

Heyinovo

Reusable Injection Needles User Manual

Technical Publications

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Intend Use

The instrument has been designed to be used with an endoscope to perform endoscopic injection for sub mucosal injection in the digestive tract. Do not use this instrument for any purpose other than its intended use.

Instruction Manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the instruments as instructed. Keep this and all related instruction manuals in a safe, accessible location. If you have any questions or comments about any information in this manual, please contact Wilson or its distributor.

User Qualifications

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures.

Instrument Compatibility

Refer to the Tables in Section 1.2, "Specifications" to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient injury or equipment damage.

Reprocessing and Storage

After use, reprocess and store the Sheath Section of this instrument using The instructions in Section 8, "Reprocessing" and Section 9, "Storage". Incomplete reprocessing can present an infection control risk, cause equipment damage or reduced performance. After purchase, store the Needle Section of this instrument using the instructions in Section 9, "Storage". Incomplete storage can present an infection control risk, cause equipment damage or reduced performance.

Repair and Modification












This instrument does not contain any user-serviceable parts. Do not disassemble, modify or attempt to repair it; patient or user injury and / or equipment damage can result.

Signal Words

The following signal words are used throughout this manual:

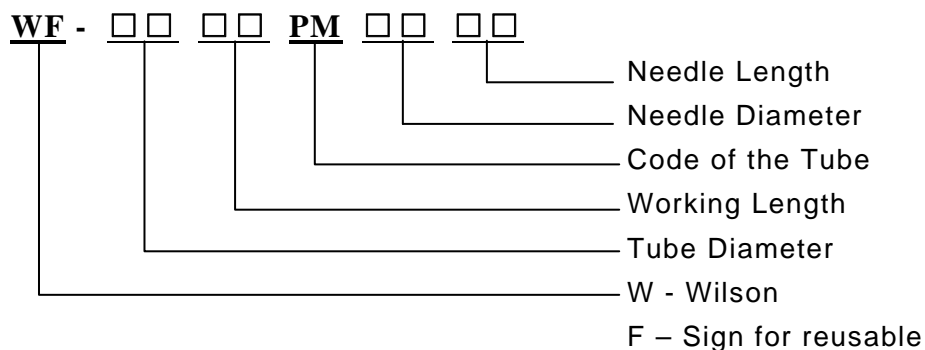
- WARNING** Indicates a potentially hazardous situation which, if not avoided could result in death or serious injury.
- CAUTION** Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.
- NOTE** Indicates additional helpful information.

Marking and labels

	<p>CE Mark: Indicates that the device conforms to Council Directive 93/42/EEC concerning medical devices.</p>
	<p>Keep away from sunlight</p>
	<p>Keep dry</p>
	<p>Consult instructions for use</p>
	<p>Manufacturer</p>
	<p>Date of manufacture</p>
	<p>Used by</p>
	<p>Authorized Representative of European community'</p>
	<p>Batch code</p>
	<p>Symbol for Attention, consult accompanying documents</p>
	<p>Indicates a medical device that has not been subjected to a sterilization process</p>

1 Instrument Nomenclature and Specifications

1.1 Nomenclature and Functions



1.2 Specifications

	Item No.	Max. Insertion Portion & Working Length	Needle Diameter	Min. Insertion channel Width (mm)
	WF-1816PM2304	Ø1.9×1650 (mm)	23G	Ø2.0(mm)
	WF-1816PM2306	Ø1.9×1650 (mm)	23G	Ø2.0(mm)
	WF-2416PM2104	Ø2.5×1650 (mm)	21G	Ø2.8(mm)
	WF-2416PM2106	Ø2.5×1650 (mm)	21G	Ø2.8(mm)
	WF-2416PM2306	Ø2.5×1650 (mm)	23G	Ø2.8(mm)
	WF-2423PM2104	Ø2.5×2300 (mm)	21G	Ø2.8(mm)
	WF-2423PM2106	Ø2.5×2300 (mm)	21G	Ø2.8(mm)
	WF-2423PM2304	Ø2.5×2300 (mm)	23G	Ø2.8(mm)
	WF-2423PM2306	Ø2.5×2300 (mm)	23G	Ø2.8(mm)

Operating Environment

Ambient Temperature 10 to 40°C (50 to 104°F)
 Relative Humidity 30 to 85%
 Air Pressure 700 to 1060hPa

Reusable Injection Needle

Inject medicament into gut tissue through endoscope



2 Preparation, Inspection and Operation

WARNING

- Do not use the Needle Section whose expiration date has passed. Doing so may cause infection control risk or tissue irritation.
- The Sheath Section of this instrument was not sterilized before shipment. Before using the Sheath Section for the first time, reprocess it according to the instructions in Section 8 “Reprocessing”. If the Sheath Section has not been reprocessed before use, this may result in an infection control risk or tissue irritation.
- Do not bring the Needle in contact with or allow it to pierce non-target tissue. This may result in infection control risk, operator or patient injury.

CAUTION

- Do not coil the Insertion Portion with a diameter of less than 15cm. That could result in damage to the Insertion Portion.

2.1 Preparation

- (1) Prepare all equipment and personal protection equipment which will be used with the instrument in accordance with their respective Instruction manuals. Appropriate protection equipment may include: Protective eye wear, a face mask, moisture resistant protective clothing and gloves, etc.
- (2) Always have spare Sheath Sections and Needle Sections available.
- (3) Prepare reprocessing equipment as described in Section 6.2, Preparation of Equipment for Reprocessing for immediate reprocessing after use.
- (4) Prepare the sterile syringe and a medicine intended for patient use.

2.2 Inspection

If any of following irregularities are detected, replace with a spare. In this case, inspect the spare Sheath Section or Needle Section in the same manner

WARNING

- Before each use, always inspect the instrument according to the following procedure. Should damage be detected, Do not use the Sheath Section or Needle Section. This may result in perforation, excessive bleeding, mucosal damage, infection control risk, endoscope damage or instrument damage. If damage is detected when the Sheath Section or Needle Section are Inspected for the first time after purchase, these products are defective. In this case, contact Wilson or its distributor.
- Before use, inspect the insertion portion and the tube for damage. Do not use the instrument if either component is crushed or excessively bent. Confirm that the needle can be smoothly extended from and retracted into the tube. Do not use the instrument if it cannot be operated smoothly. Otherwise, the needle may not properly extend from and / or withdraw into the sheath. The extended needle could cause perforation, bleeding, mucous membrane damage or inflammation of the tissues, and / or damage the endoscope. If needle operation is lost or becomes difficult

during a procedure. stop the procedure immediately and withdraw the needle and the endoscope from the patient.

2.2.1 Inspect of the appearance

If any of following irregularities are detected, replace with a spare.

- a. Confirm the instrument does not fall off and loose.
- b. Use fingertips to touch the surface of the insertion portion, verify that no crushing, excessive bending, cracking or other damage.
- c. Confirm handle no cracks.

2.2.2 Inspect of the operation

CAUTION

- Straighten out the instrument before inspecting it. The instrument can be damaged if it is coiled while the Handle is operated.
 - Operate the Slider slowly, otherwise the Tube could buckle.
- a. Confirm the needle can be completely retracted into the sheaths.
 - b. Straighten the instrument, hold the tube sheath, push the slide handle, until the slide handle into the right place.
 - c. Confirm the needle protruding from the tip of the sheath.
 - d. Pull the slide handle in the end, confirm the needle can be completely retracted into the sheaths.

2.2.3 Inspect of the injection

WARNING

- If liquid and medicine liquid can not be injected, or outflow from the outside of the tip of the insertion portion, please use a spare instead.
 - When checking the injection, be sure to use the liquid and medicine liquid which will be used for the patient. If use the other liquid and medicine liquid, remaining on the instrument, it may cause infection or inflammation of the tissues.
- a. Push the slide handle until it clicks, so that the needle can protrude from the sheath.
 - b. Inject medicine liquid from injection port with a sterile injector, make sure the medicine liquid outflow from the tip of the insertion portion.
 - c. Make sure the medicine liquid do not outflow from the outside of the tip of the insertion portion.
 - d. Through the injection port to inject air with a injector, in order to discharge the liquid from the needle.

2.3 Operation

The operator of the instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this instrument.

WARNING

- When operating, always wear appropriate personal protection equipment. If not worn, blood, mucous and other infectious material from the patient could pose an infection control risk.
- Do not insert the instrument into the endoscope unless Distal End of Sheath is clearly visible and you have a clear endoscopic field of view. This may result in perforation, excessive bleeding, mucosal damage, endoscope damage or instrument damage.
- Do not angle the endoscope and operate the forceps elevator abruptly when the Distal End of the Sheath is projected from the endoscope. This may result in perforation, excessive bleeding or mucosal damage.
- Do not push the Distal End of the Sheath against tissue by force, otherwise perforation, excessive bleeding or mucosal damage can result.

2.3.1 Insert instrument into endoscopy

WARNING

- If you encounter resistance when inserting the instrument, do not forcibly insert. Please reduce the angle until it can be smoothly inserted. Otherwise, it may cause patient injury, such as punctures, hemorrhages or mucus membrane damage. And it may damage the endoscopy and the instruments.
- If you encounter resistance when inserting the equipment, do not forcibly insert. Please reduce the angle until it can be smoothly inserted.

CAUTION

When the instrument is inserted into the endoscopy, hold the insertion portion, advance the opening of the forceps channel and try to straighten. Otherwise, it may damage the endoscopy and the instruments.

- a. Pull the slide handle in the end, withdraw the needle into sheath apex.
- b. Carefully insert the instrument into the opening of the forceps channel.
- c. Push the instrument, until endoscopic vision appeared the tip of the insertion.

2.3.2 Piercing Tissue and Injecting the Medicine

WARNING

- Do not push the Slider abruptly. Otherwise the Needle will be rapidly extended from the Distal End of the Tube. This could result in patient injury such as punctures, hemorrhages or mucous membrane damage. It could also damage the Instrument.
 - While piercing tissue and injecting medication, always hold the Holder Portion and Slider. Otherwise, could result in patient injury, such as hemorrhages.
 - Do not pierce tissue with excessive force. This could result in patient injury such as punctures, hemorrhages or mucous membrane damage.
- a. push the slide handle until it clicks, so that the needle can protrude from the sheath.
 - b. Connect the injector filled with the medicinal liquid to the sliding handle injection port.

- c. Gently press the injector plunger, confirm liquid outflow from the needle tip.
- d. Target tissue with needle, push the plunger, inject the liquid.
- e. Withdraw the needle from the target tissue.
- f. Pull the slide handle in the end, confirm the needle can be completely retracted into the sheaths.

3 Reprocessing

With proper care, the Injection Needle is reusable. The Injection Needle must be cleaned and disinfected or sterilized immediately after each use. Always wear appropriate personal protective equipment when reprocessing endoscopic accessories.

- 1) Prepare the detergent solution.

Fill a basin with water and low-foaming, medical grade detergent solution at a temperature and concentration recommended by the manufacturer.

- 2) soak the Injection Needle in detergent solution.
 - a. Immerse the Injection Needle in the detergent solution.
 - b. Soak the Injection Needle for the amount of time and at the temperature recommended by the detergent solution's manufacturer.

WARNING

- Extended immersion of the brush in detergent or ultrasonic cleaning solution will limit the life of the brush.

- 3) Manually clean the Injection Needle.

Keeping the brush immersed in the detergent solution.

- 4) Rinse the Injection Needle.

Remove the Injection Needle from the detergent solution and rinse it thoroughly with clean water.

- 5) Ultrasonic cleaning.

The use of an ultrasonic cleaner is necessary to aid in removing particulate matter.

- a. immerse the Injection Needle in an ultrasonic cleaner.

CAUTION

- Do not coil the shaft into a diameter smaller than 15cm. The brush can be damaged if coiled too tightly.
- b. Process at 40kHz or higher output for a minimum of five minutes. Ultrasonic cleaning will take longer if you use a lower output frequency.

- 6) Rinse and dry the Injection Needle.

Rinse the brush and use a clean, lint-free cloth or gauze to thoroughly wipe the brush dry.

7) Disinfect or sterilize the Injection Needle.

The Injection Needle must be meticulously cleaned and thoroughly dried prior to disinfection or sterilization. The actual method chosen by your institution to disinfect or sterilize the Injection Needle should be determined by national and local guidelines and your hospital infection control committee.

a. Disinfection

Refer to the reprocessing instructions for the endoscope for details on disinfectant solutions.

- 1) Immerse the Injection Needle in disinfectant solution following any special instructions outlined by the disinfectant solution manufacturer. The manufacturer's recommended dilution percentage and contact time should be met, but not exceeded.
- 2) Remove the Injection Needle from the disinfectant solution and thoroughly rinse it with sterile water.
- 3) Dry the Injection Needle with a sterile gauze pad.

b. Sterilization

No.	Temperature	Pressure	Exposure Time
1	134°C (274°F)	0.15MPa	5 minutes
2	126°C (266°F)	0.10MPa	20 minutes

CAUTION

- When loading the autoclave, ensure that the Injection Needle is not crushed by surrounding objects.

4 Storage

WARNING

- ★ Do not store the instrument in a sterile package that is damaged, wet or improperly sealed. Otherwise, the sterile condition of the instrument may be compromised and pose an infection control risk or cause tissue irritation may result.
- ★ Do not store the instrument in place where they will be damaged, wet or improperly sealed. Otherwise, the sterile condition of the instrument may be compromised and pose an infection control risk or cause tissue irritation.

CAUTION

- ★ Do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.

4.1 Inspection Before Storage

Prior to storage, inspect the sterile package as follows:

- Confirm that the sterile package is free of tears and inadequate sealing. If tears or inadequate sealing are detected, remove the instrument from the package and sterilize again as described in Section 4.
- Confirm that the sterile package is free from water damage. If water damage

is detected, repackage and sterilize again.

4.2 Storage

Store the instrument in the sterile package at room temperature in a clean and dry environment. Do not store it in direct sunlight. Ensure that the packaged instrument is not crushed by surrounding objects during storage. Follow any additional storage instructions provided by the manufacturer of the sterile package.

4.3 Storage conditions

Ambient temperature: from -40 °C to 70 °C;
Humidity: 10% to 95%;
Atmospheric pressure: 700hPa-1060hPa.

5 Disposal of the Waste

WARNING

- Dispose of the Needle Section in an appropriate manner after use. If the Needle Section is not disposed of properly, an infection control risk or operator injury can result.
- Do not reuse the Needle Section. Reuse may result in infection control risk, cause tissue irritation or malfunction.

The waste of the products should be destroyed and disposed according to related local law and regulatory requirements of the state or area. Randomly cast off is strictly forbidden.

6 Service information

If you have any questions about any information in these instructions, contact WILSON.



Wilson Instruments (SHA) Co., Ltd.

25D, He Yi Business Plaza No.420, Jiang Ning Rd. Shanghai, China.(200041)

[TEL: +0086-21-66311471](tel:+0086-21-66311471)

FAX: +0086-21-66311472

EC REP Lotus Global Co., Ltd.

1 Four Seasons Terrace, West Drayton, Middlesex, London, UB7 9GG, United Kingdom

TEL: +0044-20-75868010

FAX: +0044-20-79006187