Non-sterile instruments for eXpress®

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en Surgical instruments for orthopaedic use.

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Manufactured for:
Extremity Medical, LLC.
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en These instruments are designed to be used in surgical procedures in association with eXpress® staples. For more specific instructions, please refer to the instructions for use dedicated to eXpress® staples.

PRESENTATION
Non-sterile instrument is delivered in plastic bag or directly in a tray adapted for steam sterilisation.

COMPOSITION
Stainless steel | Titanium alloy

TARGET GROUP(S)
Target population
Adult patients.
Intended user
For surgery: orthopaedic surgeons
For cleaning and sterilization: Sterilization officer
CAUTION: American federal laws require this device to be supplied by a physician or in accordance with a medical practitioner's prescription.

INDICATIONS FOR USE
Surgical instruments are indicated:
• to prepare the bone site for the insertion of the implant.
• to hold the bone fragments and instruments and to guide the instruments.
• to insert the implant in the bone site.

CONTRA-INDICATIONS
• Hypersensitivity to one or more components.

DIRECTIONS FOR USE
WARNING: The instrument is supplied non-sterile and must be sterilised before first use and between uses (for reusable device) to avoid cross-contamination. Read and apply the paragraph "Sterilization and reprocessing instructions".
• Before each use, all the instruments of the set should be removed then visually checked to ensure that they are in perfect technical condition.
- Check **drilling and cutting instruments** for the following indications to avoid any risk of injury to the patient and the user:
  - blunt (rounded) blades and notches
  - damage to the shank,
  - bent or "out of true" instruments,
- Check that the instruments are working properly, including the moving parts.
- Check the legibility of the various markings on the instrument to avoid loss of device traceability (absence of corrosion, etc.),
- Check that the instrument cavities are clean before, during and after the procedure to ensure that no bone debris accumulates and so reduce any risk of obstruction.

• If an instrument is dull, damaged, corroded or its markings are no longer legible, do not use it and return it to Extremity for replacement.
• At the beginning of the procedure check the interface between instruments designed to be connected together.
• Insert rotary instruments in the hand piece to the stop position or in the motor (using an adaptor if necessary) and check that the components are correctly connected.
• During the use of rotating instruments, ensure sufficient cooling, otherwise this leads to clogging of the blades which results in increased heat generation and may cause irreversible damage to the bone (thermal necrosis) and the life of the instruments will be reduced.
• During use, take care to prevent the instruments from becoming bent, jammed or levered.
CAUTION: In the case of breakage during use, it is at the practitioner's discretion to take appropriate measures depending on the clinical situation
CAUTION: Do not use the surgical instruments provided for eXpress® staples with other instruments or implants from other manufacturers.

WARNINGS AND PRECAUTIONS FOR USE
• Not authorized for work on metal. Do not allow the instrument to come in conflict during use, as this might cause nicks in the blades.
• Do not exert excessive contact pressure and avoid prying on the instrument during operation as this may lead to damage to the functional part of the instruments as well as to blade breakage.

SIDE EFFECTS
No known side effects.

Please report any serious incident that occurred in relation to the device to Novastep (regulatory-IntFA@enovis.com) and to the local competent authority for medical devices.

DISPOSAL
CAUTION: The disposal of sharp or cutting instruments must be carried out with the utmost care to prevent all risks of physical harm to users.
The blunt or damaged devices should be handled carefully and should be disposed of according to hospital protocol.

STERILIZATION AND REPROCESSING INSTRUCTIONS

The information provided relates exclusively to reusable instruments or unused instruments.

Warnings
• Sterilise the instrument before the first use and between each use to avoid cross contamination.

Limitations processing
- *Reusable device*: visual check to ensure that instruments are in perfect technical conditions.

Initial treatment at the point of use
• Before steam sterilisation, place the instrument in the sterilisation tray.

CLEANING PROCEDURE
In accordance with AAMI TIR12, ANSI/AAMI ST98, , ANSI/AAMI ST81 and ISO 17664 the following cleaning procedures have been validated:

Manual cleaning
NOTICE: Due to its significantly lower efficiency and reproducibility, it is preferable to use automatic cleaning rather than manual cleaning

Equipment required: Enzymatic solution (neutral pH)

For a cannulated device: using the cleaning pin (provided with the device), remove gross soil from the device lumen by inserting the wire and moving it back and forth a minimum of 3 times.
1) Rinse soiled device under running, cold tap water (target temperature 71.6°F and 109.4°F) for a minimum of 1min. During rinsing, remove gross soil from the outer surfaces using a soft-bristled brush or clean, soft, lint-free cloth.
For a cannulated device: Using a syringe, pipette, or water jet, flush the hole with a minimum of 10ml of water.
2) Prepare an enzymatic solution (neutral pH) following the detergent manufacturer's instructions (target temperature between 91.4°F and 96.8°F).).
3) Immerse the device completely in the enzymatic solution for at least 5min.
4) Manually clean the device for at least 1min in the freshly prepared enzymatic solution. Use a soft-bristled brush to remove soil and debris from the outer surfaces of the device.
For a cannulated device: Using a syringe, pipette or water jet, flush the lumen with a minimum of 10ml of solution.
5) Prepare an enzymatic solution (neutral pH) following the detergent manufacturer's instructions (target temperature between 91.4°F and 96.8°F).
6) Immerse the device in an ultrasonic bath filled with fresh enzyme solution and vibrate it for at least 10min.
7) Flush the device with clean water for at least 1min. Use only purified water (target temperature 71.6°F and 109.4°F) with low germ contamination (<100 CFU/ml).
For a cannulated device: Using a syringe, pipette or water jet, flush the lumen with a minimum of 10ml of water.

Automated cleaning
Equipment required: Enzymatic solution (neutral pH)

❖ *Perform a manual pre-wash before automated cleaning procedure as follows:*

For a cannulated device: using the cleaning pin (provided with the device), remove gross soil from the device lumen by inserting the wire and moving it back and forth a minimum of 3 times.
1) Rinse device under running, cold tap water (target temperature between 71.6°F and 109.4°F) for a minimum of 1min. During rinsing, remove gross soil from the outer surfaces using a soft-bristled brush or clean, soft, lint-free cloth.
For a cannulated device: Using a syringe, pipette, or water jet, flush the lumen with a minimum of 10ml of water.
2) Prepare an enzymatic solution (neutral pH) following the detergent manufacturer's instructions (target temperature between 91.4°F and 96.8°F).
3) Immerse the device completely in the enzymatic solution for at least 5min.
4) Manually clean the device for at least 1min in the freshly prepared enzymatic solution. Use a soft-bristled brush to remove soil and debris from the outer surfaces of the device.
For a cannulated device: Using a syringe, pipette or water jet, flush the lumen with a minimum of 10ml of solution.
5) Prepare an enzymatic solution (neutral pH) following the detergent manufacturer's instructions (target temperature between 91.4°F and 96.8°F).
6) Immerse the device in an ultrasonic bath filled with fresh enzyme solution and vibrate it for at least 10min.
7) Rinse device under cold running tap water for a minimum of 1min (target temperature between 71.6°F and 109.4°F).
For a cannulated device: Use a syringe, pipette, or water jet to flush the lumen. Remove residual water from the lumen using filtered compressed air or a syringe.

❖ *Perform an automated cleaning procedure as follow:*

Process the devices using a standard washing cycle in a washer-disinfector compliant with EN ISO 15883-1 and EN ISO 15883-2 or equivalent national standards.
For the cannulated device: Ensure that devices and the lumens can drip freely.

Cycle	Time (min)	Temperature (°F)	Type of detergent
Prewash	2	Cold	Tap water
Enzyme wash	4	≥131	Enzymatic detergent
Wash	2	≥131	Neutral Detergent
Rinse	2	≥122	Purified water (<100 CFU/ml)
Dry	15	≥208.4	NA

INSPECTION AND MAINTENANCE
Visually check the device, including the device lumen in a well-lit area; it should be clean, dry and free of residue.

Check that the devices have not suffered any damage such as corrosion, scratches, other mechanical wear or has markings that are no longer legible.
Dispose of devices if this is the case (refer to §Disposal).

PACKAGING

Store the cleaned and dried instruments in the dedicated tray. Also use a sterilization wrapper (single or double wrapper) or a suitable reusable rigid sterilization container system, such as a sterile barrier system complying with ISO 11607 and packaging techniques such as those described in ANSI/AAMI ST79.

STERILISATION PROCEDURE

Use a moist heat process validated according to ISO 17665, ISO 17664 and AAMI TIR12:

• Equipment required: Pre-vacuumed autoclave

Sterilisation cycle	Exposure temperature (°F)	Exposure time (min)	Drying time (min)
Cycle 1*	269.6	4	20

**Use an FDA cleared wrap for sterilization*

• Equipment required: Gravity autoclave

Sterilisation cycle	Exposure temperature (°F)	Exposure time (min)	Drying time (min)
Cycle 2*	269.6	15	20

**Use an FDA cleared wrap for sterilization*

STORAGE

After sterilisation, the instruments should be stored in such a way as to maintain their sterile condition, in accordance with the procedures defined by the health facilities.

SYMBOLS GLOSSARY

ISO 15223-1:2021: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

	5.1.1	Manufacturer
	5.4.3	See instructions for use
	5.2.7	Non-sterile
	5.7.7	Medical device
	/	Use in accordance with a medical prescription only