Heyinovo

Disposable Grasping 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	Apr-02-2007	Mr. Yaodong,Wang	Mr. Xin,Huang
Rev. B	Jun-05-2010	Mr. Yaodong,Wang	Mr. Xin,Huang
Rev. C	Sep-13-2013	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 Grasping 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

This instrument has been designed to be used with endoscopes to retrieve foreign bodies，calculus or tissue specimens from the digestive tract．Do not use this instrument 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

Follow the warnings given below when handing the instrument. This information is to be supplemented by the warnings and cautions described in each section.

WARNING

★ The product is special accessories of endoscopy, can not be used alone, shall not be altered without authorization or used for other purposes.

★ Before use, thoroughly review the method of use for this instrument in accordance with the instruction manuals. Using the instrument without learning such information could cause patient injury.

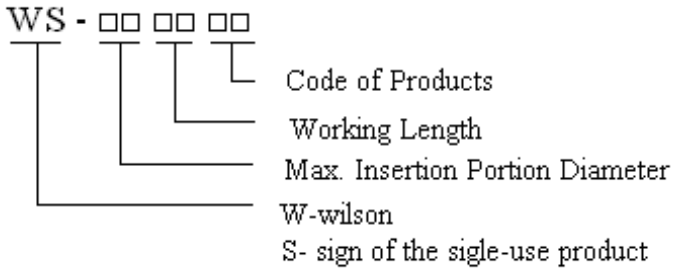
★ Do not use this instrument for a calculus that is assumed impossible to be retrieved by this instrument preoperative diagnosis，intraoperative contrast enhancing or after papillotomy／papillary dilation. Do not use this instrument when it is inevitable to grasp many calculus at a time. The basket with calculus engaged may not be removed from the body.

★ Use this instrument by having the settings to switch to open surgery and the hospitalization plan ready in case this instrument with calculus engaged may not be removed from the body.

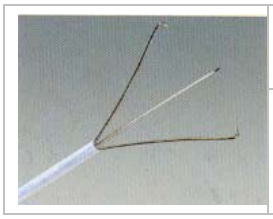
Chapter 1

Instrument Nomenclature and Specifications

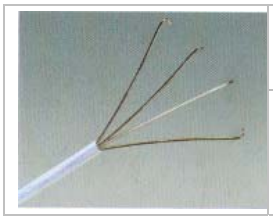
1.1 Nomenclature



1.2 Specifications

	Oval Fenestrated Cups	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WS-2418GM3G WS-2423GM3G	Ø2.4 Ø2.4	Ø2.8, Ø3.2 Ø2.8, Ø3.2	1800 2300

	Oval Fenestrated Cups	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WS-2418GM3Q WS-2423GM3Q	Ø2.4 Ø2.4	Ø2.8, Ø3.2 Ø2.8, Ø3.2	1800 2300

	Oval Fenestrated Cups	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WS-2418GM4G WS-2423GM4G	Ø2.4 Ø2.4	Ø2.8, Ø3.2 Ø2.8, Ø3.2	1800 2300

	Oval Fenestrated Cups	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WS-2418GM4Q WS-2423GM4Q	Ø2.4 Ø2.4	Ø2.8, Ø3.2 Ø2.8, Ø3.2	1800 2300

Medical Device Directive	CE	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.

★ This instrument was sterilized before shipment.

CAUTION ★ Do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.

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

2.1 Preparation

1) 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) Have a spare instrument available at any moment.

2.2 Inspection

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

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

- ◆ When operating the Grip to open and close the Retrieval Basket, confirm that there is no peeling or looseness at the connecting section.
- ◆ Open the Grasping Forceps. Make sure that there are no unraveled wires, disconnections, sharp protrusions, sharp edges or any other apparent abnormalities. Confirm that the distal end of the instrument appears exactly as shown in the Table in Section 1.2, “Specifications” and is not damaged.
- ◆ Lightly run your fingertips over the entire length of the Insertion Portion to check for any crushed areas, excessive bends, etc.

2.2.3 Inspect of the operation

WARNING ★ Check that no abnormality is detected in the action of the handle. If there is any abnormality, the calculus may not be retrieved and / or the basket with calculus engaged may not be removed from the body.

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

1) Holding the instrument form a loop in the Insertion Portion approximately 20 cm in diameter.
2) Operate the Grip and confirm that the Retrieval Basket opens and closes 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 pose a risk of 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 while the Distal End of the Insertion Portion is extended from the Distal End of the endoscope. This could result in punctures, hemorrhages or mucous membrane damage.

★ Do not force the distal end of the Insertion Portion against body cavity tissue. This could result in punctures, hemorrhages or mucous membrane damage.

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 until the instrument passes smoothly. Forcing the instrument could result in punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope and /or instrument.

★ DO not insert the instrument into the endoscope if the Grasping Forceps is not completely retracted into the Insertion Portion. The distal end of the Insertion Portion may extend from the endoscope tip abruptly. This could result in punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope or instrument.

★ When inserting the instrument into the endoscope, make sure to hold the Grid firmly. If the Grip is not held still, the Grasping Forceps may open and extend from the endoscope tip abruptly. This could result in punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope or instrument.

★ Do not advance or extend the instrument abruptly. This could result in punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope or instrument.

1) Pull the Grip until the Grasping Forceps is completely retracted into the Insertion Portion.
2) Carefully insert the instrument into the opening of the forceps channel.
3) Push the Grip until endoscopic vision appeared the insertion.

2.3.2 Grasping

WARNING ★ Do not push the Grip abruptly. The Basket may open abruptly. This could result in punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope or instrument.

1) To grasp foreign bodies, calculus or resected tissue operate the angulation of the endoscope

and/or advance the instrument the required distance.

2) Push the Grip to open the Retrieval Grasping Forceps.

3) Surround the foreign body，calculus or resected tissue with the opened Grasping Forceps.

4) Pull the Grip to grasp the foreign body，calculus or resected tissue.

2.3.3 Retrieval

WARNING ★ Do not withdraw this instrument abruptly from the bile duct. This could cause mucous membrane, damage or edema.

CAUTION ★ Do not retract retrieved foreign bodies calculus or resected tissue into the endoscope. This could damage to the endoscope or instrument.

NOTE ★ To retrieve small calculus from the Bile Duct，it may be useful to leave the Grasping Forceps open while withdrawing it.

1) If the endoscope is equipped with a Forceps Elevator，lower the Forceps Elevator. Also,keep the insertion portion of the endoscope straight.

2) Withdraw the grasped foreign body，calculus or resected tissue together with the endoscope from the patient，while observing the endoscopic image.

3) Push the Grip to open the Grasping Forceps.

4) Remove the retrieved foreign body，calculus or resected tissue from the Grasping Forceps.

2.3.4 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 Grasping Forceps is open. This could damage the endoscope or Instrument.

1) Pull the Grip to close the Grasping Forceps.

2) Withdraw the instrument from the endoscope.

Chapter 3

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.

3.1 Inspection Before Storage

Prior to storage，inspect the sterile package as follows:

1) Confirm that the sterile package is free of tears and inadequate sealing.

2) 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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