Abutment Screw Retrieval Instrumentation

Instructions for use

Important – Disclaimer of Liability:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

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:

- **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 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.
- **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 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.
- **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.

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.

Table 1: Abutment Screw Retrieval Instruments and Compatible Screws/Implants

Instrument	Connection Type	Platform	Prosthetic Torque Wrench Adapter	Handpiece (Compatible with DIN EN ISO 17509)
Abutment Screw Remover 3.0	Conical Connection External Hex Internal Tri-Channel Trioval Conical Connection (NP and RP platform only)	3.0	-	X
Abutment Screw Remover NP		NP	-	X
Abutment Screw Remover RP/WP/6.0		RP	-	X
		WP	-	X
		6.0	-	X
Abutment Screw Retrieval Reverse Drill 3.0/NP	Conical Connection External Hex Internal Tri-Channel	3.0	-	X
		NP	-	X
		RP	-	X
Abutment Screw Retrieval Reverse Drill RP/WP/6.0		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
		NP	X	X
		RP	X	X
Abutment Screw Retrieval Instrument RP/WP/6.0		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	RP	-	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		RP	-	X

Intended Use/Intended Purpose:

Abutment Screw Removers, Abutment Screw Retrieval Reverse Drills, Rescue Drill Guides, Abutment Screw Retrieval Instruments, Screw Retrieval Tool Nobel Biocare N1™ TCC, Screw Tap Repairs, and Screw Tap Repair Tools Nobel Biocare N1™ TCC:
Intended for use to facilitate the removal of dental implant system components.

Indications:

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

Abutment Screw Retrieval Reverse Drills:
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.

Rescue Drill Guides:
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 Retrieval Instruments:
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.

Screw Tap Repairs:
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.

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.

Cautions:

General:
It is strongly recommended that Abutment Screw Retrieval Instrumentation is used only with compatible Nobel Biocare instruments and/or prosthetic components. Use of instruments and/or prosthetic components that are not intended to be used in combination with Abutment Screw Retrieval Instrumentation can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment for the first time, working with a colleague who is experienced with the new device/treatment 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 procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

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.

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 size 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. a throat shield).

Intended Users and Patient Groups:

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

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

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with the Abutment Screw Retrieval Instrumentation:
The Abutment Screw Retrieval Instrumentation 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 the 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, perforation of neighboring structures, sinusitis, or sensory/motor disturbances. During use of this device the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

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:

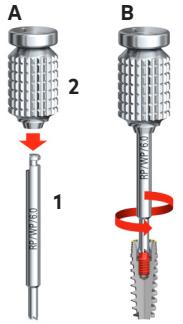
Nobel Biocare AB
https://www.nobelbiocare.com/complaint-form

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:

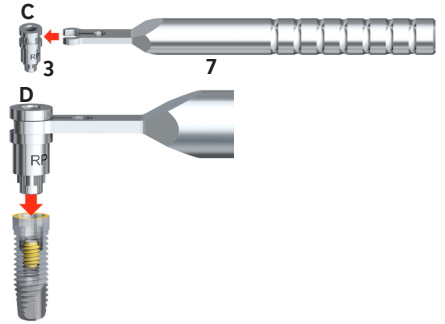
1. Select the appropriate Abutment Screw Remover according to laser marking and attach to either a handpiece or a Handle for Machined Instrument (**Figure A**).
2. To remove the screw shaft from the implant, place the end of the Abutment Screw Remover onto the fractured screw and rotate counter clockwise 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.



Figures A and B: Connection of Handle for Machine Instruments to Abutment Screw Remover (A) and Removal of Broken Screw Fragment (B)

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 (Article 3 in **Figure C**), Abutment Screw Retrieval Reverse Drill (Article 4 in **Figure E**), Abutment Screw Retrieval Instrument (Article 5 in **Figure G**), Screw Tap Repair (Article 6 in **Figure I**), Handle for Machine Instruments (Article 2 in **Figure A**), Handle for Implant Rescue Collar & Drill Guide (Article 7 in **Figure C**).

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.



Figures C and D: Attachment of Rescue Drill Guide to Handle for Implant Rescue Collar & Drill Guide (C) and Insertion of Rescue Drill Guide into Implant Connection Interface (D)

3. Ensure that the Rescue Drill Guide is held down firmly in the implant connection before using the Abutment Screw Retreival Reverse Drill.
4. Select appropriate Abutment Screw Retrieval Reverse Drill according to laser-marking and connect to the handpiece (**Figure E**).

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.

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

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.

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.

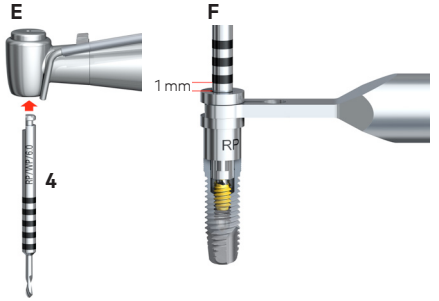
For situations where the abutment/clinical screw is broken at the thread level, drill a hole to a depth of ~1 mm into the fractured screw. Marking on the drill can be used as a support to define the depth. Image shows drill markings of 1 mm (**Figure F**).

Warning: 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.



Figures E and F: Connection of Abutment Screw Retrieval Reverse Drill to Handpiece (E) and Visualization of Depth Markings on the Abutment Screw Retrieval Reverse Drill (F).

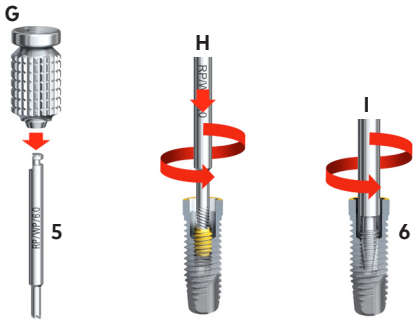
Note: During the drilling sequence the fractured abutment/clinical screw might come loose.

4. 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.
5. If the retrieval tool cannot grab 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.
6. 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.

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



Figures G, H, and I: Connection of Handle for Machine Instruments to Abutment Screw Retrieval Instrument (G), Removal of Screw Fragment (H), Rotation of Screw Tap Repair to Remove Debris from Implant Threading (I)

Materials:

- Abutment Screw Removers: Stainless steel 1.4108 according to DIN EN 10027.
- Abutment Screw Retrieval Instruments: Stainless steel 1.4125 according to ASTM F899 and DIN EN 10027.
- Screw Tap Repairs: Stainless steel 1.4197 according to ASTM F899.
- Rescue Drill Guides: Stainless Steel 303, 1.4305 according to ASTM A582.
- Abutment Screw Retrieval Reverse Drills: High Speed Steel (HSS) according to ASTM A600.

Sterility and Reusability Information:

The Abutment Screw Removers, Abutment Screw Retrieval Instruments, Abutment Screw Retrieval Reverse Drills and the Screw Tap Repairs have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

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

Caution: The Abutment Screw Removers, Abutment Screw Retrieval Instruments, Abutment Screw Retrieval Reverse Drills and the Screw Tap Repairs 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.

The Rescue Drill Guide is delivered non-sterile and 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.

The Rescue Drill Guides are reusable instruments which must be inspected prior to each use to ensure the integrity and performance of the instrument has not been compromised. Inspect the instrument to confirm there are no signs of corrosion, 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:

The Rescue Drill Guide is delivered non-sterile and 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.

Initial Treatment at Point of Use Prior to Reprocessing:

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes.
3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area:

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

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

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

Automated Cleaning and Drying (Including Pre-cleaning):

Pre-cleaning:

1. Immerse the devices 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. 1.2 mm/2.0 mm/5.0 mm 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 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum 5 minutes cleaning with minimum 55°C (131°F) tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum 3 minutes neutralization with cold desalinated water.
   - Draining.
   - Minimum 2 minutes rinsing with cold desalinated water.
   - Draining.
4. Run drying cycle at minimum 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection:

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

Manual Cleaning and Drying:

1. Immerse devices 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 lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP ; maximum 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 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) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/maximum 45°C (113°F).
7. Flush the inner surfaces, lumina and cavities of the device for a minimum of 15 seconds using a water jet pistol
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:

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

Sterilization:

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 (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 containers, pouches, and wraps.

Table 2: Recommended Sterilization Pouches

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

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

Table 3: 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		≥3042 mbar[5]
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		

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

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

[3] Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.

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

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

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

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

Containment and Transportation/Shipping to Point of Use:
The container and/or outer packaging used to transport or ship the reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (interfacility transportation or shipping to an external site) into account.

Performance Requirements and Limitations:

To achieve the desired performance, the abutment screw retrieval instrumentation 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/Intended Purpose for each product. To confirm the compatibility of products which are intended to be used in conjunction with the abutment screw retrieval instrumentation, 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
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

Distributed in Australia by:
Nobel Biocare Australia Pty Ltd
Level 4/7 Eden Park Drive
Macquarie Park, NSW 2114 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 2797 CE Mark for Class Ir Devices

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

Notice Regarding Canadian Device Licensure: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

Product	Basic UDI-DI Number
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	73327470000001757E
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

Symbols Glossary:

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

Authorized representative in the European Community

Batch code

Catalogue number


Caution


CE marking


Consult instructions for use


Contains hazardous substances

Contains or presence of phthalate

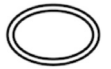
Date


Date of manufacture

Do not resterilize

Do not re-use


Do not use if package is damaged

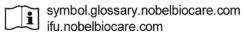

Double sterile barrier system

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional


Manufacturer

Medical device


Non-pyrogenic

Non-sterile


Patient identification


Patient information website


Patient number

Serial number


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside

Sterilized using ethylene oxide

Sterilized using irradiation

Temperature limit

Tooth number

Upper limit of temperature

Sterilized using steam or dry heat

Unique Device Identifier

Use-by date