Heyinovo

Reusable Biopsy Forceps User Manual

Technical Publications

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CE

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. 00	Jun-10-2004	Mr. Yaodong, Wang	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 Reusable Biopsy Forceps.

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

These instruments have been designed to be used with an endoscope to collect tissue within the digestive tract, respiratory organs, female reproductive organs and urinary organs.

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 Reprocessing and Storage

This instrument was not sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions in Chapter 3,"Reprocessing".

After using this instrument, reprocess and store it according to the instructions in Chapter 3, "Reprocessing" and Chapter 4"Storage". Improper and / or Incomplete reprocessing or storage can present an infection control risk, cause equipment damage or reduce performance.

0.7 Repair and Modification

WARNING This instrument does not contain any user-serviceable parts.
Do not disassemble, modify or attempt to repair it; patient or user injury and / or equipment damage can result.

0.8 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

0.9 Operating environment

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

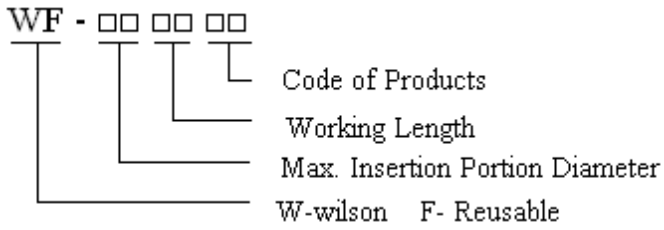
0.10 Attention

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

Item No.	Max. Insertion Portion Width & Working Length	Min. Insertion Channel Width
WF-1807BS	Ø 1.9× 700 (mm)	Ø 2.0 mm
WF-1810BS	Ø 1.9×1000 (mm)	Ø 2.0 mm
WF-1816BS	Ø 1.9×1600 (mm)	Ø 2.0 mm
WF-1825BS	Ø 1.9×2500 (mm)	Ø 2.0 mm
WF-2416BS	Ø 2.5×1600 (mm)	Ø 2.8 mm
WF-2423BS	Ø 2.5×2300 (mm)	Ø 2.8 mm

Item No.	Max. Insertion Portion Width & Working Length	Min. Insertion Channel Width
WF-1807BT	Ø 1.9× 700 (mm)	Ø 2.0 mm
WF-1810BT	Ø 1.9×1000 (mm)	Ø 2.0 mm
WF-1816BT	Ø 1.9×1600 (mm)	Ø 2.0 mm
WF-1825BT	Ø 1.9×2500 (mm)	Ø 2.0 mm
WF-2416BT	Ø 2.5×1600 (mm)	Ø 2.8 mm
WF-2423BT	Ø 2.5×2300 (mm)	Ø 2.8 mm

Item No.	Max. Insertion Portion Width & Working Length	Min. Insertion Channel Width
WF-2416BW	Ø 2.5×1600 (mm)	Ø 2.8 mm
WF-2423BW	Ø 2.5×2300 (mm)	Ø 2.8 mm

Item No.	Max. Insertion Portion Width & Working Length	Min. Insertion Channel Width
WF-1807BU	Ø 1.9× 700 (mm)	Ø 2.0 mm
WF-1810BU	Ø 1.9×1000 (mm)	Ø 2.0 mm
WF-1816BU	Ø 1.9×1600 (mm)	Ø 2.0 mm
WF-1825BU	Ø 1.9×2500 (mm)	Ø 2.0 mm
WF-2416BU	Ø 2.5×1600 (mm)	Ø 2.8 mm
WF-2423BU	Ø 2.5×2300 (mm)	Ø 2.8 mm

Item No.	Max. Insertion Portion Width & Working Length	Min. Insertion Channel Width
WF-1807BV	Ø 1.9× 700 (mm)	Ø 2.0 mm
WF-1810BV	Ø 1.9×1000 (mm)	Ø 2.0 mm
WF-1816BV	Ø 1.9×1600 (mm)	Ø 2.0 mm
WF-1825BV	Ø 1.9×2500 (mm)	Ø 2.0 mm
WF-2416BV	Ø 2.5×1600 (mm)	Ø 2.8 mm
WF-2423BV	Ø 2.5×2300 (mm)	Ø 2.8 mm

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

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

- Before every time use. prepare and inspect the instrument as instructed below. Inspect other equipment to be used with the instrument. Damage or irregularity may result in patient or user safety, such as infection control risk, tissue irritation，punctures，hemorrhage or mucous membrane damage and may result in more—severe equipment damage.
- 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.
- When using an instrument that has a Needle, be careful not to touch the Needle. Infectious Substances attached to the Needle such as the patient's blood or mucous，could pose an infection control risk and/or cause patient injury.
- Before use, confirm that the pins are fully seated at the forceps' distal end; it should not be sticking out. Do not use the forceps if the pins are sticking out, as it could fall out inside the patient，injure the mucous membrane, or damage the forceps and／or the endoscope's instrument channel. If the pins fall out inside the patient during use, stop the procedure immediately and retrieve the pins using another grasping forceps.
- Do not twist or bend the cups excessively. Doing so could dislodge the pins，causing it to be sticking out or fall out completely.
- Before use. Confirm that the distal tip of the forceps is not corroded，dented or discolored，and that the cups can be opened and closed smoothly. Using forceps that are damaged or not working properly may result in one or more of its components falling off inside the patient. If a component falls off of the distal end, or if operation of the cups suddenly becomes more difficult, immediately stop the procedure. Carefully withdraw the forceps together with the endoscope to avoid causing injury within the body cavity. Retrieve any parts that have fallen off inside the patient using another grasping forceps.

CAUTION

- Do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.
- Do not use excessive force to open or close the cups. This could damage the instrument.

2.1 Preparation

2.1.1 Equipment and personal protective Equipment

Prepare all equipment and personal protective equipment which will be used with the instrument in accordance with their respective instruction manuals. Appropriate personal protective equipment may include：Eye wear, a face mask, moisture-resistant clothing and chemical--resistant gloves.

2.1.2 Spare Biopsy Forceps

Have a spare biopsy forceps available at any moment.

2.2.3 Reprocessing Equipment

Prepare reprocessing equipment as described in Section 3.2. "Required Reprocessing Equipment" for immediate reprocessing after use.

2.2 Inspect

2.2.1 Inspect Appearance

If any of following steps reveals irregularities, do not use the instrument; use a spare instead.

- ◆ when operating the Slider to open and close the Cups, confirm that the instrument is without disconnection looseness.
- ◆ Confirm that the Cups close evenly and are properly aligned when the Slider is pulled.
- ◆ When using an instrument with a Needle. push the Slider to open the Cups and confirm that the Needle is not detached or bent conspicuously.
- ◆ Confirm that the Distal End of the instrument appears exactly as shown in the Tables in Section 1.2 "Specifications" and is not damage.
- ◆ Lightly move your fingertips over the entire length of the Insertion Portion to check for any crushed areas, excessive bends, etc.
- ◆ Confirm that there are no cracks on the Handle.

2.2.2 Operation Inspection

If the Cups do not operate smoothly and as intended, do not use the instrument; use a spare instead.

- ▲ Holding the instrument, form a loop in the Insertion Portion approximately 20cm in diameter.
- ▲ Move the Slider and confirm that the Cups open and close smoothly.

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.

★ 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 or in X ray images. 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.

★ Do not angulate the endoscope's bending Section(or operate the forceps Elevator if applicable) 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.

CAUTION ★ When using the instrument with a two channel endoscope, never use electrosurgical accessories at the same time. This could cause patient, operator or assistant injury, such as thermal injury.

2.3.1 Inserting Into the Endoscope

WARNING ★ Do not force the instrument if resistance to insertion is encountered.

Reduce the angulation (or lower the Forceps Elevator if applicable) until the instrument passes smoothly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and /or instrument.

★ When inserting the instrument into the endoscope, hold the Slider firmly. Otherwise, the Cups may open and extend from the endoscope tip abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.

2.3.2 Collecting Tissue

WARNING ★ 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.

▲ To collect the target tissue，angulate the Bending Section or advance the instrument until it reaches the target site.

▲ Push the Slider to open the Cups.

▲ Press the open Cups against the target tissue.

▲ Pull the Slider to collect the target tissue.

2.3.3 Withdrawing the Instrument from the Endoscope

WARNING ★ Do not withdraw the instrument from the endoscope quickly. This could scatter blood, mucous or other patient debris and pose an infection control risk.

CAUTION ★ Do not withdraw the instrument from the endoscope while the Cups are open. This could damage the endoscope and ／or instrument.

★ I f excessive resistance makes withdrawal difficult，adjust the angle of the endoscope until the instrument can be withdrawn smoothly. Forcible withdrawal could damage the instrument and ／or endoscope.

▲ If the endoscope is equipped with a Forceps Elevator lower the Forceps Elevator.

▲ Pull the Slider to close the Cups.

▲ Withdraw the instrument from the endoscope.

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.
- ★ Reprocess the instrument immediately after use by immersing it in a neutral，low—foaming, medical-grade detergent solution. then following the cleaning and sterilization procedures in this chapter. Failure to reprocess the instrument I immediately after use, or using another type of detergent may cause corrosion at the instrument's distal end. This could cause components to fall off during use and may interfere with operation of the cups.
- ★ 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.
- ★ 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

3.2.1 Wear the personal protective equipment

- ▲ 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.

3.2.2 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.

3.2.3 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 pH，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 pH，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 immersion Lubricant	Use a basin with a depth and diameter large enough to allow complete of the instrument when the Insertion Portion is coiled with a diameter of not less than 15cm.
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.

★ Never use excessive force to open or close the Cups. This could damage the instrument.

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.

▲ When reprocessing the instrument for the first time after purchase，remove the Forceps Cap from the Cups and dispose of it.

▲ 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 ★ 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.

★ 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.

4.1 Inspection Before Storage

Prior to storage，inspect the sterile package as follows:

- Confirm that the sterile package is free of tears and inadequate sealing. If tears or inadequate sealing are detected. remove the instrument from the package and sterilize again as described in Section 3.7. “Sterilization”.
- Confirm that the sterile package is free from water damage. If water damage is detected，repackage and sterilize again.

4.2 Storage

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.

4.3 Storage conditions

Ambient temperature: from -40 oC to 70 oC；

Humidity:10% to 95%；

Atmospheric pressure: 700hPa-1060hPa.

Chapter 5

Disposal of 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 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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