The Zimmer Biomet A.L.P.S. mvX™
Ankle Fracture System Instructions for Use

Intended Use:
The intended use of the **Zimmer Biomet A.L.P.S. mvX™** Ankle Fracture System is to bridge or otherwise stabilize bone fragments to facilitate healing.

Indications for Use:
The **Zimmer Biomet A.L.P.S. mvX™** Ankle Fracture System is indicated for use in:

- Fixation of fractures of the distal tibia included, but not limited to, ankle fractures, periarticular fractures, corrective osteotomies, non-unions, intra- and extra-articular and distal tibia fractures with a shaft extension, and malleolar fractures;
- In intra- and extra-articular fractures, osteotomies, medial malleolar fractures, and nonunions of the metaphyseal and diaphyseal region of the distal fibula, and calcaneus;
- In the distal tibia/fibula, long bones which include the metaphyseal and diaphyseal regions of the tibia and fibula in the ankle.
- The **Zimmer Biomet A.L.P.S. mvX™** Ankle Fracture System is not for Spinal Use.

Contraindications Include:

- 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.

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

Materials
The **A.L.P.S. mvX™** Ankle Fracture System plates and screws are manufactured from a Titanium alloy (ASTM F136). The instruments are made of surgical-grade stainless steel (per ASTM A564 or ASTM F899), 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 re-used or re-sterilized.
- Use only Ti-6Al-4V screws with Ti-6Al-4V plates.
- 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.
- 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 composition may occur.

MRI Safety Information:
The **A.L.P.S. mvX™** Ankle Fracture 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™** Ankle Fracture 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.

MRI Safety Information 

A patient with the Zimmer Biomet **A.L.P.S. mvX™** Ankle Fracture System 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™** Ankle Fracture 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	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	1.0 W/kg or 2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration - 1.0 W/kg SAR	1.0 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scans without breaks)
Limits on Scan Duration - 2.0 W/kg SAR	2.0 W/kg whole-body average SAR for 7 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) with a 23-minute cooling period between scanning periods for an hour-long scanning session (7-minute scan followed by a 23 minute cooling period, repeated)
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.

MRI Safety Information 

A patient with the Tyber Medical X25 standalone screw 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	Tyber Medical Anatomical Plating 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

Additional instructions for safe use in the MR environment	The MR Technologist and/or patient's point of care team should identify the location of the implant and determine its distance from isocenter (i.e., the anatomical position being imaged) to establish the SAR and scan duration limits that should be adhered to.	
Isocenter Landmark Position	**At least 40 cm from device**	**Within 40 cm of device**
1.5 T SAR and Scan Duration Limits	2.0 W/kg whole body average SAR for 60 minutes of continuous RF*	1.0 W/kg whole body average SAR for 60 minutes of continuous RF*
3 T SAR and Scan Duration Limits	2.0 W/kg whole body average SAR for 60 minutes of continuous RF*	0.5 W/kg whole body average SAR for 60 minutes of continuous RF*
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. *a sequence or back to back series/scan without breaks		

Instructions for use:

1. Using standard dissection techniques, expose the surgical site.
2. Perform the intended osteotomy or identify the fracture location.
3. After the 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 the 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 the 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:

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 Handing

Certain Zimmer Biomet components 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 implants and instruments. 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 the safe handling of biologically contaminated instruments.

Containment and Transportation

It is recommended that instruments are reprocessed as soon as reasonably practical following use.

Preparation for Cleaning of Instruments (Note: Implants are supplied cleaned from the manufacturer and do not require cleaning prior to initial use).
Where instruments interface with other devices, disassemble prior to cleaning. Remove excess soil with a clean, disposable, absorbent Kimwipe or equivalent.

Disassembly of Depth Gauge

1. The Depth Indicator is a two-piece assembly. Simply turn either component 90° to disassemble.
2. Proceed to the cleaning steps below.

Instrument Cleaning (Automated)
Equipment: Automated washer, soft bristle brush, enzymatic detergent, and neutral pH detergent.

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

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 instruments are dry. If they are not dry, dry with a soft, clean, -lint-free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat the cycle or use manual cleaning.
- Final Rinse shall be performed using reverse osmosis or distilled water at room temperature for 5 minutes.
- The rinse bath should be changed after each cleaning process.

Instrument Cleaning (Manual)
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).

Instrument Manual Cleaning Instructions:

- Preclean the instruments by placing them under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
- Bathe the instruments in the enzymatic solution for 5 minutes; where appropriate, the instrument shall be rotated and briskly moved in a 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 instruments 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.
- After drying, check instruments for complete removal of any debris. If necessary, repeat manual cleaning.

After Cleaning
Where instruments have been disassembled prior to cleaning and reassemble prior to use.

Maintenance and Repair
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 instrument requires repair or maintenance, return the instrument in the Zimmer Biomet box or other sturdy box with adequate packaging material to protect the instrument. Send the packaged instrument to:

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

Attn: Zimmer Biomet Technical Services
Note: Instruments returned to Zimmer Biomet must have a statement which testifies that each instrument 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 instrument repair.

Inspection and Function Testing
All instruments: 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.

Packaging
Instruments may be loaded into the specified Zimmer Biomet instrument 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:
For components provided Sterile, the sterilization method is noted on label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10-6. Sterile packaged components are supplied in a protective sterile barrier packaging. Inspect package for punctures or other damage prior to surgery. If sterile barrier has been broken, return component to Zimmer Biomet.

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.

If not specifically labeled STERILE, or if labeled NON-STERILE, components are supplied non-sterile and must be sterilized prior to surgery.

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

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™ instruments 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.

Customer Service

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

Tyber Medical
83 South Commerce Way, Suite 310
Bethlehem, PA 18017

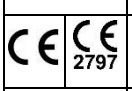
Zimmer, Inc. 1800
W. Center St
Warsaw, IN 46580
USA

BIOMET GSCC B.V.
Hazeldonk 6530
4836 LD Breda
The Netherlands

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

MDSS CH GmbH
Laurenzenvorstadt 61
5000 Aarau
Switzerland

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 of manufacture	Indicates the country 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.
	Swiss authorized representative	Indicates the authorized representative in Switzerland.
	ISO 15223-1 5.1.2 Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/ European Union.
	Regulation (EU) 2017/745 CE Mark / CE Mark with Notified Body	Indicates a product meets the requirements of the EU and can be sold throughout the EU. May contain designated identification number for notified body.
	ISO 15223-1 5.1.8 Importer	Indicates the entity importing the medical device into the locale.
	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.