Heyinovo

Disposable Injection Needles User Manual

Technical Publications

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CE 0197

Regulatory Requirement

This product complies with regulatory requirements of the following European Directive 93/42/EEC concerning medical devices.

CE 0197

Revision History

REV	DATE	Complied by	Approved by
Rev. A	Apr-02-2007	Mr. Yaodong, Wang	Mr. Xin,Huang
Rev. B	Jun-05-2010	Mr. Yaodong, Wang	Mr. Xin,Huang
Rev. C	Aug-09-2013	Ms. xiaoping, Qian	Mr. Xin,Huang

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Certifications

• General Medical Systems is ISO 9001 and ISO 13485 certified.

Original Documentation

• The original document was written in English.

Attention

This manual contains necessary and sufficient information to operate the system safely. Advanced equipment training may be provided by a factory trained Applications Specialist for the agreed-upon time period.

Read and understand all instructions in this manual before attempting to use the Disposable Injection Needle.
Keep this manual with the equipment at all times for ready use. Periodically review the procedures for operation and safety precautions.

If any queries about the content of this manual, feel free to contact us.

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Chapter 0

Notice upon Use of Product

0.1 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.

0.2 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 it's distributor.

0.3 User qualification

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.

0.4 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.

0.5 Check the Package Contents

Match all items in the package with the components shown below. Inspect each item for damage. If the instrument is damaged, a component is missing or you have any questions, do not use the instrument, immediately contact Wilson or it's distributor.

0.6 Symbols and Signal Words

a. 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

b. The meaning of the symbol shown on the package of this instrument is as follows:

CE 0197	CE Mark: Indicates that the device conforms to Council Directive 93/42/EEC concerning medical devices.
	Temperature limitation
	Keep away from sunlight
	Keep dry
	Consult instructions for use
	Do not resterilize
	Do not use if package is damaged
	Manufacturer
	Do not reuse
	Date of manufacture
	Used by
EC REP	Authorized Representative of European community'
STERILE EO	Sterilization using ethylene oxide
LOT	Batch code

0.7 Sterilization method

Sterilization of the product is sterilized with ethylene oxide.

0.8 Operating environment

Ambient Temperature	10 to 40℃ (50 to 104℉)
Relative Humidity	30 to 85%
Air Pressure	700 to 1060hPa

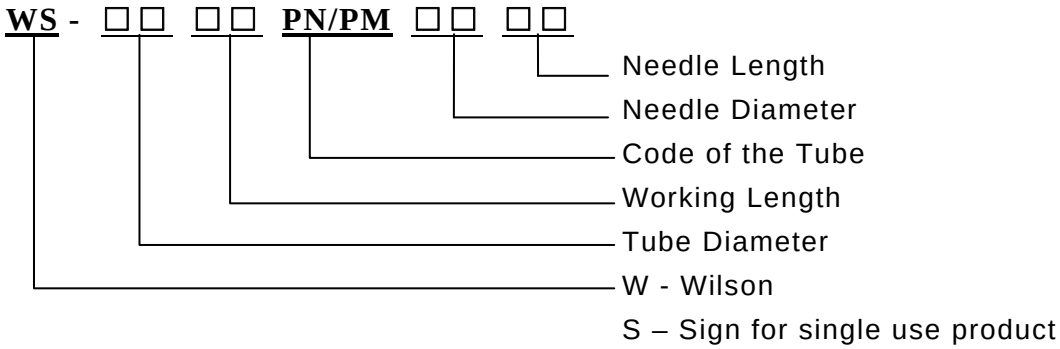
0.9 Attention

WARNING The product is special accessories of endoscopy, can not be used alone, shall not be altered without authorization or used for other purposes.

Chapter 1

Instrument Nomenclature and Specifications

1.1 Nomenclature



1.2 Specifications

Specifications	Max.insertion portion diameter & working length(mm)	Needle diameter	Needle length(mm)	Working channel diameter (mm)
WS-1816PN2304	Φ1.8×1650	Φ23G	4	Φ2.0-Φ2.2
WS-1816PN2504	Φ1.8×1650	Φ25G	4	Φ2.0-Φ2.2
WS-1816PN2305	Φ1.8×1650	Φ23G	5	Φ2.0-Φ2.2
WS-1816PN2505	Φ1.8×1650	Φ25G	5	Φ2.0-Φ2.2
WS-1816PN2306	Φ1.8×1650	Φ23G	6	Φ2.0-Φ2.2
WS-1816PN2308	Φ1.8×1650	Φ23G	8	Φ2.0-Φ2.2
WS-2416PN2104	Φ2.4×1650	Φ21G	4	Φ2.8
WS-2416PN2304	Φ2.4×1650	Φ23G	4	Φ2.8
WS-2416PN2504	Φ2.4×1650	Φ25G	4	Φ2.8
WS-2416PN2105	Φ2.4×1650	Φ21G	5	Φ2.8
WS-2416PN2505	Φ2.4×1650	Φ25G	5	Φ2.8
WS-2416PN2306	Φ2.4×1650	Φ23G	6	Φ2.8
WS-2416PN2506	Φ2.4×1650	Φ25G	6	Φ2.8
WS-2416PN2108	Φ2.4×1650	Φ21G	8	Φ2.8

WS-2423PN1904	Φ2.4×2300	Φ19G	4	Φ2.8
WS-2423PN2304	Φ2.4×2300	Φ23G	4	Φ2.8
WS-2423PN2504	Φ2.4×2300	Φ25G	4	Φ2.8
WS-2423PN2305	Φ2.4×2300	Φ23G	5	Φ2.8
WS-2423PN2505	Φ2.4×2300	Φ25G	5	Φ2.8
WS-2423PN2306	Φ2.4×2300	Φ23G	6	Φ2.8
WS-2423PN2506	Φ2.4×2300	Φ25G	6	Φ2.8
WS-2416PM2104	Φ2.4×1650	Φ21G	4	Φ2.8
WS-2416PM2304	Φ2.4×1650	Φ23G	4	Φ2.8
WS-2416PM2504	Φ2.4×1650	Φ25G	4	Φ2.8
WS-2416PM2105	Φ2.4×1650	Φ21G	5	Φ2.8
WS-2416PM2505	Φ2.4×1650	Φ25G	5	Φ2.8
WS-2416PM2306	Φ2.4×1650	Φ23G	6	Φ2.8
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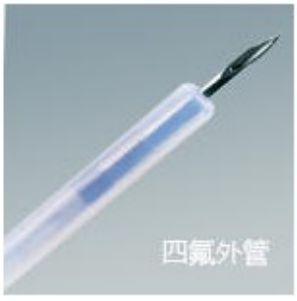
WS-2423PM2305	Φ2.4×2300	Φ23G	5	Φ2.8
WS-2423PM2505	Φ2.4×2300	Φ25G	5	Φ2.8
WS-2423PM2306	Φ2.4×2300	Φ23G	6	Φ2.8
WS-2423PM2506	Φ2.4×2300	Φ25G	6	Φ2.8

Disposable Injection Needle

Inject medicament into gut tissue through endoscope

CE 0197



Chapter 2

Preparation, Inspection and Operation

The instrument was shipped in a sterile condition.

WARNING

- Do not use an instrument after the expiration date displayed on the sterile package. Doing so may pose an infection control risk or cause tissue Irritation.
- Before each case，prepare and inspect the instrument as instructed below. Inspect other equipment to be used with the instrument as instructed in their respective instruction manuals. Should the slightest irregularity be suspected, do not use the instrument; contact Wilson or it's distributor. Damage or irregularity may compromise patient or user safety. such as infection control risk，tissue irritation. Punctures, hemorrhages, mucous membrane damage or thermal injury and may result in more—severe equipment damage.
- Do not bring the Needle in contact with or allow it to pierce non—target tissue. This may cause an infection control risk, operator or patient injury.

CAUTION

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

2.1 Preparation

a. 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.

b. Always have spare instrument available.

2.2 Inspection

Wear the appropriate personal protective equipment as specified above.

WARNING

a. 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.

b. Before each case, always inspect the instrument according to the following procedures. If an abnormality in the instrument is detected, use a spare

instrument, inspecting it thoroughly before use.

2.2.1 Inspection of the sterile package

WARNING Do not attempt to sterilize the instrument. This could pose an infection control risk, cause tissue irritation equipment damage or malfunction.

Inspect the sterile package for tears, inadequate sealing or water damage. If the sterile package shows any irregularities, the sterile condition of the instrument has been compromised. Use a spare instead.

2.2.2 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.

2.2.3 Inspect of the operation

CAUTION a. Straighten out the instrument before inspecting it. The instrument can be damaged if it is coiled while the Handle is operated.
b. 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.

2.2.4 Inspect of the injection

WARNING a. 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.
b. 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 a. When using the instrument, always wear appropriate personal protective equipment. Otherwise, blood, mucous and other potentially infectious material from the patient could pose an infection control risk. Appropriate personal protective equipment may include: Eye wear, a face mask, moisture—resistant clothing and chemica, resistant gloves that fit properly and are long enough so that your skin is not exposed.

b. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. If you cannot see the Distal End of the Insertion Portion in the endoscopic field of view, do not use it. This could cause patient injury, such as punctures，hemorrhages, or mucous membrane damage. It may also damage the endoscope and／or instrument.

c. Do not angulate the endoscope's Bending Section or operate the Forceps Elevator abruptly while the Distal End of the Insertion Portion is extended from the Distal End of the endoscope. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.

d. Do not force the Distal End of the Insertion Portion against body cavity tissue. This could cause patient injury such as punctures, hemorrhages or mucous membrane damage.

2.3.1 Insert instrument into endoscopy

WARNING a. 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.

b. 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 a. 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.

b. While piercing tissue and injecting medication，always hold the Holder Portion and Slider. Otherwise, could result in patient injury, such as hemorrhages.

c. 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.

Chapter 3

Storage

WARNING a. Do not store the sterile packages containing the instrument in places where they will become damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised and pose an infection control risk or cause tissue irritation.

b. Store the instrument in the sterile package at room temperature in a clean and dry environment. Do not store the instrument in direct sunlight. Ensure that the package is not crushed by surrounding objects during storage.

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

3.1 Inspection Before Storage

Prior to storage，inspect the sterile package as follows:
a. Confirm that the sterile package is free of tears and inadequate sealing.
b. Confirm that the sterile package is free from water damage.

3.2 Storage requirement

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.

3.3 Storage conditions

Ambient temperature: from -20 ^{o}C to 60 ^{o}C;
Humidity:10% to 90%;
Atmospheric pressure: 500hPa-1060hPa.

Chapter 4

Disposal of waste

WARNING a.The equipment is disposable products Do not reuse or attempt to sterilization again.

b. The used disposable products should be controlled and disposed together, or they may cause pollution to the environment and the public, and cause bad consequences.

4.1 Waste control

The used disposable products should be collected together and closed off. They should never be stored at will.

4.2 The Disposal of the waste

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.

Chapter 5

Service information

If you have any questions about any information in these instructions, please contact our by the following information

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