Tibial Nail Implant System

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 simple, 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 and the freedom to develop products and techniques that truly make a difference without economic considerations or compromise. Our experienced team of dedicated professionals represents a shared passion and commitment to delivering uncompromising quality to the healthcare 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

The tibia is one of two bones that comprise the leg. As a weight-bearing bone, it is significantly larger and stronger than its counterpart, the fibula. The tibia forms the knee joint proximally with the femur and forms the ankle joint distally with the fibula and talus bones.

This leaflet contains information about your tibial nail 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 nail 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 tibial nail implant system is comprised of the tibial nail, interlocking screw, end cap and a spacer.

The tibial nail implant system is designed to provide temporary stabilization of various types of fractures, malunions, and non-unions of the tibia.

The tibial nail is available in 8, 9, 10, 11, 12, and 13-mm working diameters and provided in lengths ranging from 27 – 45 cm.

The interlocking screws are fully threaded, cortical or partially threaded, cannulated cancellous (blocking) screws. The screw family is 4.2 mm in diameter and 5.0 mm in diameter with lengths ranging from 20 mm to 100 mm (in 2.5 mm or 5 mm increments).

The end caps are designed to prevent bone growth in the distal portion of the nail implant for ease of removal. The end cap family ranges from 5 to 10 mm in length for various countersinking depths.

Material Specifications

Tibial nail: The tibial nail is manufactured from titanium alloy, (ASTM F136) which contains:

Titanium, (88.5 - 90.5%)
Aluminum, (5.5 - 6.5%)
Vanadium, (3.5 - 4.5%)
Iron, (.25%)
*Other materials may be present at trace levels.

Interlocking screws, end caps, and spacer: The interlocking screws, end caps, and spacer are manufactured from titanium alloy, (ASTM F136) which contains:

Titanium, (88.5 - 90.5%)
Aluminum, (5.5 - 6.5%)
Vanadium, (3.5 - 4.5%)
Iron, (.25%)
*Other materials may be present at trace levels.

Indications

The tibial nail system is intended to provide temporary stabilization of various types of fractures, malunions, and non-unions of the tibia. The tibial nail system is indicated for long bone fracture fixation of tibial fractures, which may include the following: traverse, oblique, spiral, segmental and comminuted fractures; fractures with bone loss and bone transport; open and closed fractures, pathologic fractures; corrective osteotomies; pseudarthrosis of the tibial shaft; non-unions, malunions, metaphyseal and epiphyseal fractures.

Contraindications

1. Insufficient quantity or quality of bone that would inhibit fusion of the joints and stabilization of the arthrodesis.
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. Foreign Body Reactions. See 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.
8. Do not use for surgeries other than those indicated.
9. Patients with a high level of physical activity.

Risks/Adverse Effects

1. Infections, both deep and superficial.
2. Foreign body sensitivity.
3. Patient sensitivity to implant device materials must be considered prior to implantation.
4. Allergies and other reactions to device materials.
5. Wound hematoma and delayed wound healing.

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
- You develop a fever greater than 38 °C (100.4 °F)
- 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 your local emergency care or report immediately to your local emergency room.

European emergency services – 112

North America emergency services – 911

Australia emergency services - 000

Precautions

1. An additional procedure may be required for the removal of the implant.
2. Please carefully review the postoperative instructions provided by the surgeon and nursing staff.
3. Early weight and/or load bearing substantially increases implant loading and increases the risk of loosening, bending, or breaking the device.
4. Patients who are obese and/or non-compliant, as well as patients who could be pre-disposed to delayed union or non-union, must have auxiliary support.
5. Do not engage in unassisted weight-bearing activity without physician direction or medical release. Postoperative care and physical therapy should be structured to prevent the loading of the operative extremity until directed by the physician.

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. Caution: Federal law restricts this device to sale by or on the order of a physician.
2. This device is intended to be used by a trained medical professional.
3. An internal fixation device must never be re-used.
4. All metallic implant devices used for this surgical procedure should have the same composition properties.
5. 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.
6. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device. The appropriate Arthrex delivery system is required for the proper implantation of the device.
7. 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.
8. Detailed instructions and limitations of this device are provided to the surgeon in addition to this patient information leaflet and your patient implant card.
9. Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.
10. METAL SCREWS: Devices that have been implanted for a long period of time may require the use of screw removal instrumentation.
11. These are single-use devices. Reuse of this device could result in the failure of the device to perform as intended and could cause harm to the patient and/or user.

12. Over time, metallic implants may loosen, fracture, or cause pain after the bone fracture or osteotomy is healed. Removal of metallic implants is at the surgeon's discretion and 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.

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

14. The correct selection and placement of the implant is extremely important. The appropriate type and size should be selected for the patient. Failure to use the correct implant size or improper positioning may result in loosening, bending, cracking, or fracture of the device, bone, or both.

15. Bone fixation devices are neither intended to carry the full load of the patient nor intended to carry a significant portion of the load for extended periods of time. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, non-union, or incomplete healing. Improper insertion of the device during implantation can increase the possibility of loosening or migration.

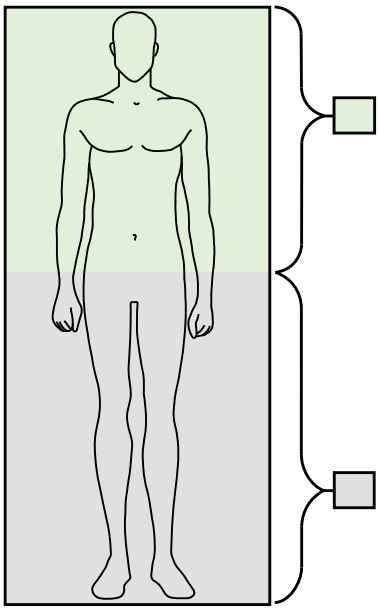
MRI Safety Information

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 Tibial Nail Implant System 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	Tibial Nail Implant System	
Static Magnetic Field Strength (B_0)	1.5-Tesla and 3-Tesla	
Maximum Spatial Field Gradient	25 T/m or 2,500 Gauss/cm	
RF (Radio Frequency) Excitation	Circularly Polarized (CP)	
RF (Radio Frequency) Transmit Coil Type	**Body Coil:** See scan region limitations below.	
	Local Coils: Head transmit-receive coil, no restrictions on local transmit-receive coils that the device is not within.	
Operating Mode	Normal Operating Mode	
Maximum Whole-Body SAR (Specific Absorption Rate)	See details below.	
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)	
SAR and Scan Duration Limits Based on Anatomical Isocenter Landmarks* (for imaging with Body Coil)	<u>When the landmark is inferior to the groin*</u> Only use local transmit-receive coils that the device is not within. Refer to the Patient Implant Card for the device sizing and indication.	<u>When the landmark is superior to the groin*</u> 2 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks).

	 2.0 W/kg maximum whole body average SAR when imaging this region (i.e, when isocenter is landmarked in this region). Body coil imaging exclusion zone when imaging this region (i.e., when isocenter is landmarked in this region). Use local transmit-receive coils according to the local coil restrictions. *Landmark guidelines are for imaging with the body coil. Refer to local coil restrictions for use of local transmit-receive coils.
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 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 bone nail 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.

Tibial Nail Implant System

Tibial Nail Implant Models

Consult your Tibial Nail Implant Identification Card for information on the device type/model of the implant used in your procedure.

Product Description	Item Number
Tibial Nail, 8.0 mm x 27.0 cm	AR-9098-08-270
Tibial Nail, 8.0 mm x 28.5 cm	AR-9098-08-285
Tibial Nail, 8.0 mm x 30.0 cm	AR-9098-08-300
Tibial Nail, 8.0 mm x 31.5 cm	AR-9098-08-315
Tibial Nail, 8.0 mm x 33.0 cm	AR-9098-08-330
Tibial Nail, 8.0mm x 34.5 cm	AR-9098-08-345
Tibial Nail, 8.0 mm x 36.0 cm	AR-9098-08-360
Tibial Nail, 8.0 mm x 37.5 cm	AR-9098-08-375
Tibial Nail, 8.0 mm x 39.0 cm	AR-9098-08-390
Tibial Nail, 8.0 mm x 40.5 cm	AR-9098-08-405
Tibial Nail, 8.0 mm x 42.0 cm	AR-9098-08-420
Tibial Nail, 8.0 mm x 43.5 cm	AR-9098-08-435
Tibial Nail, 8.0 mm x 45.0 cm	AR-9098-08-450
Tibial Nail, 9.0 mm x 27.0 cm	AR-9098-09-270
Tibial Nail, 9.0 mm x 28.5 cm	AR-9098-09-285
Tibial Nail, 9.0 mm x 30.0 cm	AR-9098-09-300
Tibial Nail, 9.0 mm x 31.5 cm	AR-9098-09-315
Tibial Nail, 9.0 mm x 33.0 cm	AR-9098-09-330
Tibial Nail, 9.0 mm x 34.5 cm	AR-9098-09-345
Tibial Nail, 9.0 mm x 36.0 cm	AR-9098-09-360
Tibial Nail, 9.0 mm x 37.5 cm	AR-9098-09-375
Tibial Nail, 9.0 mm x 39.0 cm	AR-9098-09-390

Product Description	Item Number
Tibial Nail, 9.0 mm x 40.5 cm	AR-9098-09-405
Tibial Nail, 9.0 mm x 42.0 cm	AR-9098-09-420
Tibial Nail, 9.0 mm x 43.5 cm	AR-9098-09-435
Tibial Nail, 9.0 mm x 45.0 cm	AR-9098-09-450
Tibial Nail, 10.0 mm x 27.0 cm	AR-9098-10-270
Tibial Nail, 10.0 mm x 28.5 cm	AR-9098-10-285
Tibial Nail, 10.0 mm x 30.0 cm	AR-9098-10-300
Tibial Nail, 10.0 mm x 31.5 cm	AR-9098-10-315
Tibial Nail, 10.0 mm x 33.0 cm	AR-9098-10-330
Tibial Nail, 10.0 mm x 34.5 cm	AR-9098-10-345
Tibial Nail, 10.0 mm x 36.0 cm	AR-9098-10-360
Tibial Nail, 10.0 mm x 37.5 cm	AR-9098-10-375
Tibial Nail, 10.0 mm x 39.0 cm	AR-9098-10-390
Tibial Nail, 10.0 mm x 40.5 cm	AR-9098-10-405
Tibial Nail, 10.0 mm x 42.0 cm	AR-9098-10-420
Tibial Nail, 10.0 mm x 43.5 cm	AR-9098-10-435
Tibial Nail, 10.0 mm x 45.0 cm	AR-9098-10-450
Tibial Nail, 11.0 mm x 27.0 cm	AR-9098-11-270
Tibial Nail, 11.0 mm x 28.5 cm	AR-9098-11-285
Tibial Nail, 11.0 mm x 30.0 cm	AR-9098-11-300
Tibial Nail, 11.0 mm x 31.5 cm	AR-9098-11-315
Tibial Nail, 11.0 mm x 33.0 cm	AR-9098-11-330
Tibial Nail, 11.0 mm x 34.5 cm	AR-9098-11-345
Tibial Nail, 11.0 mm x 36.0 cm	AR-9098-11-360
Tibial Nail, 11.0 mm x 37.5 cm	AR-9098-11-375
Tibial Nail, 11.0 mm x 39.0 cm	AR-9098-11-390
Tibial Nail, 11.0 mm x 40.5 cm	AR-9098-11-405

Product Description	Item Number
Tibial Nail, 11.0 mm x 42.0 cm	AR-9098-11-420
Tibial Nail, 11.0 mm x 43.5 cm	AR-9098-11-435
Tibial Nail, 11.0 mm x 45.0 cm	AR-9098-11-450
Tibial Nail, 12.0 mm x 27.0 cm	AR-9098-12-270
Tibial Nail, 12.0 mm x 28.5 cm	AR-9098-12-285
Tibial Nail, 12.0 mm x 30.0 cm	AR-9098-12-300
Tibial Nail, 12.0 mm x 31.5 cm	AR-9098-12-315
Tibial Nail, 12.0 mm x 33.0 cm	AR-9098-12-330
Tibial Nail, 12.0 mm x 34.5 cm	AR-9098-12-345
Tibial Nail, 12.0 mm x 36.0 cm	AR-9098-12-360
Tibial Nail, 12.0 mm x 37.5 cm	AR-9098-12-375
Tibial Nail, 12.0 mm x 39.0 cm	AR-9098-12-390
Tibial Nail, 12.0 mm x 40.5 cm	AR-9098-12-405
Tibial Nail, 12.0 mm x 42.0 cm	AR-9098-12-420
Tibial Nail, 12.0 mm x 43.5 cm	AR-9098-12-435
Tibial Nail, 12.0 mm x 45.0 cm	AR-9098-12-450
Tibial Nail, 13.0 mm x 27.0 cm	AR-9098-13-270
Tibial Nail, 13.0 mm x 28.5 cm	AR-9098-13-285
Tibial Nail, 13.0 mm x 30.0 cm	AR-9098-13-300
Tibial Nail, 13.0 mm x 31.5 cm	AR-9098-13-315
Tibial Nail, 13.0 mm x 33.0 cm	AR-9098-13-330
Tibial Nail, 13.0 mm x 34.5 cm	AR-9098-13-345
Tibial Nail, 13.0 mm x 36.0 cm	AR-9098-13-360
Tibial Nail, 13.0 mm x 37.5 cm	AR-9098-13-375
Tibial Nail, 13.0 mm x 39.0 cm	AR-9098-13-390
Tibial Nail, 13.0 mm x 40.5 cm	AR-9098-13-405
Tibial Nail, 13.0 mm x 42.0 cm	AR-9098-13-420

Product Description	Item Number
Tibial Nail, 13.0 mm x 43.5 cm	AR-9098-13-435
Tibial Nail, 13.0 mm x 45.0 cm	AR-9098-13-450

Tibial Nail Implant System

Interlocking Screw Implant Models

Product Description	Item Number
Cortical Screw, Captured, 4.2 mm x 20 mm	AR-9098-42-020
Cortical Screw, Captured, 4.2 mm x 22.5 mm	AR-9098-42-022
Cortical Screw, Captured, 4.2 mm x 25 mm	AR-9098-42-025
Cortical Screw, Captured, 4.2 mm x 27.5 mm	AR-9098-42-027
Cortical Screw, Captured, 4.2 mm x 30 mm	AR-9098-42-030
Cortical Screw, Captured, 4.2 mm x 32.5 mm	AR-9098-42-032
Cortical Screw, Captured, 4.2 mm x 35 mm	AR-9098-42-035
Cortical Screw, Captured, 4.2 mm x 37.5 mm	AR-9098-42-037
Cortical Screw, Captured, 4.2 mm x 40 mm	AR-9098-42-040
Cortical Screw, Captured, 4.2 mm x 42.5 mm	AR-9098-42-042
Cortical Screw, Captured, 4.2 mm x 45 mm	AR-9098-42-045
Cortical Screw, Captured, 4.2 mm x 47.5 mm	AR-9098-42-047
Cortical Screw, Captured, 4.2 mm x 50 mm	AR-9098-42-050
Cortical Screw, Captured, 4.2 mm x 55 mm	AR-9098-42-055
Cortical Screw, Captured, 4.2 mm x 60 mm	AR-9098-42-060
Cortical Screw, Captured, 4.2 mm x 65 mm	AR-9098-42-065
Cortical Screw, Captured, 4.2 mm x 70 mm	AR-9098-42-070
Cortical Screw, Captured, 4.2 mm x 75 mm	AR-9098-42-075
Cortical Screw, Captured, 4.2 mm x 80 mm	AR-9098-42-080
Cortical Screw, Captured, 4.2 mm x 85 mm	AR-9098-42-085
Cortical Screw, Captured, 4.2 mm x 90 mm	AR-9098-42-090
Cortical Screw, Captured, 4.2 mm x 95 mm	AR-9098-42-095
Cortical Screw, Captured, 4.2 mm x 100 mm	AR-9098-42-100
Blocking Screw, Cannulated, PT, 5 mm x 30 mm	AR-9098-50-030

Product Description	Item Number
Blocking Screw, Cannulated, PT, 5 mm x 35 mm	AR-9098-50-035
Blocking Screw, Cannulated, PT, 5 mm x 40 mm	AR-9098-50-040
Blocking Screw, Cannulated, PT, 5 mm x 45 mm	AR-9098-50-045
Blocking Screw, Cannulated, PT, 5 mm x 50 mm	AR-9098-50-050
Blocking Screw, Cannulated, PT, 5 mm x 55 mm	AR-9098-50-055
Blocking Screw, Cannulated, PT, 5 mm x 60 mm	AR-9098-50-060
Blocking Screw, Cannulated, PT, 5 mm x 65 mm	AR-9098-50-065
Blocking Screw, Cannulated, PT, 5 mm x 70 mm	AR-9098-50-070
Blocking Screw, Cannulated, PT, 5 mm x 75 mm	AR-9098-50-075
Blocking Screw, Cannulated, PT, 5 mm x 80 mm	AR-9098-50-080
Blocking Screw, Cannulated, PT, 5 mm x 85 mm	AR-9098-50-085
Blocking Screw, Cannulated, PT, 5 mm x 90 mm	AR-9098-50-090
Blocking Screw, Cannulated, PT, 5 mm x 95 mm	AR-9098-50-095
Blocking Screw, Cannulated, PT, 5 mm x 100 mm	AR-9098-50-100
End Cap, Compression, Tibial Nail	AR-9098-00-00
End Cap, 5 mm, Tibial Nail	AR-9098-00-05
End Cap, 10 mm, Tibial Nail	AR-9098-00-10

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 +1 800 934-4404 arthrex.com
EC REP Arthrex GmbH	Erwin-Hielscher-Strasse 9 81249 München, Germany +49 89 90 90 05-0 arthrex.de
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CH REP confinis ch-rep ag,	Hauptstrasse 16 3186 Düdingen, Switzerland +41 26 494 8 494
Manufacturer's Australian Sponsor Arthrex Australia Pty Ltd	Suite 501, 20 Rodborough Road Frenchs Forest, NSW, 2086 Australia +1 800 950 637 arthrex.com.au

USA – U. S. Food & Drug Administration website: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

Australia – Therapeutic Goods Administration website: https://www.tga.gov.au

European Union – https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

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

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.

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