Abutment 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.

Description:

Abutment retrieval instruments are used to remove dental implant abutments or finalized prosthetic restorations that have become stuck to a dental implant, after the abutment screw or clinical screw attaching the abutment to the implant has been removed.

Abutment Retrieval Instrument/Tool Titanium and Abutment Retrieval Tool Nobel Biocare N1™ TCC:

The Abutment Retrieval Instrument CC RP/WP Titanium, Abutment Retrieval Tool CC NP Titanium and Abutment Retrieval Tool Nobel Biocare N1™ TCC are used to remove titanium abutments. They consist of a pin with a threaded portion that is threaded through the abutment inner threads (see Figure A). By applying torque with the screwdriver, the unthreaded portion of the pin comes into contact with the implant, which pushes the abutment up so that it can be removed by hand.

- The Abutment Retrieval Instrument/Tool Titanium CC is available in the NP (magenta) and RP/WP (silver) platform sizes and is compatible with Nobel Biocare titanium abutments (see Table 1).
- The Abutment Retrieval Tool Nobel Biocare N1™ TCC is available in the NP and RP platform sizes and is compatible with Nobel Biocare N1™ TCC titanium abutments (see Table 2).

Figure A: Abutment Retrieval Instrument Titanium CC and Abutment Retrieval Tool Nobel Biocare N1™ TCC

Table 1: Abutments compatible with Abutment Retrieval Instrument Titanium CC and Abutment Retrieval Instrument Zirconia CC

	Abutment Description	Retrieval Tool	Screwdriver
NP	Temporary Abutment Engaging CC NP	Abutment Retrieval Tool CC NP Titanium	Screwdriver Unigrip
	Esthetic Abutment CC NP		
	Snappy™ Abutment CC NP		
	NobelProcera® Abutment Titanium NP		
RP/ WP	Temporary Abutment Engaging CC RP/WP	Abutment Retrieval Instrument CC RP/WP Titanium	Screwdriver Unigrip
	Esthetic Abutment CC RP/WP		
	Snappy™ Abutment CC RP/WP		
	NobelProcera® Abutment CC Titanium RP/WP		

Table 2: Abutments compatible with Abutment Retrieval Tool Nobel Biocare N1™ TCC

	Abutment Description	Retrieval Tool	Screwdriver
NP	Healing Abutment Nobel Biocare N1™ TCC NP	Abutment Retrieval Tool Nobel Biocare N1™ TCC NP	Screwdriver Machine/ Manual Multi-unit
	Temporary Abutment Nobel Biocare N1™ TCC NP*		
	Universal Abutment Nobel Biocare N1™ TCC NP**		
	Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC NP		
	17° Multi-unit Abut Xeal™ Nobel Biocare N1™ TCC NP		
	Nobel Biocare N1™ Base Xeal™ TCC Tri NP		
	Esthetic Abutment Nobel Biocare N1™ TCC NP		
RP	Healing Abutment Nobel Biocare N1™ TCC RP	Abutment Retrieval Tool Nobel Biocare N1™ TCC RP	Screwdriver Machine Multi-unit
	Temporary Abutment Nobel Biocare N1™ TCC RP*		
	Universal Abutment Nobel Biocare N1™ TCC RP**		
	Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC RP		
	17° Multi-unit Abut Xeal™ Nobel Biocare N1™ TCC RP		
	30° Multi-unit Abut Xeal™ Nobel Biocare N1™ TCC RP		
	Nobel Biocare N1™ Base Xeal™ TCC Tri RP		
	Esthetic Abutment Nobel Biocare N1™ TCC RP		

* The Abutment Retrieval Tool Nobel Biocare N1™ is only compatible if post length (upper part of the abutment) is reduced below 50%. Alternatively, use grasping instruments, e.g. forceps.

** Widening of crown screw access hole is required to fit the Abutment Retrieval Tool into the abutment.

Intended Use:

Abutment Retrieval Instrument Titanium CC, Abutment Retrieval Tool Nobel Biocare N1™ TCC:
Intended for use to facilitate the removal of dental implant system components.

Indications for Use:

Abutment Retrieval Instrument/Tool Titanium CC and Abutment Retrieval Tool Nobel Biocare N1™ TCC:
The Abutment Retrieval Instrument/Tool Titanium CC and Abutment Retrieval Tool Nobel Biocare N1™ TCC are indicated for use to facilitate the removal of titanium abutments from an endosseous dental implant placed in the maxilla or mandible.

Contraindications:

In general, contraindications are applicable for implant surgery related procedures in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are allergic or hypersensitive to medical grade stainless steel, stainless steel or any of its alloying components and commercially titanium alloy grade 5 (Ti6Al4V).

It is contraindicated to use the Abutment Retrieval Instruments with components not manufactured by Nobel Biocare and which are not listed as compatible in this Instruction for Use.

Cautions:

General:
Abutment Retrieval Instrument/Tool CC Titanium, Abutment Retrieval Tool Nobel Biocare N1™ TCC must only be used with compatible Nobel Biocare prosthetic components. Use of prosthetic components that are not intended to be used in combination with Abutment Retrieval Instrument/Tool CC Titanium, Abutment Retrieval Tool Nobel Biocare N1™ TCC 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. gauze, dental dam or a 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.

Procedure for Retrieval of Titanium Abutments using Abutment Retrieval Instrument/Tool Titanium CC or Abutment Retrieval Tool Nobel Biocare N1™ TCC:
These tools are used to remove titanium abutments when the abutment screw or clinical screw has been removed but the abutment cannot be removed due to a tight conical seal.

Note: The abutment screw must be unthreaded from both the internal threads of the implant and the abutment. In case the loose abutment/clinical screw is difficult to remove, use a small amount of sticky wax on the tip of the screwdriver which will aid in retention of the abutment screw head.

1. Insert the Abutment Retrieval Instrument/Tool into the abutment and screw it clockwise into place using the screwdriver until the tip of the screw touches the bottom of the hole inside the implant (Figure B).
2. Apply torque to the screwdriver to release the abutment from the implant.

Figure B: Insertion of Abutment Retrieval Instrument into abutment

Materials:

- Abutment Retrieval Tool Nobel Biocare N1™ TCC: Stainless steel according to ASTM A895/ F899 and ISO 5832-1.
- Abutment Retrieval Instrument/Tool Titanium CC: Titanium alloy according to ASTM F136 and ISO 5832-3.

Sterility and Reusability Information:

The Abutment Retrieval Instruments 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.

The Abutment Retrieval Instruments are re-usable instruments which shall be inspected before each re-use to ensure that the integrity and performance continues to be maintained. Inspect the devices for signs of degradation that may limit the useful life of the devices, such as:

- Compromised legibility of the lasermarking.
- Visible corrosion.
- Mechanical wear/damage.

The Abutment Retrieval Instruments shall be disposed if any of these signs of degradation are evident.

Cleaning and Sterilization Instructions:

The Abutment Retrieval Instruments 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 described reprocessing instructions.

Caution: Keep dissimilar metals separated during sterilization to resist corrosion.

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

Automated Cleaning and Drying:

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

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

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

Note: FDA-cleared washer-disinfectors are to be used for the recommended cleaning parameters.

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 components prior to cleaning (applicable only for Abutment Retrieval Instrument Zirconia CC).
2. Immerse devices for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP; maximum 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
5. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
6. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
7. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/maximum 45°C (113°F).
8. Flush the inner surfaces, lumina and cavities of the device for a minimum of 15 seconds using a water jet pistol.
9. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
10. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:

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

Sterilization:

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 (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. Disassemble the components prior to sterilization (applicable only for Abutment Retrieval Instrument Zirconia CC 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 3 presents examples of suitable sterilization pouches.

Table 3: 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:
   - Gravity Cycle: Steam sterilization at 132°C (270°F) for 15 minutes at saturated steam pressure, followed by drying 15-30 minutes in chamber.
   - Pre-Vacuum Cycle: Steam sterilization at 132°C (270°F) for 4 minutes at saturated steam pressure, followed by drying 20-30 minutes in chamber.

Note: FDA-cleared sterilization equipment and accessories are to be used for the recommended sterilization parameters.

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.

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
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Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

Distributed in USA by:
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, CA, 92887
USA

Caution: Federal law restricts this device to sale by or on the order of a dentist or physician.

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.

Batch code

Catalogue number

Date


Date of manufacture


Manufacturer

Serial number

Unique Device Identifier

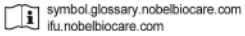

Health care centre or doctor


Patient identification


Patient number


Tooth number


Consult instructions for use



Link to Online Symbols Glossary and IFU Portal


Patient information website


Caution

Do not resterilize


Do not re-use


Do not use if package is damaged and consult instructions for use


Use-by date


Temperature limit


Upper limit of temperature


Keep away from sunlight


Keep dry

Contains biological material of animal origin


Contains hazardous substances

Contains or presence of DEHP phthalate

Contains or presence of natural rubber latex

Contains or presence of phthalate


Non-pyrogenic

Magnetic resonance conditional

Magnetic resonance safe

Non-sterile

Sterilized using Ethylene Oxide

Sterilized using irradiation

Sterilized using steam or dry heat


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside


Double sterile barrier system

Authorised Representative in Switzerland

Authorized representative in the European Community / European Union

UK Responsible Person

CE mark

CE mark with Notified Body number

EU Importer

Swiss Importer

UKCA mark

UKCA mark with Approved Body number

Medical device

Rx only

For prescription use only