Heyinovo

Disposable Biopsy Forceps 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	OCT-15-2011	Mr. Yaodong, Wang	Mr. Xin,Huang
Rev. B	Aug-29-2013	Ms. xiaoping, Qian	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 Disposable 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 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

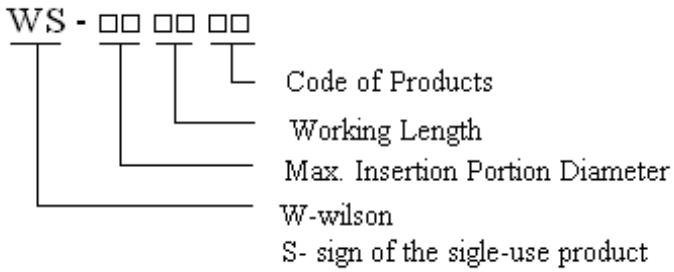
0.9 Attention

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

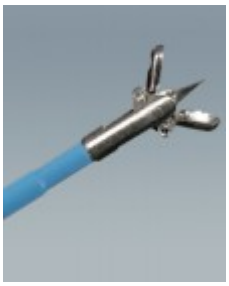


1.2 Specifications

	Oval Fenestrated Cups	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WS-1810BT WS-1815BT WS-2415BT WS-2422BT	Ø1.8 Ø1.8 Ø2.4 Ø2.4	Ø2，Ø2.2 Ø2，Ø2.2 Ø2.8, Ø3.2 Ø2.8, Ø3.2	1000 1500 1500 2200

	Oval Fenestrated Cups	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WS-2415BTH WS-2422BTH	Ø2.4 Ø2.4	Ø2.8, Ø3.2 Ø2.8, Ø3.2	1500 2200

	Oval Fenestrated Cups With Needle	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WS-2415BW WS-2422BW	Ø2.4 Ø2.4	Ø2.8, Ø3.2 Ø2.8, Ø3.2	1500 2200

	Oval Fenestrated Cups With Needle	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WS-2415BWH WS-2422BWH	Ø2.4 Ø2.4	Ø2.8, Ø3.2 Ø2.8, Ø3.2	1500 2200

	Alligator Jaws Type Biopsy Forceps	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WS-2415BU WS-2422BU	Ø2.4 Ø2.4	Ø2.8, Ø3.2 Ø2.8, Ø3.2	1500 2200

	Alligator Jaws Type Biopsy Forceps	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WS-2415BUH WS-2422BUH	Ø2.4 Ø2.4	Ø2.8, Ø3.2 Ø2.8, Ø3.2	1500 2200

	Alligator, Single Moving Cup Biopsy Forceps	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WS-2415BN WS-2422BN	Ø2.4 Ø2.4	Ø2.8, Ø3.2 Ø2.8, Ø3.2	1500 2200

	Alligator, Single Moving Cup Biopsy Forceps	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WS-2415BNH WS-2422BNH	Ø2.4 Ø2.4	Ø2.8, Ø3.2 Ø2.8, Ø3.2	1500 2200

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 ★ 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.

★ 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 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

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.

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

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