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

Description of the Medical Device:
The implants – delivered non-sterile – are:

- Various bone plates of different shapes and hole configurations
- Variable angle locking and non-locking screws in various lengths and diameters
- Optional bone screw washers in various sizes for use with non-locking screws

The plates and screws are manufactured from Titanium Alloy per ASTM F136. The optional bone screw washers are manufactured 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™** Mini-Fragment System implant devices.

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 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.

Limitations:
This device is not approved for plate, screw, or washer 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™** Mini-Fragment System is for skeletally mature patients undergoing fixation of bones appropriate for the size of the implants. The application of all implants is according to the judgment of the experienced trauma or orthopedic surgeon with utilization at the appropriate anatomical locations as defined in the indications.

Intended User:
The Zimmer Biomet **A.L.P.S. mvX™** Mini-Fragment System is intended for use by experienced trauma and orthopaedic surgeons.

Intended Use Environment:
The Zimmer Biomet **A.L.P.S. mvX™** Mini-Fragment System is intended to be used in an operating room or surgical setting.

Clinical Benefit:
The expected clinical benefit of the **Zimmer Biomet A.L.P.S. mvX™** Mini-Fragment System, when used as intended, is to achieve bone union.

Device Lifetime:
The Zimmer Biomet **A.L.P.S. mvX™** Mini-Fragment System 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 19 weeks depending on the bone(s) treated and the procedure(s) performed).

The expected treatment lifetime of the Zimmer Biomet **A.L.P.S. mvX™** Mini-Fragment System single-use instruments is intended for short-term (transient) use defined by the time the instruments are functioning during the clinical procedure.

The expected lifetime of the Zimmer Biomet **A.L.P.S. mvX™** Mini-Fragment System 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, as described in the section below, is the best method for determining the reusable instrumentation end of life.

Contraindications:
The Zimmer Biomet **A.L.P.S. mvX™** Mini-Fragment System should not be used in a patient who has current, or who has a history of:

- Active infection or inflammation.
- 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.

Materials

The **A.L.P.S. mvX™** Mini-Fragment System plates and screws are manufactured from a Titanium alloy (ASTM F136). The specialized instruments are made of surgical-grade stainless steel (ASTM F899), Aluminum (per ASTM B221) and Silicone. 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 **Zimmer Biomet A.L.P.S. mvX™** Mini-Fragment System implants are delivered non-sterile as specified by the packaging.

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

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

Warnings & Potential Risks:

The surgeon should be aware of the following:

- Use of the **A.L.P.S. mvX™ Mini-Fragment System** could lead to re-operation to remove or replace implants at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- The **A.L.P.S. mvX™ Mini-Fragment System** is 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.
- The **A.L.P.S. mvX™ Mini-Fragment System** implants are designed for **single patient use only and must never be reused under any circumstances**. Reuse may lead to adverse tissue reaction, tissue damage and/or minor surgical delay.
- 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.
- The **A.L.P.S. mvX™ Mini-Fragment System** 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.
- 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 condition; 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 possible 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 information.

Precautions

- The implantation of plates, screws, and optional screw washers should be performed only by experienced surgeons with specific training in the use of this plating 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 Guide (STG) prior to device use.
- Under no circumstances should damaged devices or surgically excised implants 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.
- The **A.L.P.S. mvX™ Mini-Fragment System** should never be used with dissimilar materials, as this can cause electrolytic action, corrosion, metal debris, and other negative outcomes including adverse tissue reaction, bone loss, non-union, infection, hardware removal and/or implant revision.
- 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 STG prior to device use.

- The 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 be considered. The decision to leave or remove implants postoperatively rests with the surgeon. The surgeon must be aware of the content of this IFU and the STG prior to device use.
- Improper insertion of the device during implantation may result in implant loosening or implant migration.
- 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.
- 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 implant.
- Loosening or migration and loss of fixation due to incorrect implantation, delayed union, non-union, and incomplete healing may occur.
- Bending or fracturing of the implants due to applied excessive stress may occur.
- IMPORTANT: The guidewires included in the **A.L.P.S. mvX™** Mini-Fragment 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.
- The Kirschner wires (K wires) and plate tacks are designed for single patient use only and should not be reprocessed or re-sterilized following use.
- Guidewires, drills, and cutting instruments contain sharp features. Improper handling may result in injury.
- 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.
- Failure to follow postoperative care instructions may result in procedure complications or failure.

Possible Adverse Effects

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:

- Fracture of the implant due to excessive loading
- Incomplete or inadequate healing
- Implant migration and/or loosening
- Infection
- Pain, discomfort, wound healing complications, or abnormal sensations due to the presence of an implant
- Nerve, vascular, or tissue damage resulting from surgical trauma
- Bone necrosis or bone resorption
- Delayed healing or nonunion of bone fragments
- Allergic reaction to the implant and/or instrument materials
- 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:
The **A.L.P.S. mvX™** Mini-Fragment System is MR Conditional and may only be in an MR environment under specific conditions. The patient should consult with their healthcare providers prior to an MR exam and inform the MRI personnel that they have an MR Conditional device prior to the MR exam. 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.

MRI Safety Information

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.

Name/Identification of device	Zimmer Biomet **A.L.P.S. mvX™** Mini-Fragment System (plate/screw construct)
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	**1.5 T MRI Systems** B_1^+RMS ≤ 3.40 μT for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks) 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 B_1^+RMS ≤ 1.45 μT for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks) or Whole body average SAR ≤ 0.8 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 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 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** B_1^+RMS ≤ 1.7 µT 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 B_1^+RMS ≤ 1.4 µT 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.

Directions for Use:
To implant the **A.L.P.S. mvX™** Mini-Fragment System implants, use only the specialized instrumentation referenced in the Surgical Technique Guide (STG). Do not use implants or instruments from any other system or manufacturer.

The **A.L.P.S. mvX™** Mini-Fragment System implants and 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 **A.L.P.S. mvX™** Mini-Fragment 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 **A.L.P.S. mvX™** Mini-Fragment System devices must not be used or processed and should be returned to the manufacturer for evaluation.

Before using the **A.L.P.S. mvX™** Mini-Fragment System for the first time, the surgeon should be thoroughly familiar with the **A.L.P.S. mvX™** Mini-Fragment System STG 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 larger and smaller sizes than those expected to be used.

For complete instructions regarding the proper use and application of all **A.L.P.S. mvX™** Mini-Fragment System implants and instruments, please refer to the Zimmer Biomet **A.L.P.S. mvX™** Mini-Fragment System STG (available at no charge upon request).

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 Handling
The **Zimmer Biomet A.L.P.S. mvX™** Mini-Fragment System 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 cleaned and sterilized according to the standard hospital procedure. Refer to the CLEANING and STERILIZATION sections for recommended parameters.

Limitations on Reprocessing
The devices labelled as single use only are not to be reprocessed under any circumstances. For devices not labelled as single use only/reusable devices, repeated processing has minimal effect on these devices, as 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, if reusable, the instructions outlined below should be followed to ensure safe handling of biologically contaminated devices.

Containment and Transportation
It is recommended that the devices not labeled as single use only are cleaned 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.
2. Rotate the body 90° to fully disassemble.
3. Proceed to cleaning steps below.

Cleaning (Automated)

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

- 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
- After drying, check devices for complete removal of any debris. If necessary, repeat cycle or use manual cleaning. Replace any device 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 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 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 any devices that cannot be cleaned.

After Cleaning

Visually inspect the cleaned devices to ensure cleaning was effective. Perform cleaning again on devices that are not clean. Replace a device that cannot be cleaned (see the Device Replacement section).

Reassembly of Depth Gauge

NOTE: The depth gauge is stored in the system tray in an assembled state. Reassembly should occur prior to device storage in the tray.

1. Insert the body into the sleeve as far as possible.
2. Rotate the body 90° to reassemble and store or reuse.

Inspection and Function Testing

Visually inspect all devices under normal lighting prior to use for damage and/or 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.

Repeat cleaning and/or replace affected devices as needed to ensure proper operation before proceeding with sterilization.

Prior to use, inspect devices for surface damage such as:

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

Replace any devices affected.

[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.

Assess the instruments for proper use. Inspect instruments for:

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

Inspect instruments 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 instrument that does not perform as intended. If the resistance increases while using a cutting instrument, replace this instrument immediately.

Repeat the cleaning and/or replace affected instruments 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 **A.L.P.S. mvX™** 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

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. Visually inspect the tray before loading the implants and/or instruments. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA cleared/marketed for pre-vacuum steam sterilization.

Sterilization:

If labelled as non-sterile, then the devices are provided non-sterile. Non-sterile devices must be cleaned and sterilized prior to use.

Warning: The manufacturer 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}, the manufacturer recommends the following parameters:

Sterilizer Type	Gravity	Pre-Vacuum		
Minimum Temp.	132℃ (270℉)	132℃ (270℉)	134℃ (273.2°F)	135℃ (275℉)
Exposure*	15 min	4 min	4 min	3 min
Dry Time	20 minutes			
**The manufacturer has validated the above sterilization cycles and has the data on file. 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.*				

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

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.

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.

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.

Reporting of Serious Adverse Events or Incidents

Zimmer Biomet requests users and patients 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 Clinical Performance (SSCP) can be accessed at the following link:
https://ec.europa.eu/tools/eudamed/#/screen/search-device

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 CH GmbH
Laurenzenvorstadt 61
5000 Aarau, Switzerland

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

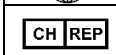
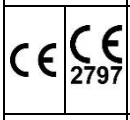
UKRP

MDSS-UK RP LIMITED
6 Wilmslow Road
Rusholme, Manchester M14 5TP
United Kingdom

Australia Sponsor

ACRA Regulatory Services Pty Ltd
7/84 Poinciana Avenue
Tewantin, QLD 4565
Australia

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 and date 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 in the 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.