Abutment Retrieval Instrumentation

Important – Disclaimer of Liability

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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. There are two types of abutment retrieval instruments, one type for removing zirconia abutments, and the other for removing titanium abutments.

The Abutment Retrieval Instrument CC Zirconia: it is used to remove zirconia abutments. They are comprised of two pieces: one is a hollow cylinder ("engaging pin") that is placed through the screw access hole of the zirconia abutment/prosthesis, and the second piece is the "activating pin" that is inserted through the engaging pin. After using forceps to compress the two components, the engaging pin engages the abutment and lifts it vertically, so that the abutment can be removed by hand.

The Abutment Retrieval Instrument CC Zirconia is available in the NP and RP/WP platform sizes and is compatible with Nobel Biocare zirconia abutments (see Table 1).

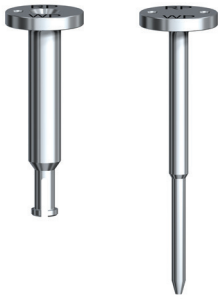

Figure A – Hollow Cylinder and Activating Pin of Two-piece Abutment Retrieval Instrument Zirconia CC.

	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		
NP	NobelProcera® Abutment Zirconia CC NP	Abutment Retrieval Instrument CC NP Zirconia	Forceps
	Adapter for Zirconia Abut. CC NP (NobelProcera® ASC Abutment Zirconia NP, NobelProcera® FCZ Implant Crown NP)		
RP/ WP	NobelProcera® Abutment Zirconia RP	Abutment Retrieval Instrument CC RP/ WP Zirconia	Forceps
	Adapter for Zirconia Abut. CC RP and WP (NobelProcera® ASC Abutment Zirconia RP/ WP, NobelProcera® FCZ Implant Crown RP/WP)		

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

The Abutment Retrieval Instrument CC RP/WP Titanium, Abutment Retrieval Tool CC NP Titanium and Abutment Retrieval Tool Nobel Biocare N1™ TCC (old version articles 300921 and 300922) 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 C). 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 (old version) is available in the NP and RP platform sizes, , and it is compatible with Nobel Biocare N1™ TCC titanium abutments (see Table 2).

Figure B – Abutment Retrieval Instrument Titanium CC and Abutment Retrieval Tool Nobel Biocare N1™ TCC old version.

The Abutment Retrieval Tool Nobel Biocare N1™ TCC (new version articles 301521, 301522, 301533, 301534) is used to remove titanium abutments. It consists of a pin with a threaded portion that is threaded through the abutment inner threads. It has to be connected to the Handle for Machine instruments or the Manual Torque Wrench Prosthetic Adapter. By applying torque with the handle, 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 Tool Nobel Biocare N1™ TCC new version is available in the NP and RP platform sizes, short and longer version, and it is compatible with Nobel Biocare N1™ TCC titanium abutments. Refer to Table 2 for compatibility summary.

Note The new version of the previously existing Abutment Retrieval Tool Nobel Biocare N1™ TCC presents a latch connection that is compatible with the Handle for Machine Instruments or the Manual Torque Wrench Prosthetic Adapter.

Old Version New Version

Figure C – old version and new version of the Abutment Retrieval Tool Nobel Biocare N1™ TCC

	Abutment Description	Retrieval Tool	Screwdriver/Handle
NP	Healing Abutment Nobel Biocare N1™ TCC NP	Abutment Retrieval Tool Nobel Biocare N1™ TCC NP*	Handle for Machine Instrument/Manual Torque Wrench Adapter The old version is compatible with the Screwdriver 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		
	Titanium Abutment Blanks Nobel Biocare N1™ NP		
RP	Healing Abutment Nobel Biocare N1™ TCC RP	Abutment Retrieval Tool Nobel Biocare N1™ TCC RP*	Handle for Machine Instrument/Manual Torque Wrench Adapter The old version is compatible with the Screwdriver 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		
	Titanium Abutment Blanks Nobel Biocare N1™ RP		

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

*The Short version of the Abutment Retrieval Tool Nobel Biocare N1™ TCC short is not compatible with the Temporary Abutment Nobel Biocare N1™ TCC 3.0mm.

Intended Use / Intended Purpose

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

Indications

Abutment Retrieval Instrument Zirconia CC

The Abutment Retrieval Instrument Zirconia are indicated for use to facilitate the removal of zirconia abutments from an endosseous dental implant placed in the maxilla or mandible.

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 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 not Nobel Biocare prosthetic components.

Materials

- Abutment Retrieval Instrument Zirconia CC, and 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.

Cautions

General

Abutment Retrieval Instrument CC Zirconia, 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 CC Zirconia, 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.

Intended Users and Patient Groups

Abutment Retrieval Instruments are to be used by dental health care professionals.

Abutment Retrieval Instruments are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Abutment Retrieval Instruments

Abutment Retrieval Instruments 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 Retrieval Instruments

The use of these devices 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.

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

Procedure for Retrieval of Zirconia Abutments Using the Abutment Retrieval Instrument Zirconia CC

These tools are used to remove zirconia abutments when the abutment screw or clinical screw has been removed (see Figure A) using a screwdriver, but the abutment cannot be removed due to a tight conical seal.

1. The abutment/clinical 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 Unigrip™, which will aid in retention of the abutment screw head.

2. Insert the engaging pin (Figure A) into the abutment until it reaches a stop.

Note The engaging pin has to be pushed in rather firmly to reach its end stop. There is first an intermediate stop that has to be passed before the pin is in final position.

3. Assemble the instrument by inserting the activating needle (Figure A).

4. Squeeze the abutment retrieval instrument parts together using e.g. a hemostat or pliers until the abutment is released (Figure D).

In case the Adapter for Zirconia Abutment has been used:

1. Remove the abutment so that only the adapter stays in place.

2. Insert the engaging pin into the adapter until it reaches a stop.

Note The engaging pin has to be pushed in rather firmly to reach its end stop. There is first an intermediate stop that has to be passed before the pin is in final position.

3. Assemble the instrument by inserting the activating needle (Figure A).

4. Squeeze the abutment retrieval instrument parts together using e.g. a hemostat or pliers until the adapter is released (Figure D).

Figure D – Squeezing of abutment retrieval instrument parts together

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 or compatible handle until the tip of the screw touches the bottom of the hole inside the implant (Figure E).

2. Apply torque to the screwdriver to release the abutment from the implant.

Figure E – Insertion of Abutment Retrieval Instrument into abutment (example with the Abutment Retrieval Tool Titanium CC)

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 reuse. Prior to each use the devices must be cleaned and sterilized by the user.

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

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

– Manual and Automated Cleaning: AAMI TIR 12

– Sterilization: AAMI ST79 and ISO 17665 -1

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

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

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

Caution Do not deviate from the following reprocessing instructions.

Initial Treatment at Point of Use Prior to Reprocessing

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

2. Remove excess soil and debris from reusable devices to be (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. Disassemble Abutment Retrieval Instrument Zirconia CC prior to cleaning by removing the hollow cylinder from the activating pin.

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

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

4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED – 100.33) for a minimum of 20 seconds until all visible soil is removed.

5. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2mm / 2.0mm / 5.0mm 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 of 2 minutes pre-cleaning with cold tap water
   - Draining
   - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5 % mildly alkaline detergent (e.g. Neodisher Mediclean)
   - Draining
   - Minimum of 3 minutes neutralization with cold desalinated water
   - Draining
   - Minimum of 2 minutes rinsing with cold desalinated water
   - Draining

4. Run drying cycle at a minimum of 50°C (122°F) for a minimum of 10 minutes.

5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection

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

Manual Cleaning and Drying

1. Disassemble components prior to cleaning (applicable only for Abutment Retrieval Instrument Zirconia CC).

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

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

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

5. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.

6. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.

7. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz, effective ultrasonic power 300 W_{eff}) containing an 0.5% enzymatic cleaning agent (e.g. Cydezyme ASP) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).

8. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water 20 ml using an irrigation needle connected to a 20 ml syringe.

9. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.

10. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection

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

Sterilization

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

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

Table 3 presents examples of suitable sterilization pouches.

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

Table 3 – 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 4):

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		

Table 4 – 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 reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Performance Requirements and Limitations

To achieve the desired performance, these 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 these 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
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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.

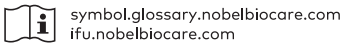
Basic UDI-DI Information

Product	Basic UDI-DI Number
Abutment Retrieval Instrument Zirconia CC Abutment Retrieval Instrument/Tool Titanium CC	73327470000001747C
Abutment Retrieval Tool Nobel Biocare N1™ TCC (art. 300921, 300922)	
Abutment Retrieval Instrument Zirconia CC Abutment Retrieval Instrument/Tool Titanium CC	
Abutment Retrieval Tool Nobel Biocare N1™ TCC (art. 301521, 301522, 301533, 301534)	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	