

Cystoscopic Injection Needle

Device Description

Cystoscopic Injection Needle is a semi rigid injection needle, It is a hollow tubular device with bevel tip needle designed to be inserted through cystoscope for injection into urethra, bladder neck and bladder wall. Device is detectable by X-Ray or other means of fluoroscopy. The Cystoscopic Injection Needle are available in the following sizes & Lengths:

Size (G)	Length (cm)
21, 22, 23 & 24/25	30, 35, 40 & 45

Intended Purpose

Used for Cystoscopic injection into urethra, bladder neck and bladder wall up to a period of 60 minutes.

Indications For Use & Contraindications

Intended for patients with proven bladder overactivity and urge incontinence or in patients with a neurological injury affecting bladder function. The injections have the effect of partially 'paralyzing' the bladder, reducing the urgency and urge incontinence. The device is contraindicated in the presence of conditions which create unacceptable risk to the patient during cystoscopy.

Potential Complications

Complications may include, but are not limited to: Inadvertent puncture with tissue damage or bleeding, Infection, Inadvertent injection of therapeutic agent.

Warnings And Precautions

- Do not reuse the device. Reuse can cause severe infection. Intended use may fail on reuse. Do not use if package is opened or found defected. Do not use the product if there is suspect that the device is not sterile.
- Device is intended to be used by physicians trained and experienced in the use of cystoscopy techniques with support from qualified technicians using aseptic technique and not intended by unauthorized or untrained personnel. On completion of the procedure, dispose off the device and its components, if any, as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.
- Inspect the needle for bends and other possible damage. Please do not use the product if the device is found damaged.
- Do not force the device during the procedure; stop and determine the cause of resistance before proceeding.

Instructions For Use

1. Securely attach a prefilled syringe to the luer lock fitting on device, then flush air from the needle. Check for patency and leaks.
2. With the cystoscope already placed in the urethra, introduce the needle into the working channel of the cystoscope.
3. Advance the needle in the short increments until it is visualised exiting the cystoscope. Needle should not be advanced no further than 5cm from the end of the scope.
4. Cystoscopically visualize the desired injection site and maintain the position of cystoscope.
5. Advance the needle into the injection site.
6. Perform injection(s) to desired location(s).
7. Upon completion of injection(s), carefully remove the needle from the cystoscope.

Target Population Group

Patients who require treatment for over reactive bladder.

Supply and Storage

The device is packed in primary pack made of polyethylene and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20°C to 40°C and away from direct sunlight.

Report Any Serious Incident

If problems occur using this device or any serious incidents or adverse events, please contact our customer relations department or call to the contact provided in our manufacturing address and competent authority of the Member State in which the user and/or patient is established.

Symbol Glossary And Definitions

Standard Reference:

ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer

Symbol	Symbol Title
	Do not re-sterilize
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use
	Temperature limit
	Keep away from sunlight
	Do not re-use
	Not made with natural rubber latex
	Sterilized using ethylene oxide
	Non-pyrogenic
	Keep dry
	Medical device
	Single sterile barrier system with protective packaging inside
	Does not contain DEHP
	Unique device identifier
	Date of Manufacture
	Use-by date
	Batch code

	Catalogue number
	Authorized Representative in the European Community/ European Union
	Manufacturer
	Caution
	Prescription
	MR Unsafe



- This device is to be sold by/on the directions of a physician. Sterile (ETO) if package is unopened or undamaged.
- Read all the instructions before use.
- On completion of the procedure, dispose off device and its components if any as per institutional and local regulatory guidelines for bio-hazardous medical waste dispose.



Manufacturer

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