Nobel Biocare Replacement Parts

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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.

O-Ring Clinical White

O-Ring Clinical White is a spacer which is placed around an O-Ring Abutment and should be exchanged when signs of wear become evident. The O-Ring Abutment is a permanent abutment for implant retained, tissue supported overdentures, typically with two or more relatively parallel (<10°) implants. The O-ring Abutments are to be used with Steri-Oss™ and Replace External Hex Systems.

O-Ring Abutment Analog with Spacer

O-Ring Abutment Analog with spacer is a replica of the retentive element (the implant) and abutment (O-ring Abutment) of a dental restoration and is used during the fabrication of a master cast in the laboratory to replicate the shape and position of the implant and abutment. The O-ring Abutments are to be used with Steri-Oss™ and Replace External Hex Systems.

O-Ring for Tools

Replacement part to be used with the torque wrench and torque wrench insert.

To be used with Steri-Oss™ and Replace External Hex Systems.

Retainer Ring

Retainer Ring is retainer which is placed around an O-Ring Abutment and should be exchanged when signs of wear become evident. O-Ring Abutment is a permanent abutment for implant retained, tissue supported overdentures, typically with two or more relatively parallel (<10°) implants.

To be used with Steri-Oss™ and Replace External Hex Systems.

Transmucosal Abutment Wrench

Transmucosal Abutment Wrench is a reusable manual wrench used for insertion and tightening or loosening of PME abutments and abutment screws with a specific amount of torque.

To be used with Steri-Oss™ and Replace External Hex Systems.

Healing Abutment Ø3.5x3 mm 3.5 mm RPL, Healing Abutment Ø4.5x3 mm 4.3 Replace® Hex

A pre-manufactured dental implant abutment or cap to be directly connected to the endosseous dental implant or abutment intended for use as a temporary aid in prosthetic rehabilitation.

To be used with the Replace External Hex System.

Healing Abutment Ø4.5x3 mm 3.8/4.5 HL, Healing Abutment Ø4.5x3 mm 3.25 HL

A pre-manufactured dental implant abutment or cap to be directly connected to the endosseous dental implant or abutment intended for use as a temporary aid in prosthetic rehabilitation.

To be used with the Steri-Oss™ System.

Healing Abutment Ø6x3 mm 5.0 HL/Replace® Hex, Healing Abutment Ø6x3 mm 6.0 HL/RPL

A pre-manufactured dental implant abutment or cap to be directly connected to the endosseous dental implant or abutment intended for use as a temporary aid in prosthetic rehabilitation.

To be used with Steri-Oss™ and Replace External Hex Systems.

Coping Screw Hex 2 mm

Coping screw is a pre-manufactured dental implant screw designed to fix dental implant prostheses or dental implant system components such as implant abutments and implant healing abutments to an endosseous dental implant or to another abutment.

To be used with the Steri-Oss™ and Replace Select Systems.

Abutment Screw TorqTite™ 3.8/4.3/4.5/5.0/6.0 HL/ RPL, Abutment Screw TorqTite™ 3.25 HL/3.5 RPL

Abutment screws are pre-manufactured dental implant screws designed to fix dental implant prostheses or dental implant system components such as implant abutments and implant healing abutments to an endosseous dental implant or to another abutment.

To be used with the Steri-Oss™ and Replace External Hex Systems.

Prosthetic screw Unigrip™ Novum, Prosthetic Screw Conical, Prosthetic Screw Slot, Prosthetic Screw Internal Hexagon

Prosthetic screws are pre-manufactured dental implant screws designed to fix dental implant prostheses or dental implant system components such as implant abutments and implant healing abutments to an endosseous dental implant or to another abutment.

To be used with the Brånemark Novum System.

Coronal Screw Set 3.25 Non-Hex, Coronal Screw Set 3.8 Non-Hex

The coronal screw set is a versatile system that accommodates both parallel and non-parallel implants. The coronal screw system is typically used for full-arch or shorter span bridges and to fabricate a cast alloy bar to support an overdenture.

To be used with the Steri-Oss™ Non-Hex System.

Converter Screw Titanium Unigrip™ fit Ø3

Converter screw to be used to fix the existing Brånemark NP prosthetic options available in the portfolio on phased-out 3.0 Brånemark implants. The converter screw is used due to different screw channel configuration on old 3.0 Brånemark implant.

Lower bar screw Unigrip™ Novum

Clinical screws used to attach bridge to Novum implant(s).

To be used with the Brånemark Novum System.

Screwdriver Manual Ball Abutment 22 mm, Screwdriver Machine Ball Abutment 24 mm

Screwdrivers are reusable instruments which are used in conjunction with clinical screws, abutment screws, cover screws, prosthetic screws, prosthetic components (e.g. laboratory screws, abutments, healing abutments, impression copings), rescue tools and drill stops.

To be used with the Ball Abutment System.

Screwdriver Hex 0.050" Length 0.75", Screwdriver Hex 0.050" Length 1.25", Screwdriver Machine Slot

Screwdrivers are reusable instruments which are used in conjunction with clinical screws, abutment screws, cover screws, prosthetic screws, prosthetic components (e.g. laboratory screws, abutments, healing abutments, impression copings), rescue tools and drill stops.

To be used with the Steri-Oss™ System and Replace External Hex Systems.

Machine screwdriver hex long, Machine screwdriver slot long, Screwdriver Hexagon 27 mm, Screwdriver Medium 37 mm, Screwdriver Slot Short 27 mm

Screwdrivers are reusable instruments which are used in conjunction with clinical screws, abutment screws, cover screws, prosthetic screws, prosthetic components (e.g. laboratory screws, abutments, healing abutments, impression copings), rescue tools and drill stops.

To be used with the Brånemark System®, Steri-Oss™ and Replace External Hex Systems.

Torque Wrench Insert Hex 0.050" Short, Torque Wrench Insert Hex 0.050" Long

Torque Wrench Insert Hex is reusable screwdriver that is inserted in the wrench body and is used to support the insertion and tightening or loosening of implants, abutments and abutment screws with a specific amount of torque. It can also be used with implant retrieval instruments and abutment screw retrieval instruments.

To be used with Steri-Oss™ and Replace External Hex Systems.

Torque Wrench Insert Transmucosal Abutment

Torque Wrench Insert Transmucosal Abutment is reusable screwdriver that is inserted in the wrench body and is used to support the insertion and tightening or loosening of implants, abutments and abutment screws with a specific amount of torque. It can also be used with implant retrieval instruments and abutment screw retrieval instruments.

To be used with the Steri-Oss™ and Replace External Hex Systems.

Implant Analog 3.8/4.5 HL

An implant analog is a replica of the retentive element (the implant) of a dental restoration and is used during the fabrication of a master cast. The implant analog is placed in the laboratory stone or plaster model in the location and position determined for the final prosthesis.

To be used with the Steri-Oss™ System.

Implant Analog Non-Hex

An implant analog is a replica of the retentive element (the implant) of a dental restoration and is used during the fabrication of a master cast in the laboratory to replicate the shape and position of the implant.

To be used with the Steri-Oss™ Non-Hex System.

Implant Analog 5.0 HL/6.0 HL/RPL

An implant analog is a replica of the retentive element (the implant) of a dental restoration and is used during the fabrication of a master cast. The implant analog is placed in the laboratory stone or plaster model in the location and position determined for the final prosthesis.

To be used with the Steri-Oss™ and Replace External Hex Systems.

Implant Analog 3.5 RPL, Implant Analog 4.3 RPL

An implant analog is a replica of the retentive element (the implant) of a dental restoration and is used during the fabrication of a master cast in the laboratory to replicate the shape and position of the implant. To be used with the Replace External Hex System.

Replica Fixture Novum

An implant replica is a replica of the retentive element (the implant) of a dental restoration and is used during the fabrication of a master cast in the laboratory to replicate the shape and position of the implant. To be used with the Brånemark Novum System.

Implant Replica NobelPerfect® NP, Implant Replica NobelPerfect® RP, Implant Replica NobelPerfect® WP

An implant replica is a replica of the retentive element (the implant) of a dental restoration and is used during the fabrication of a master cast in the laboratory to replicate the shape and position of the implant.

To be used with the NobelPerfect® System.

Abutment NobelPerfect® NP, Abutment NobelPerfect® RP, Abutment NobelPerfect® WP

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in a prosthetic rehabilitation.

To be used with the NobelPerfect® System.

Implant Lev Impr Coping NobelPerfect® NP, Impl Level Impr Coping NobelPerfect® RP, Implant Lev Impr Coping NobelPerfect® WP

Impression copings are pre-manufactured components which facilitate the transfer of an intra-oral location of an implant or abutment from the patient's jaw to the relative position on a master cast in the dental laboratory, to support creation of an implant restoration in the dental laboratory.

To be used with the NobelPerfect® System.

Impression Coping to Fixture Novum

Impression copings are pre-manufactured components which facilitate the transfer of an intra-oral location of an implant or abutment from the patient's jaw to the relative position on a master cast in the dental laboratory, to support creation of an implant restoration in the dental laboratory.

To be used with the Brånemark Novum System.

Thread Timed Transfer Pin 3.25 Non-Hex

Impression copings are pre-manufactured components which facilitate the transfer of an intra-oral location of an implant or abutment from the patient's jaw to the relative position on a master cast in the dental laboratory, to support creation of an implant restoration in the dental laboratory. Impression copings open tray are used with a guide pin. The apical part of the impression coping is fixed to the implant or abutment connection with the guide pin.

To be used with the Steri-Oss™ Non-Hex System.

Transfer Assy Hex Open Tray 4.5D 3.25 HL, Transf Assy Hex Open Tray 4.5 3.8/4.5 HL

Impression copings are pre-manufactured components which facilitate the transfer of an intra-oral location of an implant or abutment from the patient's jaw to the relative position on a master cast in the dental laboratory, to support creation of an implant restoration in the dental laboratory. Impression copings open tray are used with a guide pin. The apical part of the impression coping is fixed to the implant or abutment connection with the guide pin.

To be used with the Steri-Oss™ System.

Transfer Assy Hex Open Tray 3.5D 3.5 RPL, Transfer Assy Hex Open Tray 4.5D 4.3 RPL

Impression copings are pre-manufactured components which facilitate the transfer of an intra-oral location of an implant or abutment from the patient's jaw to the relative position on a master cast in the dental laboratory, to support creation of an implant restoration in the dental laboratory. Impression copings open tray are used with a guide pin. The apical part of the impression coping is fixed to the implant or abutment connection with the guide pin.

To be used with the Replace External Hex System.

Transf Assy Hex Open Tray 6D 5.0 HL/RPL, Transf Assy Hex Open Tray 6D 6.0 HL/RPL

Impression copings are pre-manufactured components which facilitate the transfer of an intra-oral location of an implant or abutment from the patient's jaw to the relative position on a master cast in the dental laboratory, to support creation of an implant restoration in the dental laboratory. Impression copings open tray are used with a guide pin. The apical part of the impression coping is fixed to the implant or abutment connection with the guide pin.

To be used with the Steri-Oss™ and Replace External Hex Systems.

Direct Abut Engaging/Non-Engaging Gold/Plastic 5.0/6.0 HL/RPL

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in a prosthetic rehabilitation. It includes a plastic sleeve for wax-up support during laboratory procedure.

To be used with the Steri-Oss™ and Replace External Hex Systems.

Direct Abut Engaging/Non-Engaging Gold/Plastic 3.5/4.3 RPL

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in a prosthetic rehabilitation. It includes a plastic sleeve for wax-up support during laboratory procedure.

To be used with the Replace External Hex System.

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 or EsthetiCone Abutment	Prosthetic screw internal hexagon	10 Ncm	Screwdriver Hexagon 27 mm Machine Screwdriver Hex Long
	Prosthetic screw slot		Screwdriver Medium 37 mm Screwdriver Slot Short 27 mm
	Prosthetic screw conical		Machine Screwdriver Slot Short Machine Screwdriver Slot Long
Brånemark 3.0 NP Abutment for 3.0 Brånemark Implant	Converter Screw Titanium Unigrip™ fit Ø 3.0	15 Ncm	Unigrip™ Screwdriver*

* 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 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™ Novum Prosthetic screw Unigrip™ Novum	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® NP, RP, WP	Healing Abutment NobelPerfect®	Abutment NobelPerfect® NP, RP, WP	35 Ncm	Unigrip™ Screwdriver*	Implant Level Impression Coping NobelPerfect® NP, RP, WP	Implant Replica NobelPerfect® NP, RP, WP

* 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 Steri-Oss™ and Replace External Hex

The replacement parts portfolio for Steri-Oss™ and Replace External Hex is comprised of the following components (Table 4 and Table 5):

Table 4 – Steri-Oss™ and Replace External Hex Replacement Parts Portfolio – Implant Level

Original Implant	Replacement Healing Abutment	Replacement Final Abutment	Screw	Tightening Torque	Screwdriver	Replacement Impression Coping	Replacement Implant Replica
Steri-Oss™ and Replace External Hex	Healing Abutment	Direct Abutment Engaging Gold/Plastic Direct Abutment Non-Engaging Gold/Plastic	Abutment Screw TorqTite™	35 Ncm	Screwdriver Hex 0.050" (Length 0.75" and 1.25")	Transfer Assembly Hex Open Tray	Implant Analog
Replace External Hex		Direct Abutment Engaging Gold/Plastic 3.5 RPL and 4.3 RPL Direct Abutment Non-Engaging Gold/Plastic 3.5 RPL and 4.3 RPL					

Table 5 – Steri-Oss™ 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 Steri-Oss™ Non-Hex

The replacement parts portfolio for Steri-Oss™ Non-Hex is comprised of the following components (Table 6):

Table 6 – Steri-Oss™ Non-Hex Replacement Parts Portfolio

Original Implant	Replacement Abutment	Tightening Torque	Replacement Screwdriver	Replacement Impression Coping	Replacement Implant Replica
Steri-Oss™ Non-Hex	Coronal screw set 3.25 and 3.8 Non-Hex	35 Ncm	Screwdriver Hex 0.050" (Length 1.75" or 1.25")	Thread Timed Transfer Pin 3.25 Non-Hex	Implant Analog Non-Hex

Replacement Parts Portfolio for the Ball Abutment

The replacement parts portfolio for the Ball Abutment is comprised of the following components (Table 7):

Table 7 – Ball Abutment Replacement Parts Portfolio

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

Intended Use/Intended Purpose

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.

O-Ring Abutment Analog w Spacer

Intended for use in the dental laboratory to facilitate the manufacture of dental prostheses.

O-Ring for Tools

N/A, no intended use assigned for spare part. See intended use for Torque Wrench Inserts.

Retainer Ring

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.

Transmucosal Abutment Wrench

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

Healing Abutments

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

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.

Torque Wrench Inserts

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

Implant Replica, Implant Analog, Replica Fixture

Intended for use in the dental laboratory to facilitate the manufacture of dental prostheses.

Abutments NobelPerfect®

Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.

Impression Coping, Thread Timed Transfer Pin, Transfer Assy Hex Open

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

Direct Abut Engaging/Non-Engaging Gold/Plastic

Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.

Indications

O-Ring Clinical White

Dental implant abutments and retainer rings are indicated to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

O-Ring Abutment Analog w Spacer

Same as Intended Use/Intended Purpose.

O-Ring for Tools

The O-Ring for Tools is a spare part used in conjunction with the torque wrench and torque wrench insert and therefore follows that indication.

Retainer Ring

Dental implant abutments and retainer rings are indicated to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

Transmucosal Abutment 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.

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.

Coping Screw Hex 2 mm, Coronal Screw Set 3.25 Non-Hex, Coronal Screw Set 3.8 Non-Hex

Same as Intended Use/Intended Purpose.

Abutment Screw TorqTite™ 3.8/4.3/4.5/5.0/6.0 HL/RPL, Abutment Screw TorqTite™ 3.25 HL/3.5 RPL, Prosthetic screw Unigrip™ Novum

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.

Lower bar screw Unigrip™ Novum

Indicated for use to secure a dental abutment or framework to a dental implant in the mandible for supporting tooth replacements to restore chewing function.

Converter Screw Titanium Unigrip™ fit Ø3

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

Prosthetic Screw Conical, Prosthetic Screw Slot, Prosthetic Screw Internal Hexagon

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.

Torque Wrench Insert

Torque wrench inserts are indicated for use as an interface between a wrench and the instrument used to tighten or loosen dental implant system components.

Implant Replica, Implant Analog, Replica Fixture

Same as Intended Use/Intended Purpose.

Abutments NobelPerfect®

Abutments NobelPerfect® are premanufactured prosthetic components directly connected to the endosseous dental implants and are indicated for use as an aid in prosthetic rehabilitation.

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.

Thread Timed Transfer Pin, Transfer Assy Hex Open

Same as Intended Use/Intended Purpose.

Direct Abut Engaging/Non-Engaging Gold/Plastic

A premanufactured prosthetic component directly connected to the endosseous dental implant and is indicated for use as an aid in prosthetic rehabilitation.

Contraindications

It is contraindicated to use Replacements 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 white silicone 80 shore, silicone 70 shore, stainless steel, unalloyed titanium grade 4, titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium), brass, POM (Polyoxymethylene), aluminium alloy, and/or gold alloy.

Materials

Product Name	Materials Information
O-Ring Clinical White	White silicone 80 shore
O-Ring Abutment Analog w Spacer	Brass
O-Ring for Tools	Silicone 70 shore
Retainer Ring	Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.
Transmucosal Abutment Wrench	Unalloyed titanium grade 4 according to ASTM F67 and ISO 5832-2, titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3, and silicone 70 shore.
Healing Abutment Ø4.5x3 mm 3.8/4.5 HL	Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.
Healing Abutment Ø4.5x3 mm 3.25 HL	
Healing Abutment Ø6x3 mm 5.0 HL/ Replace® Hex	
Healing Abutment Ø6x3 mm 6.0 HL/RPL	
Healing Abutment Ø3.5x3 mm 3.5 mm RPL	
Healing Abutment Ø4.5x3 mm 4.3 Replace® Hex	
Coronal Screw Set 3.25 Non-Hex	Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3 and POM (Polyoxymethylene) according to ASTM D6778.
Coronal Screw Set 3.8 Non-Hex	
Coping Screw Hex 2 mm	Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3
Abutment Screw TorqTite™ 3.8/4.3/4.5/5.0/6.0 HL/RPL	
Abutment Screw TorqTite™ 3.25 HL/3.5 RPL	
Prosthetic screw Unigrip™ Novum	
Lower bar screw Unigrip™ Novum	
Converter Screw Titanium Unigrip™ fit Ø3	
Prosthetic Screw Conical	
Prosthetic Screw Slot	
Prosthetic Screw Internal Hexagon	
Screwdriver Hex 0.050" Length 0.75"	Stainless steel 1.4305/AISI 303 austenitic steel according to ASTM F899 and EN 10088-3 and unalloyed titanium grade 4 according to ASTM F67 and ISO 5832-2.
Screwdriver Hex 0.050" Length 1.25"	
Screwdriver Machine Slot	Stainless steel 1.4543 GG according to ASTM F899
Screwdriver Manual Ball Abutment 22 mm	Stainless steel 1.4197/AISI420F Mod according to ASTM F899.
Screwdriver Machine Ball Abutment 24 mm	
Machine screwdriver hex long	Stainless steel according to ASTM F899.
Machine screwdriver slot short	
Machine screwdriver slot long	
Screwdriver Hexagon 27 mm	Stainless steel according to ASTM F899, stainless steel 1.4305/AISI 303 austenitic steel according to ASTM F899 and EN 10088-3, and stainless steel 1.4301/AISI 304 austenitic steel according to ASTM F899.
Screwdriver Medium 37 mm	
Screwdriver Slot Short 27 mm	
Torque Wrench Insert Hex 0.050" Short	Stainless steel 1.4543 GG according to ASTM F899 and silicone 70 shore
Torque Wrench Insert Hex 0.050" Long	
Torque Wrench Insert Transmucosal Abutment	Stainless steel 1.4542/AISI 630 according to ASTM F899 and silicone 70 shore
Implant Analog 3.8/4.5 HL	Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.
Implant Analog 5.0 HL/RPL	
Implant Analog 6.0 HL/RPL	
Implant Replica NobelPerfect® NP	
Implant Replica NobelPerfect® WP	
Implant Replica NobelPerfect® RP	
Implant Analog 3.5 RPL	
Implant Analog 4.3 RPL	
Replica Fixture Novum	
Implant Analog Non-Hex	Aluminium alloy (SM01-1057)
Abutment NobelPerfect® NP	Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.
Abutment NobelPerfect® RP	
Abutment NobelPerfect® WP	
Implant Lev Impr Coping NobelPerfect® NP	
Impl Level Impr Coping NobelPerfect® RP	
Implant Lev Impr Coping NobelPerfect® WP	
Impression Coping to Fixture Novum	Unalloyed titanium grade 1 according to ASTM F 67 and stainless steel 1.4305/AISI 303 austenitic steel according to ASTM F899 and EN 10088-3.
Thread Timed Transfer Pin 3.25 Non-Hex	Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.
Transfer Assy Hex Open Tray 4.5D 3.25 HL	Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3 and silicone 70 shore.
Transfer Assy Hex Open Tray 3.5D 3.5 RPL	
Transfer Assy Hex Open Tray 4.5D 4.3 RPL	
Transf Assy Hex Open Tray 6D 5.0 HL/RPL	
Transf Assy Hex Open Tray 6D 6.0 HL/RPL	
Transf Assy Hex Open Tray 4.5 3.8/4.5 HL	

Direct Abut Eng Gold/Plastic 5.0 HL/RPL	Gold alloy, Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3. and POM (Polyoxymethylene) according to ASTM D6778.
Direct Abut Non-Eng Gold/Plc 5.0 HL/RPL	
Direct Abut Eng Gold/Plastic 6.0 HL/RPL	
Direct Abut Non-Eng Gold/Plc 6.0 HL/RPL	
Direct Abutment Engaging Gold/Plastic 3.5 RPL	
Direct Abutment Non-Engaging Gold/Plastic 3.5 RPL	
Direct Abutment Engaging Gold/Plastic 4.3 RPL	
Direct Abutment Non-Engaging Gold/Plastic 4.3 RPL	

Cautions

General

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

Nobel Biocare's replacement parts must only be used with compatible Nobel Biocare or 3rd-party instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with Nobel Biocare's 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 and/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. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. gauze, dental dam, or throat shield).

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

Replacement parts are to be used by dental health care professionals.

Replacement parts are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Replacement parts

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 Replacement parts

Abutments

The placement of this device is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, swelling. During abutment placement or removal, the pharyngeal reflect (gag reflex) may be triggered in patients with a 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, ulcers, soft tissue hyperplasia, soft and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area such as graying.

Screws

During screw placement or removal, the pharyngeal reflect (gag reflex) may be triggered in patients with a sensitive gag reflex.

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the abutments and screws. The SSCP can be obtained at the following website:

ec.europa.eu/tools/eudamed[1]

[1] Website available upon launch of the European Database on Medical Devices (EUDAMED)

Notice regarding serious incidents

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

Nobel Biocare AB
www.nobelbiocare.com/complaint-form

Torque Wrenches and Screw Drivers

During use of this device the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Instruments Intended for Clinical Use

During use of this device the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Laboratory Devices

None known.

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 IFU1098 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.

Steri-Oss™ and Replace External Hex

Steri-Oss™ and Replace External Hex – O-Ring Abutment

To exchange the O-ring or retainer ring, remove the old part and position a new O-ring or retainer ring in its place.

Steri-Oss™ 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. It is recommended to cast alloys.

Caution Do not sandblast the seating surfaces

- 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.

Steri-Oss™ Non-hex

Clinical Procedure

- Connect the impression coping into the implant and hand-tighten it using the dedicated screwdriver as per Table 6.
- 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 6.
- 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 6.

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 IFU1024 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.

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 as the device sterility and/or integrity may be compromised.

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

O-Ring Clinical White, Coping Screw Hex, Retainer Ring, Coronal Screw Set, Abutment Screw TorqTite™, Prosthetic screw Unigrip™ Novum Lower bar screw Unigrip™ Novum, Abutment NobelPerfect®, and Direct Abutments Gold/Plastic are delivered non-sterile and are intended 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 O-Ring Clinical White, Coping Screw Hex, Retainer Ring, Coronal Screw Set, Abutment Screw TorqTite™, Prosthetic screw Unigrip™ Novum Lower bar screw Unigrip™ Novum, Abutment NobelPerfect®, Converter Screw Titanium Unigrip™ Prosthetic Screw Conical, Prosthetic Screw Slot, Prosthetic Screw Internal Hexagon, O-Ring for Tools 2 sets, and Direct Abutments Gold/Plastic 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.

Warning Do not use device if the packaging has been damaged.

The Implant Replicas and Implant Analog are used in the dental laboratory only (no intraoral use) and has/have no cleaning and/or sterilization requirements.

Screwdriver Hex, Transmucosal Abutment Wrench, Screwdriver Machine Slot, Torque Wrench Insert Hex, Torque Wrench Insert Transmucosal Abutment, O-Ring Abutment Analog w Spacer, Screwdriver Manual Ball Abutment, Implant Lev Impr Coping NobelPerfect®, Impression Coping to Fixture Novum, Thread Timed Transfer Pin, Transfer Assy Hex Open Tray, Machine screwdriver, Screwdriver Medium, Screwdriver Slot Short and Screwdriver Hexagon are delivered non-sterile and are intended for reuse. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Inspect for visible corrosion, when applicable, and inspect for mechanical wear or damage.

Warning Do not use device if the packaging has been damaged.

Cleaning and Sterilization Instructions

O-Ring Clinical White, Coping Screw Hex, Retainer Ring, Coronal Screw Set, Abutment Screw TorqTite™, Prosthetic screw Unigrip™ Novum Lower bar screw Unigrip™ Novum, Abutment NobelPerfect®, and Direct Abutments Gold/Plastic 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.

Screwdriver Hex, Transmucosal Abutment Wrench, Screwdriver Machine Slot, Torque Wrench Insert Hex, Torque Wrench Insert Transmucosal Abutment, O-Ring Abutment Analog w Spacer, Screwdriver Manual Ball Abutment, Implant Lev Impr Coping NobelPerfect®, Impression Coping to Fixture Novum, Thread Timed Transfer Pin, Transfer Assy Hex Open Tray, Machine screwdriver, Screwdriver Medium, Screwdriver Slot Short and Screwdriver Hexagon are delivered non-sterile by Nobel Biocare and are intended for reuse. Prior to each use, the devices must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

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 devices have been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following reprocessing instructions.

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. Use a dental probe to remove soil and debris from cavities, where applicable.

Caution All dental debris adhering to impression copings (such as impression material) must be cleaned away after use. It may not be possible to remove the dried debris later in the process. Impression copings shall be discarded if all dental debris cannot be removed.

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 Transmucosal Abutment Wrench prior to cleaning by pushing out the pin.
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 washers were used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program/MMM GmbH Type: Uniclean PL-II 15-2 EL.

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 of 2 minutes pre-cleaning with cold tap water
   - Draining
   - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean)
   - Draining
   - Minimum of 3 minutes neutralization with cold desalinated water
   - Draining
   - Minimum of 2 minutes rinsing with cold desalinated water
   - Draining
4. Run drying cycle at a minimum of 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 Transmucosal Abutment Wrench prior to cleaning by pushing out the pin.
2. Immerse the device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of 0.5% lukewarm enzymatic cleaning agent (e.g. Cydezyme ASP and/or Neodisher Medizym; maximum of 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 an 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_{eff}) containing an 0.5% enzymatic cleaning agent (e.g. Cydezyme ASP and/or Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F)/maximum 45°C (113°F).
8. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water 20 ml using an irrigation needle connected to a 20 ml syringe.
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 discard any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX- 320 and/or Selectomat PL/669-2CL and/or Selectomat PL/666-1 CL (pre-vacuum cycle); Amsco Century Sterilizer and/or Selectomat PL/669-2CL and/or Selectomat PL/666-1 CL (gravity cycle).

Note When using Systec HX- 320, Amsco Century Sterilizer, it is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches. When using Selectomat PL/669-2CL/Selectomat PL/666-1 CL, it is recommended to perform sterilization with a maximum load of 1 container with metal instruments and 2 packages of linen.

1. Reassemble any multi-piece devices 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 8 presents examples of suitable sterilization pouches.

Table 8 – 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 the information necessary to identify the device (e.g. 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 9):

Table 9 – Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)	Minimum Pressure
Gravity Cycle[1]	132°C (270°F)	15 minutes	20 minutes	≥2868.2 mbar[4]
Pre-Vacuum Cycle[1]	132°C (270°F)	4 minutes		
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes		
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		≥3042 mbar[5]

[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 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 processed/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

MRI Safety Information		
Non-clinical testing has demonstrated the abutments and screws are MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentioned here below. Failure to follow these conditions may result in injury to the patient.		
Nominal value(s) of Static Magnetic Field [T]	1.5-Tesla (1.5 T)	3-Tesla (3 T).
Maximum Spatial Field Gradient [T/m and gauss/cm]	Maximum spatial field gradient of 44.4 T/m (4,440 G/cm).	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Whole body transmit coil	
Maximum Whole-Body SAR [W/kg]	Inferior to the shoulders: 2.0 W/kg	Inferior to the navel: 2.0 W/kg
	Superior to the shoulders: 0.2 W/kg	Superior to the navel: 0.1 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0 °C after 15 minutes of continuous scanning.	
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 3.0 cm from the devices or device assemblies when imaged in a 3T MRI system.	
Caution	Configurations with more than 2 Zygoma implants 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 of configurations with more than 2 Zygoma implants in the MR environment is unknown. Scanning a patient who has this configuration may result in patient injury.	

Performance Requirements and Limitations

To achieve the desired performance, 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 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 new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

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	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
UK Responsible Person UK RP	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
Distributed in Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105 New Zealand Phone: +64 0800 441 657
CE Mark for Class I Devices	CE
CE Mark for Class IIa/IIb Devices	CE 2797
UKCA Mark for Class I Devices	UK CA
UKCA Mark for Class IIa/IIb Devices	UK CA 0086

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

Note Regarding Canadian Device Licensure, not all products described in the IFU may have a device licence according to Canadian Law.

Basic UDI-DI Information

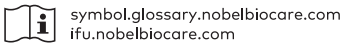
Product	Basic UDI-DI Number
Healing Abutment Ø4.5x3 mm 3.8/4.5 HL	73327470000001236T
Healing Abutment Ø4.5x3 mm 3.25 HL	73327470000001236T
Healing Abutment Ø6x3 mm 5.0 HL/Replace® Hex	73327470000001236T
Healing Abutment Ø6x3 mm 6.0 HL/Replace® Hex	73327470000001236T
Healing Abutment Ø3.5x3 mm 3.5 mm RPL	73327470000001236T
Healing Abutment Ø4.5x3 mm 4.3 Replace® Hex	73327470000001236T
O-Ring Clinical White 12/pkg	7332747000001506W
Retainer Ring 2/pkg	7332747000001506W
Abutment NobelPerfect® NP	73327470000001697K
Abutment NobelPerfect® WP	73327470000001697K
Abutment NobelPerfect® RP	73327470000001697K
Screwdriver Hex 0.050" Length 0.75"	73327470000001777J
Screwdriver Hex 0.050" Length 1.25"	73327470000001777J
Screwdriver Manual Ball Abutment 22 mm	73327470000001777J
Screwdriver Hexagon 27 mm	73327470000001777J
Screwdriver Medium 37 mm	73327470000001777J

Screwdriver Slot Short 27 mm	73327470000001777J
Screwdriver Machine Slot	7332747000001797N
Screwdriver Machine Ball Abutment 24 mm	7332747000001797N
Machine screwdriver hex long	7332747000001797N
Machine screwdriver slot short	7332747000001797N
Machine screwdriver slot long	7332747000001797N
Coping Screw Hex 2 mm 4/pkg	73327470000001837D
Coronal Screw Set 3.25 Non-Hex	73327470000001837D
Coronal Screw Set 3.8 Non-Hex	73327470000001837D
Abutment Screw TorqTite™ 3.8/4.3/4.5/5.0/6.0 HL/RPL	73327470000001837D
Prosthetic screw Unigrip™ Novum 2-pack	73327470000001837D
Lower bar screw Unigrip™ Novum 3-pack	73327470000001837D
Converter Screw Titanium Unigrip™ fit Ø3	73327470000001837D
Prosthetic Screw Conical	73327470000001837D
Prosthetic Screw Slot	73327470000001837D
Prosthetic Screw Internal Hexagon	73327470000001837D
Torque Wrench Insert Hex 0.050" Short	73327470000001897R
Torque Wrench Insert Hex 0.050" Long	73327470000001897R
Torque Wrench Insert Transmucosal Abutment	73327470000001897R
Implant Level Impression Coping NobelPerfect® NP	73327470000001977Q
Implant Level Impression Coping NobelPerfect® WP	73327470000001977Q
Impression Coping to Fixture Novum	73327470000001977Q
Implant Level Impression Coping NobelPerfect® RP	73327470000001977Q
Thread Timed Transfer Pin 3.25 Non-Hex	73327470000001977Q
Transfer Assembly Hex Open Tray 4.5 mmD 3.25 HL	73327470000001977Q
Transfer Assembly Hex Open Tray 3.5 mmD 3.5 mm Replace® Hex	73327470000001977Q
Transfer Assembly Hex Open Tray 4.5 mmD 4.3 mm Replace® Hex	73327470000001977Q
Transfer Assembly Hex Open Tray 6.0 mmD 5.0 mm HL/ Replace® Hex	73327470000001977Q
Transfer Assembly Hex Open Tray 6.0 mmD 6.0 mm HL/ Replace® Hex	73327470000001977Q
Transfer Assembly Hex Open Tray 4.5 mmD 3.8/4.5 HL	73327470000001977Q
O-Ring Abutment Analog w Spacer 2/pkg	73327470000002026Q
Implant Analog 3.8/4.5 HL	73327470000002026Q
Implant Analog 5.0 HL/RPL	73327470000002026Q
Implant Analog 6.0 HL/RPL	73327470000002026Q
Replica Fixture Novum	73327470000002026Q
Implant Replica NobelPerfect® NP	73327470000002026Q
Implant Replica NobelPerfect® WP	73327470000002026Q
Implant Replica NobelPerfect® RP	73327470000002026Q
Implant Analog Non-Hex	73327470000002026Q
Implant Analog 3.5 RPL	73327470000002026Q
Implant Analog 4.3 RPL	73327470000002026Q
Transmucosal Abutment Wrench	7332747000002316X
O-Ring for Tools 2 sets of 5/pkg	SPARE PART NOT CE MARKED
Direct Abut Eng Gold/Plastic 5.0 HL/RPL	73327470000001697K
Direct Abut Non-Eng Gold/Plc 5.0 HL/RPL	73327470000001697K
Direct Abut Eng Gold/Plastic 6.0 HL/RPL	73327470000001697K
Direct Abut Non-Eng Gold/Plc 6.0 HL/RPL	73327470000001697K
Direct Abutment Engaging Gold/Plastic 3.5 RPL	73327470000001697K
Direct Abutment Non-Engaging Gold/Plastic 3.5 RPL	73327470000001697K
Direct Abutment Engaging Gold/Plastic 4.3 RPL	73327470000001697K
Direct Abutment Non-Engaging Gold/Plastic 4.3 RPL	73327470000001697K

Legal Statements

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/ European Union	 UK Responsible Person	 Authorised Representative in Switzerland	 Sterilized using Ethylene Oxide	 Sterilized using irradiation	 Sterilized using steam or dry heat	
 Batch code	 Catalogue number	 Unique Device Identifier	 Serial number	 Medical device	 Magnetic resonance safe	
 Caution	 Magnetic resonance conditional	 Non-sterile	 Contains hazardous substances	 Contains or presence of DEHP phthalate	 Contains or presence of natural rubber latex	 Contains or presence of phthalate	 Contains biological material of animal origin
 CE mark	 CE mark with Notified Body number	 UKCA mark	 UKCA mark with Approved Body number	 Consult instructions for use	 For prescription use only	 Link to Online Symbols Glossary and IFU Portal	
 Date of manufacture	 Manufacturer	 Use-by date	 Upper limit of temperature	 Temperature limit	 Do not resterilize	 Do not re-use	 Non-pyrogenic
 Date	 Tooth number	 Patient number	 Patient identification	 Health care centre or doctor	Patient information website	EU Importer	Swiss Importer
Double sterile barrier system	Single sterile barrier system	Single sterile barrier system with protective packaging inside	Single sterile barrier system with protective packaging outside	Do not use if package is damaged and consult instructions for use	Keep away from sunlight	Keep dry	