Instructions for use
-
Intramedullary Reamer Next Gen. Nail

Contents

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1. Introduction

This document provides instructions for use and reprocessing for users of the Next Gen. Nail Intramedullary Reamers marketed under the name of the manufacturer.

It contains the instructions for use of the instruments and also instructions for cleaning, inspection, sterilisation and storage.

The cleaning and sterilisation procedures described in this manual have been validated by the manufacturer. Other reprocessing methods may be suitable, but they must be validated beforehand by the end user and remain the responsibility of the latter. Moreover the end user must comply with the laws and regulations in countries with stricter reprocessing requirements than those specified in this manual.

2. Overview

a. Description and composition

Next Gen. Nail Intramedullary Reamers, including the entry reamer, are reusable instruments designed to shap the medullary canal of long bones during traumatology or orthopaedic surgery.
They are composed of stainless steel and Nitinol.

The principal action is obtained by cutting edges with front cutting, their shape enabling debris to be rolled-up.
The flexibility of the shaft allows the respect of natural bones curvature.

The specific shape of the reamer head may allow the surgeon to constrain the reaming with K-wire set along the patient's extremity.

b. Intended use

The instruments described in this manual are used to drill the epiphysis cortex and to enlarge the medullary cavity of long bones (femur, humerus and tibia) via a surgical motor providing rotational power.

They are used on adult patient during orthopaedic and traumatology surgery.

The instruments have been validated for 75 cycles of use, including the required reprocessing (cleaning and sterilisation), without encountering any functional problem. Any further use is the responsibility of the user. The use of the instrument is not limited by the number of validation cycles, but must only be reused if inspection after reprocessing shows the absence of signs of wear or damage such as described in chapter 5.c.

They must only be used by qualified personnel fully trained in their use and in the appropriate surgical procedures in an operating theatre

c. Contra-indications

Next Gen. Nail Intramedullary Reamers are not intended for use on children under 8 years old because reaming the growth plate impairs bone growth. The use of intramedullary reamers in pregnant women is also forbidden because of the contra-indication to anaesthesia in this patient population.

Next Gen. Nail Intramedullary Reamers are not intended for use in maintenance operations such as for sharpening cutting edges.

d. Performance characteristics

The cutting diameter of the entry reamer is 12.5mm and a length of 301mm. The cutting diameter of the intramedullary reamers is from 8 to 16mm and a length of 570mm. They will withstand a maximum axial load of 100N and 6Nm.

3. Warnings and precautions for use

a. Prerequisites before use

A full cycle of reprocessing consisting of cleaning, inspection and sterilisation must be performed before each use and this applies to new instruments as well. The use of non-reprocessed instruments can damage the patient's health by causing infection.

An inspection must be performed before each use. Any instrument showing signs of wear or damage must under no circumstances be used and must be replaced by a new instrument. In particular, if scratches or cracks are visible on the titanium-nickel alloy (Nitinol) tube, the instrument must not be used under any circumstances and must be absolutely replaced by a new one. Tests show that these defects cause the bursting of the tube during the use. This could occurs in the medullary cavity of the patient with the risk of not removing all fragments.

Before using the Next Gen. Nail intramedullary reamers, the connections between the various parts, including that with the surgical motor, must be duly checked. If the coupling between the parts breaks during surgery, the duration of the procedure will be extended.

The coupling system between the reamer head and the flexible drive shaft for the modular version is specific to MPS Precimed's Next Gen. Nail and is not compatible with other modular systems. Therefore, it is strictly prohibited to use a competitor's flexible drive shaft with an MPS Precimed's Next Gen. Nail reaming head, and vice versa. The assembly instructions of the Next Gen. Nail Intramedullary Reamer head with the flexible drive shaft is available in chapter 4.
Similarly, the guide wire required to use the products is specific to MPS Precimed's Next Gen. Nail intramedullary reamers. It is not permitted to use a competitor's guide and vice versa.

b. Precautions for use

Avoid contact between instruments and any other equipment or tools present, specifically within the location around the open wound during use. This situation could lead to the creation of metal particles entering the surgical cavity due to friction and shock.

It is recommended to start the power tool gradually before applying axial force. This allows early detection and reaction in case of interference and reduce the risk of applying an excessive torque and/or an abrupt stoppage of the instrument, which can cause a fracture of the Nitinol shaft and its fragmentation. In case of resistance, do not force the instrument, but reverse the drive direction and remove it from the medullary cavity.

During the use, it is recommended to stop the surgical motor as soon as bone debris appear for taking them out and avoiding accumulation.

The use of personal protective equipment is strongly recommended during the handling of contaminated or potentially contaminated instruments.
Careful handling of the Next Gen. Nail intramedullary reamers is recommended to

avoid the risk of injury and tearing of surgical gloves on the cutting edges.

c. Environment for use

The products covered by this manual are intended for use in operating theatres in sterile areas, in the human body including contact with vital fluids such as blood.

During the entire life cycle of the product, the maximum permissible temperature for instruments is 137°C, beyond which they may deteriorate. In addition, strongly alkaline solutions (pH > 11) and hypochlorite solutions should be avoided because they promote corrosion of metallic parts.

d. Reprocessing precautions

During cleaning processes, the use of personal protective equipment is strongly recommended because contact with instruments soiled with human blood may cause infection and contamination of staff.

It is strictly prohibited to use metal brushes for cleaning, they cause premature wear of the instrument.

Intramedullary reamers are complex instruments, with long narrow tubes and blind holes which require special attention during cleaning.

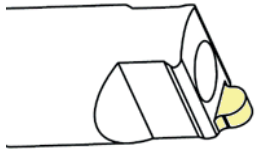
The cleaning process of the Next Gen. Nail intramedullary reamers must be started as soon as possible after use, soiled instruments which have dried are more difficult to clean.

As far as possible, any abrupt contact with the cutting parts of the Next Gen. Nail intramedullary reamers must be avoided because there is a risk of injury and tearing of surgical gloves.

4. Instructions for use

Before use, consult the precautions for use described in chapter 3.b.

The good condition of the next Gen. Nail intramedullary reamer must be checked before use.
The flexible drive shaft has a finger when pointing downwards will avoid the reamer head to fall down on the floor. The reamer head could be positioned in both side on the flexible drive shaft.



All instruments should be used with a guide of appropriate diameter inside the medullary cavity to guide the reamer and to lock the reaming head onto the flexible drive shaft for the modular version. The recommended guide diameter is 3mm.

The surgical power tool will be connected to the proximal end of the intramedullary reamer by a Stryker / Zimmer-Hall coupling in a sterile area of the operating theatre.

The flexible drive shaft may be extended with the dedicated Reamer Extender from the implant's manufacturer. The Reamer Extender is first linked to the coupling and the retaining rod is then screwed.

The reaming procedure shall be performed in compliance with current surgical techniques. Before reaming ensure that the bone is sufficiently accessible.

The epiphysis cortex is opened in with the entry reamer aiming to have the entry portal.

The medullary cavity is initially reamed with the smallest diameter and then the diameter is increased in 0.5 mm steps up to the desired size.

The reamer head must be completely introduced in the canal before placed in action to avoid an excessive reaming of the anterior cortex.

During the surgical procedure, check frequently the guide wire's position using a image intensifier to prevent the guide wire from advancing and penetrating unintentionally into the neighbouring tissues. Check also the advance of the reamer head with the image intensifier.

5. Reprocessing

Before reprocessing, consult the reprocessing precautions described in chapter 3.d.

a. Reprocessing at the point of use

It is recommended to remove excess soil with lint-free disposable wipes as promptly as possible after the end of the procedure.

Transport the instruments wrapped in damp paper between the various sites of use and/or reprocessing, avoiding shocks and mechanical damage.

b. Cleaning

The instruments must be cleaned using one of the two techniques described below. It is recommended to start cleaning as soon as possible to prevent any soil drying on the instrument.

Only agents, solutions and detergents of proven efficacy must be used. The agents, solutions and detergents listed below are those used by the manufacturer during the validation of these instructions. The use of other products may lead to incomplete cleaning or premature wear of the instrument.

- Manual cleaning

Equipment and consumables:

- Enzyme solution Alkazyme®
- Alkaline detergent Neodisher® MediClean Forte
- Osmosed water or water of equivalent chemical and microbiological quality
- Soft nylon bristle brush
- Disposable towels
- Ultrasonic bath

Method:

1) Rinse and brush the instrument for at least 90 seconds, by insisting for 30 seconds on the inside of each cannulation side (see details in appendix), to remove excess soil while completely immersed in a bath of osmosed water or water of equivalent chemical and microbiological quality at ambient temperature (15 to 25°C).
2) Completely immerse the instrument in the Alkazyme® 1% v/v enzyme solution (prepared according to the manufacturer's instructions) for 18 minutes at ambient temperature (15 to 25°C, ideally 20°C).
3) Brush Brush all surfaces, including inside of each cannulation (see details in appendix), with a soft nylon bristle brush for at least 90 seconds until all visible soil is eliminated. Ensure that the grooves and holes are thoroughly cleaned.
4) Remove the instrument from the solution.
5) Rinse the instrument under running water at ambient temperature (15 to 25°C) for at least 3 minutes.
6) Perform ultrasonic cleaning of the instrument completely immersed in MediClean 1% v/v detergent (prepared according to the manufacturer's instructions) for 18 minutes at a maximum temperature of 40°C.
7) Rinse the instrument with osmosed water at ambient temperature (15 to 25°C) for at least 3 minutes by first pouring into the cannulation 3 volumes of 50 mL running water each. Check that the water enters the grooves and that the blind holes are filled and emptied several times.
8) Carefully dry the instrument with disposable towels.
9) Visually inspect the instrument in a well-lit room to confirm that there is no remaining soil.
10) Repeat steps 1 to 9 described above if any visible soil persists.

- Automated cleaning

Equipment and consumables:

- Enzyme solution Alkazyme®
- Alkaline detergent Neodisher® MediClean Forte
- Osmosed water and purified water or water of equivalent chemical and microbiological quality
- Soft nylon bristle brush
- Ultrasonic bath
- Washer-disinfector validated and maintained in compliance with current local procedures

Method:

1) Rise and brush the instrument for at least 30 seconds to remove excess soil while completely immersed in a bath of osmosed water or water of equivalent chemical and microbiological quality at ambient temperature (15 to 25°C).
2) Perform ultrasonic cleaning of the instrument completely immersed in the

Alkazyme® 0.5% v/v enzyme solution (prepared according to the manufacturer's instructions) for 15 minutes at ambient temperature (15 to 25°C).

3) Brush all surfaces with a soft nylon bristle brush for at least 30 seconds in the solution until all visible soil is eliminated. Ensure that the grooves and holes are thoroughly cleaned.
4) Rinse the instrument carefully with purified water at ambient temperature (15 to 25°C) for at least 1 minute.
5) Load the instrument into the washer-disinfector, placing it in a position to ensure drainage of the grooves and holes.
6) Run the washer-disinfector for one 10-minute cycle at a temperature of 55°C with MediClean 0.5% v/v detergent (prepared according to the manufacturer's instructions).
7) When unloading, visually inspect the grooves, the holes and other difficult to access zones of the instrument in a well-lit room to check that all visible soil has been eliminated. If necessary, repeat the cycle and/or clean manually.
8) In addition, check that the instrument is completely dry. If necessary, use disposable towels to remove any possible traces of water.

c. Inspection

Visually inspect the instruments in a well-lit room to detect any sign of corrosion, damage and wear. The cutting edges must be uniform and free from nicks.

Remove any damaged or blunt instruments, cleaning them of all biological substances and place them for disposal in compliance with current laws and regulations.

d. Sterilisation

- Packaging

The instruments must be double-wrapped individually in a medical quality sterilisation pouch. Ensure that the size of the packaging is sufficient so that the wrapped instrument does not strain the seams or tear the pouch. Also ensure as far as possible that the instruments do not collide with each other.

- Cycles

The instruments must be moist heat sterilised in an autoclave with an active air removal cycle (ISO 17665-1). The autoclave must be validated, maintained and calibrated in compliance with current local procedures.
The following cycles have been validated to ensure a sterility assurance level (SAL) of 10^{-6}:

Type of cycle	*Active air removal*		
Temperature	132°C	134°C	134°C
Exposure time (minimum)	4 min.	3 min.	18 min.*
Drying time (minimum)	30 min.	30 min.	30 min.

*Steam sterilisation parameters recommended by the World Health Organisation (WHO) for instruments subject to risk of TSE/CJD (transmissible spongiform encephalopathy and Creutzfeldt-Jakob disease) contamination.

6. Storage and disposal

Instruments at the end of their life must be stored protected from dust, moulds, insects and pests avoiding extremes of temperatures and humidity.

When the inspection step (cf. chapter 5.c) designates an instrument as unsuitable for use, it must be cleaned of all biological substances and placed for disposal in compliance with current laws and regulations.

A shelf-life for sterilised instruments must be defined by each healthcare centre.

7. Definition of symbols

SYMBOLE	DESCRIPTION
	Manufacturer
	Consult the instructions for use
NON STERILE	Non sterile
LOT	Lot code
REF	Catalogue reference
UDI	Unique device identifier
QTY	Quantity
MD	Medical Device

8. Appendix

Details for brushing