

Heyinovo

Reusable Grasping Forceps User Manual

Technical Publications

Document No: WI-RD-13-G07-F, Rev. C



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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	Sep-13-2013	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 Reusable 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 its 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 its 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°C (50 to 104°F)
Relative Humidity	30 to 85%
Air Pressure	700 to 1060hPa

0.10 Attention

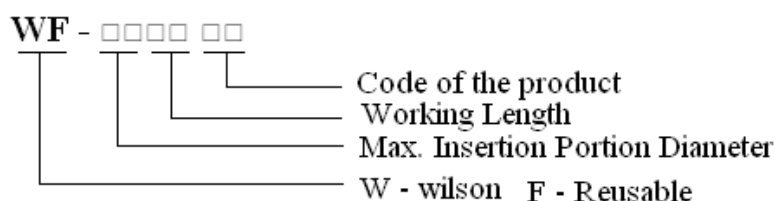
Follow the warnings given below when handling the instrument. This information is to be supplemented by the warnings and cautions described in each section.

- 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.
 - ★ When the basket may not be removed from the body. Refer to Section3.1, “General Policy”. and perform open surgery etc.


Chapter 1


Instrument Nomenclature and Specifications


1.1 Nomenclature





1.2 Specifications

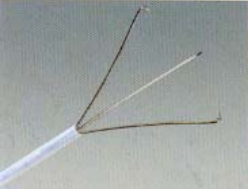
	Standard biopsy Forceps	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WF-1807GH	Ø1.8	Ø2, Ø2.2	700
	WF-1810GH	Ø1.8	Ø2, Ø2.2	1000
	WF-1815GH	Ø1.8	Ø2, Ø2.2	1500
	WF-1825GH	Ø1.8	Ø2, Ø2.2	2500
	WF-2415GH	Ø2.4	Ø2.8, Ø3.2	1500
	WF-2423GH	Ø2.4	Ø2.8, Ø3.2	2300


	Standard biopsy Forceps	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WF-1807GI	Ø1.8	Ø2, Ø2.2	700
	WF-1810GI	Ø1.8	Ø2, Ø2.2	1000
	WF-1815GI	Ø1.8	Ø2, Ø2.2	1500
	WF-1825GI	Ø1.8	Ø2, Ø2.2	2500
	WF-2415GI	Ø2.4	Ø2.8, Ø3.2	1500
	WF-2423GI	Ø2.4	Ø2.8, Ø3.2	2300

	Standard biopsy Forceps	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WF-1807GJ	Ø1.8	Ø2, Ø2.2	700
	WF-1810GJ	Ø1.8	Ø2, Ø2.2	1000
	WF-1815GJ	Ø1.8	Ø2, Ø2.2	1500
	WF-1825GJ	Ø1.8	Ø2, Ø2.2	2500
	WF-2415GJ	Ø2.4	Ø2.8, Ø3.2	1500
	WF-2423GJ	Ø2.4	Ø2.8, Ø3.2	2300


	Standard biopsy Forceps	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WF-1807GK	Ø1.8	Ø2, Ø2.2	700
	WF-1810GK	Ø1.8	Ø2, Ø2.2	1000
	WF-1815GK	Ø1.8	Ø2, Ø2.2	1500
	WF-1825GK	Ø1.8	Ø2, Ø2.2	2500
	WF-2415GK	Ø2.4	Ø2.8, Ø3.2	1500
	WF-2423GK	Ø2.4	Ø2.8, Ø3.2	2300

	Standard biopsy Forceps	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WF-1807GN	Ø1.8	Ø2, Ø2.2	700
	WF-1810GN	Ø1.8	Ø2, Ø2.2	1000
	WF-1815GN	Ø1.8	Ø2, Ø2.2	1500
	WF-1825GN	Ø1.8	Ø2, Ø2.2	2500
	WF-2415GN	Ø2.4	Ø2.8, Ø3.2	1500
	WF-2423GN	Ø2.4	Ø2.8, Ø3.2	2300

	Standard biopsy Forceps	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WF-1807GM3G	Ø1.8	Ø2, Ø2.2	700
WF-1810GM3G	Ø1.8	Ø2, Ø2.2	1000	
WF-1815GM3G	Ø1.8	Ø2, Ø2.2	1500	
WF-1825GM3G	Ø1.8	Ø2, Ø2.2	2500	
WF-2415GM3G	Ø2.4	Ø2.8, Ø3.2	1500	
WF-2423GM3G	Ø2.4	Ø2.8, Ø3.2	2300	

	Standard biopsy Forceps	Max.Insertion Portion Diameter(mm)	Working Channel Diameter (mm)	Working length (mm)
	WF-1807GM3Q	Ø1.8	Ø2, Ø2.2	700
WF-1810GM3Q	Ø1.8	Ø2, Ø2.2	1000	
WF-1815GM3Q	Ø1.8	Ø2, Ø2.2	1500	
WF-1825GM3Q	Ø1.8	Ø2, Ø2.2	2500	
WF-2415GM3Q	Ø2.4	Ø2.8, Ø3.2	1500	
WF-2423GM3Q	Ø2.4	Ø2.8, Ø3.2	2300	

★Other specification can be customized according to requirement

Medical Device Directive		This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class I
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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 3. “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. This could damage the Insertion Portion.
- ★ Never use excessive force to open or close the Grasping Forceps. 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 Grasping Forceps

Have a spare grasping 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 Grip to open and close the Grasping Forceps, 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" on page 7-8 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.
- ◆ Confirm that there are no cracks on the Handle.

2.2.2 Operation Inspection

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.

- a) Holding the instrument form a loop in the Insertion Portion approximately 20 cm in diameter.
- b) Operate the Grip and confirm that the Grasping Forceps opens and closes smoothly.

2.3 Operation

WARNING ★ When using the instrument. Always wear appropriate personal protective equipment. Otherwise, blood, mucous and other potentially infectious 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 electro-surgical 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.
 - ★ 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.

2.3.2 Grasping

- WARNING** ★ Do not push the Grip abruptly. The Grasping Forceps may open abruptly. This could result in punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope or instrument.
- ▲ To grasp foreign bodies, calculus or resected tissue operate the angulation of the endoscope and/or advance the instrument the required distance.
 - ▲ Push the Grip to open the Grasping Forceps.
 - ▲ Surround the foreign body, calculus or resected tissue with the opened Grasping Forceps.
 - ▲ 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 basket open while withdrawing it.

- ▲ If the endoscope is equipped with a Forceps Elevator, lower the Forceps Elevator. Also, keep the insertion portion of the endoscope straight.
- ▲ Withdraw the grasped foreign body, calculus or resected tissue together with the endoscope from the patient, while observing the endoscopic image.
- ▲ Push the Grip to open the Grasping Forceps

- ▲ 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.

- ▲ Pull the Grip to close the Grasping Forceps.
- ▲ 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 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 be 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 and 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 immersion 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 your 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.

Temperature	Exposure Time
Prevacuum	132 to 134°C (270 to 274°F) 5 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 -20 °C to 60 °C;

Humidity: 10% to 90%;

Atmospheric pressure: 500hPa-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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