Humeral Plating System, Lateral and Anatomic Humeral Plates

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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Introduction

The Arthrex Humeral Plating System consists of series of Lateral and Anatomic plates and cerclage buttons that are permanent implant devices (plates and cerclage buttons) manufactured from titanium alloy. The Arthrex Humeral Plating System is designed for repairing proximal fractures of the humerus. The cerclage button is an adjunct device designed to fit securely in the holes of the humeral plating system. The Arthrex Humeral Plating System is intended for the internal bone fixation of fractures of the humerus.

This leaflet contains information about your Proximal Humerus Plate 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 Proximal Humerus Plate implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

The implant model list begins on page 15.

THIS PRODUCT IS NOT SOLD TO THE GENERAL PUBLIC.

Device Description

The Arthrex Humeral Plating System and Cerclage Button consists of series of Lateral and Anatomic plates and cerclage buttons that are permanent implant devices (plates and cerclage buttons) manufactured from titanium alloy. The Arthrex Proximal Humeral Plating System is designed for repairing proximal fractures of the humerus. The cerclage button is an adjunct device designed to fit securely in the holes of the humeral plating system. The Arthrex Humeral Plating System is intended for the internal bone fixation for fractures of the humerus.

The Arthrex Humeral Plating System is compatible with the following existing FDA cleared Arthrex Screws:

- 3.5 mm Low Profile Screws, Cortical
- 3.5 mm Variable Angle Locking (VAL) Screws, Reinforced
- 3.5 mm Variable Angle Locking (VAL) KreuLock Screws, Reinforced
- 4.0 mm Low Profile Screws, Cancellous
- 4.5 Low Profile Screws, Ti *(for use with Anatomic plates only)*
- 4.5 Low Profile Locking Screws, Ti *(for use with Anatomic plates only)*

Material Specifications

Arthrex Humeral Plating System devices are manufactured from Titanium (Ti-6Al-4V ELI) (ASTM F-136 and ISO 5832-3) contain:

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

Screws compatible with the Arthrex Humeral Plating System: The screws compatible with the Proximal Humeral Plating System is manufactured from titanium alloy, either Titanium (Ti-6AL-4V-ELI) (ASTM F136) or Titanium (Ti-6AL-4V-ELI) (ASTM F1472) which contains titanium, aluminum, vanadium, and iron.

Screws that are manufactured from titanium alloy (ASTM F136) contain:

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

Screws that are manufactured from titanium alloy (ASTM F1472) contain:

Titanium (Balance)
Aluminum, (5.5 - 6.75%)
Vanadium, (3.5 - 4.5%)
Iron, (.30%)
*Other materials may be present at trace levels.

Indications

The Humeral Plating System is used to treat broken bones in the upper arm near the shoulder. It can also be used when the bone has broken and shifted out of place, needs to be surgically cut and realigned, or has not healed properly. It is especially helpful in patients with weaker bone.

The Cerclage Button is used together with the humeral plating system and a strong suture to provide extra support to the repair. It helps hold the bone fragments in place during healing but is not meant to be used on its own.

Contraindications

1. Not enough or poor quality of bone.
2. Limited blood supply and past infections that may slow healing.
3. Sensitivity to foreign materials. Tests should be done before using any implants.
4. Any current infection or blood supply limitations.
5. Serious injury to muscles, tendons, or other tissues around the area.
6. Conditions that may make it difficult for the patient to follow activity restrictions or care instructions during healing.
7. This device may not be right for patients with too little or immature bone. The doctor should check the bone quality before doing surgery on patients who are still growing.

Risks/Adverse Effects

1. Infections, both deep and on the surface.
2. Allergies and other reactions to device materials.
3. Patient sensitivity to implant device materials must be considered prior to implantation.
4. Injury to nearby tissues.
5. Bones not healing properly.
6. Bone damage.
7. Implant problems (loosen, break, or stop working as intended).
8. Long-term pain.
9. 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 the 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
- Develop a fever greater than 100 °F (38 °C)
- Notice continued drainage from the wound
- Have increased swelling, tenderness, or pain at the surgical site, making it harder to do your exercises

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

North America emergency services – 911

Precautions

1. An additional procedure may be required for the removal of the implant.

2. Please carefully review postoperative instructions provided by the surgeon and nursing staff.

Life of the Device

The lifetime of a medical device is how long it works as expected when used normally.

The Arthrex Humeral Plating System 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.

⚠ Warnings

1. After surgery and until fully healed, the support from this device is temporary and may not withstand weight or other stress. It should be protected. Follow your doctor's post-surgery instructions carefully to avoid putting too much pressure on the device.

2. Any decision to remove the device should consider the risk to the patient of a second surgical procedure. Please discuss this with your doctor. If the device is removed, follow your doctor's post-surgery instructions carefully.

3. Detailed instructions and limitations of this device are provided to the surgeon in addition to this patient information leaflet and your patient implant card.

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

5. Over time, metal implants can become loose, break, or start causing pain, even after the bone has healed. The decision to remove the implant is up to the surgeon. If the implant is left in place after it is no longer needed, the following issues may occur:

   - The metal may corrode and irritate nearby tissue, causing pain
   - The implant could move out of place and cause injury
   - There may be a higher risk of injury if another accident happens
   - The implant could bend, loosen, or break, making it harder to remove later
   - You may feel pain, discomfort, or unusual sensations because the implant is still there
   - There may be an increased risk of infection
   - Bone loss can occur due to reduced stress on the bone

   The surgeon will carefully consider the risks and benefits before deciding whether to remove the implant. If the implant is removed, proper care afterward is important to reduce the risk of the bone breaking again.

6. Patient sensitivity to the device materials should be considered prior to implantation. See Risks/Adverse Effects.

7. The clinical benefits associated with the use of these devices outweigh the known clinical risks.

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 Humeral Plating 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	Humeral Plate Systems
Static Magnetic Field Strength (B_0)	1.5 Tesla (T) and 3.0 T
Maximum Spatial Field Gradient	30 T/m or 3,000 Gauss/cm
RF (Radio Frequency) Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Volume RF body coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR (Specific Absorption Rate)	1.5 T: 1 W/kg (Normal Operating Mode) 3 T: 2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	1.5 T: At 1 W/kg whole-body average SAR for 15 minutes of continuous RF (a sequence or back-to-back series/scan without break) followed by a wait time of 15 minutes. This can be repeated twice in a 60-minute session.
	3 T: 2 W/kg whole-body averaged 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.
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 Humeral Plating System 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 or by calling Arthrex customer service at +1 800 934-4404.

Implant Models

Humeral Plating Systems (Lateral)

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

Humeral Plating System - Lateral Plates and Cerclage Button (3.5 mm)	
Product Description	**Item Number**
Humeral Plating System - Lateral, 3 Hole	AR-9953UH-03
Humeral Plating System - Lateral, 5 Hole	AR-9953UH-05
Humeral Plating System - Lateral, 7 Hole	AR-9953UH-07
Humeral Plating System - Lateral, 10 Hole	AR-9953UH-10
Humeral Plating System - Lateral, 12 Hole	AR-9953UH-12
Humeral Plating System - Lateral, 14 Hole	AR-9953UH-14
Humeral Plating System - Lateral, 17 Hole	AR-9953UH-17
Humeral Plating System - Lateral, 3 Hole, Sterile	AR-9953UH-03S
Humeral Plating System - Lateral, 5 Hole, Sterile	AR-9953UH-05S
Humeral Plating System - Lateral, 7 Hole, Sterile	AR-9953UH-07S
Humeral Plating System - Lateral, 10 Hole, Sterile	AR-9953UH-10S
Humeral Plating System - Lateral, 12 Hole, Sterile	AR-9953UH-12S
Humeral Plating System - Lateral, 14 Hole, Sterile	AR-9953UH-14S
Humeral Plating System - Lateral, 17 Hole, Sterile	AR-9953UH-17S
Cerclage Button, 3.5 mm	AR-9953CB-T35
Cerclage Button, 3.5 mm, Sterile	AR-9953CB-T35S

Implant Models

Humeral Plating Systems (Anatomic)

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

Humeral Plating System - Anatomic Plates and Cerclage Button (4.5 mm)	
Product Description	**Item Number**
Humeral Plating System - Anatomic, Right, 3 Hole	AR-9953AR-03
Humeral Plating System - Anatomic, Left, 3 Hole	AR-9953AL-03
Humeral Plating System - Anatomic, Right, 5 Hole	AR-9953AR-05
Humeral Plating System - Anatomic, Left, 5 Hole	AR-9953AL-05
Humeral Plating System - Anatomic, Right, 7 Hole	AR-9953AR-07
Humeral Plating System - Anatomic, Left, 7 Hole	AR-9953AL-07
Humeral Plating System - Anatomic, Right, 9 Hole	AR-9953AR-09
Humeral Plating System - Anatomic, Left, 9 Hole	AR-9953AL-09
Humeral Plating System - Anatomic, Right, 11 Hole	AR-9953AR-11
Humeral Plating System - Anatomic, Left, 11 Hole	AR-9953AL-11
Humeral Plating System - Anatomic, Right, 13 Hole	AR-9953AR-13
Humeral Plating System - Anatomic, Left, 13 Hole	AR-9953AL-13
Humeral Plating System - Anatomic, Right, 15 Hole	AR-9953AR-15
Humeral Plating System - Anatomic, Left, 15 Hole	AR-9953AL-15
Humeral Plating System - Anatomic, Right, 3 Hole, Sterile	AR-9953AR-03S
Humeral Plating System - Anatomic, Left, 3 Hole, Sterile	AR-9953AL-03S
Humeral Plating System - Anatomic, Right, 5 Hole, Sterile	AR-9953AR-05S
Humeral Plating System - Anatomic, Left, 5 Hole, Sterile	AR-9953AL-05S
Humeral Plating System - Anatomic, Right, 7 Hole, Sterile	AR-9953AR-07S
Humeral Plating System - Anatomic, Left, 7 Hole, Sterile	AR-9953AL-07S
Humeral Plating System - Anatomic, Right, 9 Hole, Sterile	AR-9953AR-09S
Humeral Plating System - Anatomic, Left, 9 Hole, Sterile	AR-9953AL-09S
Humeral Plating System - Anatomic, Right, 11 Hole, Sterile	AR-9953AR-11S
Humeral Plating System - Anatomic, Left, 11 Hole, Sterile	AR-9953AL-11S
Humeral Plating System - Anatomic, Right, 13 Hole, Sterile	AR-9953AR-13S
Humeral Plating System - Anatomic, Left, 13 Hole, Sterile	AR-9953AL-13S
Humeral Plating System - Anatomic, Right, 15 Hole, Sterile	AR-9953AR-15S
Humeral Plating System - Anatomic, Left, 15 Hole, Sterile	AR-9953AL-15S
Cerclage Button, 4.5 mm	AR-9953CB-T45
Cerclage Button, 4.5 mm, Sterile	AR-9953CB-T45S

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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