR Safe or MR Conditional for the Replacement Parts such as screws, abutments, temporary copings, gold copings, impression copings and healing abutments.

The Replacement Parts such as screwdrivers, wrenches and replicas 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 of Replacement Parts such as screwdrivers, wrenches in the MR environment is unknown. Scanning a patient who has these devices may result in patient injury.

Performance Requirements and Limitations:

To achieve the desired performance, Nobel Biocare replacement parts 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 Nobel Biocare replacement parts , 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.

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:
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Phone: +64 0800 441 657

CE Mark for Class I Devices

CE 2797 CE Mark for Class IIa Devices

Note: Refer to the product label to determine the applicable CE mark for each device.

Basic UDI-DI Information:

Product	Basic UDI-DI Number
Healing Abutments PME Temporary Coping	7332747000000 1236T
Abutment Screws RP Abutment Screws Easy Abutment RPL Abutment Screws EsthetiCone Abutment Screw PS RP-NP Abutment Screws TorqTite Converter Screw Titanium UniGrip fit Ø 3 Coping Screw Hex 2 mm 4/pkg Coping Screw Slot 16 mm Lower Bar Screw UniGrip™ Novum Prosthetic Screws Conical/Internal Hexagon Prosthetic Screw Slot Prosthetic Screw UniGrip™ Novum	7332747000000 1837D
Prosthetic Screws Multi-unit Slot NP/RP	7332747000000 1827B
Clinical Screw for Straumann	7332747000000 2066Y
PME Coping Gold/Plastic	7332747000000 1256X
Abutment NobelPerfect Direct Abutment Engaging/Non-Engaging	7332747000000 1697K
Coronal Screw Set	7332747000000 1697K
Screwdriver/Activator	7332747000000 1767G
PME Impression Coping Open Tray	7332747000000 1987S
Impression Coping to Fixture Novum Transfer Assemblies Hex Open Tray Transfer Assembly Hex Open Tray Implant Level Impression Copings NobelPerfect NP/RP/WP Thread Timed Transfer Pin 3.25 Non-Hex	7332747000000 1977Q
Implant Analogs/Replicas Replica Fixture Novum O-Ring Abutment Analog w Spacer 2/pkg PME Abutment Analog	7332747000000 2026Q
Analog Conical Abutment	7332747000000 2036S
O-Ring Clinical White 12/pkg Retainer Ring 2/pkg	7332747000000 1506W
Screwdrivers Hex 0.030" Screwdrivers Hex 0.050" Screwdriver Hexagon 27 mm Screwdriver Manual Ball Abutment 22 mm Screwdriver Medium 37 mm Screwdriver Slot Short 27 mm	7332747000000 1777J
Screwdriver Machine Ball Abutment 24 mm Screwdriver Machine Slot Machine Screwdriver Hex Long Machine Screwdrivers Slot Long/Short	7332747000000 1797N
Torque Wrench Inserts	7332747000000 1897R
Transmucosal Abutment Wrench	7332747000000 1917C

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.

Authorized representative in the European Community

Batch code

Catalogue number


Caution


CE marking


Consult instructions for use


Contains hazardous substances

Contains or presence of phthalate

Date


Date of manufacture

Do not resterilize

Do not re-use


Do not use if package is damaged

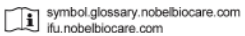

Double sterile barrier system

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional


Manufacturer

Medical device


Non-pyrogenic

Non-sterile


Patient identification


Patient information website

Patient number

Serial number


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside

Sterilized using ethylene oxide

Sterilized using irradiation

Temperature limit

Tooth number

Upper limit of temperature

Sterilized using steam or dry heat

Unique Device Identifier

Use-by date