

Heyinovo

Disposable Cytology Brushes

Technical Publications

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Regulatory Requirement

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



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	JUL-24-2013	Ms.Xiaoping Qian	Mr Xin,Huang

**Wilson Instruments (SHA) Co., Ltd.
25D, He Yi Business Plaza, No. 420,
Jiang Ning Rd., Shanghai 200041,
P.R.China**

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 Cytology Brush.

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 the general attachment in endoscopy clinical diagnosis and treatment. It enter the coulomb of human body through the endoscopy forceps working channel, brush and collect tissue for pathology analysis under the observe of endoscopy.

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 Check before using

- a. Check the product packaging box in content. The box with the exception of product shall be provided with instructions for use, product certification
- b. Inspection products within the packaging bag sealing is tight and model specification on the label is consistent with product.
- c. Open the packaging, check whether the product is in good condition. If the product is found damaged, do not use, contact with the supplier or the company immediately, in order to change.

0.5 Symbols and Signal Words













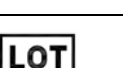

- a. The following signal words are used throughout this manual

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 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 re-sterilize
	Do not use if package is damaged
	Manufacturer
	Do not reuse
	Date of manufacture
	Used by
	Authorized Representative of European community'
	Sterilization using ethylene oxide
	Batch code

0.6 Sterilization method

Sterilization of the product is sterilized with ethylene oxide.

0.7 Working principle

Pulling and turning can be controlled by handle.

0.8 Operating environment

Ambient Temperature 10 to 40°C (50 to 104°F)

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 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**
- a. Do not coil the insertion portion with a diameter of less than 15 cm,which could damage the insertion portion
 - b. Do not extend and retract the brush, or move it forward or back if resistance is encountered. Otherwise, it may damage the endoscopy and instrument.

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

- WARNING**
- a. Before each use, always inspect the instrument according to the following procedure. 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 and contact 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.
 - b. If an abnormality in the instrument is detected, use a spare instrument, inspecting it thoroughly before use.
 - c. 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.

- a. Operating forceps ring, extending and retracting the brush, determined that the equipment 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. extending the brush from PTFE outer tube, Verify that no random wire, loose, sharp protrusions, sharp edges or other damage.
- d. Confirm handle no cracks.

2.2.3 Inspect of operation

Straighten out the instrument. While holding the instrument's tube, operate the ring and confirm that the brush extends and retracts smoothly.

2.3 Operation

- WARNING**
- a. Appropriate personal protective equipment may include: Eye wear, face mask moisture-resistant clothing and chemical—resistant gloves that fit properly and are long enough so that your skin is not exposed. When using the instrument, always wear appropriate personal protective equipment. Otherwise, blood mucus and other potentially infectious material from the patient could pose an infection control risk.
 - b. Do not insert the instrument into the endoscopy 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 or in the X. ray images, do not use it. This could cause patient injury, such as punctures, hemorrhages or mucus membrane damage.
 - c. Do not angulate the insertion portion of the endoscopy abruptly while the distal end of the insertion portion is extended from the distal end of endoscopy. This could cause patient injury. such as punctures, hemorrhages or mucus membrane damage.

2.3.1 Insert instrument into endoscopy

- WARNING**
- a. If the brush is not completely into the PTFE outer tube, do not insert the equipment into the endoscopy, even more not insert sudden. Otherwise, the tip of Insert portion will extend from the tip of endoscopy suddenly. This could 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**
- a. When the instrument is inserted into the endoscopy, incorporate the brush into the PTFE outer tube completely. Holding insertion portion, advance the opening of the forceps channel and try to straighten. Otherwise, it may damage the endoscopy and the instruments.
 - b. 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 damage the endoscopy and the instruments.

- a. Pull forceps ring, incorporated the brush into the PTFE outer tube.
- 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.
- d. Push the tip of the insertion slowly towards the target position.

2.3.2 Collect tissue

WARNING Do not force the distal end of the insertion portion against body cavity tissue, and do not advance or extend the instrument abruptly. If you cannot see the distal end of the insertion portion properly, do not extend the brush from the tube or move the brush. Doing so could cause patient injury such as punctures, hemorrhages or mucus membrane damage.

- a. Push the forceps ring slowly, extend the brush from the PTFE outer tube, make it contact with the target tissue.
- b. Brushing target tissue to collect tissue samples.
- c. Pull forceps ring, incorporated the brush into the PTFE outer tube.
- d. Pull the instrument until the the tip of the insertion is away from the target tissue.

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

CAUTION If you encounter resistance when drawing out instrument, do not forcibly insert. Please reduce the angle until it can be smoothly inserted. Otherwise, it may damage the endoscopy and the instruments.

Pull the instrument from the endoscopy.

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 °C to 60 °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



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 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