Heyinovo

Disposable Spray Catheters 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-04-2008	Mr Yaodong,Wang	Mr Xin,Huang
Rev. B	JUL-18-2013	Ms.Xiaoping Qian	Mr Xin,Huang

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 Spray Catheters.
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 Product description and function

The product is auxiliary equipment of flexible endoscopy clinical diagnosis, it is for endoscopic diagnosis on the digestive tract, respiratory tract and other body's natural cavity in fluid transport, irrigation, spraying and other operations.

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 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

0.6 Sterilization method

Sterilization of the product is sterilized with ethylene oxide.

0.7 Operating environment

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

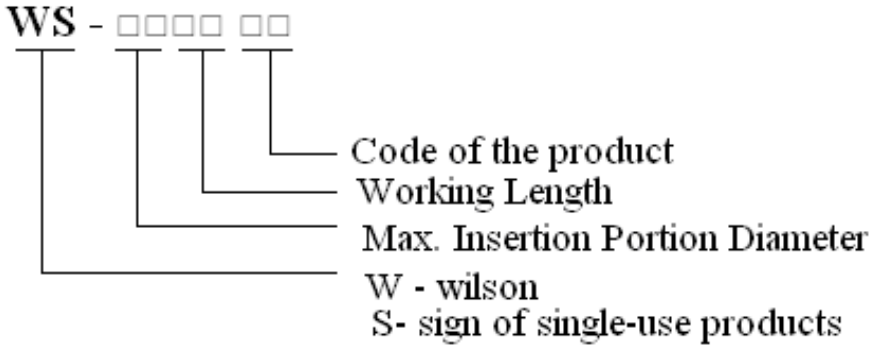
0.8 Attention

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

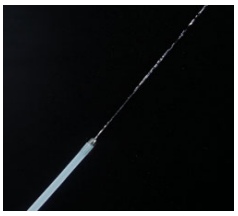
Chapter 1

Instrument Nomenclature and Specifications

1.1 Nomenclature



1.2 Specifications

Specifications	Figure	Max.insertion portion diameter & working length(mm)	Working channel diameter（mm）	spray head forms and characteristics
WS-1810PA		Φ1.8×1000	Φ2.0~Φ2.2	Single hole, Standard, for routine lavage
WS-1818PA		Φ1.8×1800	Φ2.0~Φ2.2	
WS-2418PA		Φ2.4×1800	Φ2.8	
WS-2423PA		Φ2.4×2300	Φ2.8	
WS-2418PB		Φ2.4×1800	Φ2.8	Mist spray form, used for large area spraying hemostatic drugs or coloring
WS-2423PB		Φ2.4×2300	Φ2.8	
WS-1818PC		Φ1.8×1800	Φ2.0~Φ2.2	Back spray form, reverse spray rushed for bile
WS-1825PC		Φ1.8×2500	Φ2.0~Φ2.2	
WS-2418PC		Φ2.4×1800	Φ2.8	

Medical Device Directive	CE 0197	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class Ⅱa

Chapter 2

Preparation,Inspection and Operation

WARNING a. Do not use an instrument after the expiration date displayed on the sterile package. Otherwise, it may pose an infection control risk or cause tissue irritation.

b. Before use, prepare and inspect the instrument as instructed below. If the slightest irregularity be suspected, do not use the instrument; use a spare instead. Damage or irregularity may compromise patient or user safety, such as infection , tissue irritation, puncture hemorrhage or mucous membrane damage, it also can be result in more severe equipment damage.

CAUTION Do not coil the insertion portion with a diameter of less than 15 cm, which 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.

c. Prepare a sterile injector and medicinal liquid which is used to a patient.

2.2 Inspection

WARNING a. 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 endoscopy 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 it's distributor.

b. Before use，inspect the insertion portion and the tube for damage. Do not use the instrument f 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. 1f needle operation is lost or becomes difficult during a procedure. stop the procedure immediately and withdraw the needle and the endoscope from the patient.

c. If an abnormality in the instrument is detected, use a spare instrument, inspecting it thoroughly before use.

d. Comprehensive inspection of the spare instrument.

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 the appearance

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.

a. Conform the equipment 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 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. Inject medicine liquid from injection port with a sterile injector, make sure the medicine liquid outflow from the tip of the insertion portion.

b. Make sure the medicine liquid do not outflow from the outside of the tip of the insertion portion.

2.3 Operation

WARNING a. 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.

b. Do not insert the instrument into the endoscopy unless Distal End of Sheath is clearly visible and you have clear endoscopic field of view. This may result in perforation, excessive bleeding, mucosal damage. And it may damage the endoscopy and the instruments.

c. Do not angle the endoscopy and operate the forceps elevator abruptly when the Distal End of the Sheath is projected from the endoscopy. This may result in peroration, excessive bleeding or mucosal damage.

d. 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 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. Carefully insert the instrument into the opening of the forceps channel.

b. Push the instrument, until endoscopic vision appeared the tip of the insertion.

2.3.2 Spray liquid or medicine liquid

a. Connect the injector filling with the liquid or medicine liquid to the injection port.

b. Gently press the injector plunger, make use the medicine liquid outflow from the tip of the insertion portion.

c. Target the tissue, press the plunger and spray the liquid or medicine liquid.

2.3.3 draw out instrument from endoscopy

WARNING Do not pull the instrument from the endoscopy suddenly. This could cause patient injury, such as punctures, hemorrhages or mucus membrane damage. And it may damage the endoscopy and the instruments

a. If endoscopy is equipped with lift forceps device, lower the lift forceps device.

b. Pull the instrument from the endoscopy.

Chapter 3

Storage

WARNING a. 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.

b. 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.

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

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

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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