ZIMMER BIOMET

Zimmer Biomet **A.L.P.S. mvX™**
IM THREADED NAIL SYSTEM
PACKAGE INSERT

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DESCRIPTION OF THE MEDICAL DEVICE

The implants – delivered sterile and 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.

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.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

MATERIAL

The implants are manufactured from a Titanium alloy (ASTM F136). The specialized instruments are made of surgical grade stainless steel (ASTM F899).

HOW SUPPLIED

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

All implants labeled as sterile are exposed to a minimum dose of 25.0 kGy gamma radiation to obtain a minimum Sterility Assurance Level (SAL) of 10-6. The package should be inspected prior to use to ensure the barrier has not been compromised. Do not resterilize.

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

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 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.

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.

Serious post-operative complications 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.

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

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.

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 implants should never be used with dissimilar materials.

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 INDICATIONS FOR USE section should be selected.

Correct selection of the implant is extremely important. The morbidity as well as patient weight, height, occupation, and/ or degree of physical activity should be considered.

Proper implant handling before and during the operation is crucial. Handle the implant components properly. Ensure packaging integrity. Do not allow the implants surfaces to be damaged.

ADEQUATELY INSTRUCT THE PATIENT . The physician should inform the patient about 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.

IMPORTANT: The k-wires included in the system are not intended as implants. The k-wires are only intended for use as instruments to facilitate implant insertion.

POSSIBLE ADVERSE EFFECTS

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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 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), bilateral paraplegia, appearance of radiculopathy, and paralysis (complete or incomplete);
- 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 the Zimmer Biomet A.L.P.S. mvX™Threaded Nail 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™Threaded Nail 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, no restriction on transmit receive coils that the device is not within
Operating Mode	Normal Operating Mode
Maximum B1 +RMS	See details below
Limits on B1 +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 sterile and non-sterile. The instruments are provided non- sterile. Non-sterile implants and instruments must be cleaned and sterilized prior to use 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 by the surgeon should determine the type of implant required and an adequate supply of the implant sizes should be available prior to surgery, including r 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 Threaded 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 section for recommended parameters.

Limitations on Processing

All devices provided and labeled as sterile have undergone two reprocessing procedures: cleaning and gamma radiation sterilization. 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.

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 requires replacement, return the device in the original box or other sturdy box with adequate packaging material to protect the device. Send the packaged device to:

Attn: Product Service
1777 West Center St.
Warsaw, IN 46850

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 device repair.

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.

PACKAGING FOR STEAM STERILIZATION

For sterilizing **non-sterile** devices, the devices may be loaded into the specified Zimmer Biomet 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

For devices provided **sterile**, the sterilization method is noted on label. Sterile devices 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 the sterile barrier has been broken, return the component to Zimmer Biomet. Do not re-sterilize.

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)	135° C (275° F)
Exposure*	15 min	4 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. 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.*

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

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 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 Zimmer Biomet or your local Zimmer Biomet Distributor.

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SYMBOL	MEANING
	Caution: Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.
	Reference Number
	Lot Number
	Medical Device
	Date of Manufacture/ Country of Manufacture
	Do Not Re-Use
	Consult Instructions for Use
	Non-Sterile
	Distributor
	Manufacturer
	Unique Device Identifier
	ASTM F2503 Magnetic Resonance (MR) Conditional
	Patient Identification
	Patient Information Website
	Health Care Centre or Doctor
	Date Information Was Entered or Procedure Took Place
	Sterilized using irradiation
	Expiration Date
	Double Sterile Barrier
	Do Not Resterilize
	Do Not Use if Package is Damaged

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