

# English

## A. DEVICE DESCRIPTION

The Arthrex Compression Screws are threaded, cannulated implants that are available in a variety of sizes.

## B. INDICATIONS

The Arthrex Compression Screw is intended for fixation of small bone fragments, such as apical fragments, osteochondral fragments and cancellous fragments. Specific applications include the following:

- Osteochondral fragments
- Cancellous fragments
- Transverse ligamentous tears
- Tarsal and metatarsals
- Phalanges
- Intra-articular fractures
- Ankle
- Proximal humerus (Except in EU)
- Osteochondral fixation and fractures
- Osteochondral fissures
- Oblique fractures of the fibula
- Reconstructive surgeries of the foot
- Malleolar fixation

## C. CONTRAINDICATIONS

- Insufficient quantity or quality of bone.
- Blood supply limitations and previous infections, which may retard healing.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Bioabsorbable only:** Foreign Body Reactions. See Adverse Effects-Allergic Type Reactions.
- Any active infection or blood supply limitations.
- Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
- 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 should not be rigid, disturb or disrupt the growth plate.
- Do not use for surgeries other than those indicated.

## D. ADVERSE EFFECTS

- Infections, both deep and superficial.
- Foreign body reactions.
- Non-healing due to inadequate blood supply in the area of the repair.
- Bioabsorbable only:** Allergic-like reactions to PLA materials (PLLA, PLDLA) have been reported. These reactions have sometimes necessitated the removal of the implant. Patient sensitivity to device materials must be considered prior to implantation.

## E. WARNINGS

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- Procedures carried out using these devices may be used on the general population.
- The clinical benefits associated with the use of these devices outweigh the known clinical risks.
- There are no unacceptable residual risks or uncertainties associated with the clinical use of these devices.
- This device is intended to be used by a trained medical professional.
- The joint or osteotomy should be stabilized prior to insertion of the screw to prevent damage to the screw or insertion.
- An internal fixation device must never be re-used.
- Bioabsorbable only:** Do not re-sterilize this device.
- Metal only:** All metallic implant devices used for this surgical procedure should have the same metallurgical composition.
- Postoperative and until healing is complete. Temporary use 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.
- Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implant, are important considerations in the successful utilization of this device. The appropriate Arthrex delivery system is required for proper implantation of the device.
- Any decision to remove the device should take into consideration the potential risks to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.
- Metal only:** Devices that have been implanted for a long period of time may require the use of screw removal instrumentation.
- 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.
- Patient sensitivity to the device materials should be considered prior to implantation. See Adverse Effects.
- Biohazard waste, such as explanted devices, needles and contaminated surgical equipment, should be safely disposed of in accordance with the institutions policy.
- Serious incidents should be reported to Arthrex, Inc., or an in-country representative, and to the health authority where the incident occurred.

## F. MRI SAFETY INFORMATION

### 1. MR Conditions

*Non-clinical testing and in-vitro electromagnetic simulations demonstrated that the metal (titanium and stainless steel) Compression Screws are MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:*

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system

Under the scan conditions defined, the Compression Screws are expected to produce a maximum temperature rise of up to 6 °C after 15 minutes of continuous scanning.

*In non-clinical testing, the image artifact caused by the Compression Screws can extend up to approximately 120 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.*

- MR Safe**  
The Compression Screws devices manufactured from only Poly(L-Lactide) are MR safe.

**MR Safety Exception:** The 2.5 mm Micro Compression FT Screws (32 to 50 mm), 3.5 mm Mini Compression FT Screws (36 to 60 mm) and the Standard Compression FT Screws (52 to 60 mm) have not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. These devices have not been tested for heating, migration or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury.

- PRECAUTIONS**  
1. Surgeons must apply their professional judgment when determining the appropriate suture-anchor type and size based on the specific indication, preferred surgical technique, and patient history.

- Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or, contact your Arthrex representative for an onsite demonstration.

## H. PACKAGING AND LABELING

- Arthrex devices and accepted only if the factory packaging and labeling arrive intact.
- Contact Customer Service if the package has been opened or altered.
- All of the symbols used on the labeling along with the title, description and standard designation number may be found on our website at [www.arthrex.com/symbolglossary](http://www.arthrex.com/symbolglossary).

## I. VALIDATION

The recommended cleaning, disinfection, and sterilization methods in this DFU have been validated in compliance with federal and international guidance/standards. In accordance with ISO 17665, the "overall" approach was used for sterilization validation, and demonstrates a sterility assurance level (SAL) of 10<sup>-6</sup>. Cleaning, disinfecting, and sterilizing equipment and materials vary in performance characteristics. Therefore, it is the responsibility of the facility/end user to perform the appropriate validation testing for any use beyond recommended performance characteristics.

In accordance with EN ISO 17664 and ANSI TR190, limit values and a means for monitoring chemical residues following cleaning have been established for the product. In assessing the level of cleaning residuals following the manual cleaning and disinfection process or the machine (automated) cleaning and disinfection process, a clinically relevant method was utilized for testing the safety of residuals as part of the validation protocol. Deionized (critical) water was utilized as the terminal rinse water quality to ensure that residuals will not interfere with subsequent processing steps.

Repeated processing has minimal effect on these devices. The end life is normally determined by wear and damage due to intended use. The user assumes liability and is responsible for the use of a damaged and dirty device.

A device labeled as a Single Use device must **never** be re-used. Using blood, bone, tissue, or other body fluids that have come into contact with, used with, or used by other body fluids. Any unused single use device that has been exposed to blood, bone, tissue, or body fluids must **not be reprocessed and must be discarded**.

The instructions in this DFU were developed using the guidance given in the following standards:

- ANSI/AMI ST79, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities"
- ISO 17664, Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 17665-1, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices
- AMI TR30:2011: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- AMI S177, Containment devices for reusable medical device sterilization

## J. CLEANING AND DISINFECTION

Certain Arthrex devices that may be used during this procedure are provided non-sterile and must be adequately cleaned and sterilized prior to use or re-use. All devices are to be cleaned, disinfected, and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile device. An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the devices. Single-use devices must be cleaned separately from soiled devices.

If possible, the Machine (Automated) procedure should be used for cleaning and disinfection of the instruments. The Manual Cleaning procedure should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of the manual procedure should be considered. The Preliminary Cleaning step is to be performed in both cases. Manual cleaning may require onsite validation by the healthcare facility and appropriate procedures should be in place to avoid human factor variability.

### I. DETERGENT SELECTION

Consider the following points during selection of the cleaning detergent:

- Suitability of the cleaning agent for ultrasonic cleaning (no foam development).
- Compatibility of the cleaning agent with the instruments. Arthrex recommends the use of neutral pH or enzymatic cleaning agents. Alkaline agents may be used on devices in countries where required by law or local ordinance, or where prior diseases such as Transmissible Spongiform Encephalopathy (TSE) or Creutzfeldt-Jakob disease (CJD) are a concern. **Caution: Low acid or alkaline solutions are not recommended, as they corrode metal parts and anodized aluminum and compromise polymer plastics, such as FEP (Fluorinatedethylenepropylene), ABS (Acrylonitrile-butadiene Styrene), Ultem™, Lexan™, and Cyoclear™.** If non-neutral pH cleaning chemistries are utilized, care should be taken to ensure appropriate rinsing as validated by the end-user facility, and neutralization steps are taken so as to not negatively impact the fit, finish, or function of the device.
- Follow the instructions of the detergent manufacturer regarding use concentration and temperature for either manual or automated cleaning. Use only freshly prepared solutions as well as only purified water at least for final rinse, and a soft, low-linting cloth and/or filtered medical grade air for drying equipment.

### II. PRELIMINARY CLEANING

**Note:** No assembly/disassembly of these devices is required unless stated on the labeling, directions for use, or literature assembly instructions (IAI) pertaining to cleaning, disinfection, and sterilization. Devices that require disassembly are to be disassembled prior to cleaning.

1. Remove excess soil from devices, especially in areas such as joints and crevices, by cleaning the surfaces with a sponge or brush under cold running water or with a non-shedding disposable wipe for a minimum of 30 seconds.

- Rinse the devices at least 1 minute under running utility water (temperature < 35 °C/95 °F). Special attention should be given to lumens, joint, crevices, and other hard-to-reach areas.
- Immerse the devices in cleaning solution inside an ultrasonic bath. While immersed in solution, brush the devices for 1 minute using a soft-bristled brush. Special attention should be given to lumens, joints, crevices, and other hard-to-reach areas. Lumens should be brushed with appropriate diameter and length bristle sizes for the particular lumens. Actuate movable parts at least (5) times during soaking, as applicable.
- After brushing, turn on ultrasonic power and soak and sonicate for 10 minutes at a minimum of 40-5 kHz. Ensure devices are in the open position and that lumens have complete contact with cleaning solution during soaking.
- Remove the devices from the cleaning solution and rinse at least 1 minute with utility water. Thoroughly and aggressively rinse lumens, joints, crevices, and other hard-to-reach areas.
- After the completion of preliminary cleaning, the end user has the option to perform either Manual Cleaning and Disinfection or Machine (Automated) Cleaning and Thermal Disinfection (preferred).

### III. MACHINE (AUTOMATED) CLEANING AND THERMAL DISINFECTION

Considerations for the selection of the washer-disinfector:

- Capable of providing an approved program for thermal disinfection (appropriate exposure time and temperature according to A concept)
  - Final rinse completed with purified (critical, e.g. RO or DI) water, and utilizes only filtered (if unused) water
- After preliminary cleaning is complete, load the devices in the washer-disinfector such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, hinges should be open and cannulations/holes positioned to drain).

- For preliminary cleaning is complete, load the devices in the washer-disinfector such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, hinges should be open and cannulations/holes positioned to drain).

- If using alkaline cleaning agents, a neutralization step should be utilized as appropriate.

- Run an automatic wash cycle with fundamentally approved efficiency of the washer-disinfector (for example, CE marking according to EN ISO 15883 or FDA Approval/clearance/registration). The following minimum recommended automated wash cycle parameters were utilized by Arthrex during the validation of these instructions.

RECOMMENDED WASHING CYCLE PARAMETERS				
Phase	Recirculation Time	Temperature	Detergent	
Pre-Wash	3 Minutes	Cold Water	N/A	
Cleaning Wash	10 Minutes	Follow detergent manufacturer's recommendation	Enzymatic or alkaline detergent	
Neutralization Rinse (optional)	2 Minutes	Follow detergent manufacturer's recommendation	Neutralizing agent (as needed)	
Rinse	3 Minutes	Cold Water	N/A	
Thermal Disinfection Rinse	5 Minutes	90°C (194°F)	N/A	
Drying	Minimum 6 Minutes or until visibly dry	Minimum 100°C (212°F)	N/A	

- Remove the devices from the washer-disinfector following the completion of the program and check devices for visible soil. Repeat cleaning if soil is visible and re-inspect; otherwise, proceed to Sterilization section.

### IV. MANUAL CLEANING AND DISINFECTION

Following preliminary cleaning, the instructions for Manual Cleaning and Disinfection may be followed as an alternative cleaning method to Machine (Automated) Cleaning and Thermal Disinfection if an automated procedure is not available.

- After preliminary cleaning is complete, repeat steps 1-5 provided in the Preliminary Cleaning section within this DFU, including rinsing, immersion and sonication, and post-rinsing. Final rinsing should be completed with purified (critical, e.g. RO or DI) water.
- Check devices for visible soil. Repeat cleaning if soil is visible and re-inspect.
- Soak the devices for the given soaking time (provided by the disinfectant manufacturer) in disinfectant solution so that the devices are sufficiently covered. Make sure that there is no contact between the devices. Ensure that the device is in the open position during soaking. Actuate movable parts at least five times during disinfection, as applicable.
- Remove the devices from the disinfectant solution and rinse per disinfectant manufacturer's instructions.
- Dry devices thoroughly utilizing filtered medical grade air or a soft, low-linting cloth. Proceed to Sterilization section.

## K. STERILIZATION

This device may be provided either sterile or non-sterile. Check the package labeling for more information. For devices that are not provided in a terminally sterilized configuration, sterilization is to be performed following cleaning, disinfection, and sterile packaging prior to use, and may be re-sterilized (if unused) following cleaning, disinfection, and sterile packaging prior to use.

Devices that are provided in a terminally sterilized configuration should never be re-sterilized under any conditions.

Certain Arthrex instruments that may be used during this procedure are provided non-sterile and must be adequately cleaned and sterilized prior to use or re-use. Please refer to DFU-0023-XX and ANSI/AMI ST79 for specific information.

### I. STERILE PACKAGING

Singly: Single devices should be packed as to ensure that the pack is large enough to contain the device without stressing the seals. Packaging should be completed utilizing a pouch or wrap which conforms to the recommended specifications for steam sterilization as outlined below. If a wrap is utilized, it should be cleaned following ANSI AAMI double-wrap or equivalent guidelines with an appropriate wrap. An appropriate wrap is one that, for example, is cleared by the FDA or the local governing body at the point of use. Devices may also be placed into an approved reusable rigid sterilization container. Aseclup SterilContainer™ rigid containers with perforated bottoms and lids are approved for use with Arthrex, Inc. devices.

**Sets:** Where appropriate, cleaned, disinfected and inspected devices should be placed into trays/cases as provided or in general-purpose sterilization trays. The total weight of trays/cases should not exceed 11.4kg/25 lbs. (other local limits below 11.4kg/25 lbs. may apply). Trays/cases should be double wrapped following AAMI or equivalent guidelines with an appropriate wrap. An appropriate wrap is one that, for example, is cleared by the FDA or the local governing body at the point of use. Sets may also be placed into an approved reusable rigid sterilization container. Aseclup SterilContainer™ rigid containers with perforated bottoms and lids are approved for use with Arthrex, Inc. sets.

Areas designated for specific devices shall contain only devices intended for those areas. Devices should not be stacked or placed in close contact. Only Arthrex devices should be included in the trays or cases. These validated reprocessing instructions are not applicable to Arthrex trays or cases.

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table below. Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

RECOMMENDED STEAM STERILIZATION PARAMETERS				
Cycle Type	Minimum Exposure Temperature	Minimum Exposure Time	Minimum Drying Time <sup>1</sup>	Minimum Cooling Time <sup>2</sup>
US Prevacuum Cycle	132°C (270°F)	4 Minutes	30 Minutes	30 minutes
UK Prevacuum Cycle	134°C (273°F)	3 Minutes	30 minutes	30 minutes
Prevacuum Cycle <sup>3</sup> (Print Cycle)	134°C (273°F)	18 minutes	30 Minutes	30 minutes

<sup>1</sup>Drying times vary according to load size and should be increased for larger loads.

<sup>2</sup>Cooling times vary according to the sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AMI ST79.

<sup>3</sup>Reprocessing parameters recommended by the World Health Organization (WHO) where there is concern regarding TSE/CJD contamination.

### III. SPECIAL PRECAUTION – TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY AGENTS

It is outside the scope of this document to describe in detail the precautions that should be taken for Transmissible Spongiform Encephalopathy Agents. The agents for transmission of Creutzfeldt-Jakob disease are believed to be resistant to normal processes of disinfection and sterilization and therefore the normal processing methods of decontamination and sterilization as described above may not be appropriate where CJD transmission is a risk. In gen-

eral, the tissues that come into contact with orthopedic surgical instruments are those of low TSE infectivity. However, particular precautions should be taken when handling instruments that have been used on known, suspected, or at-risk patients. Refer to AAMI ST79 for further information.

## L. MATERIAL SPECIFICATIONS

Refer to the package label for the materials.  
This device is made of Poly (L-Lactide), or titanium.

## M. STORAGE CONDITIONS

Sterile devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date. Non-sterile metal devices should be stored in a clean, dry environment. The shelf life of non-sterile devices is not limited; the devices are manufactured from non-degradable material, which does not require any form of device stability when stored under recommended conditions.

It is the responsibility of the end-user to ensure devices, once sterilized, are stored in such a way as to maintain the sterility of the device until use. Sterile, packaged devices should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, and temperature/humidity extremes. Sterile device packages should be carefully examined prior to opening to ensure that package integrity has not been compromised. Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, shows any evidence of tampering, or has been exposed to moisture, the device or set must be cleaned, repackaged, and sterilized.

Under the defined Scanbedingungen wird erwartet, dass die Kompressionsrauben einen maximalen Temperaturanstieg von 6 °C nach 15 Minuten unterbrochenen Saugens verursachen. Bei nichtklinischen Tests kann das durch die Kompressionsrauben verursachte Image-Verlänger bis zu ca. 120 mm über diese Implantat hinausragen, wenn die Bildgebung mit einer Gradientenfeldspindelung und einem MR-System mit 3 Tesla erfolgt.

- MR-sicher**  
Die nur aus Poly(L-Laktid) gefertigten Kompressionsrauben sind MR-sicher.

**MR-Sicherheitsausnahme:** Die 2,5 mm Mikro-Kompressions-Vollgewinde-schrauben (32 bis 50 mm), 3,5 mm Mini-Kompressions-Vollgewinde-schrauben (36 bis 60 mm) und die Standard-Kompressions-Vollgewinde-schrauben (52 bis 60 mm) wurden nicht auf Sicherheit und Kompatibilität in der Magnetresonanztomographie (MR) geprüft. Diese Produkte wurden nicht in Hinblick auf eine Erwärmung, Wanderungsbeugungen oder Bildartefakte bei der Verwendung in einem MR-System untersucht. Es liegen keine Informationen zur Sicherheit dieses Produkts während einer Magnetresonanztomographie (MRT) vor. Beim Scannen von Patienten mit diesen Produkten besteht für den Patienten ein Verletzungsrisiko.

## IV. MANUAL CLEANING AND DISINFECTION

Following preliminary cleaning, the instructions for Manual Cleaning and Disinfection may be followed as an alternative cleaning method to Machine (Automated) Cleaning and Thermal Disinfection if an automated procedure is not available.

- After preliminary cleaning is complete, repeat steps 1-5 provided in the Preliminary Cleaning section within this DFU, including rinsing, immersion and sonication, and post-rinsing. Final rinsing should be completed with purified (critical, e.g. RO or DI) water.
- Check devices for visible soil. Repeat cleaning if soil is visible and re-inspect.
- Soak the devices for the given soaking time (provided by the disinfectant manufacturer) in disinfectant solution so that the devices are sufficiently covered. Make sure that there is no contact between the devices. Ensure that the device is in the open position during soaking. Actuate movable parts at least five times during disinfection, as applicable.
- Remove the devices from the disinfectant solution and rinse per disinfectant manufacturer's instructions.
- Dry devices thoroughly utilizing filtered medical grade air or a soft, low-linting cloth. Proceed to Sterilization section.

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Devices that are provided in a terminally sterilized configuration should never be re-sterilized under any conditions.

Certain Arthrex instruments that may be used during this procedure are provided non-sterile and must be adequately cleaned and sterilized prior to use or re-use. Please refer to DFU-0023-XX and ANSI/AMI ST79 for specific information.

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### I. STERILE PACKAGING

Singly: Single devices should be packed as to ensure that the pack is large enough to contain the device without stressing the seals. Packaging should be completed utilizing a pouch or wrap which conforms to the recommended specifications for steam sterilization as outlined below. If a wrap is utilized, it should be cleaned following ANSI AAMI double-wrap or equivalent guidelines with an appropriate wrap. An appropriate wrap is one that, for example, is cleared by the FDA or the local governing body at the point of use. Devices may also be placed into an approved reusable rigid sterilization container. Aseclup SterilContainer™ rigid containers with perforated bottoms and lids are approved for use with Arthrex, Inc. devices.

**Sets:** Where appropriate, cleaned, disinfected and inspected devices should be placed into trays/cases as provided or in general-purpose sterilization trays. The total weight of trays/cases should not exceed 11.4kg/25 lbs. (other local limits below 11.4kg/25 lbs. may apply). Trays/cases should be double wrapped following AAMI or equivalent guidelines with an appropriate wrap. An appropriate wrap is one that, for example, is cleared by the FDA or the local governing body at the point of use. Sets may also be placed into an approved reusable rigid sterilization container. Aseclup SterilContainer™ rigid containers with perforated bottoms and lids are approved for use with Arthrex, Inc. sets.

Areas designated for specific devices shall contain only devices intended for those areas. Devices should not be stacked or placed in close contact. Only Arthrex devices should be included in the trays or cases. These validated reprocessing instructions are not applicable to Arthrex trays or cases.

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table below. Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

RECOMMENDED STEAM STERILIZATION PARAMETERS				
Cycle Type	Minimum Exposure Temperature	Minimum Exposure Time	Minimum Drying Time <sup>1</sup>	Minimum Cooling Time <sup>2</sup>
US Prevacuum Cycle	132°C (270°F)	4 Minutes	30 Minutes	30 minutes
UK Prevacuum Cycle	134°C (273°F)	3 Minutes	30 minutes	30 minutes
Prevacuum Cycle <sup>3</sup> (Print Cycle)	134°C (273°F)	18 minutes	30 Minutes	30 minutes

<sup>1</sup>Drying times vary according to load size and should be increased for larger loads.

<sup>2</sup>Cooling times vary according to the sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AMI ST79.

<sup>3</sup>Reprocessing parameters recommended by the World Health Organization (WHO) where there is concern regarding TSE/CJD contamination.

