Heyinovo

Disposable Biopsy Valves User Manual

Technical Publications

Document No: WI-RD-13-M07, Rev. B

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	Jun-06-2010	Mr. Yaodong, Wang	Mr. Xin,Huang
Rev. B	Sep-06-2013	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 Biopsy Valves.

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.

Table of Contents

Chapter 0

Notice upon Use of Product

0.1 Intend Use

This valve has been designed to be attached to the endoscopes listed in the 4,"ENDOSCOPE COMPATIBILITY" and to prevent reflux of body fluids. This device should not be used 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

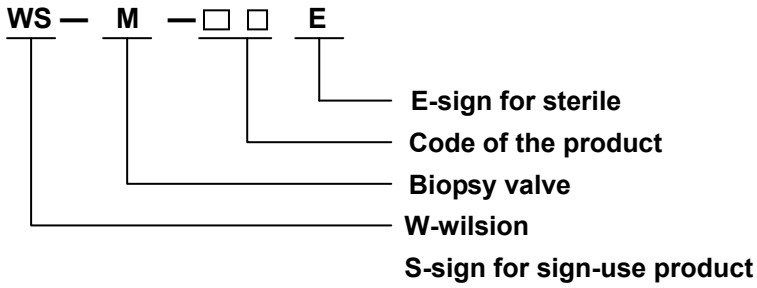
0.9 Attention

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

	Oval Fenestrated Cups	Sterile	Application: Endoscope Compatibility
	WS-M-01 WS-M-01E	NO YES	FIT FOR **OLYMPUS & FUJINON** GI ENDOSCOPES
	Oval Fenestrated Cups	Sterile	Application: Endoscope Compatibility
	WS-M-02 WS-M-02E	NO YES	FIT FOR **PENTAX** GI ENDOSCOPES
	Oval Fenestrated Cups	Sterile	Application: Endoscope Compatibility
	WS-M-03 WS-M-03E	NO YES	FIT FOR **OLYMPUS** GI ENDOSCOPES

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

Chapter 2

Preparation, Inspection and Operation

2.1 Preparation

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; replace with a new valve immediately and contact Wilson or it's distributor.

CAUTION

- This valve is single use, performing sterilization by ETO gas (with E).
- Before use, if any irregularities are detected, replace with a new valve immediately.
- Do not crush the product, otherwise it will damage the product.

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 Inspect

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

Inspect that there are no cracks, tears or deformation of the Biopsy Valve.

2.3 Operation

WARNING

- When using the instrument. Always wear appropriate personal protective equipment. Otherwise, blood, mucous and other potentially infections 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 chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.

NOTE

- At low temperature, the Biopsy Valve may become stiff and difficult to be attached.

2.3.1 Attaching the Biopsy Valve to the Endoscope

Push the Biopsy Valve down on to the Suction Valve Holder or the Instrument Channel Port until the valve snaps into place.

2.3.2 Feeding solution with a syringe

CAUTION Angled or incomplete insertion may result in leakage of solution from the valve.

Insert a syringe firmly and hold it perpendicular to the valve. Press the plunger to feed solution.

2.3.3 Aspirating solution with a syringe

Remove the valve from the Suction Valve holder or Instrument channel Port. Insert a syringe and withdraw the plunger to aspirate solution.

2.3.4 Inserting and withdrawing the Endo-Therapy Accessories

CAUTION Inserting the Endo-Therapy Accessory straight into the valve.

1. Insert the Endo-Therapy Accessory through the slit.
2. After use, slowly withdraw the Endo-Therapy accessory.

2.3.5 Removing the Biopsy Valve from the Endoscope

Remove the Biopsy Valve from the Suction Valve Holder or Instrument Channel Port.

Chapter 3

Storage

WARNING

- 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.
- 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.

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.

WILSON INSTRUMENTS (SHA) CO., LTD.

25D，He Yi Business Plaza No.420, Jiang Ning Rd. Shanghai, China. (200041)
Tel:+0086-21-66311471
Fax:+0086-21-66311472

EC REP **EC Representative**

Company: Lotus Global Co., Ltd.
Address: 15 Alexandra Road, London, NW80DP, United Kingdom
Contact Person: Peter
Tel: +0044-20-75868010
Fax: +0044-20-79006187