



Arthroscopy Tubing Set

Instructions for use

Ref. no: 0222-ATS01G

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Attention:

These Instructions For Use cannot be used as a surgical manual describing the use of Arthroscopy Tubing Set. As needed, please contact our company or your authorized distributor. You should acquaint yourself with appropriate technical instructions, review the professional medical literature, and obtain formal graduate training under the supervision of a surgeon experienced in surgical endoscopic techniques. We recommend thoroughly reviewing all information in this IFU; inattention to the instructions provided below may have serious clinical consequences such as patient injury, contamination, cross-infection, or death.

Product description:

Arthroscopy Tubing Set is sterile, single use, disposable device consisting of 3 tubes connected to the transparent chamber. Two of the tubes deliver irrigation fluid to the chamber while one transports fluid from the chamber to the operating site. Each tube is equipped with the clamp for easy fluid passage management. After connecting set to fluid bottles and arthroscopy cannula, fluid flows by gravity.

Indications:

Arthroscopy Tubing Set is intended to fill and irrigate joint capsule in arthroscopic procedures.

Contraindications:

This device is not intended for use except as indicated.

Prior to the first use:









Carefully inspect the shipping carton, its contents and individual pouch for any sign of damage. If damage is visible, do not use the device.

Instructions for use:

1. Open the package by using standard aseptic technique and put the device on the sterile field.
2. Close all 3 clamps.
3. Remove spike caps.
4. Insert spikes into solution bags.
5. Open both upper clamps. Fill chamber with irrigation fluid to 1/2 - 3/4 of its' volume. Press and release chamber few times to facilitate filling, if necessary
6. Open lower clamp. Fully prime lower tube. Close lower clamp. Close one upper clamp.
7. Attach Luer-lock connector of the lower tube to the cannula (not delivered with the device) for fluid delivery.
8. Open lower clamp and adjust flow of solution as required.
9. Before solution bag is empty, open clamp on opposite upper tube and close clamp on the upper tube below empty bag.

Additional warnings and precautions:

1. Do not use after expiry date.
2. Use immediately after opening.
3. Check all the connections for tightness prior to the procedure.
4. Verify that the devices are compatible with other products that will be used in surgery prior to the procedure.
5. This device is not intended to generate high pressure irrigant streams in hysteroscopic procedures or in encapsulated areas.
6. Arthroscopic procedures should be performed only by physicians having adequate training and familiarity with those techniques. A thorough understanding of the operating principles, risks versus benefits, and the hazards involved in utilizing an arthroscopic approach is necessary to avoid possible injury to the user and/or patient.
7. If one solution bag is connected open the clamp on the tube with solution bag only. The other clamp on the upper tube must remain closed at all times during procedure. .
8. Caution should be used when the possibility for exposure to blood or body fluids exists. Follow hospital policy regarding the use of protective wear.
9. This product is intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
10. To be used by qualified physician only
11. Take care to discard the product and packing after use, as well as unused but opened devices in accordance with hospital waste disposal practices and local regulations.

 	 	<p>Keep dry</p> <p>Caution, consult accompanying documents</p>	 	<p>Consult instructions for use</p> <p>Do not reesterilize</p>	 	<p>Manufacturer</p> <p>Do not use if package is damaged</p>	<div style="border: 1px solid black; display: inline-block; padding: 2px;">EC</div> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin-left: 10px;">REP</div> <p>Authorized representative in EU</p>
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