Arthrex Spine Compression FT Screws

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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Device Description

The Arthrex Spine Compression FT Screws are threaded, cannulated titanium implants that are available in a variety of sizes and feature hydroxyapatite (HA) coating over the entire thread length.

Material Specifications

The Arthrex Spine Compression FT Screw System

The Arthrex spine compression FT screws are manufactured from titanium alloy (ASTM F1472 and ASTM F136) which contains:

ASTM F1472

Titanium, (balance)
Aluminum, (5.5 - 6.75%)
Vanadium, (3.5 - 4.5%)
Iron, (0.30% max)
Oxygen, (0.20% max)
*Other materials may be present at trace levels.

ASTM F136

Titanium, (balance)
Aluminum, (5.5 - 6.50%)
Vanadium, (3.5 4.5%)
Iron, (0.25% max)
Oxygen, (0.13% max)
*Other materials may be present at trace levels.

The compression screw threads are fully coated with thermally sprayed coatings of hydroxyapatite (ISO 13779-2). Thermally sprayed coatings of hydroxyapatite (ISO 13779-2), which contains*:

α-TCP + β-TCP + TTCP sum of a tricalcium phosphate, β tricalcium phosphate, and tetracalcium phosphate, (≤30%)
CaO Calcium Oxide, (≤5%)
* Other materials may be present at trace levels.

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.

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. MRI Safety Information

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 Spine Compression FT Screws
Static Magnetic Field Strength (B_0 - B subscript)	1.5 Tesla and 3 Tesla
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)	1 W/kg (Normal Operating Mode)
Maximum Head SAR	N/A
Scan Duration	Expected maximum temperature rise of less than 4 °C after 15-minutes of continuous scanning. Since this is less than 4 °C, continuous scanning for 60-minutes without cooling can be done under the scan conditions defined above.
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 as 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.	

A person with an Arthrex Spine Compression FT Screw 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 Spine Compression FT Screws

Consult your Arthrex Spine Compression FT Screws Patient Implant Card (PIC) for information on the device type/ model of the implant used in your procedure.

Length (mm)	D = 4.0 mm	D = 5.0 mm
12	AR-S8740-12HA-S	
14	AR-S8740-14HA-S	
16	AR-S8740-16HA-S	
18	AR-S8740-18HA-S	
20	AR-S8740-20HA-S	AR-S8750-20HA-S
22	AR-S8740-22HA-S	AR-S8750-22HA-S
24	AR-S8740-24HA-S	AR-S8750-24HA-S
26	AR-S8740-26HA-S	AR-S8750-26HA-S
28	AR-S8740-28HA-S	AR-S8750-28HA-S
30	AR-S8740-30HA-S	AR-S8750-30HA-S
32	AR-S8740-32HA-S	AR-S8750-32HA-S
34	AR-S8740-34HA-S	AR-S8750-34HA-S
36	AR-S8740-36HA-S	AR-S8750-36HA-S
38	AR-S8740-38HA-S	AR-S8750-38HA-S
40	AR-S8740-40HA-S	AR-S8750-40HA-S
42	AR-S8740-42HA-S	AR-S8750-42HA-S
44	AR-S8740-44HA-S	AR-S8750-44HA-S
46	AR-S8740-46HA-S	AR-S8750-46HA-S
48	AR-S8740-48HA-S	AR-S8750-48HA-S
50	AR-S8740-50HA-S	AR-S8750-50HA-S
52	AR-S8740-52HA-S	
54	AR-S8740-54HA-S	
55		AR-S8750-55HA-S
56	AR-S8740-56HA-S	
58	AR-S8740-58HA-S	
60	AR-S8740-60HA-S	AR-S8750-60HA-S

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 www.arthrex.com
Arthrex GmbH	Erwin-Hielscher-Strasse 9 81249 München Germany +49 89 90 90 05-0 www.arthrex.de

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

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

arthrex.com