

# Disposable Spray Catheter

## 1. STANDARD SET LIST

This package includes the following items:

- Heyinovo Disposable Spray Catheter
- 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, and infection.

## 2. INTENDED USE

This device is intended to be used with a flexible endoscope to aid physicians in endoscopic spraying and injection of fluids into patient.

### 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.

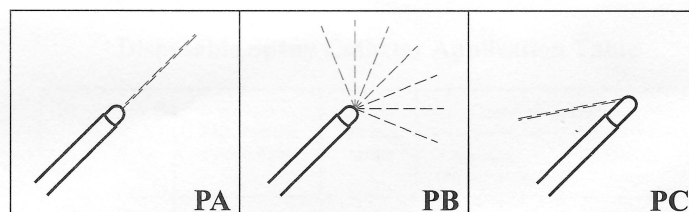
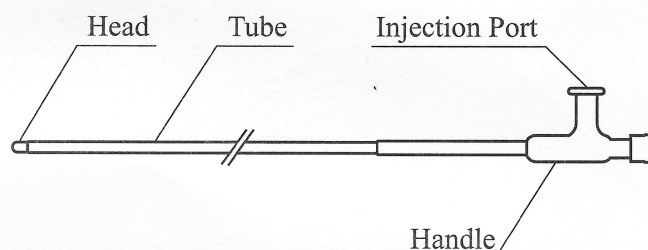
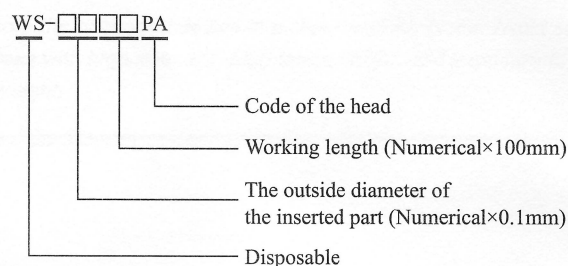
### WARNING:

- 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

Do not use this device to introduce any fluid into a patient with known allergies (e.g., contrast medium).

## 4. NOMENCLATUR



## 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 Spray Catheter Application Table  
See attached



**⚠ CAUTION:**

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

- 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) 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.
- 6) Using a 10ml syringe, inject sterile water and ensure that it flows smoothly. Flush air to force residual water out of the tube.
- 7) Gently straighten the tube if there is any excessive bending.
- 8) 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.
- 9) After the device exits the distal tip of the endoscope, withdraw it from the endoscope.

**⚠ 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

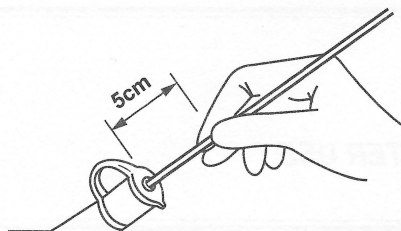
**WARNING:**

- 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) When an endoscope equipped with a device elevator is used, raise the elevator mechanism.
- 3) Insert the device through the slit in the rubber inlet seal with the endoscope in a straight position.

**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.*



- 4) When an endoscope with a device elevator is used (such as a duodenoscope), the previously raised elevator mechanism will stop advancement of the device before it exists the distal tip of the endoscope. Once the device reaches the elevator, the mechanism should be lowered to allow the device to advance approximately 1cm. The elevator may then be maneuvered as needed to bring the device into view and to aid in the application of the device.
- 5) When the distal portion of the device becomes visible in the viewing field, always slowly and carefully advance the device into the target area.

### **CAUTION:**

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

- 6) Connect a syringe with the liquid to be introduced to the injection port.
- 7) Aim at target tissues, and gently press down the syringe piston.

### **WARNING:**

- If the syringe is removed during the procedure, it will be possible for patient debris, fluids, etc. to back up into the sprayer tube and potentially be expelled from the proximal opening. In addition, insufflated air may escape through the open (unsealed) port of the sprayer. Therefore, minimize the time during which the injection port remains open (unsealed), or leave the syringe attached to the injection port.*

- 8) After having completed the spraying of fluid, withdraw the sprayer from the endoscope slowly with the elevator mechanism lowered.

### **WARNING:**

*NEVER withdraw the device quickly. This can result in potential cross-contamination due to the possible scattering 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°C ~ 40°C	-40°C ~ 70°C
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.*

### **Attached:**

**Disposable Spray Catheter Application Table**

Model	(mm) Max. Insertion Portion Width	Working Length	Compatible Endoscope	
			Minimum Channel Width	Working Length
WS-1810PA	φ 1.9	1000	φ 2.0	700 or less
WS-1818PA		1800		1500 or less
WS-1825PA		2500		2200 or less
WS-2418PA	φ 2.5	1800	φ 2.8	1500 or less
WS-2423PA		2300		2000 or less
WS-1810PB	φ 1.9	1000	φ 2.0	700 or less
WS-1818PB		1800		1500 or less
WS-1825PB		2500		2200 or less
WS-2418PB	φ 2.5	1800	φ 2.8	1500 or less
WS-2423PB		2300		2000 or less
WS-1810PC	φ 1.9	1000	φ 2.0	700 or less
WS-1818PC		1800		1500 or less
WS-1825PC		2500		2200 or less
WS-2418PC	φ 2.5	1800	φ 2.8	1500 or less
WS-2423PC		2300		2000 or less

\* 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.



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Manufacturer



Date of  
manufacturer



EU authorized rep



Batch code



Catalogue  
number



Do not  
resterilize



Sterilized using  
ethylene oxide



Do not re-use



Use by



Do not use  
if damaged



Caution



Consult  
instructions  
for use



Keep away  
from sunlight



Keep dry

**USA**

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