Heyinovo

Reusble Cleaning Brushes User Manual

Technical Publications

Document No: WI-RD-13-07-W-F, Rev. 01

CE

Revision History

REV	DATE	Complied by	Approved by
Rev. 00	Aug-28-2013	Ms. Xiaoping Qian	Mr. Xin,Huang
Rev. 01	Mar-24-2017	Mr. Tony Qiu	Mr. Xin,Huang

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Attention

This manual contains necessary and sufficient information to operate the system safely. Read and understand all instructions in this manual before attempting to use the Reusble Cleaning 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.

Chapter 0

Notice upon Use of Product

0.1 Product description and function

These products are to be used for cleaning the forceps channel of the flexible endoscopy and port holes. They are also suitable for cleaning laparoscopic and other rigid endoscopy working channel.

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 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 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.

0.4 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.

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

	Keep away from sunlight
	Keep dry
	Consult instructions for use
	Do not use if package is damaged
	Manufacturer
	Date of manufacture

EC REP	Authorized Representative of European community'
	Used by
LOT	Batch code

0.5 Operating environment

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

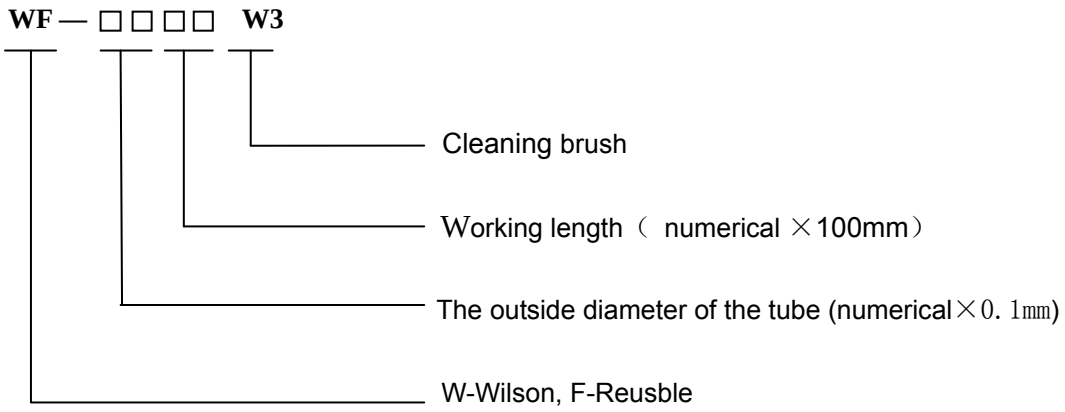
. 0.6 Attention

WARNING ★ Do not use the cleaning brush for cytologic tissue sampling or other diagnostic or therapeutic purposes. Patient injury, cross-contamination, or equipment damage may occur.

Chapter 1

Instrument Nomenclature and Specifications

1.1 Nomenclature



1.2 Specifications

Item No.	Brush Diameter & Working Length	Working Channel Diameter	Autoclavable
WF-1810W3	Ø5.0×1000 (mm)	Ø 2.0~2.8 mm	●
WF-1816W3	Ø5.0×1600 (mm)	Ø 2.0~2.8 mm	●
WF-2416W3	Ø6.0×1600 (mm)	Ø 2.8~3.2 mm	●
WF-2423W3	Ø6.0×2300 (mm)	Ø 2.8~3.2 mm	●

The above product specifications are only partial, just for reference.

★Other specification can be customized according to requirement

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

Chapter 2

Preparation, Inspection and Operation

WARNING ★ Do not use the cleaning brush for cytologic tissue sampling or other diagnostic or therapeutic purposes. Patient injury, cross-contamination, or equipment damage may occur.

To avoid facial contact with spraying detergent solution, keep your face away from the endoscope, when removing the brush from the channel-opening.

★ This instrument was not sterilized before shipment. Before using this instrument for the first time，reprocess it according to the instruction in Chapter 4. “Reprocessing”.

★ Do not use an instrument that has not been cleaned and sterilized. This poses an infection control risk or cause tissue irritation.

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

★ Do not move the brush 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 ★ 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.

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

★ Comprehensive inspection of the spare instrument.

Inspect the appearance

Use fingertips to touch the surface of the insertion portion, verify that no crushing, excessive bending, cracking or other damage.

2.3 Operation

WARNING ★ If you encounter resistance when inserting the equipment, do not forcibly insert. Please reduce

the angle until it can be smoothly inserted. Otherwise, it may damage the endoscopy and the instruments.

★ Do not pull the instrument from the endoscopy suddenly. It may damage the endoscopy and the instruments.

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

b. In order to facilitate cleaning endoscopic forceps channel, push and pull the cleaning brush, at the same time rotating it. When the operation added the digestive enzymes and other cleaning agents, cleaning effect will be more.

c. Pull the cleaning brush from the endoscopy.

Chapter 3 Reprocessing

WARNING ★ This instrument was not sterilized shipment. Before using this instrument for the first time. reprocess it according to the in this Chapter. Do not use an instrument that has not been Cleaned and sterilized. This poses an infection control risk or can cause tissue irritation.

★ This instrument are not allowed to be sterilized in EOW (Electrolyzed Oxidizing Water).

3.1 General Policy

The medical literature reports incidents of patient cross contamination resulting from improper cleaning or sterilization. It is strongly recommended that reprocessing personnel have a thorough understanding of and follow all national and local hospital guidelines and policies. A specific individual or individuals in the endoscopy unit should be responsible for reprocessing endoscopic equipment. It is highly desirable that a trained backup be available the primary reprocessing individual(s) be absent.

All individuals responsible for reprocessing should thoroughly understand:

- ▲ your institution's reprocessing procedures
- ▲ occupational health and safety regulations
- ▲ national and local hospital guidelines and policies
- ▲ the instructions in this manual
- ▲ the mechanical aspects of endoscopic equipment
- ▲ pertinent germicide labeling

Endoscopy Accessory are compatible with 2.0%to 3. 2% glutaraldehyde solution. However, routine biological monitoring is not feasible with glutaraldehyde and, therefore, it should not be used to sterilize reusable medical devices that are compatible with other methods of sterilization that can be biologically monitored, such as steam sterilization.

WARNING ★ Failure to properly clean and sterilize the instrument after each examination can compromise patient safety. During use, the instrument normally comes in contact with intact mucous membranes. To minimize the risk of transmitting diseases from one patient to another, after each examination the instrument must undergo thorough cleaning followed by sterilization.

★ If the instrument is not cleaned meticulously, effective sterilization cannot obtained. Clean the instrument thoroughly before sterilization to remove microorganisms or organic material which can limit the effectiveness of the sterilization process.

★ Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals and infectious material. During cleaning and sterilization, always wear appropriate personal protective equipment, such as 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. Always remove contaminated protective clothing before leaving the reprocessing area.

★ The reprocessing procedures described in this manual should be completed the same day the instrument has been used. If reprocessing is delayed，residual organic debris will solidify and be difficult to effectively reprocess the instrument.

3.2 Required Reprocessing Equipment

Wear the personal protective equipment as specified in the following table.

▲ Prepare the following equipment. The required amount of detergent solution，lubricant an other equipment depends on the number of instrument to be reprocessed.

▲ Fill an immersion basin with detergent solution and fill a second immersion basin with lubricant at the temperatures and concentrations recommended by the manufacturers. Also fill the ultrasonic cleaner with a detergent solution appropriate for ultrasonic cleaning.

3.2.1 Equipment Needed for Reprocessing

To perform proper reprocessing，the equipment in the following Table is required. For details on preparation and directions for use of the following equipment，refer to the respective instruction manuals or contact the equipment manufacturer.

Equipment Needed

Protective Equipment	Appropriate personal protective equipment may include：Eye wear，face mask moisture-resistant clothing and chemical-resistant gloves.
Immersion Basin for Detergent Solution	Use a basin with a depth and diameter large enough to allow complete immersion of the instrument when the Insertion Portion is coiled with a diameter of not less than 15cm.
Detergent Solution for Immersion	Use a neutral，low-foaming，medical grade detergent solution.
Ultrasonic Cleaner	Use a medical grade ultrasonic cleaner with a frequency range of 38 to 47 kHz. and with a depth and a diameter large enough to allow complete immersion of the instrument when the Insertion Portion is coiled with a diameter of not less than 15 cm.
Detergent Solution for Ultrasonic Cleaning	Use a neutral，low-foaming，medical grade detergent solution with no abrasive.
Lubricant	Use a medical grade water soluble or low-viscosity emulsion type lubricant.
Immersion Basin for Lubricant	Use a basin with a depth and diameter large enough to allow complete immersion of the instrument when the Insertion Portion is coiled with a diameter of not less than 15cm.
Lubricant	Use a medical grade water soluble or low-viscosity emulsion type lubricant. Using a high-viscosity will make it difficult to inject lubricant into the Injection Port.

Packages for Steam Sterilization	Use a packages compatible with sterilization(autoclaving). The packages should be large enough to accommodate the instrument when the Insertion Portion is coiled with a diameter of not less than 15cm.
Sealing Device for packages	Sealing the packages may require a device such as a heat sealer. Prepare an appropriate searing device according to the packages to be used.
Autoclave	Use an autoclave that will operate at the conditions specified in Section 3.7,"Sterilization".

3.3 Cleaning

WARNING ★ When cleaning，avoid exposure to the processing chemicals. It may pose an infection control risk or cause skin irritation.

CAUTION ★ When reprocessing. do not coil the Insertion Portion with a diameter less than 15cm. This could damage the Insertion Portion.

3.4 Immersion

WARNING ★ Immerse the instrument in detergent solution immediately after use. If the instrument is not cleaned immediately. It may be difficult to effectively reprocess，and this could result in reduced performance.

▲ Immerse the entire instrument in the detergent solution for the time specified in manufacturer's instructions. If no time is specified，immerse for between 5 minutes and 3 hours.

▲ Remove the instrument from the detergent solution.

3.5 Ultrasonic Cleaning

▲ Immerse the entire instrument in the ultrasonic cleaner containing detergent solution.

▲ Clean ultrasonically for 30 minutes. For details on operation of the ultrasonic cleaner refer to the instruction manual of the ultrasonic cleaner.

▲ Remove the instrument from the detergent solution.

3.6 Rinsing

CAUTION ★ After ultrasonic cleaning，rinse the instrument thoroughly to remove residual detergent. Residual detergent solution could cause tissue irritation in the next patient.

★ Do not forcefully squeeze，wipe or scrub the instrument. This could cause damage to the instrument or result in reduced performance.

▲ Rinse the instrument under clean running tap water.

▲ Confirm that no debris is left on the surfaces of the instrument.

▲ Wipe the exterior of the instrument with a clean, dry lint-free cloth.

3.7 Sterilization

Steam Sterilization(Autoclaving)

WARNING ★ use biological indicator as recommended by you r hospital's policy and follow the manufacturer's instructions. all national and local hospital guidelines and policies.

★ Always leave space between the packages in the autoclave. If the packages are placed too close together, effective sterilization will not be possible.

★ Allow the packages to dry within autoclave using the autoclave's drying cycle(if

applicable)or by opening the door of the autoclave and allowing packages to air dry. Handling a wet package can compromise its sterility.

▲ Place the sealed package containing the instrument in the autoclave and sterilize in accordance with the conditions listed below. For details on operation of the autoclave, refer to the instruction manual for the autoclave or other manufacturer instructions.

▲ After steam sterilization，let the instrument gradually cool down to room temperature. Sudden change in temperature may damage the instrument.

NOTE Autoclavable products have a green reference label. Products that do not have green reference labels are not autoclavable.

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

Chapter 4

Storage

WARNING ★ Store the instrument in the 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.

Storage conditions

Ambient Temperature: -40℃ to 70℃;
Relative Humidity: 10% to 95%;
Atmospheric Pressure: 700hPa-1060hPa (0.7 to 1.1kgf/cm^2) (10.2 to15.4 psia)

Chapter 5

Disposal of waste

WARNING ★ The equipment is disposable products. Do not reuse .

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

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 6

Service information

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

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