Disposable Injection Needles

1. STANDARD SET LIST

This package includes the following items:

- Heyinovo Disposable Injection Needles
- Instructions for Use

NOTE:

- *Read this manual before operating.*
- *Failure to read and thoroughly understand the information presented in this manual, as well as those developed for other endoscopic equipment, may result in serious injury to the patient and/or user. Furthermore, failure to follow the instructions in this manual may result in damage to, and/or malfunction of, this equipment.*
- *It is the responsibility of each medical facility to ensure that only well-educated and appropriately trained personnel, who are competent and knowledgeable about endoscopic equipment, antimicrobial agents/processes, and hospital infection control protocol be involved in the use of these medical devices.*
- *Known risks and/or potential injuries associated with flexible endoscopic procedures include, but are not limited to, the following: hemorrhage, perforation, pleural effusion, hepatic failure, chest pain, ulceration after delayed injection, esophageal stenosis, aspiration pneumonia, dysphagia, septicemia, esophageal ulcers, and other respiratory tract problems.*

2. INTENDED USE

This device is intended to be used with a flexible endoscope to aid physicians in performing an endoscopic injection for the treatment of esophageal and gastric varices and for submucosal injection in the digestive tract.

⚠ CAUTION:

Never use this device for any purpose other than that for which it has been designed. Since endoscopic accessories are designed to be used in conjunction with other medical devices, the effectiveness of an accessory is dependent upon a number of factors, including the condition of the endoscope.

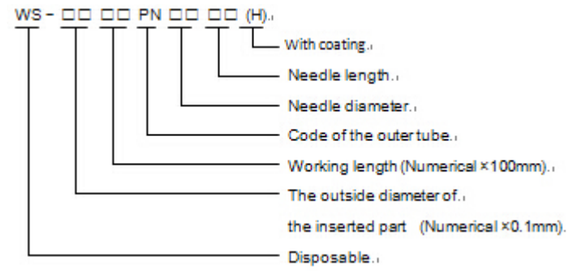
⚠WARNING:

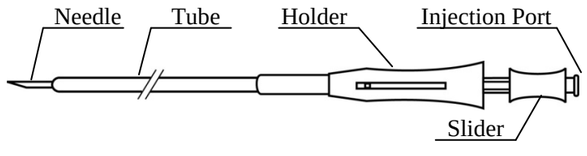
- *This device has been ETO sterilized for single patient use. Never reuse, reprocess, or re-sterilize. Reuse, reprocessing, or re-sterilization may lead to device failure, patient injury, and/ or illness. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection. Contamination of the device may lead to injury and/or illness of the patient.*
- *Never attempt to repair or modify this device. The use of a repaired or modified device may result in patient injury.*

3. CONTRAINDICATIONS

This device is contraindicated for injection and treatment in patients, including but not limited to those who are allergic to hardener and vasoconstrictor, and injured patients who are not suitable for injection of hardener and vasoconstrictor.

4. NOMENCLATURE





5. PREPARATION AND INSPECTION BEFORE USE

⚠ CAUTION:

Wear sterile surgical gloves when performing the pre-use inspection.

1) Prior to use, the endoscope with which this device will be used must be carefully and thoroughly inspected for cleanliness and proper function to determine that it is appropriate for patient use. Please refer to the manual supplied with the endoscope.
2) Select an appropriate device to satisfy the technical characteristics as well as the intended application of the endoscopic accessory.

Disposable Injection Needles Application Table

See attached.

⚠ CAUTION:

Use of this device with an incompatible endoscope can result in endoscope and/or accessory damage/failure.

⚠ CAUTION:

This device should only be used in an endoscope with forward viewing optics. Never use this device with an endoscope with oblique or side viewing optics.

3) Check the sterilization expiration date printed on the package/ labeling and confirm that the product has not expired. Make sure that there are no signs of abnormalities such as stains, wetness, tears, or any other indications that the packaging has previously been opened or compromised.

⚠ WARNING:

Do not use this device if it is expired or if the sterilization package is opened、damaged, or displays any abnormalities. In such cases, sterility can' t be guaranteed, and clinical use of the device can result in patient infection or allergic reaction.

4) Remove the device from the packaging.
5) Check the device needle for proper operation by advancing and retracting the slider.
6) With the gloves on, gently run your fingertips over the entire length of the insertion portion to check for any sign of crushed surfaces, excessive bends, broken areas, or other damages.
7) While the insertion portion is maintained in a 20-30cm loop, move the slider several times to confirm that the device has no disconnected or loose parts and the needle can be retracted completely into the tube

⚠ WARNING:

Do Not use the device if the needle cannot be retracted completely into the tube as it may damage the endoscopic channel.

⚠ CAUTION:

Avoid tight coiling or bending of the insertion portion into a diameter less than 15cm. Doing so can damage the insertion portion of the device.

8) Using a 10mL syringe, inject sterile water with the needle advanced, and ensure that water flows smoothly. Flush air to force residual water out of the tube.
9) Gently straighten the tube if there is any excessive bending.
10) With the needle retracted, this device should be slowly inserted through the channel inlet with the endoscope in a straight position. There should be no resistance encountered. If resistance is encountered, do not attempt to advance the device further, as the endoscope channel may be damaged. Remove the endoscope from service for inspection and repair.
11) After the device exits the distal tip of the endoscope, withdraw it with the needle retracted.

⚠ CAUTION:

As a precaution, always have an extra device available for use in the event that the original device becomes inoperable and/or unsafe for patient use. If a spare device is used, the above preparation and inspection steps should be followed.

⚠ WARNING:

Do not use a device that shows any signs of damage or operational difficulty. Any malfunction of the device during a patient procedure can result in serious injury to the patient.

6. OPERATION

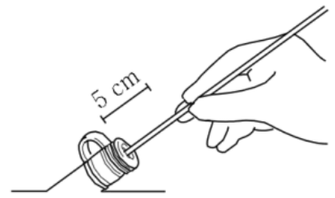
⚠WARNING:

- *The user must carefully read and follow all instructions in the operating manuals supplied with all related equipment. The equipment should be carefully and thoroughly inspected to determine that it is appropriate for patient use.*
- *Technical criteria, clinical applications, and accompanying risks must be well understood before using this device.*
- *Physicians and assistants should wear personal protective equipment such as gloves, gowns, face masks, goggles, etc. to minimize the risk of cross contamination.*
- *To avoid damaging the device when inserting or withdrawing it through the instrument channel inlet of an endoscope, keep the endoscope in a straight position and slowly insert, advance, or withdraw the device. Never apply excessive force. Do NOT twist, rotate, or bend any of the rubber strain reliefs of an endoscope, as these areas are particularly susceptible to damage.*

1) Slowly insert the endoscope under direct vision.
2) Insert the device through the slit in the rubber inlet seal with the endoscope in a straight position. Be certain to hold the slider in such a way as to ensure that the needle is in a retracted position during insertion.

NOTE:

- *When the distal end of the device is first passed through the inlet seal, temporary resistance will be encountered. Overcome this resistance by holding the tube tightly at about 5cm from the distal end and pushing it past the area of resistance.*
- *During insertion, if the device becomes difficult to advance, decrease the deflection of the bending section to a level suitable for smooth insertion, and insert the device again. Alternately, withdraw the device, and then attempt to insert it again.*



⚠ CAUTION:

- *Never apply excessive pressure when introducing any device, since the instrument channel or the device may be damaged.*

3) When the distal portion of the device becomes visible in the viewing field, always slowly and carefully advance the device towards the target area.

⚠ CAUTION:

Always maintain a view of the device during its advancement beyond the scope tip.

⚠ CAUTION:

Before injection, if endoscopic irrigation is necessary to clear blood, debris, etc. from a particular area of interest to improve visualization, move the injection needle away from the working channel of endoscope to enhance the irrigation and suction ability of the endoscope.

4) When the distal portion of the needle becomes visible in the viewing field, attach a syringe filled with medication to the injection port, and inject the medication into the needle fully to expel air out of the device.
5) Carefully advance the device onto the target area and slowly, push the slider into the holder portion until it clicks into position to expose the distal needle.

⚠ CAUTION:

The actual projected or exposed length of the needle will vary slightly during use, depending on the degree to which the insertion portion (protective tube) bends or curve.

⚠ CAUTION:

Always maintain a view of the device during its advancement beyond the scope tip.

6) Carefully place the device into the target tissue as necessary.

⚠WARNING:

The injection needles are available in various lengths. Always ensure that appropriate size has been chosen to satisfy the clinical requirements of the particular patient and procedure. Exercise extreme caution, especially when using longer length needles, to avoid inadvertent perforation/puncture of untargeted tissues/organs.

⚠ CAUTION:

- *If the needle does not move back and forth smoothly, reduce the angulation of the endoscope. Never apply excessive force.*
- *Always ensure that the needle is completely retracted within its protective tube during passage of the needle through the endoscope channel.*

7) After injection, move the slider back to retract the needle.

⚠WARNING:

- *If the needle cannot be completely retracted into the outer tube, position the endoscope to be in as straight a position as possible, try to retract the needle again.*
- *If the needle still can not be retracted into the tube, pull the needle to the distal end of the endoscope until the tip has been drawn into the endoscope. This will store the needle in the working channel to prevent injury to the patient.*

8) Slowly withdraw the device with the needle tip retracted.

⚠WARNING:

NEVER withdraw the device quickly. This can result in potential cross-contamination due to the scatter of patient debris.

7. CARE AFTER USE

⚠WARNING:

This device is for single patient use. Never reuse or resterilize the device. For disposal, follow the applicable protocol at your medical facility, as well as local or national regulations.

	Operation Environment	Storage Environment
Ambient temperature	10℃ - 40℃	-40℃ - 70℃
Relative humidity	30% - 85%	10% - 95%
Atmospheric pressure	700hPa -1060hPa (0.7atm - 1.05atm)	700hPa -1060hPa (0.7atm - 1.05atm)

⚠WARNING:

Store the packaged device in a clean and dry place. Avoid storage areas with high humidity, high temperature, and exposure to direct sunlight.

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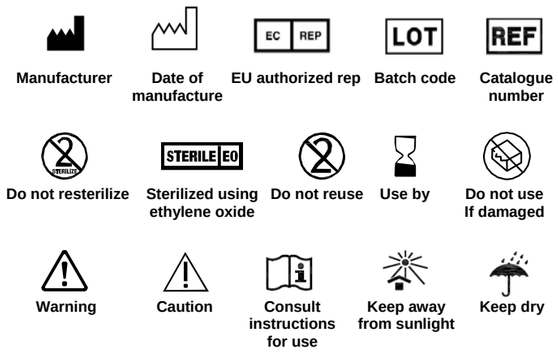

USA

Federal (USA) law restricts this device to sale by or on the order of a physician or other appropriately licensed medical professional.

Disposable Injection Needles Application Table

Model / (mm)	Max. Insertion Portion Width	Working Length	Needle		Compatible Endoscope	
			Size	Length	Minimum Channel Width	Working Length
WS-1816PN2104	ϕ1.9	1650	21G	4	ϕ2.0	1350 or less
WS-1816PN2105				5		
WS-1816PN2106				6		
WS-1816PN2304			23G	4		
WS-1816PN2305				5		
WS-1816PN2306				6		
WS-1816PN2308				8		
WS-1816PN2504			25G	4		
WS-1816PN2505				5		
WS-1816PN2506				6		
WS-2416PN1904	ϕ2.5	1650	19G	4	ϕ2.8	1350 or less
WS-2416PN1905				5		
WS-2416PN1906				6		
WS-2416PN2104			21G	4		
WS-2416PN2105				5		
WS-2416PN2106				6		
WS-2416PN2108				8		
WS-2416PN2304			23G	4		
WS-2416PN2305				5		
WS-2416PN2306				6		
WS-2416PN2504			25G	4		
WS-2416PN2505				5		
WS-2416PN2506				6		
WS-2423PN1904	ϕ2.5	2300	19G	4	ϕ2.8	2000 or less
WS-2423PN1905				5		
WS-2423PN1906				6		
WS-2423PN2104			21G	4		
WS-2423PN2105				5		
WS-2423PN2106				6		
WS-2423PN2108				8		
WS-2423PN2304			23G	4		
WS-2423PN2305				5		
WS-2423PN2306				6		
WS-2423PN2504			25G	4		
WS-2423PN2505				5		
WS-2423PN2506				6		

Model / (mm)	Max. Insertion Portion Width	Working Length	Needle		Compatible Endoscope	
			Size	Length	Minimum Channel Width	Working Length
WS-2430PN2304	ϕ2.5	3000	23G	4	ϕ2.8	2700 or less
WS-2430PN2305				5		
WS-2430PN2306				6		
WS-2430PN2504			25G	4		
WS-2430PN2505				5		
WS-2430PN2506				6		
WS-2435PN2304		3500	23G	4		3200 or less
WS-2435PN2305				5		
WS-2435PN2306				6		
WS-2435PN2504			25G	4		
WS-2435PN2505				5		
WS-2435PN2506				6		
WS-2416PM2104	ϕ2.5	1650	21G	4	ϕ2.8	1350 or less
WS-2416PM2105				5		
WS-2416PM2106				6		
WS-2416PM2304			23G	4		
WS-2416PM2305				5		
WS-2416PM2306				6		
WS-2416PM2504			25G	4		
WS-2416PM2505				5		
WS-2416PM2506				6		
WS-2423PM2104	ϕ2.5		21G	4	ϕ2.8	2000 or less
WS-2423PM2105				5		
WS-2423PM2106				6		
WS-2423PM2304			23G	4		
WS-2423PM2305				5		
WS-2423PM2306				6		
WS-2423PM2504			25G	4		
WS-2423PM2505				5		
WS-2423PM2506				6		

Model / (mm)	Max. Insertion Portion Width	Working Length	Needle		Compatible Endoscope	
			Size	Length	Minimum Channel Width	Working Length
WS-2416PM2104(H)	ϕ2.5	1650	21G	4	ϕ2.8	1350 or less
WS-2416PM2105(H)				5		
WS-2416PM2106(H)				6		
WS-2416PM2304(H)			23G	4		
WS-2416PM2305(H)				5		
WS-2416PM2306(H)				6		
WS-2416PM2504(H)			25G	4		
WS-2416PM2505(H)				5		
WS-2416PM2506(H)				6		
WS-2423PM2104(H)	ϕ2.5		21G	4	ϕ2.8	2000 or less
WS-2423PM2105(H)				5		
WS-2423PM2106(H)				6		
WS-2423PM2304(H)			23G	4		
WS-2423PM2305(H)				5		
WS-2423PM2306(H)				6		
WS-2423PM2504(H)			25G	4		
WS-2423PM2505(H)				5		
WS-2423PM2506(H)				6		

* The above product specifications are only partial, just for reference.

* There is no guarantee that instruments selected solely using this minimum Instrument channel width will be compatible in combination.