Athena Surgical RMUS™ System

Instructions for Use

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Made in USA

DISCLAIMER

Please read all directions, warnings and precautions prior to use. Failure to properly follow instructions may result in improper device function and/or may lead to injury.

These instructions to not constitute a complete training manual, nor are they a substitute for appropriate training and experience in surgical technique. The Athena™ Surgical RMUS™ System should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in the use of this system. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

CONTENTS

The shelf box contains three (3), individually packaged, sterile, single use RMUS retropubic mid-Urethral sling assemblies. Each RMUS Sling Assembly contains one blue polypropylene mesh sling (1.1 x 46 cm), covered by a clear plastic sheath and attached on each end to a stainless steel needle (Figure 1).

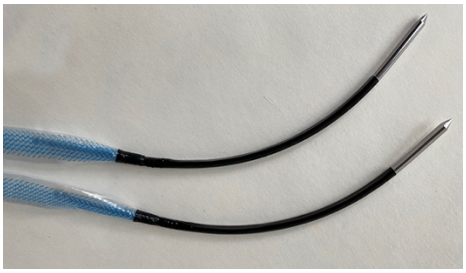


Figure 1

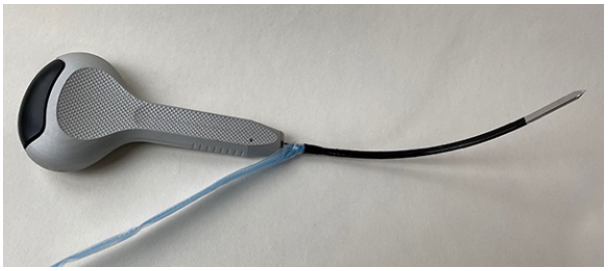


Figure 2

The RMUS Sling Assembly is designed to be used with the reusable Athena RMUS Handle Assembly, provided separately (Athena Catalog Number 9003, Figure 2). The RMUS Handle Assembly is supplied non-sterile and must be sterilized prior to use. The RMUS Handle Assembly consists of two parts, the Handle Body and the Handle Insert. Other instruments are also required for use including a rigid catheter guide, a cystoscope and general surgical instruments typically used for RMUS sling placement.

INDICATIONS FOR USE

The Athena Surgical RMUS System is indicated for use as a pubourethral sling for treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

CONTRAINDICATIONS

- It is the surgeon's responsibility to advise the prospective patient of contraindications associated with use of this product, prior to surgery.
- The product is contraindicated for use in women with the following conditions:
    - Pregnancy or desire for future pregnancy
    - Potential for further growth (e.g., in adolescents)
    - Known active urinary tract infection and/or infection in operative field
    - Sensitivity/allergy to polypropylene
    - Taking anti-coagulant therapy

PATIENT FACTORS

Physicians should use their surgical experience and judgment to determine if polypropylene mesh is appropriate for certain patients. Patient-specific factors may impair wound healing, which may increase the likelihood of adverse reactions.

WARNINGS AND LIMITATIONS

- The risks and benefits of using the Athena RMUS Sling Assembly should be carefully considered in patients with compromised immune systems or any conditions that may affect healing (e.g., diabetes).
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Avoid placing the Athena RMUS Sling in patients with an abnormal urethra (e.g., fistula, diverticulum).
- Users must be familiar with the surgical technique for RMUS placement and should be adequately trained in the use of the Athena Surgical RMUS System implantation procedure before employing the device. It is important that the Implant be located without tension under mid-urethra.
- Knowledge of local anatomy and the correct use of needles are critical to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of the Needles will minimize risks.
- The Athena RMUS Sling Assembly is sold sterile and for single use only. It should never be re-sterilized.
- Do not use the product with damaged or opened packaging, as sterility may have been compromised.
- Each device should be inspected prior to and during surgery to ensure structural integrity. A device that has been damaged or on which repairs have been attempted should not be used or implanted.
- A rigid catheter guide (not provided) should be gently pushed into a Foley catheter so that the catheter guide does not extend into the holes of the Foley catheter.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- When removing the rigid catheter guide, open the handle completely so that the Foley catheter remains properly in place.
- Ensure that the Implant is placed with minimal tension under the mid-urethra.
- Do not remove the Implant Sheath until the Implant has been properly positioned.

PRECAUTIONS

- Since no clinical experience is available with vaginal delivery following the procedure, in case of pregnancy, delivery via cesarean section is recommended.
- Post-operatively, the patient is recommended to refrain from heavy lifting and/or exercise (i.e., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding, or other problems occur, the patient should be instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the Handle Assembly should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- As with other incontinence procedures, de novo detrusor instability may occur following the procedure. To minimize this risk, make sure to place the Implant tension-free in the mid-urethral position.

- Do not contact the polypropylene mesh with any staples, clips or clamps, as mechanical damage to the mesh may occur.
- Do not re-sterilize/reuse any portion of the Athena RMUS Implant Assembly. Reuse of the Implant Assembly (or portions of the Implant Assembly) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.
- Discard opened, unused Implant Assemblies.

ADVERSE EFFECTS

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel may occur and may require surgical repair.
- Polypropylene mesh is a permanent implant that integrates into the tissue. In cases in which the polypropylene mesh needs to be removed in part or whole, significant dissection may be required.
- As with any implant, a foreign body response may occur, which could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs may occur. Exposed mesh may cause pain or discomfort to the patient's partner during intercourse, and in some patients may not resolve.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, polypropylene mesh may potentiate an existing infection.
- Over correction, i.e., too much tension applied to the Implant, may cause temporary or permanent lower urinary tract obstruction.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- Additional adverse effects may include the following: Acute and/or chronic pain; voiding dysfunction; transitory local irritation, recurrence of incontinence, bleeding including hemorrhage, or hematoma; seroma; urge incontinence; urinary frequency or retention; adhesion formation; and atypical vaginal discharge.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- Death is an extremely rare but possible adverse effect.

MRI SAFETY INFORMATION

The Athena Surgical RMUS System is safe for use in the magnetic resonance (MR) environment.

INSTRUCTIONS FOR USE

The procedure can be carried out under local anesthesia, but it can also be performed using regional or general anesthesia.

Patient Preparation

1) Before the patient is prepped and draped, she should be placed in the lithotomy position, taking care to avoid hip flexion greater than 60°.
2) Insert an 18 French Foley catheter into the bladder and leave open to drainage.
3) Locate and mark the two exit sites, which should be 2–2.5cm on each side of the midline, immediately above the pubic symphysis and in contact with the dorsal aspect of the pubic bone (See Figure 3 below).

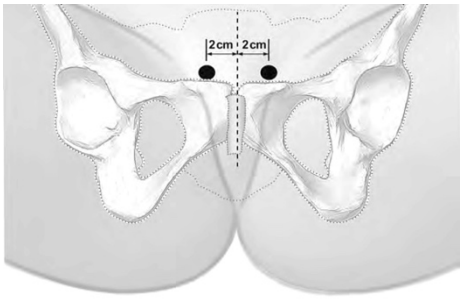


Figure 3

Caution: To avoid the inferior epigastric vessels, it is important that the intended exit sites are not more than 2.5cm from the midline. The exit sites must be near midline and close to the superior aspect of the pubic bone to avoid anatomic structures in the abdomen, inguinal area and lateral pelvic sidewall.

4) At the level of the mid-urethra, inject a small amount of local anesthesia submucosally to create a space between the vaginal wall and the periurethral fascia.
5) Perform a retropubic hydrodissection using two injections of normal saline on either side of midline. Starting at the exit sites, pass an 18-gauge needle along the back of the pubic bone until the tip of the needle touches the endopelvic fascia. Slowly withdraw the needle while injecting 30 to 50cc of saline to open the retropubic space to minimize the risk of bladder puncture during the implant placement.
6) Using two forceps, grasp the vaginal wall at each side of the urethra. With a small scalpel, make a sagittal incision no more than 1.5cm long starting approximately 1.0cm cephalad from the urethral meatus. This incision will be positioned over the mid-urethral zone and will allow for subsequent implant passage.
7) With a small pair of blunt scissors, make two small paraurethral lateral dissections (approximately 0.5 to 1.0cm) between the vaginal wall and periurethral fascia to accommodate insertion of the Needle tips.
8) Drain the bladder via the 18 French Foley catheter and confirm that the bladder is empty.
9) Insert a rigid catheter guide (not provided) into the channel of the 18 French Foley catheter to allow contralateral displacement of the bladder, bladder neck and urethra away from the tip of the Needle as it is passes through the retropubic space.

Implant Passage

10) Locate the Handle Body (Figure 4) and install the Handle Insert as shown in Figure 5. Ensure the Handle Insert is fully rotated counter-clockwise such that it is perpendicular to the flat of the Handle Body (See Figure below).

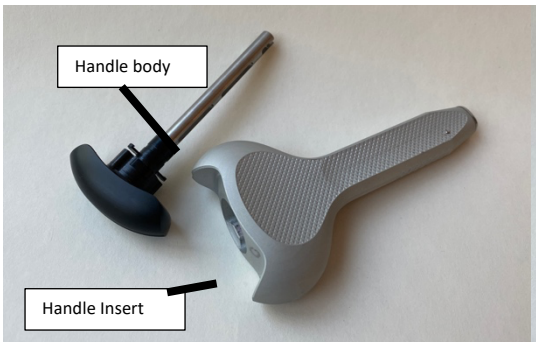


Figure 4: Handle, disassembled

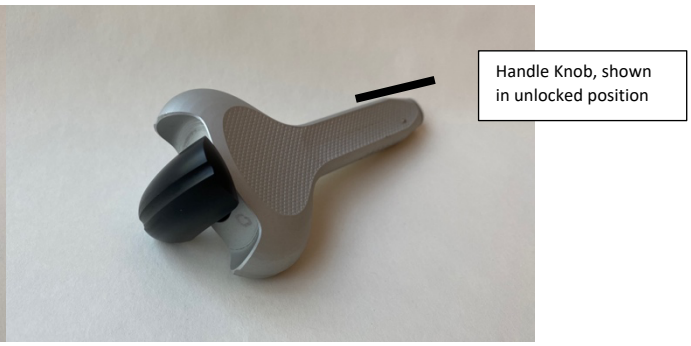


Figure 5: Handle, assembled

11) Insert one of the Needles into the Handle Body and secure it in position by rotating the Handle Knob clockwise until aligned with the shape of the Handle Body (Figure 6).

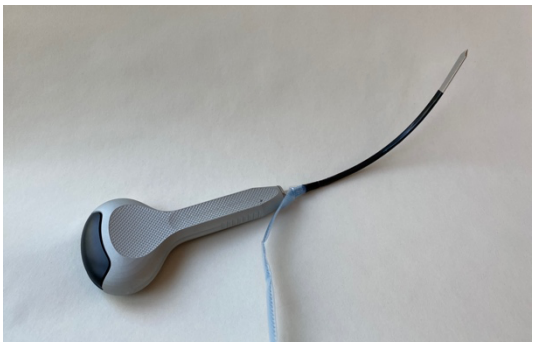
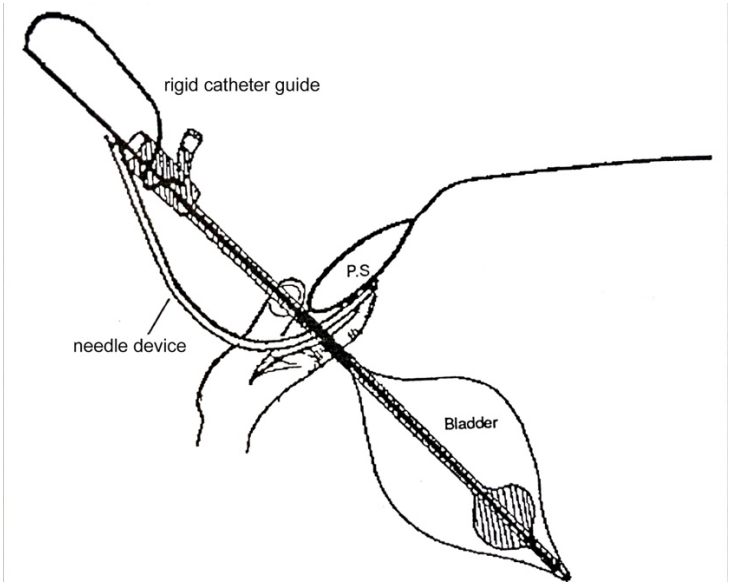


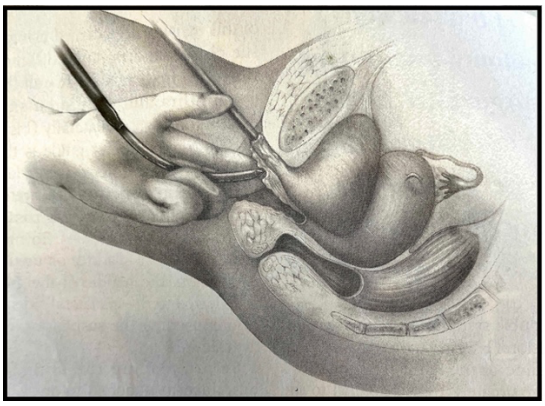
Figure 6: Handle, shown with needle installed

Note: Confirm that the Needle is properly secured to the Handle by pulling on the Needle.

12) Gently push the tip of the 18 French Foley catheter/rigid guide toward the posterior lateral wall of the bladder opposite to the intended Needle passage.

Note: Pushing the catheter/rigid guide toward the side of the patient opposite to that of the intended needle path will elongate and displace the bladder away from the back of the pubic symphysis and position the bladder neck and urethra to allow passage of the Needle with minimal risk of bladder perforation (See Figure 7 below).





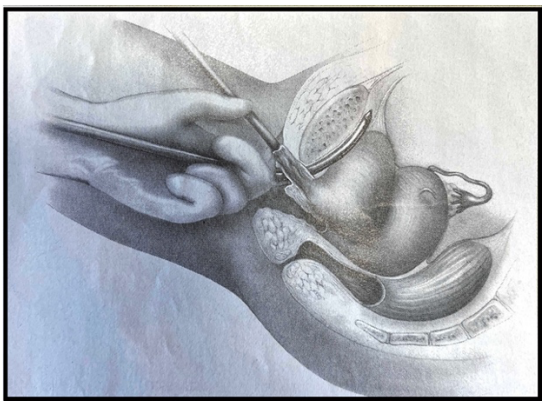


Figure 7

13) Holding the Handle in the dominant hand, pass the tip of the Needle paraurethrally through the urogenital diaphragm at the level of the mid-urethra.

14) Control the initial insertion of the device by using the tip of the index finger of the non-dominant hand placed in the vagina under the anterior vaginal wall, just lateral to the sub-urethral incision.

15) Orient the Needle tip horizontal to the frontal plane during the initial submucosal passage in the periurethral dissected space. Pass the tip of the Needle until has reached the end of the dissected space.

16) Immediately after perforation of the urogenital diaphragm, lower the Handle Assembly to transition the position of the Needle tip from horizontal to vertical to remain in close contact with the back of the pubic symphysis. After passing the Needle tip through the urogenital diaphragm and into the retropubic space, resistance to the passage of the Needle is significantly reduced.

    Note: The starting edge of the black Needle Jacket, as shown in Figure 8, may be used to assist with defining the proper depth of insertion when transitioning the orientation of the Needle tip from a horizontal to vertical position via lowering of the Handle (see Figure 8 below).

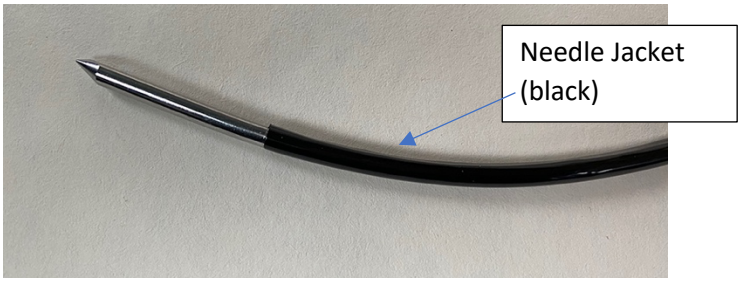


Figure 8

17) Move the non-dominant hand from the vagina to the pre-marked suprapubic exit site. Keeping the Handle Assembly low, continue to advance the Needle tip in close contact with the pubic symphysis until the Needle tip passes through the rectus muscle and penetrates the skin at the exit site.

18) Advance the Needle tip approximately 5cm past the skin and place a clamp of the Needle shaft to secure its position.

    Caution: Do not grasp the black needle jacket with the clamp; doing so may cause damage to the jacket and may increase the risk of infection.

    Caution: Do not advance the Needle any further at this time.

19) Release the Needle from the Handle by holding the Handle Body and rotating the Handle Knob counterclockwise one quarter turn.

20) Repeat Steps 10-19 (Implant Passage) on the opposite side of the patient.

    Note: To reduce the risk of bladder injury, it is important to displace the bladder to the contralateral side when using the rigid catheter (Step 12).

<u>Implant Tensioning</u>

21) With both Needles clamped just above the skin, remove the 18 French Foley catheter and perform a cystoscopy to confirm bladder integrity (Recommendation: 70° Lens).

    Note: During cystoscopy, the black color of the Needle Jacket can be used to assist with visual confirmation of the Needle location.

22) Once bladder integrity has been confirmed, gently pull each Needle upward and through the skin to position the mesh portion of the Implant loosely under the mid-urethra (i.e., without tension).

23) Adjust the Implant to the desired tension under the mid-urethra.

    Note: If using local anesthesia, use patient feedback (i.e., coughing with a full bladder, ~300cc) to reduce urinary leakage to a few drops when under stress.

24) Cut the Implant Assembly just below the Needle bilaterally and remove each Needle such that only the Implant and Implant Sheath remain.

    Note: Premature removal of the Needle may make subsequent Implant adjustments difficult.

<u>Implant Final Adjustments</u>

25) Using a clamp, grasp each Implant Sheath, while being careful to avoid clamping the Implant.

26) Place a blunt instrument (scissors, forceps) between the Implant and urethra to stabilize the Implant during Implant Sheath removal.

27) One at a time, carefully remove each Implant Sheath by gently pulling up on the clamp away from the abdomen. Pulsing the hand while pulling on the Sheath will reduce friction and ease removal.

28) Complete any final Implant tension adjustments (as applicable).

Closure

29) Cut the abdominal ends of the Implant just below skin level and leave the ends in the subcutis, do not suture the Implant.

30) Close the vaginal and abdominal skin incisions using suture or surgical skin adhesive.

31) Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty their bladder 2-3 hours after the operation.

DISPOSAL

Dispose of devices and packaging according to facility and/or local government policies and procedures concerning biohazardous materials and waste.

STORAGE INSTRUCTIONS

1) The Athena RMUS Implant Assembly and Handle Assembly should be stored at room temperature.

2) Implants and instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature and humidity extremes.

3) Sterile implant packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.

4) Do not use sterile items after the expiration date.

HANDLE CLEANING AND STERILIZATION INSTRUCTIONS

Scope

These cleaning instructions apply to the reusable Athena RMUS Handle Assembly only.

The Handle Assembly must be cleaned and sterilized before initial use and after each procedure to ensure reliability and functionality.

Cleaning

Warnings and Limitations

Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Enzymatic and cleaning agents with neutral pH are recommended.

Automated washer/disinfector systems are not recommended to be used as the sole cleaning method for the Athena RMUS Handle. The Handle Body and Handle Insert should be cleaned following the manual cleaning procedure below. An automated system may be used as a follow-up method but is not required.

Pre-Treatment

Prior to cleaning, the Handle Insert should be separated from the Handle Body.

Do not allow devices contaminated with blood, body fluids, tissue debris, saline, or disinfectants to dry prior to reprocessing. Place devices in a container of saline, purified water or neutral pH cleaning solution, or cover with damp towels.

Manual Cleaning Procedure

1) Prepare neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer.
2) Completely submerge the instrument in enzyme solution and allow it to soak for a minimum of 20 minutes. Use a soft-bristled brush to gently clean the device until all visible soil has been removed, paying close attention to holes, crevices and other hard-to-clean areas. The central lumen of the instrument should be cleaned with a long, narrow, soft-bristled brush (e.g., a pipe cleaner brush). The enzyme solution should be changed when it becomes contaminated per hospital/clinic procedure.
3) Remove the device from the enzyme solution and rinse in purified water, defined as water processed using one or any combination of the following processes: ultra-filtration, reverse osmosis, deionization or distillation. Rinse for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
4) Prepare the neutral pH detergent solution and place in a sonication unit.
5) Completely submerge device in cleaning solution and sonicate for a minimum of 10 minutes, preferably at 45-50 kHz.
6) Thoroughly rinse the instrument in purified water for at least 3 minutes or until there is no sign of soil in the rinse stream.
7) Repeat steps 5 and 6 with freshly prepared cleaning solution until the system components are thoroughly clean.
8) Dry instrument with a clean, disposable, absorbent, non-shedding wipe or filtered compressed air.

Lubrication

Following cleaning, lubrication of the instrument handle with a biocompatible lubricant solution approved for use on surgical instruments (e.g., Miltex Spray Lube or equivalent) is strongly recommended. Mineral, silicone, or machine oils should not be used because sterilizing agents may not be able to fully penetrate the lubricant, which might be contaminated by microorganisms.

Inspection / Function Testing

1) Carefully inspect the Handle Body and Handle Insert to ensure that there is no visible contamination and that all visible soil has been removed. If visible contamination is evident, repeat the Manual Cleaning Procedure above.
2) Visually inspect for damage and/or wear, corrosion, pitting, or discoloration of items. Do not use the Handle Assembly if there is any evidence of damage that may affect its function.
3) Visually inspect the spring in the Handle Body to ensure that it is undamaged and in place, as shown in Figure 9.
4) Check that the handle components can be assembled properly; if the items cannot be properly assembled, lubricate and attempt assembly again. If the components still cannot be mated, return both pieces to Athena Surgical and replace with another Handle Assembly.

5) Figure 9: Handle Assembly illustrating spring placement.

Sterilization

The following steam sterilization method should be performed on the disassembled Handle Body and Handle Insert using FDA-cleared sterilizers, wraps, pouches and accessories:

PROCEDURE	PREVACUUM (4-PULSE) CONDITIONING
Exposure Time	4 minutes
Temperature	132°C
Drying Time	30 minutes

These instructions have been validated by Athena Surgical, LLC as being capable of preparing Athena RMUS Handle Assembly for use. To achieve the desired result, it is the responsibility of the re-processor to ensure that reprocessing is performed using

the appropriate equipment and materials and those personnel in the reprocessing facility have been adequately trained. Any deviation by the re-processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

No latex is used in the manufacturing of the product.

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

Symbol Glossary

Symbol	Symbol Title	EXPLANATORY TEXT	ISO 15223-1 STANDARD REFERENCE
	Do Not Re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	Clause 5.4.2
	Do Not Re-sterilize	Indicates a medical device that is not to be resterilized.	Clause 5.2.6
	Sterilized Using Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide.	Clause 5.2.3
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	Clause 5.2.7
	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.	Clause 5.6.3
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	Clause 5.1.5
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.	Clause 5.4.3
	Catalog number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	Clause 5.1.6
	Caution: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	Clause 5.4.4
	Use-by Date YYYY-MM-DD	Indicates the date after which the medical device is not to be used.	Clause 5.1.4
	Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	Clause 5.2.8
	Manufacturer	Indicates the medical device manufacturer.	Clause 5.1.1
	Prescription Use Only	Caution: Federal Law (USA) Restricts this device to sale by or on the order of a physician	N/A

	MR Safe	Indicates the devices is safe and compatible for use in a magnetic resonance (MR) environment.	N/A

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