HITACHI
Inspire the Next

Laparoscopic Probe

EUP-OL334

INSTRUCTION MANUAL

Notes for operators and responsible maintenance personnel

★ Please read through this Instruction Manual carefully prior to use.

★ Keep this Instruction Manual together with the system with care to make it available anytime.

Hitachi, Ltd.

Tokyo, Japan

Q1E-EP0304-8

CE 0123

Manufacturer:

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http://www.hitachi.com/businesses/healthcare/index.html

European
Representative:

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EU Importer: Hitachi Medical Systems Europe Holding AG
Address: Sumpfstrasse 13 CH-6300 Zug, Switzerland

Local Distributor:

About this manual

Before handling the Laparoscopic Ultrasound probe, read this instruction manual carefully.
This instruction manual is intended to provide the ultrasound system user with important information relating to the features, specifications, and proper care of the Laparoscopic Ultrasound probe.
This instruction manual presents warnings about possible probe damage that can occur as a result of improper handling and the potential hazards such probe damage presents to patients undergoing a laparoscopic ultrasound imaging procedure.
This instruction manual in no way presumes to provide instructions or recommendations in laparoscopic imaging techniques or protocol.

The following conventions are used throughout the manual to denote information of special emphasis.

WARNING: "Warning" is used to indicate the presence of a hazard which can cause severe personal injury, death, or substantial property damage if the warning is ignored.

CAUTION: "Caution" is used to indicate the presence of a hazard which will or can cause minor personal injury or property damage if the caution is ignored.

NOTICE: "Notice" is used to notify people of installation, operation, or maintenance information which is important, but not hazard related.

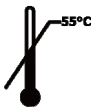
Graphical Symbols for Use in Labeling of Hitachi Ultrasound Probes

Some graphical symbols that are used in labeling of Hitachi Ultrasound Probes are compliant with EN980:2008 standard. Refer to the following table about the meanings of them.

Explanation of Symbol	Symbol	Descriptive Content
Manufacturer Company Name and Address		Hitachi,Ltd 2-16-1,Higashi-Ueno,Taito-ku, Tokyo,110-0015,Japan +81-3-6284-3668 http://www.hitachi.com/businesses/healthcare/index.html
Authorized Representative in The European Community		Hitachi Medical Systems GmbH Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany
Keep away from Sunlight		Store the probe in a cool place and keep away from high temperature, high humidity, or direct sunlight.

Definition of symbol

The following symbol is also used for HITACHI Ultrasound Probes.

Location	Symbol	Definition
Probe connector	CE 0123	This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS
Probe connector	IPX7	IPX7 mark See section 3.
Probe connector		Type BF APPLIED PART
Probe connector		General warning sign
Probe connector		Warning; dangerous voltage
Probe connector		Caution; Biohazard
Probe connector		Follow the instruction manual to operate this instrument. If not avoided, may result in injury, property damage, or the equipment trouble.
Probe connector		STERRAD sterilization compatibility mark
Probe connector		Upper Limit of Temperature; The probes that are applicable to Ethylene Oxide Gas Sterilization use symbol of “Upper Limit of Temperature: 55 degrees”.
Probe connector		Do not waste the instrument as general waste. Comply with a local regulation.
Probe connector	Rx Only	By prescription only. U.S. Federal Law restricts this device to sale on order of a physician only.

CONTENTS

1. Purpose, Features and Operating Conditions

1.1 Purpose

This probe has been designed to observe the gallbladder, liver and so on under the laparoscopic operation with it connected to the Hitachi Electronic Ultrasound Scanner.

1.2 Principles of operation

This probe and the ultrasound diagnostic scanner enable image diagnosis using ultrasonic waves.

This system operates under the principles described below.

1) When an electric pulse signal is applied from the transmitter to the transducer of the probe, the transducer converts electric signals into mechanical vibration energy for emitting pulse-shaped ultrasonic waves into the body part, liquid or other medium contacting the transducer.
2) The emitted ultrasonic waves are reflected by boundaries with different acoustic characteristics (acoustic impedance) within the body.
3) The transducer is also used to receive reflected ultrasonic waves. The transducer vibrates mechanically due to the received ultrasonic waves and converts mechanical vibrations into electric energy. Electric signals are converted to shades of brightness by brightness modulation to obtain an image.

1.3 Features

1) Frequency of 7.5MHz allows you to obtain a sharp image of shallow area.
2) Scanning system of 40R convex allows you to observe a wide field of view.
3) It is provided with the articulating mechanism with which the transducer tip may be articulated 90° in the up/down and right/left planes respectively. This mechanism allows you to make a diagnosis of suitable region.

1.4 Operating Conditions

Be sure to observe the following conditions when using this probe:

a) Ambient temperature : +5°C ~ +35°C

b) Relative humidity : 30 ~ 85%

c) Atmospheric pressure : 70 ~ 106hPa

2. Equipment Composition

1) Laparoscopic probe..... 1

2) Carrying case..... 1

3) Instruction Manual..... 1

3. Component Description

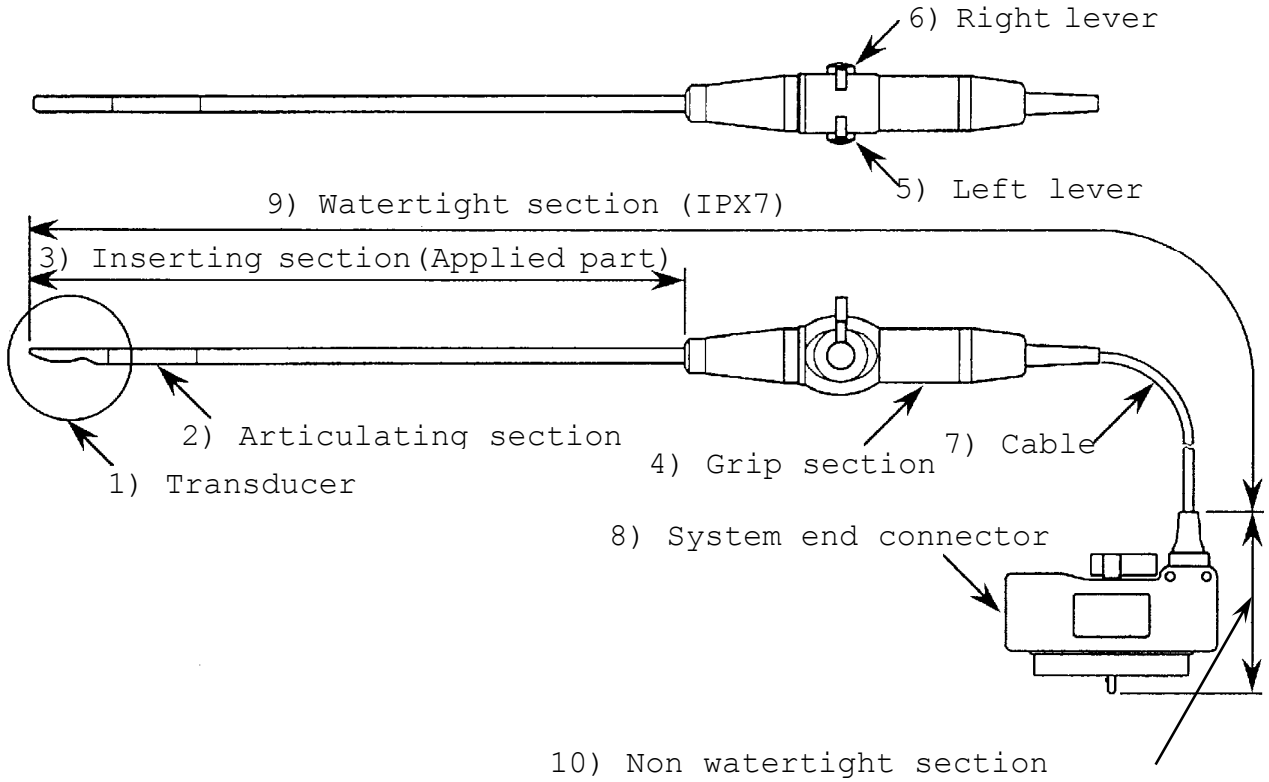


Fig.1 Component Description

1) Transducer : Transmits and receives ultrasound.
2) Articulating section : Section to articulate the transducer tip in the up/down plane or right/left plane with the right or left lever.
3) Inserting section : Section that can be inserted into the trocar.
4) Grip section : Section to grip the probe.
5) Left lever : Lever to control articulation in the up/down plane.
6) Right lever : Lever to control articulation in the right/left plane.
7) Cable : Cable to connect the grip and the system end connector.
8) System end connector : Section to connect this instrument with the ultrasound scanner unit.
9) Watertight action : Section that can be immersed in the sterilant solution and section cleaning solution.
10) Non watertight action : Section that should not be poured on section with water or the section sterilant solution, or should not be immersed in it. Otherwise it may be damaged. Never immerse it in water or the sterilant solution.

⚠ WARNING

Never use the probe which transducer and inserting section show any damage such as cracks or cuts, or which cable jacket is broken. If using as it is damaged, electric shock may result.

⚠ CAUTION

Connector section of the probe is not watertight. Never pour any liquid on it or immerse it in any liquid. If neglected, it may be damaged.

4. Articulating Controls

The control handle section of the probe features two control levers that are used to control the movement and position of the articulating section/transducer.

⚠ WARNING

Never bend or manipulate the articulating section of the probe with your hands or fingers. This can result in severe damage to the articulating mechanism.

The Laparoscopic Ultrasound probe is a precision equipment and care must be exercised to avoid damaging it. The Laparoscopic Ultrasound probe should only be handled by trained personnel.
The left lever controls articulating in the up/down plane. Forward=down; backward=up. The right lever controls articulation in the left/right plane. Forward=left; backward=right. Refer to Fig.2.

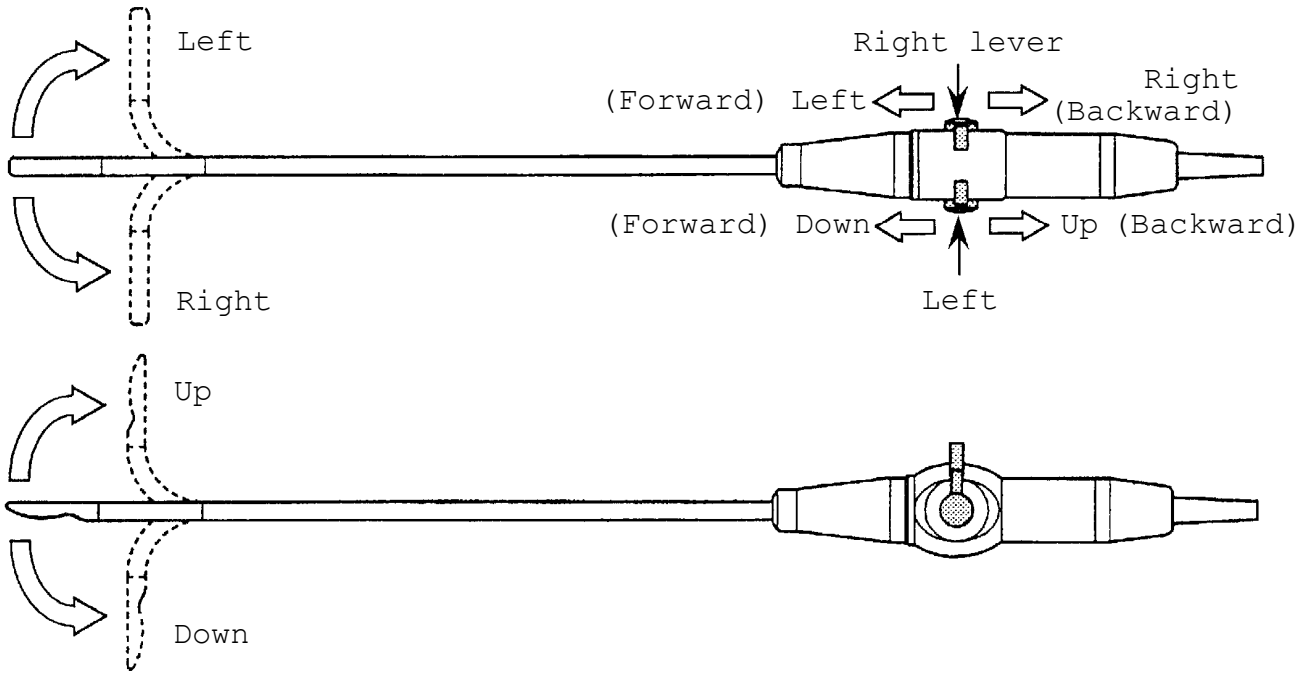


Fig.2 Articulating Controls

5. Pre-use Inspection

The Laparoscopic Ultrasound probe must be inspected prior to every exam.

- By running your fingers about the exterior surfaces of the transducer, articulating section, and rigid shaft, carefully inspect for any signs of mechanical damage such as cracks, cuts, tears, perforations, or protrusions. Any such damage could compromise the electrical safety of the probe or cause lacerations to the patient.
- Inspect the probe cable for damage, i.e. nicks, cuts, or tears in the cable jacket.
- Check the control levers for proper operation. The levers should move freely, without binding, and easily move the transducer through its full range of movement.

⚠ WARNING

If any damage is detected, do not use the probe. There are no user serviceable parts associated with this instrument. Return the probe to us or our authorized agent for service.

6. Cleaning, Disinfection and Sterilization

The probe must be reprocessed after each use. Refer to the reprocessing instruction in this chapter.

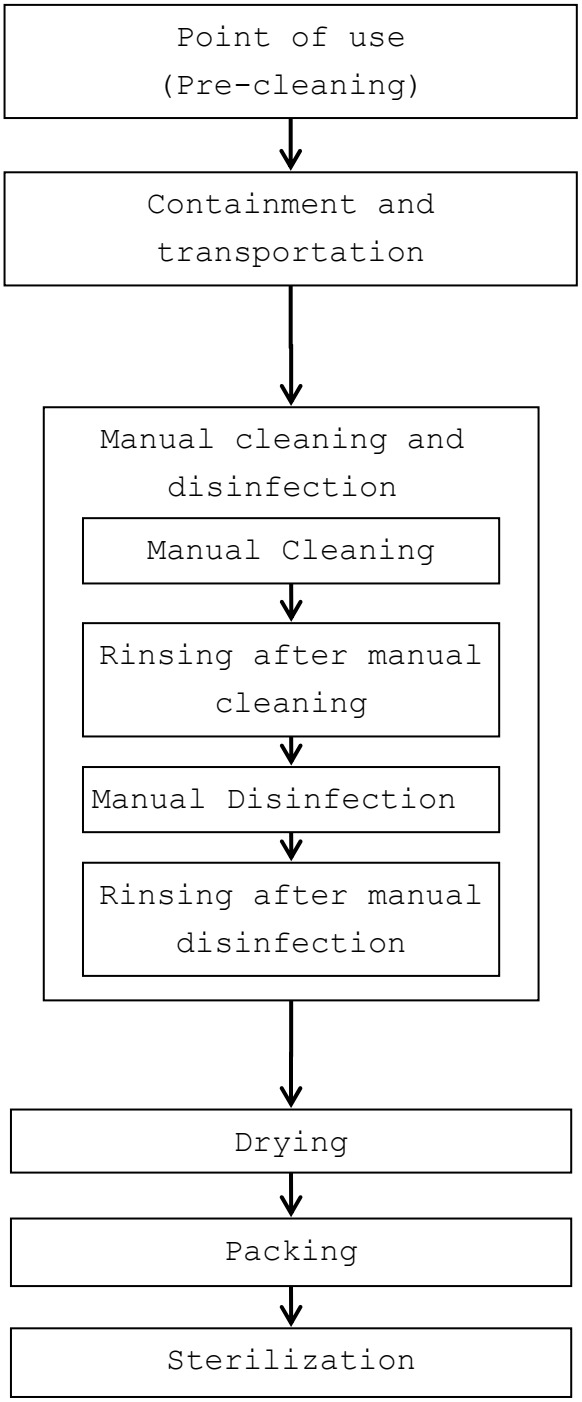
WARNINGS	- The probe is delivered unsterile. Prior to the first use, reprocess the probe. - Temperature should not exceed 60°C during reprocessing - Probe connector is not water resistant.
Limitations on reprocessing	The probe is not completely submersible. The immersible part is shown in Fig.1. The un-immersible part should be disinfected by wipe disinfection.
Transportation before using	The probe should be packed in a sterile pouch or container to transport from Central Sterile Supply Department (CSSD) to an operating room. Be careful not to damage the sterile pouch or container during transportation.

Levels of reprocessing requirements:
Depending on the application of the product and with regard to risk evaluation, the user has to classify the medical device according to the current Medical Device Directive for processing of medical devices as uncritical, semi-critical or critical. Supporting information concerning this topic is listed in the table below. The user is responsible for correct classification of the medical device.

Classification	Definition	Processing
uncritical	Application part only contacts intact and uninjured skin	Cleaning Disinfection
semicritical	Application part contacts mucosa (intracavitary application)	Cleaning Disinfection (Disinfectant with virucidal effect)
critical	Application part contacts intracorporeal tissue directly (operative application)	Cleaning Disinfection (Disinfectant with virucidal effect - minimum) Sterilization

According to the intended use, EUP-OL334 is classified as critical.

The flowchart of the reprocessing process of this probe is as follows.



6.1 Point of use (Pre-cleaning)

Point of use (Pre-cleaning)

Pre-cleaning should be done immediately after each use. The procedure is as follows:

1) Remove the protective cover.

2) Clean the probe of all patient's blood or fluid with running tap water until the surface of the probe looks visually clean.

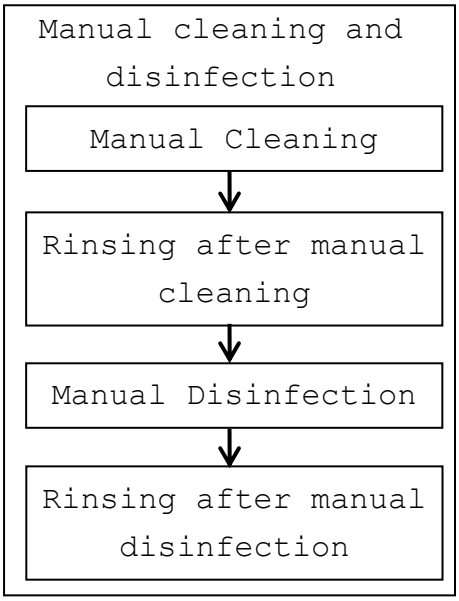
3) Wipe the whole surface of the probe with gauze pad and remove superficial visible impurities.

6.2 Containment and transportation

Containment and transportation

Putting the contaminated equipment into exclusive shock and damage proof container for transportation is recommended. It is recommended that instruments are reprocessed as soon as possible and not later than 4 hours after usage.

6.3 Manual Cleaning and disinfection



Prepare following items before manual cleaning and disinfection:

a) Detergent: Cidezyme (Johnson & Johnson, #2258)or another cleaning agent with approved material compatibility for this medical device.

b) Disinfectant: Cidex OPA (Johnson & Johnson, # 20391)or another disinfectant with approved material compatibility for this medical device.

c) Two tanks, one for cleaning and one for disinfection - optional:
1 additional tank for rinsing with deionized/tap water (sufficient size for immersion of the immersible part of the probe at full length)

d) Soft, fluff free cloth or single use towel

e) Personal protective equipment (gloves, water repellent protective

skirt, face protection mask or protective glasses, see also instructions of the manufacturer for the detergent and the disinfectant)

Manual Cleaning:

Prepare the detergent solution in a tank with cold water (please follow the instructions of the detergent manufacturer regarding application, dilution and contact time).

1) The temperature of the detergent solution should be between 15-30 °C, concentration is 1.6%. Please note the minimum contact time of the detergent in the manufacturer's instruction. If a differing detergent is used, please also note the approved material compatibility for the medical device.

2) Immerse the immersible part of the probe without connector into the diluted detergent solution (see Figure 3). Wipe the immersible part of the probe under the surface of the detergent solution with a soft cloth to remove all visible soil. Be sure that all grooves of the probe are implemented during the cleaning process.

3) The immersible part of the probe should be left in the detergent solution according to the specified contact time of the detergent manufacturer.

4) Wipe the un-immersible parts of the probe with a soft cloth dipped with the detergent solution.

5) Rinse the immersible part of the probe with running tap water for 1 minute. (alternatively: immerse the immersible part of the probe in a tray filled with deionized water/tap water (see Fig.3) for 5 min.)

6) Visually check the outer surface of the probe for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

Manual disinfection:

1) Prepare the disinfectant solution in a tank with cold water (please follow the instructions of the disinfectant manufacturer regarding application, concentration, microbiological efficiency, service life

and contact time).

2) Confirm the concentration of the disinfectant before immersing the probe. Although Cidex® OPA does not need to be diluted, it is recommended to use test strips to verify the concentration. The test strips can indicate whether or not the concentration is above the Minimum Effective Concentration (MEC). Please also note the expiration date of the test stripes. Temperature of disinfectant solution should be minimum 20 °C. The minimum contact time is 5 minutes. If a different disinfectant is used, follow the manufacturer's instructions. Please also consider the material compatibility for the medical device.

3) Immerse the immersible part of the probe into the disinfectant (see Fig. 3). Set a clock to insure the recommended contact time which is 5 minutes.

4) Rinse the immersible part of the probe with deionized water for 1 minute. (alternatively: immerse the immersible part of the probe in a tray filled with deionized water (see Fig.3) for 5 min.)

5) Visually check the outer surface of the probe for leavings of the disinfectant. If necessary, repeat the rinsing.

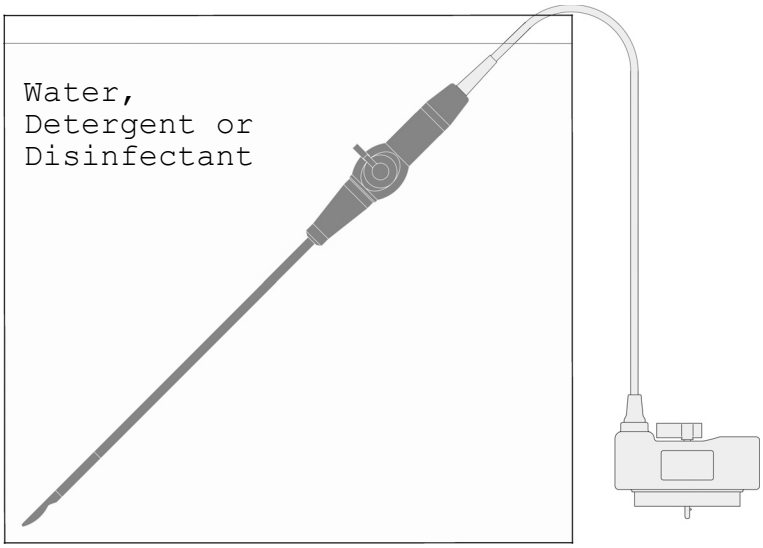


Fig.3 Immersion of the probe.

6.4 Drying

Drying

1) Wipe the equipment with a single-use, fluff-free wipe or towel to remove moisture from the surface of the equipment.

2) Dry the equipment naturally in an ambient temperature between 15-30°C for a minimum of 4 hours. Alternatively the equipment can be dried using a drying heater at a temperature of less than 60°C.

6.5 Inspection

Inspect the equipment for any damage such as crack, scratch or deformation. Do not use it if any damage is found.

6.6 Packaging

Packaging

Pack the equipment in a sterile barrier such as Polypropylene fleece or transparent package made from Polyethylene film and Tyvek®, and then place it into a tray. The tray should be also covered with a sterile barrier.

The equipment can be packed in a simple or double packing.
Please note that the size of a sterile barrier should be large enough to be able to pack the equipment leaving sufficient space to seal it completely.

A sterile barrier should be sealed by an appropriate sealing machine and it is important to confirm that the package is sealed completely. If the sealing is not complete, pack and reseal again.

6.7 Sterilization

Sterilization

The probe and accessory can be sterilized using either ethylen oxide gas (EtO) sterilization or plasma sterilization (see table below).

Follow the manufacturer's instructions of the sterilizer regarding usage, temperature and sterilization-time.

The sterilization method and operating conditions are as follows.

Sterilization Method	Condition
Plasma Sterilization: STERRAD® 100S or 200 (*)	Short Cycle
ETO Sterilization	➢ Gas Type: 10% EO/ 90% HCFC ➢ Temperature: 50-55°C ➢ Exposure Time: More than 120 minutes ➢ Pressurization: 162-200kPa Depressurization: 13-8kPa ➢ Relative humidity: 40-90% ➢ Aeration is minimum 12 hours

* STERRAD® systems are manufactured by "Johnson & Johnson"
* This probe cannot put into STERRAD® 50 system because the chamber is small for putting this probe.

⚠ WARNING

1) Before performing sterilization, check that the operation data of sterilizer are in conjunction with min. and max. data applicable for the probe.
2) Do not sterilize the probe by Steam Autoclaving. If you autoclave it, it suffers serious damage and will be not functional.

⚠ CAUTION

1) Plasma Sterilizer, STERRAD® NX™ is not applicable to this probe. Please use the systems other than STERRAD® NX™ series.
2) Never perform sterilization other than specified. The probe may be damaged.

The packaging before sterilization is as follows.

1) Put the probe into TYVEK pouch.

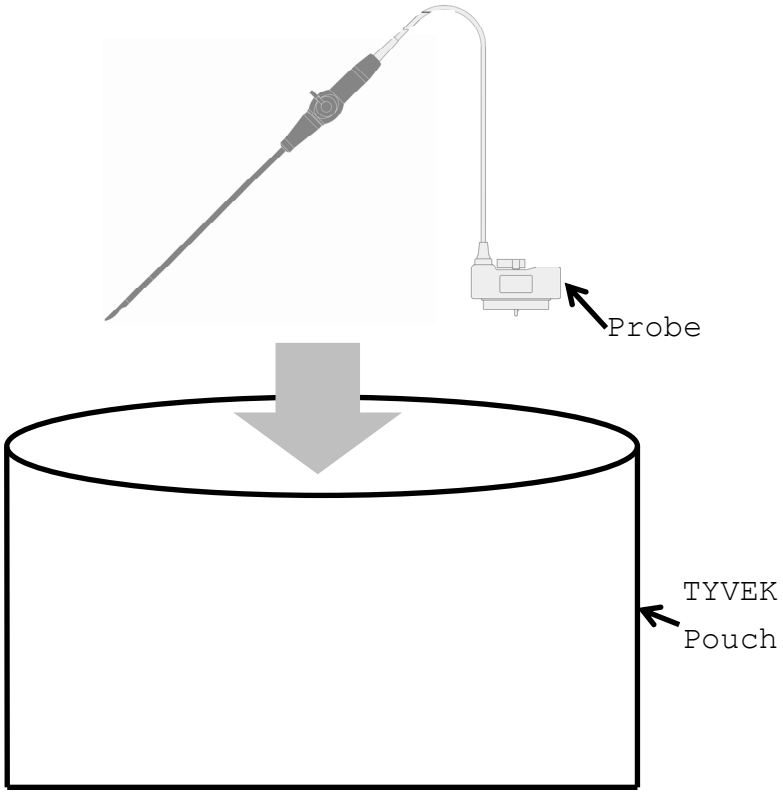


Fig.4 Packaging in the pouch

2) Seal the TYVEK Pouch using a heat sealer. Ensure that the seal is complete.

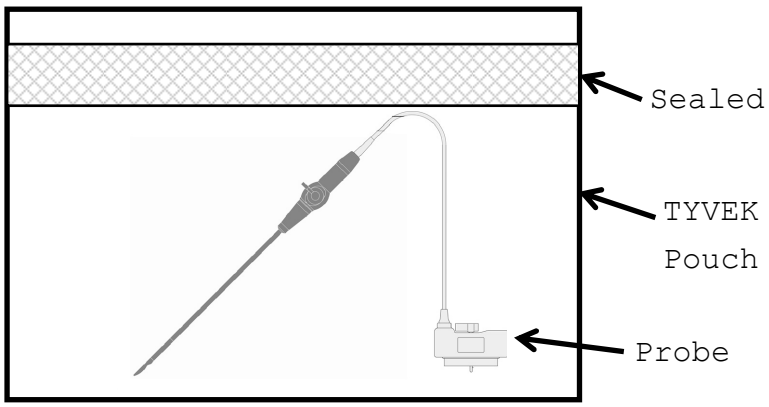


Fig.5 Sealing

3) Put the sealed pouch into a tray or plastic mesh wire for sterilization.

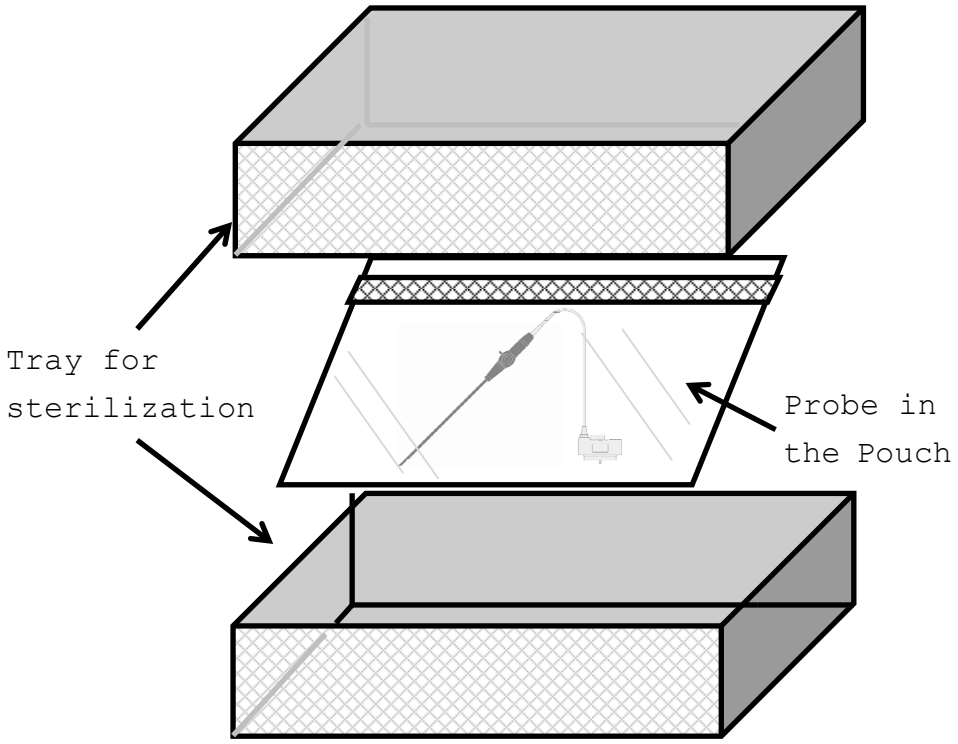


Fig.6 Packaging in a tray

6.8 Storage

Store the equipment in a cool, dustproof and dark, dry space to avoid high temperature, humidity and direct sunlight. Limitations for the time for sterilized equipment belong to package.

7. Operation

1) Inspection before use

   Follow "5. Pre-use Inspection".

2) Cleaning before use

   Follow "6. Cleaning, Disinfection and Sterilization" before use.

3) Sterilization

   Follow "6. Cleaning, Disinfection and Sterilization".

4) Imaging

   a) Connect the probe to the ultrasound scanner.
      For connecting the probe, refer to the instruction manual of the ultrasound scanner.

   b) Insert the probe into the 10mm, 10mm/11mm or 10mm/12mm trocar, and see Section 4 for controlling articulation to fit the probe to any diagnostic region.

   c) Operate the ultrasound scanner to depict an image.
      For depicting an image, adjustment, etc., refer to the

instruction manual of the ultrasound scanner.

5) Cleaning after use

Follow "6. Cleaning, Disinfection and Sterilization" after use.

6) Sterilization

Follow "6. Cleaning, Disinfection and Sterilization".

⚠ WARNING

Never use the probe which transducer and inserting section show any damage such as cracks or cuts, or which cable jacket is broken. If using as it is damaged, electric shock may result.

⚠ CAUTION

Use certainly a sterilized probe cover in order to prevent infection and minimize sticking of body fluid to the probe. We recommend "CIVCO 610-941"latex free laparoscopic probe cover. In case of using this probe cover,12mm trocar is recommended for use.

⚠ CAUTION

The probe is not sterilized when it is shipped. Be sure to sterilize it before use.

⚠ CAUTION

Connector section of the probe is not watertight. Never pour any liquid to it nor immerse it in any liquid. If neglected, the probe may be damaged.

〈 REMINDER 〉

The following should be observed before connecting/ disconnecting the probe. If doing so in the state other than the following, malfunction or fault of the equipment may result. Avoid such operation.

- Turn the power switch OFF.
- For any model having more than two probe connectors, select the other connector than that for the probe to be connected/disconnected using the probe selection key to make Freeze ON.

⚠ CAUTION

Great care must be exercised to handle the probe.
Never give shock, hit any hardware, nor drop it. Otherwise, fault may result.

⚠ CAUTION

Do not use 5mm/10mm, 5mm/11mm and 5mm/12mm trocars. Using these may damage the probe.

⚠ CAUTION

Ultrasound jelly supplemented to the ultrasound scanner unit is not sterilized. Never use it if the probe is to be used during operation.

8. Maintenance and Safety Inspection

Daily visually check the surface of the probe head, Articulating and insertion section housing, cable and connector for any crack, scratch or denaturalization. If you find damage, do not use the probe and immediately contact a service support.

9. Storage

For shipping or long-distance transport of the probe, it is strongly recommended that the carrying case provided with the probe be used. For shipping, the carrying case should be properly packed and placed in a suitable cardboard shipping container.

For normal storage in the clinical environment, do not use the carrying case, as this may cause contamination of the case lining material.

Do not store the Laparoscopic Ultrasound probe in a drawer, as this may cause the probe shaft, articulating section, transducer tip or probe cable to become ”pinched” or otherwise damaged.

For proper storage, a wall rack that securely holds the probe and protects it from impacts by other objects is recommended.

Do not store the Laparoscopic Ultrasound probe in areas subject to temperature extremes or direct sunlight.

10. When Fault is Suspected

When a fault is suspected, check the following points. When no abnormality is found even if checking the following points, have a contact with us or our authorized agent.

1) Any abnormality such as scratches, cuts, cracks, exfoliation is detected outside the probe including the cable and system end connector)?
2) The probe is securely connected with the ultrasound scanner?
3) Any abnormality is detected in operating the probe and ultrasound scanner?

⚠ CAUTION

Even when the equipment seems faulty, do not disassemble or repair the equipment unnecessarily. The one who repairs it assumes full responsibility for any fault caused by the repair. The manufacturer is not responsible for the result.

11. Specifications

Item	Laparoscopic Probe EUP-OL334
Frequency	7.5MHz
Scan system	40R convex
Scan angle	40°
Cable length	3,000mm
Diameter of inserting section	10.0mm
Articulation	Up/down plane : ±90° Left/right plane : ±90°
Trocar/cannula size	See CAUTION below.
Outside view	See Fig. 7.

⚠ CAUTION

The Laparoscopic Ultrasound probe is designed to fit standard 10mm, 10/11mm and 10/12mm cannulas. Do not use 5/10mm cannulas as these may cause damage to the articulating section of the probe.

12. Disposal of the probe

Recycle or dispose of equipment properly in compliance with your organizational rules and your local laws.

⚠ CAUTION

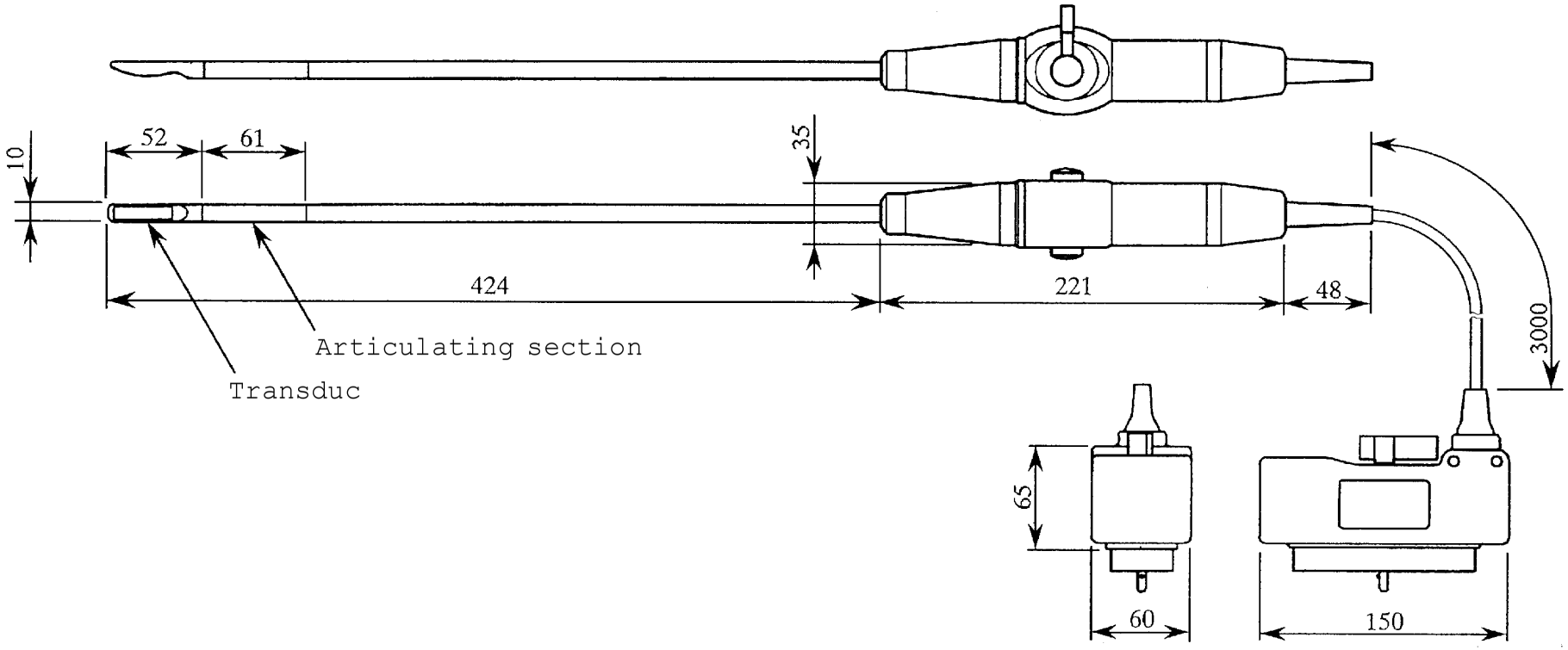
Before disposing of equipment, disinfect or take other infection-prevention measures.

Disposal of equipment without taking the proper preventative measures can lead to infection.

Waste Electrical and Electronic Equipment (WEEE) Directive

The illustration on the right is required by the EU WEEE Directive to appear on all electrical and electronic equipment.

For proper disposal of this product in an EU nation, contact an EU office or agency and observe appropriate local and national regulations and laws.



Unit : mm

Fig. 7 Outside Dimensions