Implant 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:

Implant retrieval instrumentation can be used to remove an osseointegrated dental implant where an implant driver cannot be used, for example, due to a damaged implant connection interface.

Implant retrieval instrumentation consists of the following:

- **Implant Retrieval Instruments** are designed to remove implants with damaged connection interfaces by engaging the implant inner threads and rotating the instrument in counterclockwise direction. Implant Retrieval Instruments are available for use with Nobel Biocare implants which feature a Conical Connection, Tri-oval Conical Connection, External Hex, or Internal Tri-Channel connection, in a variety of platform sizes.

  The Implant Retrieval Instrument is compatible with the Manual Torque Wrench Surgical (reference to IFU1098).
- **Implant Rescue Collars** are designed for use in conjunction with Implant Retrieval Instruments for implants with an Internal Tri-Channel connection. They are placed around the implant collar when the connection is collapsed and to prevent expansion of the implant collar when removing the implant.

Table 1 summarizes the available Implant Retrieval Instruments and Implant Rescue Collars, their respective connection types and platform sizes, as applicable, and the implants with which they are compatible. These instruments are laser marked with the respective connection type, platform, and/or diameter as applicable.

Table 1: Implant Retrieval Instruments and Implant Rescue Collars compatibility

Instrument	Implant Connection Type	Implant Platform	Compatible Implant
Implant Retrieval Instrument CC 3.0 31 mm	Conical Connection	3.0	NobelActive
Implant Retrieval Instrument CC NP & External Hex WP 22 mm	Conical Connection	NP	NobelActive NobelReplace NobelParallel
	External Hex	WP	NobelSpeedy Groovy Branemark System
Implant Retrieval Instrument CC RP & Tri-Channel WP 22 mm	Conical Connection	RP	NobelActive NobelReplace NobelParallel
	Internal Tri-Channel	WP	Replace Select Straight NobelSpeedy Replace NobelReplace Straight Replace Select Tapered Replace Select Tapered PMC NobelReplace Tapered
Implant Retrieval Instrument CC WP 22 mm	Conical Connection	WP	NobelActive NobelParallel
Implant Retrieval Instrument External Hex & Tri-Channel NP/RP 22 mm	External Hex	NP	NobelSpeedy Groovy Branemark System
		RP	NobelSpeedy Groovy Branemark System
	Internal Tri-Channel	NP	Replace Select TC Replace Select Straight NobelSpeedy Replace NobelReplace Straight Replace Select Tapered Replace Select Tapered PMC NobelReplace Tapered Groovy NobelReplace Tapered PS
		RP	Replace Select TC Replace Select Straight NobelSpeedy Replace NobelReplace Straight Replace Select Tapered Replace Select Tapered PMC NobelReplace Tapered Groovy NobelReplace Tapered PS
Implant Retrieval Instrument External Hex & Tri-Channel NP/RP 31 mm	External Hex	NP	NobelSpeedy Groovy Branemark System
		RP	NobelSpeedy Groovy Branemark System
	Internal Tri-Channel	NP	Replace Select TC Replace Select Straight NobelSpeedy Replace NobelReplace Straight Replace Select Tapered Replace Select Tapered PMC NobelReplace Tapered Groovy NobelReplace Tapered PS
		RP	Replace Select TC Replace Select Straight NobelSpeedy Replace NobelReplace Straight Replace Select Tapered Replace Select Tapered PMC NobelReplace Tapered Groovy NobelReplace Tapered PS
Implant Retrieval Instrument Tri-Channel 6.0 22 mm	Internal Tri-Channel	6.0	Replace Select Tapered Replace Select Tapered PMC NobelReplace Tapered NobelSpeedy Replace
Implant Rescue Collar Tri-Channel Ø 3.5	Internal Tri-Channel	NP	Replace Select TC Replace Select Straight NobelSpeedy Replace NobelReplace Straight Replace Select Tapered Replace Select Tapered PMC NobelReplace Tapered Groovy NobelReplace Tapered PS
Implant Retrieval Instrument CC 3.0 & TCC NP	Tri-oval conical connection	NP	Nobel Biocare N1™ TCC TiUltra NP
	Conical Connection	3.0	NobelActive
Implant Retrieval Instrument CC RP & Tri-Ch WP & TCC RP	Tri-oval conical connection	RP	Nobel Biocare N1™ TCC TiUltra RP
	Conical Connection	RP	NobelActive NobelReplace CC NobelParallel CC
	Internal Tri-Channel	WP	Replace Select Straight NobelSpeedy Replace NobelReplace Straight Replace Select Tapered Replace Select Tapered PMC NobelReplace Tapered
Implant Rescue Collar Tri-Channel Ø 4.3	Internal Tri-Channel	RP	Replace Select TC Replace Select Straight NobelSpeedy Replace NobelReplace Straight Replace Select Tapered Replace Select Tapered PMC NobelReplace Tapered Groovy NobelReplace Tapered PS

Intended Use/Intended Purpose:

Implant Retrieval Instruments, Implant Rescue Collars:
Intended for use to facilitate the removal of dental implant system components.

Indications:

Implant Retrieval Instruments:
Implant Retrieval Instruments are indicated for use to remove osseointegrated dental implants with damaged connection interfaces or fractured body by engaging the implant inner threads, enabling rotation of the implant so that it can be removed.

Implant Rescue Collars:
Implant Rescue Collars are indicated for use in conjunction with Implant Retrieval Instruments for implants with an Internal Tri-Channel connection, when the connection is collapsed and to prevent expansion of the implant collar when removing the implant.

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, any of its alloying components or chromium (ME-92) coating.

Warnings:

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended from lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to a hemorrhage in the floor of the mouth.

Besides the mandatory precautions for any surgery such as asepsis, during drilling in the jaw bone, one must avoid damage the nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

Do not use the Implant Retrieval Instrument for any purpose other than the removal of Nobel Biocare implants with internal connection, tri-channel connection or external hex connection.

Excessive torque on the Implant Retrieval Instrument may damage or fracture the bone structure.

It is strongly recommended that Implant Retrieval Instruments are used only with Nobel Biocare related implant and surgical instruments as combining components with different dimensions can lead to mechanical and/or instrumental failure or damage the tissue.

Cautions:

General:
It is strongly recommended that the implant retrieval instrumentation is used only with compatible Nobel Biocare implants and surgical instruments. Use of the implant retrieval instrumentation with implants or instruments that are not intended to be used in combination with the implant 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:
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.

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).

Location of vital anatomical structures should be verified with X-ray images before implant retrieval.

Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy. In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

Intended Users and Patient Groups:

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

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

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with Implant Retrieval Instrumentation:
Implant retrieval instruments is 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 Implant 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.

Drilling into the jaw may also lead (in rare cases) to fenestration or fracture of bone, perforation of neighboring structures, sinusitis, or sensory/motor disturbances, depending on the location.

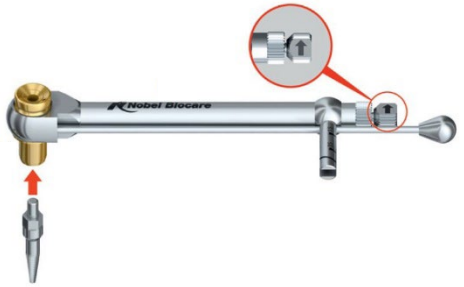
Notice regarding serious incidents:
For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to 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 for Removal of Implant with Implant Retrieval Instrument:

1. Select the appropriate Implant Retrieval Instrument based on implant connection/type and size.
2. Obtain the appropriate Manual Torque Wrench Surgical and connect the Implant Retrieval Instrument to the wrench (**Figure A1**) using a Manual Torque Wrench Adapter (**Figure A2**). Refer to Nobel Biocare IFU1098 for information regarding Manual Torque Wrenches Surgical and Manual Torque Wrench Adapters. This IFU is available for download at ifu.nobelbiocare.com.

Warning: Connect the Implant Retrieval Instrument to Manual Torque wrench adapter and Manual Torque wrench surgical.



Figures A: Connection of Implant Retrieval Instrument to Manual Torque Wrench Surgical using a Manual Torque Wrench Adapter

3. Ensure that the arrow on the wrench is pointing in reverse mode/counter-clockwise.
4. Place the Implant Retrieval Instrument into implant (**Figure B**).

Figure B: Placement of the Implant Retrieval Instrument into the Implant

Note: For removal of implants with internal tri channel connection, where the connection has collapsed, an Implant Rescue Collar and Handle may be used to facilitate implant removal (refer to Nobel Biocare Instructions for Use IFU1090 for detailed information on the Handle For Rescue Collar) (**Figure C**).

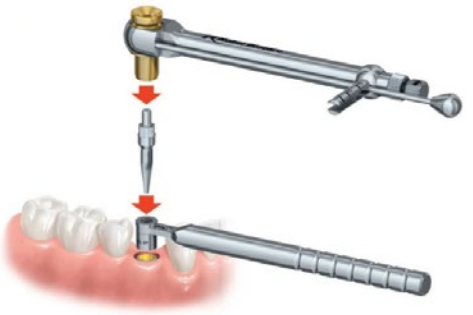


Figure C: Use of Implant Rescue Collar to Remove Implant with Internal Tri-channel Connection

5. Unscrew implant, counter-clockwise, using the Manual Torque Wrench Surgical (**Figure D**).

Figure D: Unscrewing the Implant by Rotating the Manual Torque Wrench Surgical in Counterclockwise Direction

Warning: Excessive torque on the Implant Retrieval Instrument may damage or fracture bone structure.

6. If the implant cannot be removed without applying excessive force, consider using a Trephine Drill (**see below**).

Materials:

- Implant Retrieval Instruments: Stainless steel according to ASTM F899 and DIN EN 10027 and chromium coating ME-92.
- Implant Rescue Collar: Stainless Steel ASTM A582 and ISO 5832-1.

Sterility and Reusability Information:

Implant Retrieval Instruments have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

Warning: Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

Caution: Implant Retrieval Instruments 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.

Implant Rescue Collars 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.

Before each use, inspect the devices for signs of degradation that may limit the useful life of the device, such as the following:

- Inspect for visible corrosion.
- Ensure that laser marking of device is clearly legible.

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

Cleaning and Sterilization Instructions:

Implant Rescue Collars are 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.

Caution: Do not deviate from the described reprocessing instructions

Initial Treatment at Point of Use Prior to Reprocessing:

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes.
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 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 3 presents examples of suitable sterilization containers, pouches, and wraps.

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 (Table 4):

Table 4: 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 (intrafacility transportation or shipping to an external site) into account.

Performance Requirements and Limitations:

To achieve the desired performance, the implant retrieval instrumentation must only be used with the products described in this Instructions for Use. To confirm the compatibility of products which are intended to be used in conjunction with the Implant Retrieval Instruments, 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

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
Implant Retrieval Instrument CC 3.0 31 mm Implant Retrieval Instrument CC NP & Ext Hex WP 22 mm Implant Retrieval Instrument CC RP & Tri-Channel WP 22 mm Implant Retrieval Instrument CC WP 22 mm Implant Retrieval Instrument External Hex & Tri-Channel NP/RP 22 mm Implant Retrieval Instrument External Hex & Tri-Channel NP/RP 31 mm Implant Retrieval Instrument Tri-Channel 6.0 22 mm Implant Retrieval Instrument CC 3.0 & TCC NP Implant Retrieval Instrument CC RP & Tri-Ch WP & TCC RP	73327470000001757E
Implant Rescue Collar Tri-Channel Ø 3.5 Implant Rescue Collar Tri-Channel Ø 4.3	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.

Batch code

Catalogue number

Date


Date of manufacture


Manufacturer

Serial number

Unique Device Identifier

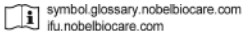

Health care centre or doctor


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