



EN

AcuJect Flex® Injection Needle
Instructions for Use



190801 Rev. B





ENGLISH

INDICATIONS

Endoscopic injection needles are used for the endoscopic injection of legally marketed sclerotherapy agents and dyes into esophageal or colonic varices.

CONTRAINDICATIONS

Contraindications for this device are those applicable to injection therapy and include, but may not be limited to, those patients allergic to dyes, sclerotherapy or vasoconstriction agents and patients with lesions inappropriate for injection therapy with sclerotherapy or vasoconstriction agents.

WARNING AND PRECAUTIONS

The device is sharp. Use same care as for any other surgical device to avoid punctures or cuts to hands, gloves, etc.

When inserting or withdrawing device from endoscope, ensure the endoscope is not in a retrofl xed position and the needle is fully retracted to avoid damaging the working channel.

INSTRUCTIONS

1. Peel open the pouch and remove the device.
2. Visually inspect the device for kinks, loose or broken parts.
3. Uncoil the device and actuate the handle to ensure that the needle is operating properly.
4. Attach the syringe with injection media to the needle via the Luer-Lock and purge the needle of air.
5. Retract the needle before inserting the device into the endoscope.
6. Advance the device in small increments until the tip emerges from end of the endoscope. If the endoscope is equipped with an elevator, load the device past the elevator before raising fully.
7. Deploy the needle until you feel the handle "click" into place and proceed with the injection(s).
8. Following the injection(s), press the release button on the handle to fully retract the needle.
9. Upon completion of the procedure remove the device from the endoscope. If the endoscope has an elevator, lower the elevator before withdrawing the device.

DISPOSAL

After use, this product may be a potential biohazard. Dispose of it in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

STORAGE

Store sterile instruments at room temperature. Do not expose to solvents, radiation, UV light or any other substance or environment that could compromise the sterility of the unit.

A symbol glossary can be found at cookmedical.com/symbol-glossary



X mm

If symbol appears on product label, X = maximum insertion portion width



X mm

If symbol appears on product label, X = minimum accessory channel



Attention, see IFU



Consult Instruction for Use



Single use – Do not reuse



Do not resterilize



Keep dry



Ethylene Oxide Sterilization



Catalog Number / Product Code



Lot Number



Use by Date



Date of Manufacture

RX ONLY

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



Manufacturer



Quantity of devices in pouch



Quantity of devices in box



Do not use if package is opened or damaged

Australian Sponsor

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