

Neo Pedicle Screw System™ - Ratcheting devices (Screwdriver and components) Instructions for use and processing (cleaning, disinfection, and sterilization)

PURPOSE

The Neo Pedicle Screw System™ is intended to help provide immobilization, correction and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. In conjunction to the standards instruments provided as single use sterile, Neo Medical provides Ratcheting devices which are intended to ease the surgeon gesture, reduce tiredness of tightening screws, and help keeping the appropriate trajectory when tightening screws. The ratcheting devices include a ratchet screwdriver which is intended for being used with ratchet handles and adaptors for the steps of inserting the pedicle screws. The ratchet screwdriver allows firm connection between the pedicle screws, the screw extender and the screwdriver, avoiding any toggling of the screws.

This instructions leaflet provides information for use of the ratcheting devices (**Section A**) and for their proper processing before first use and after each subsequent use (**Section B**).

DESCRIPTION

The Neo Pedicle Screw System™ is mainly used with single use sterile instruments which are described in the system's instructions for use. The procedure for use is described in the surgical technique. The ratcheting devices are provided by Neo Medical as non-sterile and are intended to be re-used after appropriate cleaning, disinfection, and sterilization procedure.

This Instruction for use applies to the following articles:

REF	Article Number	Description
①	SI-RH-00-HU	Ratchet Handle - Hudson, NS
②	SI-RH-00-14	Ratchet Handle - 1/4", NS
③	SI-AS-00-HU	Screwdriver Adaptor - Hudson, NS
④	SI-AS-00-AO	Screwdriver Adaptor - AO, NS
⑤	SI-AS-00-14	Screwdriver Adaptor - 1/4", NS
⑥	SI-RS-00-14	Ratchet Screwdriver 1/4", NS
⑦	SI-RS-00-HA	Screwdriver Handle, NS
⑧	SI-RS-00-AO	Screwdriver Converter - AO, NS
⑨	SI-RS-00-HU	Screwdriver Converter - Hudson, NS
⑩	SI TH-00-14	T-Handle Ratchet - 1/4", NS (for US ONLY)

Please follow these instructions for preparation of the instruments before surgery and for their reprocessing after surgery (section B of this instruction for use).

NOTA BENE: Neo Medical reusable instruments are manual instruments that are not intended for connection with active medical devices such as power tool. Use provided handles to connect with instruments and operate them.

Neo Medical's products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

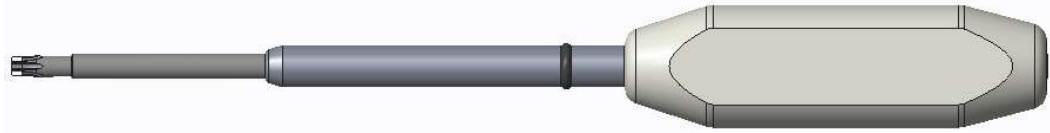
SECTION A – USE OF RATCHETING DEVICES

Two series of devices are provided in order to implement the ratcheting function with the Neo Pedicle Screw System™.

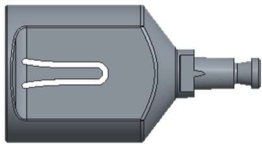
The first series is for use with the **single use screwdriver**.

The corresponding devices are the following:

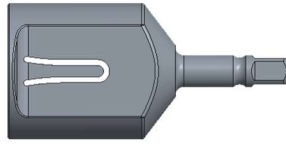
- Single use screwdriver provided in the Pedicle Screw instrument kit



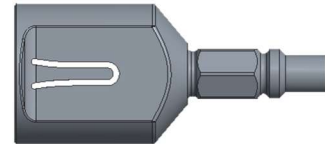
- 3 Screwdriver Adaptors with different connection bit types: Hudson Modified, 1/4", and Big AO



Hudson Modified ③

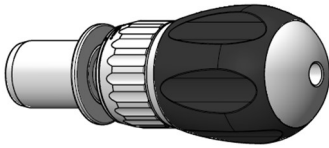


1/4" ⑤

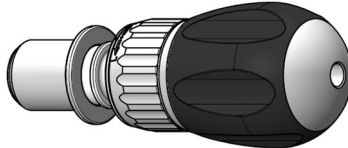


Big AO ④

- 3 Ratchet handles of the corresponding type



Hudson Modified ①



1/4" ②

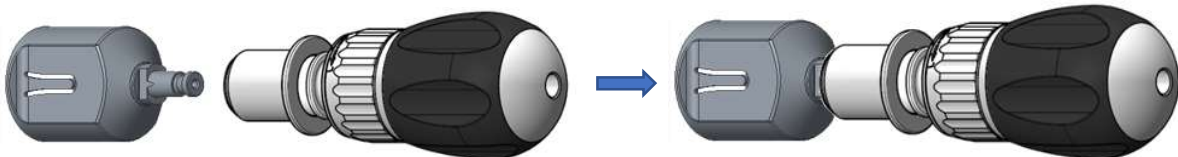


1/4" T-Handle ⑩

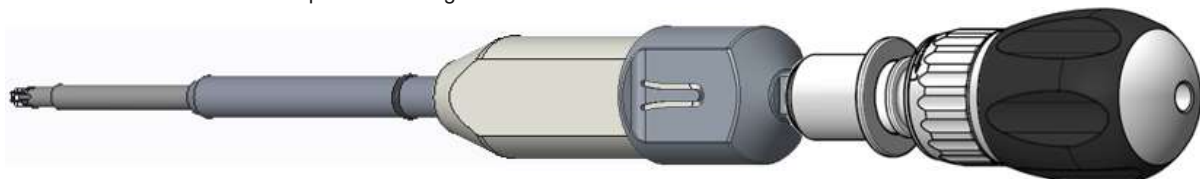
NOTE: The Big AO Adaptor is intended for customers being equipped with the corresponding handle. The handle of this type is not provided

Assembly preferred order:

1. Ratchet handle on the Adaptor



2. Ratchet handle & Adaptor on the single use screwdriver

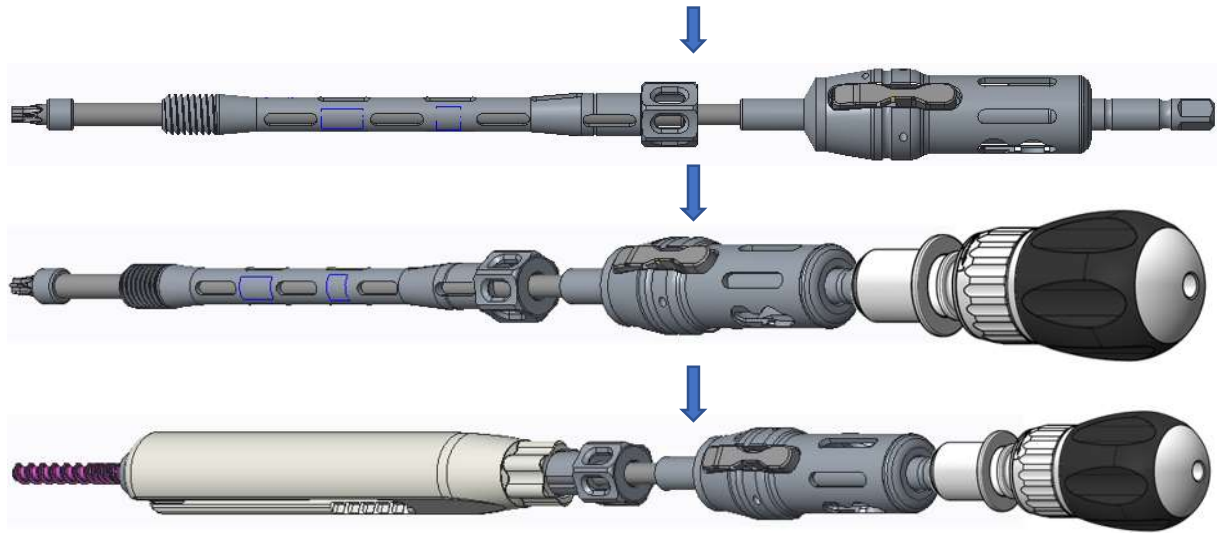
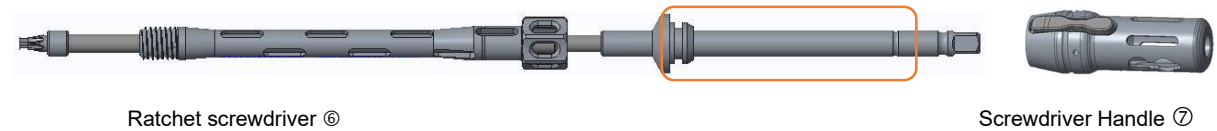


The second series is for use with a **reusable screwdriver** also intended to reduce the toggling effect that may happen with the single use screwdriver.

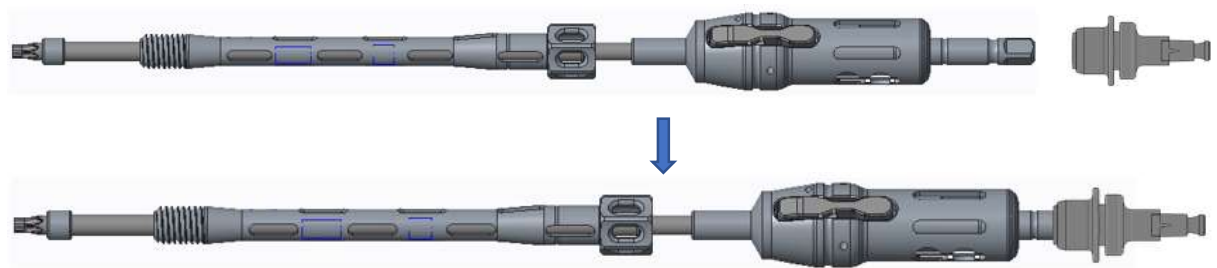
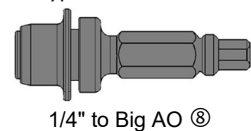
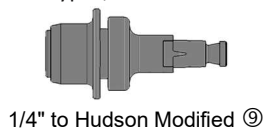
The corresponding devices are the following:


- A ratchet screwdriver, with a 1/4" connection bit, and a rotating handle to precisely maintain the trajectory during tightening, dismantlable for cleaning. Screwdriver that can be connected to a 1/4" ratchet handle.


NOTE: to ensure the best performance it is recommended to lubricate the connection between the ratchet screwdriver and the ratchet handle using approved instrument lubricants (e.g. Hinge Free™ by Steris). Follow the instrument lubricant instructions for use. The area to be lubricated is highlighted below by the orange square.




- 2 Converter types, in order to allow the use of the screwdriver with other types of handles



 **WARNING:** When using a k-wire the minimum length should be of 600 mm.

 **WARNING:** When placing iliac screws, the hole must be tapped to a minimum of 2mm less than the screw size. For example, when placing the 8.0mm iliac screw with the Ratchet Screwdriver, the 7.0mm XL tap shall be used prior to screw insertion.

 **WARNING:** The ratcheting screwdriver shall not be used to place, remove, or adjust any set screws. This could lead to excessive forces on the tip of the screwdriver.

SECTION B – PROCESSING (CLEANING, DISINFECTION, AND STERILIZATION)

FUNDAMENTAL POINTS

All instruments labelled as non-sterile are to be cleaned, disinfected, and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile instruments (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the instruments.

The sterility of the instruments falls under your responsibility. Please ensure that only product specifically validated procedures will be used for cleaning, disinfection, and sterilization, that the used devices (WD, sterilizer) will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Additionally, please pay attention to the legal provisions valid for your Country as well as to the hygienic instructions of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions (not relevant for USA), which can require the application of cleaning detergents with proven prion efficiency as well as a sterilization with more intensive parameters.

Caution: Non-sterile instruments are provided in a protective packaging designed for maintaining the integrity and cleanliness of the product. However, in no case the product shall be sterilized within this packaging but needs to be removed from the package and be treated as follows.

CLEANING AND DISINFECTION

Basics

If possible, an automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered¹.

The pre-treatment step is to be performed in both cases.

Please ensure already during use that you collect contaminated instruments separately and do not place them back in the instrument tray to avoid greater contamination of the loaded instrument tray.

¹ In case of application of a manual cleaning and disinfection procedure a product and procedure specific development and validation of the specific manual procedure under sole responsibility of the user is required.

Pre-treatment

Please remove coarse impurities of the instruments directly after application (within a maximum of 2 h).

- Procedure:
1. Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F).
 2. Soak the instruments for the given soaking time in the pre-cleaning solution², e.g. 0.5-2% neodisher® Mediclean forte for 10-30 min (with activated ultrasound) so that the instruments are completely covered. Pay attention that there is no contact between the instruments.
 3. Then, remove the instruments of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water (temperature <35°C/95 °F).



Ratcheting devices are cannulated, make sure the hole is cleaned and no impurities remain before proceeding with the automated cleaning. To obtain a clean cannula use a K-Wire or a soft brush to wipe the hole and then proceed with a water jet to flush the hole.

Pay attention to following points during selection of the cleaning detergent²:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- compatibility of the cleaning detergent with the instruments (see chapter „material resistance,“)

Pay attention to the instructions of the detergent manufacturer regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

² In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel's safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material, and be compatible with the instruments (see chapter „material resistance,“). Please consider, that a disinfectant used in the pre-treatment step serves only the personnel's safety, but cannot replace the disinfection step later to be performed after cleaning.

Automated cleaning/disinfection (WD (Washer-Disinfector))

Pay attention to following points during selection of the WD:

- WD according to EN ISO/ANSI AAMI ST15883 and with fundamentally approved efficiency (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- if possible selection of an approved program for thermal disinfection (A_0 value ≥ 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments
- program with a sufficient number of rinsing steps (at least three degrading steps after cleaning (respectively neutralization, if applied) or conductance based rinsing control recommended in order to prevent effectively remnants of the detergents)
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
- regularly maintenance and check/calibration of the WD

Pay attention to following points during selection of the cleaning detergent:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible to the used cleaning detergent
- compatibility of the used detergents with the instruments (see chapter „material resistance,“)

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

- Procedure:
1. Transfer the instruments in the WD (pay attention, that the instruments are located with the big opening downwards and that instruments have no contact).
 2. Start the program, e.g.:
 - pre-rinse 1 min with cold water <40°C
 - wash at 55°C with 0.5% neodisher® Mediclean forte for 10 min
 - rinse for 1 min with cold water <40°C
 - rinse for 2 min with deionized water <40°C
 - thermal disinfection for 5 min at >90°C with deionized water
 - drying for 30 min at 100°C
 3. Remove the instruments of the WD after end of the program.
 4. Check and pack the instruments immediately after the removal (see chapters „check,“, „maintenance,“, and “packaging,“, if necessary after additional post-drying at a clean place).

The fundamental suitability of the instruments for an effective automated cleaning and disinfection was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of an ultrasonic bath of the SONOREX series with 35 kHz (BANDELIN electronic, Berlin) for pre-cleaning, the WD PG 8535, Miele & Cie. GmbH & Co., Gütersloh (thermal disinfection) and the pre-cleaning and cleaning detergent neodisher® Mediclean forte (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.

Check

Check all instruments after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, still readable marking and impurities. Do not further use damaged instruments (for limitation of the numbers of re-use cycles see chapter „reusability,“). Still dirty instruments are to be cleaned and disinfected again.

Maintenance

Use of instrument lubricant is allowed for the junction between the ratchet screwdriver and the handle as shown in Section A.

Packaging

Please insert the cleaned and disinfected instruments in a standard sterilization tray and pack them in sterilization containers, which fulfil the following requirements (material/process):

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F), sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage
- regular maintenance according to the instructions of the manufacturer (sterilization container)

A maximum weight of 8 kg per content of the sterilization tray must not be exceeded.

Sterilization

Please use for sterilization only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization

- fractionated vacuum/dynamic air removal procedure^{3,4} (with sufficient product drying⁵)
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 137°C (278,6 °F; plus tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature):

Area	fractionated vacuum/dynamic air removal	gravity displacement
USA	4 min at 132 °C (270 °F), drying time at least 20 min ⁵	not recommended
Germany	5 min ⁶ at 134 °C (273 °F), drying time at least 20 min ⁵	not recommended
other countries	at least 4 min ⁶ at 132 °C (270 °F) / 134 °C (273 °F), drying time at least 20 min ⁵	not recommended

³ at least three vacuum steps

⁴ The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure, requires significantly longer sterilization times as well as a sterilizer, procedure, parameter, and product specific process development and validation under sole responsibility of the user.

⁵ The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

⁶ respectively 18 min (inactivation of prions, not relevant for USA)

The fundamental suitability of the instruments for an effective steam sterilization was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the steam sterilizer Tuttnauer EHS 3870 and the fractionated vacuum/dynamic air removal procedure. For this, typical conditions in clinic as well as the specified procedure were considered.

The flash/immediate use sterilization procedure must not be used.

Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

Storage

Please store the instruments after sterilization in the sterilization packaging at a dry and dust-free place.

NOTE: upon customer requests Neo Medical can provide a transport tray where to keep the ratchet screwdriver components. Do not use the tray for sterilization of ratcheting devices.

Material resistance

Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:

- organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- strong lyes (maximum admitted pH-value 11, neutral/enzymatic, weak alkaline, or alkaline cleaner recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments.

Acid neutralizing agents or rinse aids must not be applied.

Please do not clean any instruments by use of metal brushes or steel wool.

Please do not expose any instruments to temperatures higher than 142 °C (288 °F)!

Reusability

Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on Neo Medical reusable surgical instruments.

End of life of a reusable surgical instrument is normally determined by wear and damage due to use. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, deformation/twist of the screwdriver tip, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used and must be absolutely replaced by a new one. The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

NOTA BENE: Ratchet handles can be reused up to 250 times, provided they are undamaged and uncontaminated. Products marked with a UDI code (machine-readable) can be reprocessed a maximum of 200 times. Any further use or use of damaged and/or contaminated instruments beyond this is the responsibility of the user. Any liability is excluded in the event of non-compliance.

ADDITIONAL INFORMATION

It remains the responsibility of the processor to ensure that the processing is actually performed, using equipment, materials and personnel in the Central Sterile Supply Department (CSSD), and achieves the desired result. This requires verification/validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.

All users shall be qualified personnel with documented expertise, competency and training. Users shall be trained on hospital policies and procedures along with current applicable guidelines and standards.

Users shall wear appropriate personal protective equipment (PPE) when processing devices in accordance with the Department of Environmental and Occupational Health and Safety's (OSHA) bloodborne pathogen guidelines.

PRODUCT COMPLAINTS

Any health care professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the official distributor of NEO MEDICAL S.A. and, where applicable, the local competent authority. Further, if any of the implanted spinal system component(s) ever “malfunctions” (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any NEO MEDICAL S.A. product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX, or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the distributor is requested.

Before return of products which were used in hospital environment, perform a complete processing according to these instructions. Confirmation of processing including parameters used shall be provided in the delivery note.

FURTHER INFORMATION

For further information refer also to the Neo Pedicle Screw System™ Instruction for Use. Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact NEO MEDICAL S.A.

Please ensure that any waste that is generated from reprocessing of reusable instruments is disposed according to local laws and regulations.

EXPLANATION OF SYMBOLS



Manufacturer



Catalogue number



Batch Code



Date of manufacture



Consult the Instructions for use



Caution / Warning



Non-sterile



Do not re-use



Medical Device



Unique Device Identification



Temperature limit



Keep dry



Do not use if package is damaged



CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a licensed practitioner



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