Caution: Federal law restricts this device to sale by or on the order of a physician.

GLISSADE Injection Needle

Instructions for Use

Rx ONLY

STERILE EO

【Device Name】

GLISSADE Injection Needle

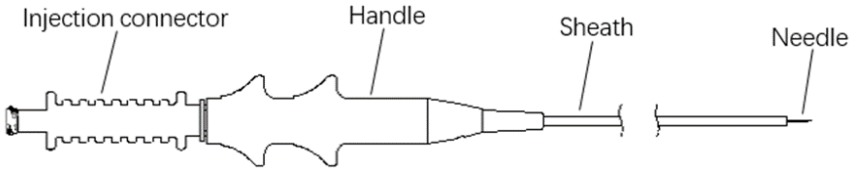
【Intended Use】

The GLISSADE Injection Needle is intended for endoscopic injection into the gastrointestinal mucosa.

【Key Components】

Injection connector, handle, sheath and needle.

【Diagram】



【Model and Dimension】

Specification	Catheter OD mm (±0.1)	Working Length mm (±100)	Model of Needle (G)	Needle Extension Length mm (±1)	Headend type
SN23230 SN25230	2.4	2300	23/25	4	Tip forming
SN23230M SN25230M	2.4	2300	23/25	4	Metal cap

【Feature】

1.Outer tube is smooth and will not cause any damage to the endoscopic channel during its insertion. The device can easily follow tortuous anatomies to reach the target via endoscope.
2. Liquid delivery channel of Endoscopy Injection Needle is clean and smooth.
3. Each connection part of product's Liquid delivery channel must be sealing.
4. The joint strength between the parts can withstand 15N and lasts for 10 seconds without loose.

【Product Inspection Before Use】

1. Inspect package upon receiving. If it is open or damage, do not use.
2. When removing the device from its package, inspect carefully for kinks, bends, and breaks. If an abnormity is found that would prohibit its proper working condition, do not use.
3. Push the Injection connector in and out to ensure it is operating properly.

【Directions for Use】

1. Prepare a luer-lock adaptable syringe with the agent to be injected. Attach the syringe to the needle via the luer-lock of the injection connector and flush out the air in the piston using the liquid agent. Inspect all joint areas to make sure no leak is detected.
2.With the needle in fully retracted position, insert the catheter into the working channel of an endoscope.
3.Advance in small increments until the catheter emerges from the endoscope. Adjust the injection needle to the position of tissue site which need to inject, then fixed the position of endoscope.
4.Keep the outer sheath completely emerging from the endoscope and maintained in the endoscopic field of view. Proceed with the injection connector to the tissue site.

5.Once the injection is completed, withdraw the needle in its fully retracted position.
6.If necessary, you can repeat the above operation, inject tissue.
7.Withdraw the catheter from an endoscope.
8.After use, this product may be a potential biohazard. Handle or dispose of it in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

【Warnings】
1.Do not use if the package is open or damaged when received.
2. Expiry product is forbidden to use.
3. Before using the device, read IFU carefully to know the using method clearly.
4. The device is a single-use sterile product. Destroy after use. Do not reuse.
5. The device must be operated by trained doctors.

【Contraindication】
Contraindications are those applicable to injection therapy and include, but may not be limited to, those patients allergic to sclerosing agent and patients with lesions inappropriate for injection therapy with sclerosing agent.

【Potential Complications】
1. Potential complications associated with the GLISSADE Injection Needle device include, but are not limited to: ulceration or necrosis, vein thrombosis and stenosis.
2.If the injection is used in Esophagus, potential complcations include but not limited to chest pain, mediastinitis, and and pleural effusion.

【Operating environment】
Ambient temperature:10~40℃, Relative humidity:30~85%

【Packaging】 One device per pouch, with box .

【Manufacturing Date】 It can be found on the package labels.

【Labeling Instructions】

	Do not reuse		Consult instruction for use
STERILE EO	Sterilized using Ethylene Oxide		Keep away from sunlight
	Do not use if package is damaged		Keep dry
	Use by date	LOT	Batch code
	Date of manufacture	REF	Catalogue number
	Fragile handle with care		Stacking no more than 6 layers
	Up		Manufacturer
	Temperature limitation		Humidity limitation
Rx ONLY	To sale by or on the order of a physician.		Atmospheric pressure limitation
	Single sterile barrier system		Single sterile barrier system with protective packaging outside
UDI	Unique Device Identifier		

【Sterilization Method】 EO sterilization.

【Expiration for Sterilization】 Three years after sterilization.

【Storage】

After packaging, the device shall be stored in an environment of relative humidity below 80%, temperature of -10℃ ~40℃, and noncorrosive gases and well-ventilated room.



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Made in China

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