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en Osteosynthesis compressive staple

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Manufactured for:
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en PRESENTATION

Each (double-wrapped) pack contains a ready-to-use sterile implant with foam holder.
Gamma sterilisation.

COMPOSITION

NiTinol alloy | ASTM-F2063.

TARGET GROUP(S)

Target population
Adult patients.
Intended user
Orthopaedic surgeons
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

eXpress® compressive staples are indicated for Hand and foot bone fragments osteotomy fixation and joint arthrodesis.

CONTRA-INDICATIONS

- Severe muscular, neurological or vascular deficiency in the extremity concerned.
- Bone destruction or poor bone quality, likely to impair implant stability.
- Hypersensitivity to NiTinol.

DIRECTIONS FOR USE

CAUTION: It is at the discretion of the practitioner to choose the product according to the patient's clinical condition and current chirurgical practices.
CAUTION: the implant is supplied sterile and must be used in a sterile environment only to avoid contamination risk.
- Select the appropriate device for the indication.
- Before use, check the condition of the packaging. If the packaging is damaged, do not use the staple and dispose of it according to the disposal section.
- Implant the device using conventional technique.

CAUTION: eXpress® is only compatible with the surgical instruments supplied by eXtremity Medical and manufactured by Novastep, do not use other instruments from other manufacturers.

Removal procedure
In case of complications and at the discretion of the surgeon, the implant can be removed using conventional removal techniques.

WARNINGS AND PRECAUTIONS

Precautions for use
- The presence of this implant within the MR image field of view may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact. The patient should be instructed to systematically declare if he has undergone a surgical procedure.

Warnings
- The device is not designed to withstand an immediate load after surgery and does not allow for immediate resumption of the patient's activities. If necessary, immobilise during osteosynthesis.
- Device is intended for single use, do not reuse the device to avoid cross contamination.
- Do not re-sterilize the device.

SIDE EFFECTS

- Pseudoarthrosis or non-union.
- Pain.
- Hypersensitivity to one of the components of eXpress®.

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.

STORAGE CONDITIONS

Store in a dry place at ambient temperature.

DISPOSAL

The explanted osteosynthesis compressive staple is in direct contact with biological tissue and should be disposed of in a biohazardous waste bin according to hospital protocol.

There are no recommendations for the disposal of packaging or an unused staple. Refer to the applicable laws for product recycling.

MRI SAFETY INFORMATION

MR Conditional	
Non-clinical testing has demonstrated that the device is MR Conditional. A patient with these devices can be safely scanned in an MRI system meeting the following conditions. Failure to follow these conditions may result in injury.	
Static magnetic field strength	1.5T, 3T
Maximum spatial field gradient	1.5T: 68.64 T/m (6864 G/cm) 3T: 34.33 T/m (3433 G/cm)
Maximum Whole Body SAR	Whole body SAR ≤ 2 W/kg
Scan Duration and Wait Time	Maximum of 1 hour of continuous scanning is allowed without a cooling period. Then, wait 15 minutes before resuming scanning. Autoscan Mode is considered continuous scanning. Short pauses between scan sequences are considered part of the scan time.
MR Image Artifact	The presence of this implant within the MR image field of view may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.
Patient characteristics	It is recommended that patients undergoing MRI scans be carefully monitored for any sensation of pain/or heat.

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
	5.1.4	Use-by date
LOT	5.1.5	Batch code
REF	5.1.6	Catalogue number
	5.4.3	Consult instructions for use
	5.2.8	Do not use if packaging is damaged and consult instructions for use
	5.4.2	Do not re-use
	5.2.6	Do not resterilize
	5.3.4	Keep dry
MD	5.7.7	Medical device
STERILE R	5.2.4	Sterilized using irradiation
	5.2.13	Single sterile barrier system with protective packaging inside
Rx Only	/	Use in accordance with a medical prescription only