Abutment Screw Retrieval Instrumentation

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

Abutment screw retrieval instrumentation can be used in the event of an abutment or clinical screw fracture in order to remove the portion of the screw which remains inside the implant screw channel.

Abutment screw retrieval instrumentation consists of the following:

- Rescue Drill Guides are designed to protect the implant interface and guide the Abutment Screw Retrieval Reverse Drill when drilling a hole into the screw fragment. Rescue Drill Guides are available for use with Nobel Biocare abutment screws with conical connection, external hex, tri-channel, and Nobel Biocare N1™ TCC connection types and in 3.0/NP/RP/WP/6.0 platform sizes. The Rescue Drill Guides are compatible with the Handle for Implant Rescue Collar and Drill Guides.

- Abutment Screw Removers consist of a shaft and a working end designed to create friction in order to rotate the broken-off fragment of the abutment screw out from the implant. Abutment Screw Removers are available for use with Nobel Biocare abutment screws in 3.0/NP/RP/WP/6.0 platform sizes. Abutment Screw Removers are compatible with Handle for Machine Instruments.

- Abutment Screw Retrieval Instruments are designed to engage the hole in the screw fragment, should it be still stuck after using the Abutment Screw Retrieval Reverse Drill, and to rotate the broken-off fragment of the abutment screw out from the implant. Abutment Screw Retrieval Instruments are available for use with Nobel Biocare abutment screws in 3.0/NP/RP/WP/6.0 platform sizes. Abutment Screw Retrieval Instruments are compatible with Handle for Machine Instruments.

- Abutment Screw Retrieval Reverse Drills are single use spiral drills used to drill a hole into the screw fragment when it is not rotatable allowing subsequent removal with the Abutment Screw Retrieval Instrument. Abutment Screw Retrieval Reverse Drills are available for use with Nobel Biocare abutment screws in 3.0/NP/RP/WP/6.0 platform sizes.

– Screw Tap Repairs are used to remove debris from the threaded implant connection prior to placing a new abutment screw in the implant. Screw Tap Repairs can be used with all Nobel Biocare implants and are available in M1.4/M1.6/M1.8/M2.0/M2.5 thread types.

– The N1 Base Screw removal tool is used to remove the Clinical Screw Nobel Biocare N1™ Base. It can be connected to the Handle for Machine Instruments or the Manual Torque Wrench Prosthetic Adapter. It consists of a shaft and a working end designed to engage the Clinical Screw Nobel Biocare N1™ Base in order to lift it up and rotate it out of the N1 Base. The N1 Base Screw removal tool is compatible with both NP and RP platforms.

Table 1 summarizes the available abutment screw retrieval instrumentation and the respective compatible connection types and platform sizes, as applicable. The Abutment Screw Retrieval Instrumentation is laser marked with the respective connection type, platform size, and/or diameter as applicable, and are compatible with Nobel Biocare abutment screws having the same connection type and/or platform size.

Instrument	Connection Type	Platform	Handle for Machine instruments/ Prosthetic Torque Wrench Adapter	Handpiece (Compatible with DIN EN ISO 17509)
Abutment Screw Remover 3.0	Conical Connection External Hex Internal Tri-Channel	3.0	-	X
Abutment Screw Remover NP		NP	-	X
Abutment Screw Remover RP/WP/6.0		RP	-	X
	Trioval Conical Connection (NP and RP platform only)	WP	-	X
		6.0	-	X
Abutment Screw Retrieval Reverse Drill 3.0/NP	Conical Connection External Hex Internal Tri-Channel	3.0	-	X
Abutment Screw Retrieval Reverse Drill RP/WP/6.0		NP	-	X
		RP	-	X
		WP	-	X
		6.0	-	X
Abutment Screw Retrieval Reverse Drill CC 3.0/NP & TCC NP/RP	Conical Connection External Hex Internal Tri-Channel	3.0	-	X
		NP	-	X
		RP	-	X
		WP	-	X
		6.0	-	X
	Trioval Conical Connection	NP	-	X
		RP	-	X
Rescue Drill Guide Conical Connection 3.0	Conical Connection	3.0	-	-
Rescue Drill Guide Conical Connection NP		NP	-	-
Rescue Drill Guide Conical Connection RP		RP	-	-
Rescue Drill Guide Conical Connection WP		WP	-	-
Rescue Drill Guide External Hex NP	External Hex	NP	-	-
Rescue Drill Guide External Hex RP		RP	-	-
Rescue Drill Guide External Hex WP		WP	-	-
Rescue Drill Guide Tri-Channel NP	Internal Tri-Channel	NP	-	-
Rescue Drill Guide Tri-Channel RP		RP	-	-
Rescue Drill Guide Tri-Channel WP		WP	-	-
Rescue Drill Guide Tri-Channel 6.0		6.0	-	-
Rescue Drill Guide Nobel Biocare N1™ TCC NP	Trioval Conical Connection	NP	-	-
Rescue Drill Guide Nobel Biocare N1™ TCC RP		RP	-	-
Abutment Screw Retrieval Instrument 3.0/NP	Conical Connection External Hex Internal Tri-Channel	3.0	X	X
Abutment Screw Retrieval Instrument RP/WP/6.0		NP	X	X
		RP	X	X
		WP	X	X
		6.0	X	X
Abutment Screw Retrieval Instrument CC 3.0/NP & TCC NP/RP	Conical Connection External Hex Internal Tri-Channel	3.0	X	X
		NP	X	X
		RP	X	X
		WP	X	X
		6.0	X	X
	Trioval Conical Connection	NP	X	X
		RP	X	X
Screw Tap Repair M1.4	Conical Connection	3.0	-	X
Screw Tap Repair M1.6	Conical Connection External Hex	NP	-	X
Screw Tap Repair M1.8	Internal Tri-Channel	NP	-	X
Screw Tap Repair M2.0	Conical Connection	RP	-	X
		WP	-	X
	Internal Tri-Channel	RP	-	X
		WP	-	X
		6.0		X
	External Hex	NP	-	X
Screw Tap Repair M2.5	External Hex	WP	-	X
Screw Tap Repair Tool Nobel Biocare N1™ TCC NP	Trioval Conical Connection	NP	-	X
Screw Tap Repair Tool Nobel Biocare N1™ TCC RP		NP	-	X
Nobel Biocare N1™ Base Screw Removal Tool NP/RP		NP/RP	X	-

Table 1

Intended Use / Intended Purpose

Intended for use to facilitate the removal of dental implant system components.

Indications

Rescue Drill Guides are indicated for use to protect the implant interface and guide the Abutment Screw Retrieval Reverse Drill when drilling a hole into the screw fragment.

Abutment Screw Removers are indicated for use to rotate a broken abutment screw fragment out from a dental implant.

Abutment Screw Retrieval Instruments are indicated for use in conjunction with an Abutment Screw Retrieval Reverse Drill, in order to engage the hole in the screw fragment and to rotate the screw fragment out from the dental implant.

Abutment Screw Retrieval Reverse Drills are indicated for use to drill a hole in an abutment screw fragment to facilitate its removal from the dental implant using an Abutment Screw Retrieval Instrument.

Screw Tap Repairs are indicated for use to remove debris from the inner threads of a dental implant, if needed, after removal of an abutment screw or screw fragment.

The Nobel Biocare N1 Base Screw Removal Tool is indicated for use to facilitate the removal of the clinical screw from the Nobel Biocare N1 Base.

Contraindications

It is contraindicated to use Abutment Screw Retrieval Instrumentation in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are allergic or hypersensitive to medical grade stainless steel, high speed steel or any of their alloying components.

It is contraindicated to use Nobel Biocare N1™ Base Screw Removal Tool with screws that are not Clinical Screw Nobel Biocare N1™ Base.

For contraindications specific to the dental implant, refer to the Nobel Biocare Instructions for Use (IFU) for the respective implant system. These IFUs are available for download at ifu.nobelbiocare.com.

Materials

- Abutment Screw Removers: Stainless steel 1.4108 according to DIN EN 10027.
- Abutment Screw Retrieval Instruments: Stainless steel AISI 440C / 1.4125/UNS S44004 according to ASTM F899 and DIN EN 10027.
- Screw Tap Repairs: Stainless steel 1.4197 / AISI420 Mod according to ASTM F899.
- Rescue Drill Guides External Hex: Stainless Steel UNS S31673 according to ASTM F138.
- Rescue Drill Guides TCC, Conical Connection and Tri-Channel: Stainless Steel AISI 303 / 1.4305 / UNS S30300 according to ASTM F899.
- Abutment Screw Retrieval Reverse Drills: High Speed Steel (HSS) S390.
- Nobel Biocare N1™ Base Screw Removal Tool: Stainless steel UNS S46910 according to ASTM F899.

Cautions

General

Abutment Screw Retrieval Instrumentation must only be used with compatible Nobel Biocare instruments and prosthetic components. Use of instruments and prosthetic components that are not intended to be used in combination with the Abutment Screw Retrieval Instrumentation 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

The device has not been evaluated in pediatric/adolescent patients and is not recommended for use in children. Routine treatment is not recommended until the end of the juvenile jaw bone growth phase has been properly documented.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery

Care and maintenance of sterile instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

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. dental dam, gauze or a throat shield).

Intended Users and Patient Groups

Abutment screw retrieval instrumentation are to be used by dental health care professionals.

Abutment screw retrieval instrumentation are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Abutment screw retrieval instrumentation

Abutment screw retrieval instrumentation are components 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 Abutment screw retrieval instrumentation

The use 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. Depending on location it may also lead in rare cases to fenestration or fracture of bone, damage/perforation of neighboring structures/ restorations, sinusitis, or sensory/motor disturbances. During use of this device the pharyngeal (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 [Implantable Device Type(s)]. The SSCP can be obtained at the following website:

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

Handling Procedure

Simple Cases/Step 1 – The Abutment/Clinical Screw is fractured, and the Remaining Fragment can be rotated.

Instruments needed: Abutment Screw Remover (Article 1 in Figure A), Handle for Machine Instruments (refer to Nobel Biocare Instructions for Use IFU1090 for detailed information on the Handle for Machine Instrument) (Article 2 in Figure A).

In this situation, drilling is typically not required. The abutment/ clinical screw can be removed as follows:

1. Select the appropriate Abutment Screw Remover according to laser marking and attach to either a handpiece or a Handle for Machined Instrument (Figure A).

2. To remove the screw shaft from the implant, place the end of the Abutment Screw Remover onto the fractured screw and rotate counterclockwise applying light pressure (Figure B). The slow speed handpiece shall be operating in reverse mode 50 rpm maximum speed. The teeth on the end of the Abutment Screw Remover are designed to grab the screw and back it out.

Figure A – Connection of Handle for Machine Instruments to Abutment Screw Remover

Figure B – Removal of Broken Screw Fragment

Advanced Cases/Step 2 – The Abutment/Clinical Screw is Fractured at the Implant Thread Level and the remaining fragment is not rotatable.

Instruments needed: Rescue Drill Guide, Abutment Screw Retrieval Reverse Drill Abutment Screw Retrieval Instrument), Screw Tap Repair (Handle for Machine Instruments Handle for Implant Rescue Collar & Drill Guide.

1. Select appropriate Rescue Drill Guide based on the implant connection type and size according to laser-marking.

2. Attach the Rescue Drill Guide to the Handle for Implant Rescue Collar & Drill Guide (Figure C) and then connect the Rescue Drill Guide to the interface of the implant (Figure D). The Rescue Drill Guide will support the Abutment Screw Retrieval Reverse Drill to be centered on the screw and allow a secure support when drilling.

Figure C – Attachment of Rescue Drill Guide to Handle for Implant Rescue Collar

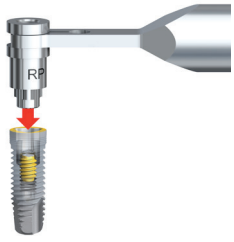


Figure D – Insertion of Rescue Drill Guide into Implant Connection Interface

3. Ensure that the Rescue Drill Guide is held down firmly in the implant connection before using the Abutment Screw Retrieval Reverse Drill.

4. Select appropriate Abutment Screw Retrieval Reverse Drill according to laser-marking and connect to the handpiece (Figure E).

Caution Incorrect position of the Rescue Drill Guide may result in drill fracture and aspiration of drill fragments.

Caution Incorrect positioning of the Rescue Drill Guide may result in incorrect drill position, damage to implant connection, inability to remove screw fragment and subsequent implant retrieval.

5. Ensure the drill unit is in reverse mode. Recommended speed is 2000 rpm. Perform the drilling in intervals using copious of irrigation to avoid heating the bone. During the procedure the Rescue Drill Guide can be heated by the drill so always hold the Rescue Drill Guide with the handle. To avoid shavings clogging the guide channel, release the Rescue Drill Guide and air-blast during procedure.

6. If the abutment screw is not broken but shows a damaged screw head connection, drill a hole to the depth of the screw head without using the Rescue Drill Guide and the Handle.

7. For situations where the abutment/clinical screw is broken at the thread level, drill a hole to a depth of ~1 mm into the fractured screw. Marking on the drill can be used as a support to define the depth. Image shows drill markings of 1 mm (Figure F).

Note The Abutment Screw Retrieval Reverse Drill may damage the implant's internal threads and make the implant no longer usable. This can be avoided by using the Rescue Drill Guide and by not exceeding a depth of 1 mm.

Warning Use of the reverse drill without a guide may result in drill fracture and aspiration of drill fragments.

Warning Copious irrigation is important when using the Abutment Screw Retrieval Reverse Drill to avoid overheating.

Warning Risk of aspiration of metal fragments/debris if irrigation/suction is not used.

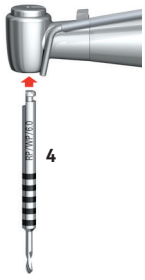


Figure E – Connection of Abutment Screw Retrieval Reverse Drill to Handpiece

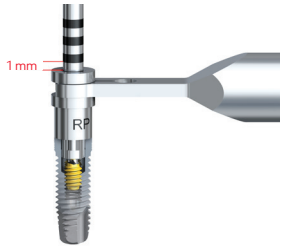


Figure F – Visualization of Depth Markings on the Abutment Screw Retrieval Reverse Drill

Note During the drilling sequence the fractured abutment/clinical screw might come loose.

8. If the fractured screw is still stuck, remove the Rescue Drill Guide and connect the Abutment Screw Retrieval Instrument to the Handle for Machine Instruments (Figure G). Place the tip of the instrument into the hole in the screw and rotate the handle in counter-clockwise direction (Figure H). Add light pressure until the instrument grips the screw and the screw can be removed.

9. If the retrieval tool cannot engage the screw, do further drilling and try again (see Step 4). If the Abutment Screw Retrieval Instrument cannot be removed with the Handle for Machine Instruments, connect the Abutment Screw Retrieval Instrument to the Manual Torque Wrench Adapter and Manual Torque Wrench Surgical in order to generate more torque.

10. Before a new screw is placed, it is recommended to evaluate the threads inside the implant for damage. This can be done with a guide pin, screw from an impression coping, or healing abutment. If resistance is encountered, a Screw Tap Repair may be used to remove debris from the thread (Figure I). In this case, select the appropriate Screw Tap Repair from the instrument selection guide according to laser-marking. Connect the Screw Tap Repair to the Handle for Machine Instruments or to the handpiece. Recommended speed is 50 rpm.

Note Ensure correct alignment of screw tap repair tool in implant before applying torque.

Warning Misalignment of screw tap repair tool in implant may damage implant threads.

11. After successful screw removal, a new screw can be inserted.

Figure G – Connection of Handle for Machine Instruments to Abutment Screw Retrieval Instrument

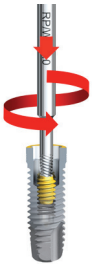


Figure H – Removal of Screw Fragment

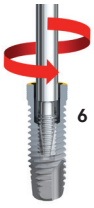


Figure I – Rotation of Screw Tap Repair to Remove Debris from Implant Threading

<u>Remove the Clinical Screw Nobel Biocare N1™ Base</u>

1. Unscrew the Clinical Screw Nobel Biocare N1™ Base using the Screwdriver Nobel Biocare N1™ Base.

2. Connect the Nobel Biocare N1™ Base Screw Removal Tool to the Handle For Machine Instruments or the Manual Torque Wrench Prosthetic Adapter.

3. Engage the head of the clinical screw. Slightly rotating the tool while pushing can facilitate the engagement.

4. To remove the screw, rotate the tool counter clockwise while gently lifting up.

Figure L – engagement of screw

Note The engagement between the retrieval tool and the clinical screw can be stronger than the engagement between the retrieval tool and the adapter/handle.

Note Use the Nobel Biocare N1™ Base Screw Removal Tool manually.

Sterility and Reusability Information

Abutment Screw Removers, Abutment Screw Retrieval Instrument, Abutment Screw Retrieval Reverse Drill, Screw Tap Repair, and Screw Tap Repair Tool Nobel Biocare N1™TCC have been sterilized using irradiation and are intended for single use. 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 Abutment Screw Removers, Abutment Screw Retrieval Instrument, Abutment Screw Retrieval Reverse Drill, Screw Tap Repair, and Screw Tap Repair Tool Nobel Biocare N1™ TCC must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Reuse could cause local or systemic infection.

Caution Rescue Drill Guides and Nobel Biocare N1™ Base Screw Removal Tool NP/RP 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 the instrument to confirm there are no signs of corrosion, pitting, cracked seals, discoloration, that any markings on the instrument are legible, and that the instrument has a stable engagement with other instruments, where applicable. Any instrument which fails to meet these criteria must be discarded.

Cleaning and Sterilization Instructions

Rescue Drill Guides and Nobel Biocare N1™ Base Screw Removal 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 (Re)processing

1. Discard single-use instruments and worn reusable instruments immediately after use.

2. Remove excess soil and debris from reusable devices to be (re)processed using absorbent paper wipes. Use a dental probe to remove soil and debris from cavities, where applicable.

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. Immerse the device in 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.

2. Fill lumina (where applicable) with 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.

3. 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.

4. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2mm / 2.0mm / 5.0mm diameter) for a minimum of 20 seconds until all visible soil is removed.

5. 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.

6. 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 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. Immerse the device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.

2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.

3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm enzymatic cleaning solution (e.g. Cydezyme ASP; maximum of 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.

4. 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.

5. 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.

6. 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 treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).

7. 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.

8. Flush the lumina and cavities of the Nobel Biocare N1™ Base Screw Removal Tool NP/RP 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 discard any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX- 320 (pre-vacuum cycle); Amsco Century Sterilizer (gravity cycle).

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

1. 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 2 presents examples of suitable sterilization pouches.

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

Table 2 – Recommended Sterilization Pouches

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 3):

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time	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		≥3042 mbar[5]
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		

Table 3 – Recommended Sterilization Cycles

[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 re-processed 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.

Performance Requirements and Limitations

To achieve the desired performance, the devices must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with the devices, 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 Ir/IIa Devices	CE 2797
UKCA Mark for Class I Devices	UK CA
UKCA Mark for Class IIa Devices	UK CA 0086

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

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

Basic UDI-DI Information

Product	Basic UDI-DI Number
Rescue Drill Guides External Hex NP/RP/WP Rescue Drill Guides Tri-Channel NP/RP/WP/6.0 Rescue Drill Guides Nobel Biocare N1™ TCC NP/RP Rescue Drill Guides Conical Connection 3.0/NP/RP/WP	73327470000001747C
Abutment Screw Removers 3.0, NP, RP/WP/6.0 Abutment Screw Retrieval Reverse Drills 3.0/NP, RP/WP/6.0 Abutment Screw Retrieval Instruments 3.0/NP, RP/WP/6.0 Abutment Screw Retrieval Instrument CC 3.0/NP & TCC NP/RP Screw Tap Repairs M1.4/M1.6/M1.8/M2.0/M2.5 Screw Tap Repair Tools Nobel Biocare N1™ TCC NP/RP Nobel Biocare N1™ Base Screw Removal Tool	73327470000001757E

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

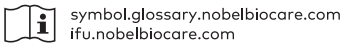
CE mark with Notified Body number

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