JAWS™ Nitinol Staple System

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION

A FULL SYMBOLS GLOSSARY CAN BE FOUND AT: www.paragon28.com/resources

Please check the website, www.paragon28.com/ifus, for the most current instructions for use document.

This booklet is designed to assist in using the JAWS Staple System. It is not a reference for surgical techniques.

GENERAL DESCRIPTION

The JAWS™ Nitinol Staple System consists of a series of nickel titanium alloy staple implants and the instruments necessary for the treatment of pathologies of the foot. The JAWS™ bone staples are made from superelastic nitinol that does not require cold storage or heating. Implant sizes range from 8mm to 25mm. The JAWS™ staples provide stable fixation across the fracture/ joint/ osteotomy site until bone healing occurs.

INTENDED/ EXPECTED CLINICAL BENEFITS

Intended/ Expected Clinical Benefits of the JAWS™ Nitinol Staple System include:

- Successful Implantation of JAWS™ Nitinol Staple.

The Summary of Safety and Clinical Performance (SSCP) can be found at:

https://ec. europa.eu/tools/eudamed by searching for Manufacturer: Paragon 28 (upon Eudamed activation). Until Eudamed is activated, to request a copy of the SSCP, please contact Paragon 28®, Inc. by phone, (+1) (855) 786-2828.

Residual Risks identified within the SSCP are included as warnings and precautions.

IMPLANT MATERIALS

The JAWS™ Nitinol Staple System implants are manufactured from Nickel-Titanium Alloy (Nitinol) per ASTM F2063.

Material	Material or substance to which the patient may be exposed	% (mass/mass)
Nickel-Titanium (Nitinol) per ASTM F2063	Nickel	54.5 to 57.0
	Titanium	Balance*
	Minor constituents	≤0.050 each
*approximately equal to the difference between 100% and the sum percentage of the other specified elements.		

CMR, EDP, PHTHALATES

The JAWS™ Nitinol Staple System do not contain substances ≥0.1% (w/w) which are classified as carcinogenic, mutagenic or toxic to reproduction (CMR), substances ≥0.1% (w/w) which have endocrine disrupting properties (EDP) and do not contain phthalates.

INTENDED USE/ INTENDED PURPOSE

The JAWS™ Nitinol Staple System is intended for use in fixation of osteotomies, arthrodesis procedures, and bone fragments in the bones and joints of the foot.

INDICATIONS FOR USE

The JAWS™ Nitinol Staple System implants are indicated for use in adult and pediatric patients for primary and revision procedures of the foot including:

- osteotomy
- arthrodesis
- fragment fixation

CONTRAINDICATIONS

Use of the JAWS™ Nitinol Staple System is contraindicated in the following instances:

- Active or suspected infection or osteomyelitis
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- Poor bone quality, i.e. osteoporotic bone that is susceptible to fracture
- Known or suspected sensitivity to metal or foreign bodies
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Physical conditions that may hinder the healing process
- Conditions that limit the patient's ability or willingness to follow postoperative instructions
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status
- Indications not included in the INDICATIONS FOR USE

WARNINGS AND PRECAUTIONS

- For safe and effective use of the JAWS™ Nitinol Staple System, the surgeon should be familiar with the procedure and devices and must exercise reasonable judgment in use of the device. Improper selection, placement or positioning may result in reduced lifetime of the implant(s).
- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Do not re-sterilize the JAWS™ Nitinol Staple System implants or instruments. The implants and instruments are intended for single use only. Any single use device which has been used may have come in contact with tissue, bone, blood or other bodily fluids. This is considered contaminated and must be discarded for the safety of the patient or other users.
- Instruments are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the JAWS™ Nitinol Staple System. Failure to use the provided, unique JAWS™ Nitinol Staple System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the implants, instruments and packaging prior to use to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- If an instrument is damaged, contact Paragon 28®, Inc. immediately to arrange replacement and/or disposal.
- In any surgical procedure, the potential for complications and adverse reactions exists. Adverse events include but are not limited to those described in this document. The risks, potential complications, and adverse reactions with these implants include:
  - Infection
  - Loosening, deformation, migration or fracture of the implant
  - Fractures resulting from unilateral joint loading
  - Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
  - Corrosion with localized tissue reaction and pain
  - Pain, a feeling of malaise or abnormal sensations due to the implant used
  - Thrombosis and embolism
  - Temporary or protracted neurological perturbation
  - Delay or failure of bone healing
  - Loss of correction

Complications and adverse effects listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28®, Inc as soon as complications occur in connection with the

implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc cannot accept any other returns of used implants.

MR SAFETY INFORMATION

MRI Safety Information
A person with the JAWS™ Nitinol Staple System Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	JAWS™ Nitinol Staple System Implant
Static Magnetic Field Strength (T)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	19 T/m (1900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2.0 W/kg
Maximum RF heating temperature increase	3.18°C
Scan Duration	2.0 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/ scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 19.28 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

MAINTANING DEVICE EFFECTIVENESS

- The surgeon should have specific training, experience, and thorough familiarity with the use of fixation devices.
- The surgeon must exercise reasonable judgment when deciding which implant type to use for specific indications.
- The JAWS™ Nitinol Staple System implants are not intended to endure excessive abnormal functional stresses.
- The JAWS™ Nitinol Staple System implants are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique JAWS™ Nitinol Staple System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the implants prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- If an instrument is damaged, contact Paragon 28®, Inc. immediately to arrange replacement and/or disposal.
- Paragon 28®, Inc. non-sterile devices are precision medical devices and must be used and handled with care. Inspect the devices for damage prior to use, and at all stages of handling thereafter. If damage is detected, do not use the device prior to consulting the manufacturer for guidance.
- Devices with cutting functions or sharp points become dull with continuous use. This condition does not indicate a defective device and may indicate normal wear. Any sign of dull or wearing devices may require replacement if they no longer perform as designed. Inspection prior to use should include verifying the cutting ability and sharpness of these points and edges.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc. products in a sterile environment.

HANDLING AND STERILIZATION

Sterile Product:

The JAWS™ Nitinol Staple System implants and instruments are provided sterile by exposure to a minimum dose of 25kGy of gamma radiation. DO NOT re-sterilize. SINGLE USE ONLY. Any device labeled as Single Use only must never be reused or reprocessed. Any device opened from its packaging is considered used and may have come in contact with tissue, bone, blood or other bodily fluids. This is considered contaminated and must be discarded for the safety of the patient and other users. DO NOT use implants after expiration date. Packages for implants should be intact upon receipt.

The sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. If the inner package integrity has been compromised, DO NOT USE THE PRODUCT. Contact the manufacturer for further instructions. The implants should be opened using an aseptic technique. Once the seal of the product is broken, the product should not be re-sterilized. The implant should only be opened after the correct size has been determined.

All sterile products should be stored in a clean, dry environment.

Please check the website, www.paragon28.com/resources/surgical-technical-guides/, for the most current Aseptic Transfer Techniques Document P99-STR-1001.

Non-Sterile Product:

Instruments that are presented in a tray are provided non-sterile. All non-sterile instruments should be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Paragon 28®, Inc. Instrument Reprocessing Instructions for Reusable Instruments (Manual Method P99-CLN-0001) (Automated Method P99-CLN-1001). For product information or to obtain a copy of the surgical technique manual and/or the Summary of safety and clinical performance, please contact Paragon 28®, Inc. This is also available by calling (+1) (855)786-2828.

Unless specifically labeled sterile, the instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of 2 layers of sterilization wrap is recommended. The following validated steam autoclave cycle is recommended:

Method	Cycle	Minimum Temperature	Minimum Exposure Time	Dry Time
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	30 Minutes

INTENDED USERS

Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant the JAWS™ Nitinol Staple System. Refer to the JAWS™ Nitinol Staple System Surgical Technique (P70-STG-1001) for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28®, Inc. by phone, (+1) (855) 786-2828.

IMPLANT REMOVAL (IF NECESSARY)

- Instrumentation can be provided for implant removal
- Removal instructions are provided in the JAWS™ Nitinol Staple System Surgical Technique (P70-STG-1001)

TARGETED POPULATION

The JAWS™ Nitinol Staple is intended for members of the adult and pediatric general population who are under the care of a physician who determines the need for fixation of an osteotomy, arthrodesis, or bone fragment in the foot. The population does not include patients that are pregnant nor any others with conditions listed in the contraindications.

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Paragon 28®, Inc. immediately. Paragon 28®, Inc., or it's EC Representative should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

DISPOSAL OF IMPLANT OR INSTRUMENT

The implant and associated instrumentation will be used in a surgical suite, and thus, any disposal of the implant(s), instrument(s), and/or packaging will occur in the surgical suite by the user.
The sterile packaged implant will be opened in the surgical suite with the packaging disposed of by the user. The outside packaging is not passed onto the operative field and should not be contaminated by human tissue or blood.

The outside packaging is disposed of in a standard waste receptacle. If the inner packaging is in contact with human tissue or blood, the inner packaging must be disposed of in a standard biowaste container. If the inner packaging does not come in contact with human tissue or blood, the inner packaging can be disposed of in a standard waste receptacle.
In the case of an implant removal, or if an implant must be disposed of during surgery, the disposal will occur in the surgical suite by the user. Because the implant has been in contact with human tissue or blood and may have a sharp physical hazard, the implant must be disposed of in a biohazard waste container intended for sharps.
In the case of instrument disposal, the disposal will occur in the surgical suite by the user. Because the instrument has been in contact with human tissue or blood and may have a sharp physical hazard, the instrument must be disposed of in a biohazard container intended for sharps.

Please contact Paragon 28®, Inc. for product inquiries, cleaning instructions and surgical techniques. To report any adverse event, please contact Paragon 28®, Inc or its EC Representative.

	EC REP	UK Responsible Person	CH REP
Paragon 28, Inc. 14445 Grasslands Dr., Englewood, CO 80112 USA (+1) (855) 786 - 2828	**Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands**	**MedEnvoy UK Ltd 85 Great Portland St. London, W1W 7LT, UK**	**Zimmer GmbH Zählerweg 4 6300 Zug Switzerland**

CE 2797	**Class Ir, IIa, IIb**
CE	**Class I Self Certify**

Basic UDI-DI information
0889795P7XIIB01GSUCMNB (Sterile Packed Implants)