Arthrex DynaNite® Staples

Patient Information Leaflet

Arthrex®

Helping Surgeons Treat Their Patients Better®

Since its inception, Arthrex has been committed to one mission: Helping Surgeons Treat Their Patients Better. We are strategically focused on constant product innovation through scientific research, surgeon collaboration, and medical education to make less invasive surgical procedures simpler, safer, and more reproducible. Each year, we develop more than 1000 new innovative products and procedures to advance minimally invasive orthopedics worldwide.

Arthrex has always remained a privately held company, which allows for the rapid evaluation of new technologies and ideas. Our economic strength enables us to develop products and techniques that truly make a difference without compromising on quality. Our experienced team of dedicated professionals represents a shared passion and commitment to delivering uncompromising quality to the health care providers who use our products and the millions of patients whose lives we impact.

The medical significance of our contributions serves as our primary benchmark of success and will continue into the future as the legacy of Arthrex.

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Anatomy and General Information

This leaflet contains information about your Arthrex DynaNite® Staples implant. It may not contain all the information related to your specific procedure and if you have any questions, talk to your healthcare provider. All implants have risks and benefits. Follow your healthcare team's advice even if it differs from what is contained within this leaflet. Please read this leaflet carefully and refer to it in the future if needed.

The name and number of your staple implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Device Description

The Arthrex DynaNite Staples consist of staple implants. The implants are formed with two or four legs connected by a bridge and are offered in multiple combinations of bridge widths, leg lengths, and cross-sections to accommodate various anatomies. The legs of the implant are superelastic and fully transformed at room temperature (i.e., no external heating is required). When implanted, the legs provide compression to accomplish fixation.

Material Specifications

The Arthrex DynaNite Staples are manufactured from Nitinol per ASTM F2063, which consists of nickel and titanium.

Indications

The Arthrex DynaNite Staples are intended to be used for fixation, such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodesis or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

The Arthrex DynaNite Staples are indicated for:

- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- Hand and foot bone fragment and osteotomy fixation, and joint arthrodesis.
- Fixation of small bone fragments (i.e., small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.

Contraindications

1. Insufficient quantity or quality of bone.
2. Blood supply limitations and previous infections, which may retard healing.
3. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.
4. Nitinol (which contains nickel): Foreign body reactions. See Risks Adverse/Effects, allergic-type reactions.
5. Any active infection or blood supply limitations.
6. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
7. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb, or disrupt the growth plate.

Risks/Adverse Effects

1. Infections, both deep and superficial.

2. Foreign body sensitivity.

3. Materials with nickel (stainless steel or nitinol): Patient sensitivity to device materials must be considered prior to implantation. Where nickel sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.

Postoperative Care

Postoperative management is patient-specific and dependent on your doctor's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes. Please be aware that surgery and recovery protocol may vary for each individual and any questions pertaining to the surgical procedure or postoperative protocol should be discussed with your surgeon.

Please call your doctor if:

- You experience loss of function/range of motion
- You develop a fever greater than 100.4 °F (38 °C)
- Drainage continues from the site of your incision
- Your surgical site becomes more swollen, tender, and painful, with increased difficulty performing your exercises.

If you have difficulty breathing or develop severe pain or chest pain, call 911 or report immediately to your local emergency room.

Life of the Device

1. These devices are long-term fixation devices intended to aid in the normal healing process. They are not intended to bear the weight of the body in the presence of incomplete healing. If healing is delayed, or does not occur, the device may eventually break due to fatigue.

2. Information specific to your implant, such as lot number and unique device identifier are included on the implant card. This information is also located in the patient records kept by your healthcare provider.

⚠ Warnings

1. ⚠ An internal fixation device must never be re-used.

2. This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.

3. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.

4. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.

5.  This is a single-use device. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user.

6. If any of the following conditions are present—nonunion, osteoporosis, a markedly unstable comminuted fracture or any of the factors listed in the Contraindications and/or Warnings and Precautions sections—then the following can occur: loosening, bending, cracking, fracture of the staple or loss of fixation in bone.

7. Removal of supplemental fixation after healing. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture.

8. The implants are not designed to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight-bearing or load bearing in the presence of nonunion, delayed union or incomplete healing. Immobilization of the treatment site using routine methods (casting, splinting, etc.) should be maintained until bone healing has occurred (4-6 weeks).

9. Patient sensitivity to the device materials should be considered prior to implantation. See Adverse Effects.

10. Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.

MRI Safety Information

MRI, or Magnetic Resonance Imaging, is an imaging technique utilizing a strong magnetic field to produce detailed anatomical images. This section details the information that you should be aware of when receiving an MRI scan.

1. MR Conditional

Non-clinical testing and electromagnetic simulations demonstrated that the Arthrex DynaNite Staples is MR Conditional.

A patient with this device can be scanned safely in an MR system under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Arthrex DynaNite Staples
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m or 3000 Gauss/cm
RF (Radio Frequency) Excitation	Circularly Polarized (CP)
RF (Radio Frequency) Transmit Coil Type	Volume RF body coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR (Specific Absorption Rate)	2 W/kg (Normal Operating Mode)
Maximum Head SAR	N/A
Scan Duration	Under the scan condition above, patients with the device can be scanned continuously for 30 minutes. It should be followed by 30-minutes wait time in 60 minutes.
MR Image Artifact	The presence of this implant may produce an image artifact.
Patients who have other MR Conditional devices can be scanned as long all as the MR Conditional scan parameters for each of the devices are met. Do not conduct an MRI scan if any conditions for safe scanning for any device cannot be met.	
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

The person with a Arthrex DynaNite Staples implant can safely undergo an MR exam only under very specific conditions. Scanning under different conditions may result in severe injury. Full MRI safety information is available in the MRI Safety Information section of this patient information leaflet, Directions for Use (https://edfu.arthrex.com) or by calling Arthrex customer service at +1 800 934-4404.

Implant Models

Arthrex DynaNite Staples

Consult your Arthrex DynaNite Staples Patient Implant Card (PIC) for information on the device type/model of the implant used in your procedure.

Product Description	Item Number
DynaNite MX4 Staple w/ Instruments, 35 mm x 25 mm x 20 mm	AR-8719MX4DS-3520
DynaNite MX4 Staple w/ Instruments, 30 mm x 20 mm x 20 mm	AR-8719MX4DS-3020
DynaNite MX4 Staple w/ Instruments, 25 mm x 15 mm x 18 mm	AR-8719MX4DS-2518
DynaNite WideLeg 5 mm Staple w/ Instruments, 15 mm x 15 mm	AR-8719W5DS-1515
DynaNite WideLeg 5 mm Staple w/ Instruments, 18 mm x 18 mm	AR-8719W5DS-1818
DynaNite WideLeg 5 mm Staple w/ Instruments, 20 mm x 20 mm	AR-8719W5DS-2020
DynaNite WideLeg 5 mm Staple w/ Instruments, 25 mm x 20 mm	AR-8719W5DS-2520
DynaNite WideLeg 6 mm Staple w/ Instruments, 20 mm x 20 mm	AR-8719W6DS-2020
DynaNite WideLeg 6 mm Staple w/ Instruments, 25 mm x 20 mm	AR-8719W6DS-2520
DynaNite MX Reduction Staple, qty. 1	AR-8719MXR-1
DynaNite MX Reduction Staple, qty. 2	AR-8719MXR-2
DynaNite Reduction Staple, qty. 1	AR-8719R-1
DynaNite Reduction Staple, qty. 2	AR-8719R-2
DynaNite MX Reduction Staple w/ Instruments	AR-8719MXRDS
DynaNite Reduction Staple w/ Instruments	AR-8719RDS

Contact Information

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the health authority where the incident occurred.

Region	Contact
 Arthrex, Inc.	1370 Creekside Blvd. Naples, FL 34108, USA USA Toll free: +1 800 934-4404 arthrex.com
Arthrex GmbH	Erwin-Hielscher-Strasse 9 81249 München, Germany +49 89 90 90 05-0 arthrex.de

USA – U. S. Food & Drug Administration website: https://www.fda.gov/medical-devices/resources-you-medical-devices/consumers-medical-devices

The information contained in this patient leaflet is not medical advice and is not meant to be a substitute for the advice provided by a surgeon or other qualified medical professional on the use of these products. You should talk with your physician or healthcare provider for more information about your health condition, and whether Arthrex products might be appropriate for you. The surgeon who performs any surgical procedure is responsible for determining and using the appropriate techniques for surgical procedures on each individual patient. Arthrex recommends that surgeons be trained on the use of any particular product before using it in surgery. A surgeon must always rely on their professional medical judgment when deciding whether to use a particular product when treating a particular patient. A surgeon must always refer to the package insert, product label, and/or directions for use before using any Arthrex product. Products may not be available in all markets because product availability is subject to regulatory approvals and medical practices in individual markets. Please contact Arthrex if you have questions about the availability of products in your area.

Symbols glossary can be found at www.arthrex.com/symbolsglossary**.**

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