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™ Nitinol Staple System. It is not a reference for surgical techniques.

CAUTION
Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

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 and ankle. The JAWS™ bone staples are made from superelastic nitinol that does not require cold storage or heating. Implant sizes range from 8mm to 25mm.

INDICATIONS FOR USE
The JAWS™ Nitinol Staple System implants are indicated for use in osteotomy, arthrodesis and fragment fixation of the bones and joints of the foot including fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement) located in the long bones of the lower extremities such as the fibula and tibia.

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

IMPLANT MATERIALS

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

Potential Complications and Adverse Effects
In any surgical procedure, the potential for complications and adverse reactions exist. These do not include all adverse effects which can occur with surgery, but are important considerations particular to metallic internal stabilization devices.

- 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
- Bone loss due to stress shielding

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® 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® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® cannot accept any other returns of used implants.

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 resterilize the JAWS™ Nitinol Staple System implants or instruments. The implants and instruments are intended for single use only.
- 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® immediately to arrange replacement and/or disposal.

MR (MAGNETIC RESONANCE) SAFETY INFORMATION
Non-clinical testing has demonstrated the JAWS Nitinol Staple System implants are MR conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, non-clinical testing results indicate the implant is expected to produce a maximum temperature rise of 3.18°C after 15 minutes of continuous scanning.

In non-clinical testing, the maximum image artifact caused by the device extends approximately 19.28 mm from the implant when imaged with a gradient echo pulse sequence and a 3 T MR system.

HANDLING AND STERILIZATION
Sterile Kits:
The JAWS™ Nitinol Staple System implants and instruments are provided sterile by exposure to a minimum dose of 25kGy of gamma radiation. Do not resterilize. Single use only. Do not use implants after expiration date.

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 implant or instruments**. Contact the manufacturer for further instructions. The implants should be opened using an aseptic technique. The implant should only be opened after the correct size has been determined.

Reusable Instruments:
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® ***Instrument Reprocessing Instructions for Reusable Instruments*** document P99-CLN-0001. 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 an FDA cleared 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

INSTRUCTIONS FOR USE
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-0001) for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28® by phone, (+1) (855) 786-2828.

IMPLANT REMOVAL

- Instrumentation can be provided for implant removal
- Removal instructions are provided in the JAWS™ Nitinol Staple System Surgical Technique (P70-STG-0001)

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. 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.

Please contact company for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.

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