ZIMMER BIOMET

Zimmer Biomet **A.L.P.S. mvX®**

IM THREADED NAIL SYSTEM

INSTRUCTIONS FOR USE

DESCRIPTION OF THE MEDICAL DEVICE

The implants – delivered non-sterile:

- exist in different diameters and lengths.
- have a recess for engaging a driver.
- have heads configured with threads to engage the proximal bone.
- are fully threaded.

The implants are made from Titanium alloy per ASTM F136.

The instruments – delivered non-sterile – are intended to support the implantation of the Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nails.

INDICATIONS FOR USE

The Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nails are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. The implants are intended for single use only.

INTENDED USE

The Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nails are intended to facilitate compression and fixation between adjacent segments of cortical and/or cancellous bone.

LIMITATIONS

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. Use of the implants in these anatomical locations can result in patient injury including vascular and central nervous system injury and longer surgery. With the exception of any limitations present in the Contraindications, Warnings and Potential Risks, and Precautions sections, there are no additional limitations of these devices when used as intended.

PATIENT TARGET GROUP

The Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nails are for skeletally mature patients undergoing fixation of bones appropriate for the size of the screw. The application of all implants is according to the medical judgement of the experienced trauma or orthopaedic surgeon with utilization at the appropriate anatomical locations as defined in the indications.

INTENDED USER

The Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nails are intended to be used by qualified physicians/healthcare professionals that have been trained in accordance with the specific procedures and material set forth in the Surgical Technique and this IFU.

INTENDED USE ENVIRONMENT

The Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nails is intended to be used in an operating room/surgical setting.

EXPECTED CLINICAL BENEFIT

The expected clinical benefit of the Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nails, when used as intended, is to achieve bone fixation.

DEVICE LIFETIME

The Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nail implants have completed their treatment lifetime and primary function of mechanical stabilization once the fusion mass has attained adequate strength to sustain the stability and integrity of the bone without necessitating external support (typically 6 weeks to 9 months depending on the bone(s) treated and the procedure(s) performed).

The expected treatment lifetime of the single-use instruments is short term (transient) use defined by the time the instruments are functioning during the clinical procedure.

The expected treatment lifetime of the reusable instruments is dependent on many factors including the method and duration of each use and the handling between uses. Careful inspection and functional testing of the device before use is the best method for determining the reusable instrumentation end of life.

MATERIAL

The implants are manufactured from a Titanium alloy (ASTM F136). The specialized instruments are made of surgical grade stainless steel (ASTM F899). Refer to the following table for the quantitative composition of elements by % for the Titanium alloy.

Element	Composition % (mass/mass)
Nitrogen, max	0.05
Carbon, max	0.08
Hydrogen, max	0.012*
Iron, max	0.25
Oxygen, max	0.13
Aluminum	5.5 – 6.50
Vanadium	3.5 – 4.5
Titanium**	balance

* Material 0.032 in. (0.813mm) and under may have hydrogen content up to 0.0150%.

** The percentage of titanium is determined by difference and need not be determined/certified.

HOW SUPPLIED

The implants and instruments are delivered **non-sterile** as specified by the packaging.

All **non-sterile** implants and instruments must be cleaned sterilized prior to use according to the procedures outlined in this document.

Information on the status of sterilization (sterile or non-sterile) is contained on the product label.

CONTRAINDICATIONS

The implant should not be used in a patient who has current, or who has a history of:

- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance

WARNINGS and POTENTIAL RISKS

The surgeon should be aware of the following:

1. The Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nails are not approved for implant attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. Use of the implants in these anatomical locations can result in patient injury including vascular or central nervous system injury, pain, tissue damage, non-union, and surgical delay.

2. The implants are designed for **single patient use only and must never be reused**. As with all other orthopedic implants, these components should never be re-implanted under any circumstances. Reuse may lead to infection, adverse tissue reaction, removal of hardware, and/or revision.

3. All non-sterile implants and instruments must be cleaned and sterilized prior to surgery. Failure to do so may result in adverse tissue reaction, infection, and/or revision.

4. The implants can become loose or break if subjected to increased loading. Factors such as the patient's weight, activity level, and adherence to weight-bearing or load-bearing instructions can affect the implant's longevity. Damage to the weight-bearing bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone. Additional risks involved in overloading include tissue damage, malunion, hardware removal, and/or implant revision.

5. Serious post-operative complications, such as tissue damage, malunion, non-union, loosening, hardware removal, and/or implant revision may occur from the implant in a patient who: lacks good general physical conditions, has severe osteoporosis, demonstrates physiological or anatomical anomalies, has immunological responses, sensitization or hypersensitivity to foreign materials; systemic or metabolic disorders.

6. These warnings do not include all adverse effects which could occur with surgery but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery, and the use of general anesthesia should be explained to the patient prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

PRECAUTIONS

1. The implantation of the device should be performed only by experienced surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Surgeons must be aware of the content of this IFU and the Surgical Technique prior to device use.

2. Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be re-sterilized. The risks associated with not following these precautions are adverse tissue reaction, hardware removal, and/or implant revision.

3. The implants should never be used with dissimilar materials, as it can cause corrosion, metal debris, and other negative outcomes including adverse tissue reaction, hardware removal, and/or implant revision.

4. Pre-operative assessment of the suitability of the patient's anatomy for accepting implants is made on the basis of x-rays, CT scans, and other radiological studies.

Only patients that meet the criteria described in the INTENDED USE / INDICATIONS FOR USE sections should be selected. Surgeons must be aware of the content of this IFU and the Surgical Technique prior to device use.

5. **Correct selection of the implant is extremely important.** The morbidity, as well as the patient's weight, height, occupation, and/or degree of physical activity should all be considered. The decision to leave or remove implants postoperatively rests with the surgeon. Surgeons must be aware of the content of this IFU and the Surgical Technique prior to device use.

6. **Proper implant handling before and during the operation is crucial.** Handle the implant components properly, as improper handling can result in glove ripping, skin pinching, unintended cuts and/or pricks to the user, and/or surgical delay. Ensure packaging integrity. Do not allow the implants surfaces to be damaged.

7. **Adequately instruct the patient.** The physician should inform the patient about the orthopedic implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage, and/or fracture of orthopedic prostheses.

8. **IMPORTANT:** The guidewires included in the Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nails System are not intended as implants. The guidewires are only intended for use as instruments to facilitate implant insertion. These misuses of the guidewires may result in adverse tissue reaction, infection and/or hardware removal.

9. The drills and other cutting instruments labeled as single-use, are for single patient use only and should not be reprocessed or re-sterilized following use. All other drills and cutting instruments are reusable and should be inspected and functionally tested, as applicable, prior to cleaning and sterilization.

Instructions on inspection and functional testing are provided below.

10. Guidewires, drills, and cutting instruments contain sharp features. Improper handling may result in injury.

11. To prevent damage or breakage of the drill, avoid contact of the drill tip or cutting flutes with other devices or striking, impacting, or bending the drill while in use.

POSSIBLE ADVERSE EFFECTS

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

Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

- Early or late loosening, disassembly and/or breakage of any or all implants;
- Metal sensitivity to a foreign body (implant or instrument material allergic reaction), including metallosis, staining, tumor formation, auto-immune disease and/or scarring;
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown, penetration, pain, irritation and/or wound complications;
- Tissue damage resulting from improper placement of implants or instruments;
- Infection;
- Hematoma;
- Allergy;
- Thrombosis;
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, neuropathy, neurological deficits (transient or permanent);
- Bone loss due to resorption or stress shielding, decrease in bone density or bone fracture at operative site;
- Pain, discomfort, or wound healing complications at the surgical site;
- Misalignment of anatomical structures;
- Bone non-union or delayed union;
- Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and /or amputation of the limb.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

MRI Safety Information 

A patient with any Zimmer Biomet **A.L.P.S. mvX®** Threaded Nail (i.e. standalone implant)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®** Threaded Nail
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 B_1^+RMS	See details below
Limits on B_1^+RMS and Scan Duration	**1.5 T MRI System** 2.80 µT for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
	3 T MRI System 0.8 µT 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.	

DIRECTIONS FOR USE

To implant the Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nails, use only the specialized instrumentation. Do not use implants or instruments from any other system or manufacturer.

These implants are provided non-sterile. The instruments are provided non-sterile. Non-sterile implants and instruments must be cleaned and sterilized prior to use. Perform all cleaning and sterilization according to the procedures outlined in this document. All system components should be carefully inspected to ensure proper working condition. Critical areas, including joint surfaces, should be checked for wear, damage, or irregularities. Damaged or broken devices must not be used or processed and should be returned to Zimmer Biomet for evaluation.

Before using the system for the first time, the surgeon should be thoroughly familiar with the Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nail Surgical Technique Manual as well as the functionality and assembly of the various components.

Pre-operative planning is performed by the operating surgeon and is solely at their discretion. It should determine the type of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.

For complete instructions regarding the proper use and application of all implants and instruments, please refer to the Zimmer Biomet **A.L.P.S. mvX®** IM Nail Surgical Technique Manual (available at no charge upon request).

CARE AND HANDLING

Certain **implants and instruments are provided non-sterile** and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be cleaned and sterilized according to the standard hospital procedure. Refer to the CLEANING and STERILIZATION sections for recommended parameters.

LIMITATIONS ON REPROCESSING

The devices labeled as single use only are not to be reprocessed under any circumstances.

For devices not labeled as single use only/reusable devices, repeated processing has minimal effect and 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 of biologically contaminated devices.

CONTAINMENT AND TRANSPORTATION

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

PREPARATION FOR CLEANING

Remove excess soil with a clean, lint-free disposable, absorbent cloth or equivalent.

CLEANING (AUTOMATED)

Equipment: Automated washer, soft bristle brush, enzymatic detergent[1], and neutral pH detergent[2].

- Preclean the devices by placing 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 the devices in such a way that the parts can drain.
- Use a standard cycle meeting the following parameters:

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

- Determine if the devices are dry. If they are not dry, dry with a soft, clean, lint free cloth.
- After drying, check the devices for complete removal of any debris. If necessary, repeat cycle or use manual cleaning. Replace devices that cannot be cleaned.

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).

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 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 in purified 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 devices for complete removal of any debris. If necessary, repeat manual cleaning. Replace devices that cannot be cleaned.

[1]ENZOL®, a trademark of Advanced Sterilization Products, was used in the cleaning validation

[2]Prolystica™ Ultra Concentrate neutral Detergent, a trademark of Steris Corporation, was used in the cleaning validation.
Steris Corporation, was used in the cleaning validation.

INSPECTION AND FUNCTION TESTING

Visually inspect all devices under normal lighting. Inspect devices for surface damage such as:

- Nicks
- Scratches
- Cracks
- Burrs
- Staining/Discoloration

Replace any device affected.

Assess the devices for proper use. Inspect devices for:

- Wear
- Sharpness
- Straightness
- Corrosion
- Misalignment
- Proper interface with other devices (as applicable)

Inspect devices with a cutting edge and/or tip cutting edge (i.e. drills) for a continuous cutting edge free from edge deformities such as:

- Dullness
- Chipping
- Cracking
- Rolling
- Other cutting-edge deformities

Replace any device that does not perform as intended. If the resistance increases while using a cutting device, replace this device immediately.

Verify the legibility of all markings. Replace any device that is unreadable.

DEVICE REPLACEMENT

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

Warning: Do not attempt to repair any device.

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

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

PACKAGING FOR STEAM STERILIZATION

For sterilizing **non-sterile** devices, the devices may be loaded into the specified trays, or general-purpose caddies/trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are intended for pre-vacuum steam sterilization.

STERILIZATION

If not specifically labeled **STERILE**, or if labeled **NON-STERILE**, then the devices are non-sterile. Non-sterile implants and instruments must be cleaned and sterilized prior to use.

Warning: It is not recommended that the devices be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple devices in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10^{-6}, the following parameters are recommended:

Sterilizer Type	Gravity	Pre-Vacuum		
Minimum Temp.	132°C (270°F)	132°C (270°F)	134°C (273.2°F)	135°C (275°F)
Exposure*	15 min	4 min	3 min	3 min
Dry Time	20 minutes			

**The sterilization cycles above have been validated to meet the minimum requirements per ISO 17665, and data is on file with the manufacturer. 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.*

The manufacturer 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

The 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 your local Zimmer Biomet customer service for the return of removed implants.

DISPOSAL

Observe internal hospital/institution procedures, practices, and guidelines, and/or government regulations for proper handling of the Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nail System.

CUSTOMER SERVICE

For further information regarding the Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nail System or a copy of the Zimmer Biomet **A.L.P.S. mvX®** IM Threaded Nail System Surgical Technique Manual, please contact your local Zimmer Biomet Distributor or the manufacturer.

REPORTING OF SERIOUS ADVERSE EVENTS OR INCIDENTS:

Users and patients should report all Serious Events or Incidents to the manufacturer (see contact details below) and to your local Competent Authority.

A copy of the current device Summary of Safety and Performance Characteristics (SSCP) can be accessed at the following link: (https://ec.europa.eu/tools/eudamed/#/screen/search-device).

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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 of manufacture	Indicates the country of manufacture of a device. Can be followed by a Date of Manufacture to also indicate the date when the medical device was manufactured.
	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 5.1.8 Importer	Indicates the entity importing the medical device into the locale.
	ISO 15223-1 / Amd 1:2025 5.1.2 Authorized Representative	Indicates the authorized representative in the identified country or jurisdiction (Switzerland).
	ISO 15223-1 5.1.2 Authorized Representative inthe European Community / European Union	Indicates the authorized representative in the European Community / European Union.
	EU Medical Device Regulation (MDR 2017/745)CE Marking / CE Marking with Notified Body	Indicates the device complies with strict EU safety, health, and environmental protection standard and has passed the necessary conformity assessments to be sold in the EU. High risk devices must have a Notified Body number with the CE Marking which corresponds to the third- party organization within EU that must audit the device.
	ISO 15223-1 5.7.7 Medical Device	Indicates the item is a medical device.
	ISO 15223-1 5.7.10 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.