MEDORAH MEDITEK

MEDORAH®

SCLEROTHERAPY NEEDLE

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

MEDORAH® Sclerotherapy Needle

Intended Use / Indications for use

Intended use- MEDORAH® Sclerotherapy Needle is intended for use in endoscopic injections of legally marketed sclerotherapy agents and dyes in Esophageal or colonic varices. It is also used to inject sclerosing agents to aid in endoscopic mucosal resection (EMR) and polypectomy procedures to control non- variceal hemorrhage.

MEDORAH® Sclerotherapy Needle is supplied sterile and is intended for single use only.

Device Description

MEDORAH® Sclerotherapy Needle consists of a handle with a locking mechanism that provides thumb-actuated needle extension that facilitates smooth needle advancement and retraction. The handle is attached with a luer connector where a standard syringe can be attached to inject material through the lumen of the needle into the tissue.

The octagon-shaped inner catheter helps promote effective tissue penetration and consistent needle performance across various scope positions. The injection needle has a beveled tip to enhance ease of injection. The needle is used to inject the solution into the esophageal or colonic varices.

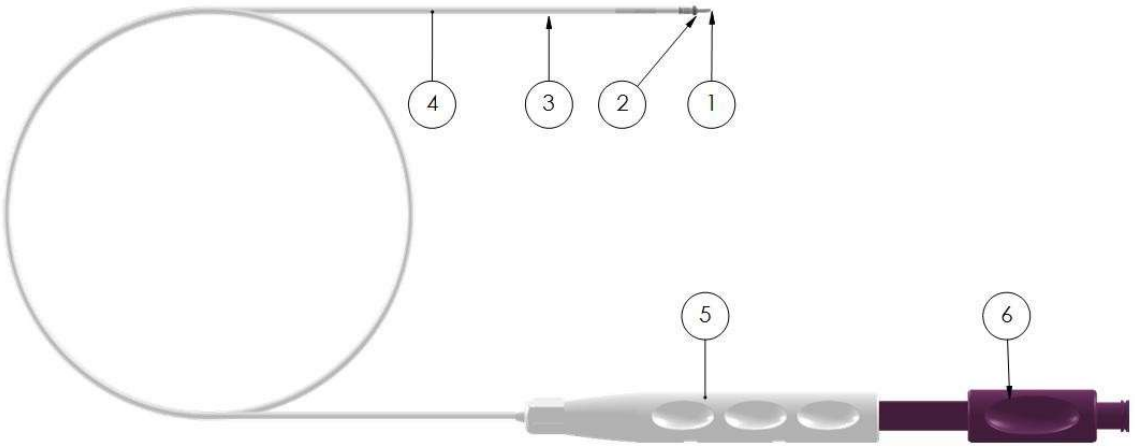
MEDORAH® Sclerotherapy Needle Specifications

Catheter Length: 180 cm, 200 cm and

230 cm Outer diameter of catheter:

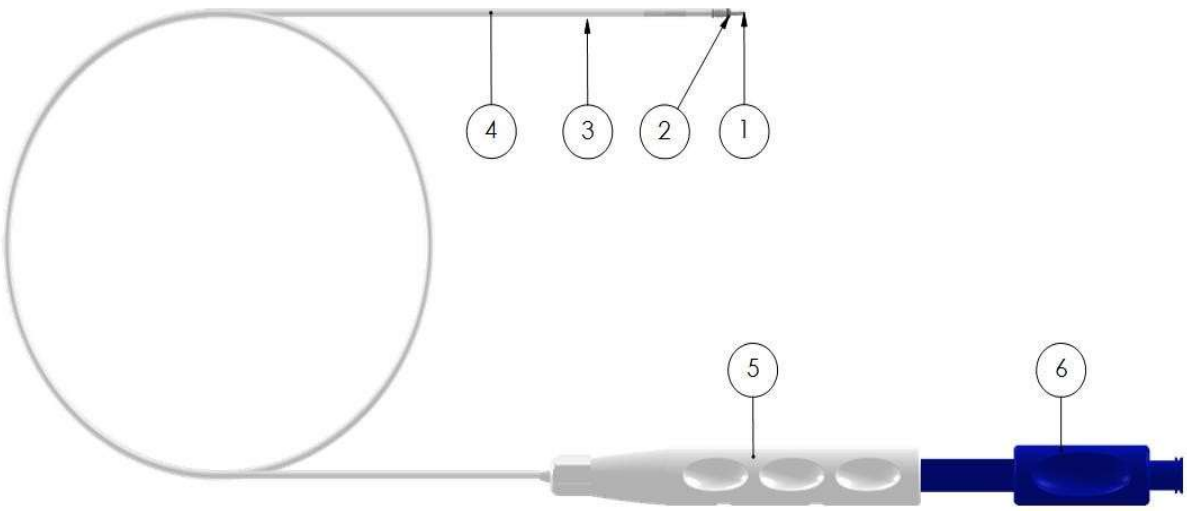
2.3 mm Diameter: 21-gauge, 23-gauge

Minimum Working Channel: 2.8 mm



21G Needle

①	Needle
②	Metal cap
③	Outer sheath
④	Inner sheath
⑤	Hub
⑥	Handle with luer lock



23G Needle

①	Needle
②	Metal cap
③	Outer sheath
④	Inner sheath
⑤	Hub
⑥	Handle with luer lock

Contraindications

This device is contraindicated for patients allergic to sclerosing or vasoconstriction agents and patients with lesions for injection therapy with sclerosing or vasoconstriction agents.

Potential Complications

The following Complications may occur when using the MEDORAH® Sclerotherapy Needle:

- Bleeding
- Perforation

- Fever
- Infection
- Sepsis
- Esophageal stricture
- Esophageal Ulcers

Warnings

The entire User's Manual must be read thoroughly before using the device. A detailed knowledge of the techniques, procedures, clinical applications and risks associated with the procedure is necessary before using the device.

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use it if the sterile barrier is damaged.
- For single use only. Do not **reuse, reprocess or re-sterilize**. Reuse, reprocessing or re- sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Do not use the device beyond its use before date.
- Dispose of product and packaging in accordance with hospital, administrative and/or local government policy after use.
- This device is only meant to be used for the purposes specified.
- If a package is opened or damaged when received, do not use it.
- Visually inspect with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working conditions, do not use.
- The instrument is intended for use under the direct supervision of a suitably trained physician only.
- In case the needle could not retract into the outer sheath, do not try to remove the instrument through the endoscope channel. It could be removed with the endoscope together.

Precautions

- Read the entire directions for use before using the MEDORAH® Sclerotherapy Needle.
- The MEDORAH® Sclerotherapy Needle should only be used by or under the supervision of trained physicians.
- Refer to the package label for minimum channel size required for this device.

- Needle must be retracted into the sheath prior to introduction, advancement, or withdrawal of the device. Failure to retract the needle may result in damage to the endoscope.
- When removing the needle from the package, ensure that the needle sheath is locked in place on the needle and the sheath covers the end of the needle tip. If the needle sheath is not locked into place on the needle, user injury may result.

Procedure

- Peel open the pouch and remove the device.
- Visually inspect the device for kinks, loose or broken parts.
- Uncoil the device and actuate the handle to ensure that the needle is operating properly.
- Prior to usage, securely connect a pre-filled syringe to the luer lock hub on the device. Then, inject the solution in the injection needle to expel air and flush the inner sheath.
- Retract the needle into the sheath and place the injection needle into the endoscope's working channel.
- Now, slowly advance the device into the channel of the endoscope until its distal end is exposed out of the endoscope's working channel.
- Position the endoscope to the appropriate target injection position.
- Fully press the handle to limit the position, extending the needle tip beyond the outer sheath. Insert the needle into the mucosa, and proceed with the injection as needed using the attached syringe.
- Now when the injection is complete, pull the handle to withdraw the needle into outer sheath. Repeat the procedure if necessary.
- After the completion of the procedure, withdraw the instrument from the endoscope with the needle retracted into the outer sheath.

Change of performance

If the device's performance is changed or the intended purpose is lost, further actions shall be taken according to the medical specialist's decision considering the clinical condition of patients.

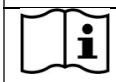
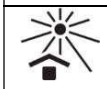
Disposal of a used device

After use, this product may be a potential biohazard. It must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of user.

Storage

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment. Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.

Explanation of Symbols

	Date of Manufacture		Use-By Date
	Catalogue Number		Do not re-use
	Consult instructions for use		Caution
	Keep away from sunlight		Batch Code
	Do not use if package is damaged		Manufacturer
	Non-Pyrogenic		Keep dry
	Do Not resterilize		Sterilized using Ethylene Oxide

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by following appropriate procedures and reasonable care has been applied in designing and manufacturing of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this device as well as other factors relating to patient, diagnosis, treatment, surgical procedures, and other matters beyond Medorah Meditek Pvt. Ltd.'s control directly affect the device and the results obtained from its use. Medorah Meditek Pvt. Ltd.'s obligation under this warranty is limited to the repair or replacement of this device and Medorah Meditek Pvt. Ltd. shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Medorah Meditek Pvt. Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Medorah Meditek Pvt. Ltd. assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or

implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.

MEDORAH MEDITEK

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