

The Zimmer Biomet A.L.P.S. mvX™ Mini-Fragment Instructions for Use

R_x Federal law restricts this device to sale by or on the order of a physician.

Intended Use:

The **Zimmer Biomet A.L.P.S. mvX™** Mini-Fragment System is intended to bridge or otherwise stabilize bone Fragments to facilitate healing.

Indications for Use:

The **Zimmer Biomet A.L.P.S. mvX™** Mini-Fragment System is indicated for fixation of fractures, osteotomies, non-unions, malunions, replantations, and fusions of short bones and small fragments of bone, including, but not limited to, the hand, wrist, foot, and ankle. The **A.L.P.S. mvX™** Mini-Fragment System is also intended for reduction and stabilization of non-load-bearing long bone fragments. The **A.L.P.S. mvX™** Mini-Fragment System is not for Spinal Use.

Contraindications:

- Infection.
- Patient conditions including blood supply limitations, obesity, and insufficient quantity or quality of bone.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Foreign body sensitivity. If material sensitivity is suspected, testing is required prior to implanting the device.

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Materials

The **A.L.P.S. mvX™** Mini-Fragment System plates and screws are manufactured from a Titanium alloy (ASTM F136). The instruments are made of surgical-grade stainless steel (per ASTM F899 or ASTM A564), Aluminum (per ASTM B221) and Silicone.

Adverse Effects:

In all surgical procedures, the potential for complications and adverse reactions exists. The risks and complications with these implants include:

- Fracture of the implant due to excessive loading
- Incomplete or inadequate healing
- Implant migration and/or loosening
- Pain, discomfort, or abnormal sensations due to the presence of an implant
- Nerve damage resulting from surgical trauma
- Bone necrosis or bone resorption
- Delayed or nonunion of bone Fragments
- Allergic reaction to the implant materials

Warnings & Precautions:


- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Implants must not be reused or re-sterilized.
- Use only Ti-6Al-4V screws with Ti-6Al-4V plates.
- Optional bone screw washers are not to be used with the plates. The washers are only for use with a screw as a standalone screw/screw washer construct. See the MRI Safety Information section for the safe scanning conditions applicable to a standalone screw (with or without a screw washer).
- Improper insertion of the device during implantation may result in implant loosening or migration.
- Loosening or migration and loss of fixation due to incorrect implantation, delayed union, nonunion, and incomplete healing may occur.
- Bending or fracture due to applied excessive stresses and load bearing may occur.
- Failure to follow postoperative care instructions may result in post-operative complications or failure of the implant.
- Electrolytic action and corrosion due to implanting with other metallic devices of different chemical compositions may occur.

MRI Safety Information:

The **A.L.P.S. mvX™** Mini-Fragment System is MR Conditional and may only be in an MR environment under specific conditions. The following tables provide the MR conditions for which the **A.L.P.S. mvX™** Mini-Fragment System may be safely scanned in the MR environment. Failure to adhere to these conditions may result in injury or device malfunction.

The patient should consult with their healthcare provider prior to an MR exam and inform the MRI site personnel that they have an MR Conditional Device during the MR screening prior to MR exam.

An MR Patient Implant Card is available at zb-eifu.info. This should be completed using the label of the implanted device and provided to the patient as part of their postoperative care.

<div style="text-align: center;">  </div> <p>MRI Safety Information</p> <p>A patient with the Zimmer Biomet A.L.P.S. mvX™ Mini-Fragment System (plate/screw construct) may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.</p>	
Name/Identification of device	Zimmer Biomet A.L.P.S. mvX™ Mini-Fragment System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	20 T/m (2000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Body Coil: see scan limitations below, Local Coils: No restrictions on local transmit-receive coils that the device is not within
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR	See details below
Maximum Head SAR	3.2W/kg (Normal Operating Mode)
RF Conditions	<p>1.5 T MRI Systems</p> <p>$B1+RMS \leq 3.40 \mu T$ for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)</p> <p style="text-align: center;">or</p> <p>Whole body average SAR ≤ 1.0 W/kg for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)</p>
	<p>3 T MRI Systems</p> <p>$B1+RMS \leq 1.45 \mu T$ for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)</p> <p style="text-align: center;">or</p> <p>Whole body average SAR ≤ 0.8 W/kg for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)</p>
MR Image Artifact	The presence of this implant may produce an image artifact of 68 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	



MR Safety Information

A patient with the Zimmer Biomet **A.L.P.S. mvX™** Mini-Fragment System (i.e., screw on its own or with a washer, not with plates) may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Zimmer Biomet A.L.P.S. mvX™ Mini-Fragment System (standalone screws and/or screw/washer constructs)
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	20 T/m (2000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, no restriction on transmit-receive coils that the device is not within
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR	See details below
RF Conditions	1.5 T MRI Systems $B1+RMS \leq 1.7 \mu T$ or whole body average SAR ≤ 1.0 W/kg for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
	3 T MRI Systems $B1+RMS \leq 1.4 \mu T$ or whole body average SAR ≤ 0.5 W/kg 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 of 20 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

Instructions for Use:

1. Using standard dissection techniques, expose the surgical site.
2. Perform the intended osteotomy or identify the fracture location.
3. After reduction of the fracture, choose the proper plate based on the size and type of indication.
4. Place the plate on the fracture/osteotomy site and fix it with plate tacks or k-wires. If forming/bending the plate to fit the anatomy – use the bending instruments for preparation of the proper contour. DO NOT REPEATEDLY BEND THE PLATE – as this will cause a weakened fatigue life of the plate.
5. Utilize the drill guide with proper drill according to screws size for angulation into the most secure bone structure - drill the hole for a screw. Repeat hole preparation as necessary for proper fixation of the plate.
6. Utilize the depth gauge to determine proper length of screw in bone anatomy for firm fixation in the opposite bone cortex.
7. Insert desired size screw matching to plate size and bone anatomy. Repeat process on remaining screw(s) with angulation holes – using either locking or standard screws.
8. Remove plate tacks or k-wires.
9. Using fluoroscopy, confirm the proper plate and screw placement on the bone anatomy. Correct as warranted & re-check.
10. Clean the surrounding area with a pulse lavage.
11. Use the surgeon's preferred method for closing the surgical site.

Postoperative Management:

Provide the patient with their completed MR Patient Implant Card.

The patient is allowed to ambulate with weight-bearing to tolerance on the operated fracture site within limits imposed by postoperative discomfort. The progression to normal use of the digit or limb is limited only by the persistence of postoperative swelling and discomfort.

Care and Handling

Certain Zimmer Biomet devices – implants, instruments, and trays – are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

Limitations on Processing

Repeated processing has minimal effect on these devices. End of life is normally determined by wear and damage due to use.

Point of Use

Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling, thorough cleaning, and sterilization of biologically contaminated devices.

Containment and Transportation

It is recommended that the reusable devices are reprocessed as soon as reasonably practical following use.

Preparation for Cleaning

Remove excess soil with a clean, disposable, absorbent Kimwipe or equivalent.

Disassembly of Depth Gauge

1. The Depth Gauge is a two-piece assembly. Separate the body and sleeve as far as possible. Then rotate the body 90° to fully disassemble.
2. Proceed to cleaning steps below.

Automated Cleaning

Equipment: Automated washer, soft bristle brush, enzymatic detergent, and neutral pH detergent.

- Preclean the devices by placing them under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each device for at least one minute.
- After precleaning, place in the automated washer, making sure the samples do not touch each other - load devices in such a way that the parts can drain.
- At a minimum, use a standard cycle with the following parameters:

Enzyme Wash	Hot (40 - 65°C) (104 - 149°F) for 3 minutes
Neutral pH Wash	60°C (140°F) for 3 minutes
Rinse	Ambient temperature for 1.5 minutes
Thermal Rinse	90°C (194°F) for 1 minute
Dry	82°C (180°F) for 6 minutes

- Determine if the devices are dry. If they are not dry, dry with a soft, clean, lint free cloth.
- Replace any device that cannot be cleaned.

Manual Cleaning

Warning: Movable components and blind holes require particular attention during cleaning.

Preparation of Cleaning Agents (Recommended):

- Add 60 mL of Endozime® AW Plus to 3.8 L of water, (1:64 dilution).

Manual Cleaning Instructions:

- Preclean the devices by placing them under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each device for at least one minute.
- Bathe the devices in the enzymatic solution for 5 minutes; where appropriate, the device shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution.
- Scrub the devices with a soft bristle brush while submerged in the detergent.
- Rinse the devices using reverse osmosis or distilled water at room temperature for 5 minutes.
- The rinse bath should be changed after each cleaning process.
- Pat dry with a soft, clean, lint free cloth.

Replace any device that cannot be cleaned.

Inspection and Function Testing

Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged. Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored, or damaged instruments. Verify the legibility of all markings. Replace any device that has unreadable markings. Replace affected devices as needed to ensure proper operation before proceeding with sterilization.

Device Replacement

Warning: The use of damaged instruments may increase the risk of tissue trauma, infection, and length of operative procedures.

Warning: Do not attempt to repair any Zimmer Biomet A.L.P.S. mvX™ instrument.

If your Zimmer Biomet device is defective or damaged, contact your local Zimmer Biomet Representative. In your correspondence, please include at a minimum, the following:

- Device Lot Number
- Device Part Number
- Description of defect or damage
- Information on whether the device is available for return

If the device is available for return, place the device in a sturdy box with adequate packaging material to protect the device. Send the packaged device to:

Zimmer, Inc.
1800 W Center St
Warsaw, IN 46580

Attn: Zimmer Biomet Technical Services

Note: Devices returned to Zimmer Biomet must have a statement which testifies that each device has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your replacement device.

Depth Gauge Assembly

Prior to placing the depth gauge back in the tray, reassemble by inserting depth gauge body into the sleeve. Once the depth gauge body hits a stop, rotate 90 degrees and continue full insertion.

Packaging

Implants and instruments may be loaded into the specified Zimmer Biomet trays, or general-purpose trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA cleared for pre-vacuum steam sterilization.

Sterilization:

WARNING: Please note that a single-use device (SUD) which comes in contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed.

Warning: Zimmer Biomet does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the 'sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10⁻⁶, Zimmer Biomet recommends the following parameters:

METHOD	TIME*	TEMPERATURE	DRY TIME
Pre-Vacuum	4 minutes	270° F (132° C)	20 MINUTES
	3 minutes	275° F (135° C)	
Gravity	15 minutes	270° F (132° C)	20 MINUTES
<i>*The sterilization cycles provided above have been validated by the manufacturer. The validated sterilization parameters meet the minimum requirements per ISO 17665. Other sterilization cycles may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques</i>			

Zimmer Biomet recommends following ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, which includes: physical monitoring of the cycle, inclusion of a chemical indicator internal and external to the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.

Storage

A.L.P.S mvX™ devices must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

Retrieval And Analysis Of Removed Implants

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant during handling and shipping. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. Please contact Zimmer Biomet customer service for return of removed implants.

Disposal

Observe internal hospital/institution procedures, practice guidelines, and/or government regulations for proper handling and disposal of the **A.L.P.S mvX™** Mini-Fragment System.

Customer Service

For further information regarding the **Zimmer Biomet A.L.P.S. mvX™** Mini-Fragment System or a copy of the Surgical Technique Guide, please contact Zimmer Biomet, or your local Zimmer Biomet Distributor.



















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Symbol Glossary:

SYMBOL	STANDARD/TITLE	MEANING
	21 CFR 801.109b Prescription Only	Caution: Federal law restricts this device to sale by or on the order of a physician.
	ASTM F2503 Magnetic Resonance (MR) Conditional	A medical device that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the MR environment include static magnetic field strength spatial gradient, time rate of change of the magnetic field (dB/dt), RF fields, and specific absorption rate (SAR). These conditions are identified on all appropriate product labeling.
	ISO 15223-1 5.1.6 Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 5.1.5 Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 5.1.11 Country and Date of manufacture	Indicates the country and date of manufacture of a device.
	ISO 15223-1 5.4.2 Do not re-use	Indicates a medical device that is intended for one single use only.
	ISO 15223-1 5.4.3 Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 5.2.7 Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 15223-1 5.1.9 Distributor	Indicates the entity distributing the medical device into the locale.
	ISO 15223-1 5.1.1 Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 5.7.7 Medical Device	Indicates the item is a medical device.
	ISO 15223-1 Unique device identifier	Indicates a carrier that contains unique device identifier information.
	ISO 15223-1 5.7.3 Patient identification	Indicates the identification data of the patient.
	ISO 15223-1 5.7.4 Patient information website	Indicates a website where a patient can obtain additional information on the medical product.
	ISO 15223-1 5.7.5 Health care centre or doctor	Indicates the address of the health care centre or doctor where medical information about the patient may be found.
	ISO 15223-1 5.7.6 Date	Indicates the date that information was entered or a medical procedure took place.