

Implant Retrieval Instrumentation

Instructions for use



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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 IFU1047).
- **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.
- **Trephine Drills** are designed to be used in situations when it is necessary to remove a dental implant from the bone site in the patient's mouth, if the implant cannot be removed with an Implant Retrieval Instrument. They consist of a shaft and a cylindrical drilling head; the shaft is used to attach the drill to a contra-angle used for drilling equipment, and the cylindrical drilling head removes the bone from around the outer diameter of the implant along its length so that it can be removed from the bone site.

Trephine drills are compatible with handpieces with connection interface according to ISO1797.

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 2 summarizes the available Trephine Drills and the implants with which they are compatible. The Trephine Drills are laser marked with the respective diameters.

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
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Table 2: Trephine Drills compatibility

Instrument	Implant diameter
Trephine Drill 3.2/4.0 mm	3.0 mm
Trephine Drill 3.8/4.6 mm	3.3 mm 3.5 mm 3.75 mm
Trephine Drill 4.4/5.2 mm	4.0 mm 4.3 mm
Trephine Drill 5.2/6.2 mm	5.0 mm
Trephine Drill 5.6/6.6 mm	5.5 mm
Trephine Drill 6.2/7.0 mm	6.0 mm

Intended Use:

Implant Retrieval Instruments, Implant Rescue Collars:

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

Trephine Drills:

Intended for use to remove bone surrounding a dental implant or connecting surface.

Indications for use:

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.

Trephine Drills:

Trephine Drills are indicated for use to remove bone from around the outer diameter of an osseointegrated dental implant along its length to facilitate its removal from the bone site.

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 and chromium coating ME-92.

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.

Cautions:

General:

Implant retrieval instrumentation must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with 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. gauze, dental dam, or 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.

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 IFU1047 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 IFU1058 for detailed information on the Handle For Rescue Collar) (Figure C).

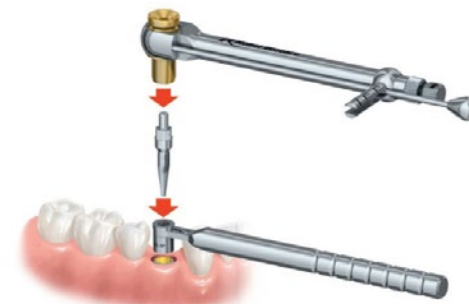


Figure C: Use of Implant Rescue Collar to Remove Implant with Internal Tri-channel Connection

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).

Surgical Procedure for Removal of Implant with Trephine Drill:

1. Select appropriate Trephine Drill based on implant diameter according to depth-marking (see A). The Trephine Drill should be selected on basis of the inner diameter slightly exceeding the outer diameter of the implant. Figure E shows Trephine Drill depth markings.

Note: The depth markings are in true millimeters.

To avoid an oversized osteotomy, ensure that the selected Trephine Drill only slightly exceeds the implant diameter.



Figure E: Depth Markings on Trephine Drills

2. Remove any abutment or prosthetic components from the implant.
3. Place the Trephine Drill over the implant (Figure F).



Figure F: Placement of Trephine Drill Over Implant

- Start the drilling procedure using low speed (60 – 100 rpm) and copious irrigation. When the Trephine Drill grips into the bone, the speed can be increased (1200 – 1500 rpm).

Warning: Do not apply excessive pressure to the trephine drill as breakage can occur.

Note: The Trephine Drill can wear out during use. If the cutting efficiency is poor, the instrument should be replaced.

Caution: Ensure steady handling during use of the Trephine Drill as it may abruptly jump sideways before fully surrounding the implant.

Caution: Copious irrigation is important when using the Trephine Drill to avoid overheating.

Warning: During the drilling procedure, care must be taken to prevent damaging adjacent vital structures due to the increased width of the implant which is being removed.

It is recommended to use the depth markings on the Trephine Drills as reference points in order to ensure that the drill does not progress deeper than planned and risk damage to vital structures.

- Stop drilling before full depth of implant is reached. Wiggle back and forth to remove implant and Trephine Drill.

Note: It may not be possible to immediately place an implant after using a Trephine Drill due to the size of the resulting hole and/or other factors.

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.
- Trephine Drills: Stainless Steel according to ASTM F899.

Sterility and Reusability Information:

Implant Retrieval Instruments and Trephine Drills 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 and Trephine Drills 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:

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

Containment and Transportation/Shipping to Reprocessing Area:

- 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.
- 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.

- 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:

- Immerse the devices in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
- Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
- 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.
- 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.
- 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.
- 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.

- Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
- Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
- 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.
- Run drying cycle at minimum 50°C (122°F) for a minimum of 10 minutes.
- 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:

- Immerse devices for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
- Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
- 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.
- 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.
- 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.
- 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).
- Flush the inner surfaces, lumina and cavities of the device for a minimum of 15 seconds using a water jet pistol.
- Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
- 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.

- 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

- 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)).
- Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
- 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 (intrafacility 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:
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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



symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com

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

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