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TRANSDUCERS AND CONSUMABLES

OPERATOR MANUAL

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Introduction

This manual provides information about the probes and consumables that can be used with the Esaote **MyLab** devices. The manual is divided into the following chapters:

- Chapter 1: Care of transducers
The chapter describes how to handle, control, store and protect ESAOTE transducers.
- Chapter 2: Cleaning and disinfecting the transducers
The chapter describes how to clean and disinfect non-invasive transducers and those used in semi-critical applications.
- Chapter 3: Examinations with transesophageal probes
The chapter lists the specific safety requirements for examinations with transesophageal probes. A description is also given on how to prepare the probe for the examination.
- Chapter 4: Examinations with the endocavity probe
The chapter lists the specific safety requirements for examinations with the endocavity probe. A description is also given on how to prepare the probe for the examination.
- Chapter 5: The Intraoperative probe
The chapter lists the specific safety requirements for examinations with the intraoperative probe. A description is also given on how to prepare the probe for the examination.
- Chapter 6: The Laparoscopic probe
The chapter lists the specific safety requirements for examinations with the laparoscopic probe. A description is also given on how to prepare the probe for the examination.
- Chapter 7: Needle guides kits
The chapter describes the procedures for assembling the kits.
- Chapter 8 Accessories and Consumables
The chapter describes how to check, clean and disinfect the ECG cable. The chapter also gives information about the characteristics of the consumables.
- Appendix A: **MyLab** Probes
The appendix details available models and their main characteristics.
- Appendix B: Cables, Consumables and Agents
The appendix details the ECG cables characteristics and recommended ECG disposable electrodes. The appendix lists the recommended cleaning, disinfection and sterilization agents.
- Appendix C: Probe Electrical Safety
The appendix explains how to check the electrical safety of the probes.

In this manual **WARNING** identifies a risk for the patient and/or the operator. The word **CAUTION** describes the precautions necessary for protecting the equipment. **Make sure you understand and follow these instructions.**

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1 - Care of Transducers

Damage caused by dropping or knocking a probe against other objects, stepping on or twisting a cable or a cable becoming entangled, are not covered by the guarantee.

Handling Transducers

Incorrect handling can seriously damage any transducer. Both the acoustic lens and the crystal elements can be damaged if the transducer is dropped or struck against another object. Cuts on the probe cable or breakage of the housing may jeopardize the electrical safety of the transducer.

There are several ways a probe can be damaged, for example:

- Dropping or knocking against another object
- Contact with sharp edged objects
- Contact with chemical agents
- Contact with hot surfaces
- Immersion in liquid substances
- Exposure to high voltage discharge
- Exposure to environmental conditions out of allowed range

WARNINGS

Do not use a probe if any of the above listed events occur until it has been established if any electrical damage to the probe has occurred by measuring the current leakage (see Appendix C for further details). Contact the Esaote Service Representative.

Do not tug the probe cable or bend it. If the probes are carried around on a trolley, make sure that the wheels do not roll over the cable.

Periodic Probe Control Schedule

The following tables describe the periodic control that must be made on the probes. The frequency suggested for non-invasive probes is considered to be the minimum; very frequent usage requires more frequent controls.

Operation to be performed	Frequency
Physical control of non-invasive probes	Every month or when the probe is dropped
Physical control of transesophageal, endocavity, intraoperative and laparoscopic probes	Before every examination
Physical control of the biopsy kit	Before every examination and if dropped

WARNING

Never use a probe, if it has been dropped, until you are sure that no electrical damage to the probe has occurred. This can be done by performing a leakage current test (see Appendix C for further details).

Transducer Controls

Non-invasive Transducers

Non-invasive transducers are intended to be used on the external parts of the body only.

A periodic control must be made on transducers to check that:

- The housing is intact. If cracks or breaks are found, have the probe repaired immediately by contacting an ESAOTE technician.
- The lens does not have any irregularities or is not broken. If any breaks are found on the scanning windows, do not use the probe again and have it repaired.
- The probe cable is not broken or damaged. If any damage is found, do not use the probe again and have it repaired.
- The connector pins are not bent. If the pins are damaged, do not use the probe and have it repaired.

WARNING

Breaks to the probe casing or to the cable could result in risks to electrical safety.

Do not use a probe if it has been dropped. A leakage current test (see Appendix C for further details) must be performed prior to re-use to ensure that no electrical damage to the probe has occurred.

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths **DO NOT** provide protection against such damage nor do they guarantee that the probe is insulated electrically. **DO NOT USE** the probe if it is known or suspected that it has been damaged; contact ESAOTE immediately.

CAUTION

Do not try to dismantle the probe; any attempt to dismantle the probe may damage it and will void the warranty.

In order to minimize the probability of damaging the probe, the following operations are suggested:

- ***Do not touch the lens*** at the end of the probe Never exert force on the lens
- The connector is not waterproof and should always be kept dry. The control unit, although waterproof, should not be unnecessarily immersed.

After use, clean and/or disinfect the probe as specified in this manual.

Invasive Transducers

Invasive transducers penetrate the patient's body through an orifice or through the surface of the body.

Control of the Transesophageal Probe

The transesophageal probe must be carefully inspected before every examination.

- Perform a manual and visual check to ensure that there are no holes, bulges, tears or dents along the entire surface of the probe.
- Perform a manual and visual check of the endoscope while bending the tip in all possible directions; deflection must function according to characteristics and the guides must not protrude during these movements.
- Check that the deflection mechanism functions in both modes (free or with friction).
- Check the cable manually and visually; there must be no cuts or irregularities.
- Check that the connector pins are not bent. If the pins are damaged, do not use the probe and have it repaired.

WARNING

Breaks in the probe casing or in the cable could expose the patient and/or the operator to an electrical safety risk.

Do not use a probe if it has been dropped. A leakage current test (see Appendix C for further details) must be performed prior to re-use to ensure that no electrical damage to the probe has occurred.

In case of incorrect operation of the flexion, do not use the probe and call Esaote Service Assistance.

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such

damage nor do they guarantee that the probe is insulated electrically. **DO NOT USE** the probe if it is known or suspected that it has been damaged; contact ESAOTE immediately.

CAUTION

Do not try to dismantle the probe; any attempt to dismantle the probe may damage it and will void the warranty.

In order to minimize the probability of damaging the probe, the following operations are suggested:

- **Do not touch the lens** at the front of the probe. Never exert force on the lens.
- The connector is not waterproof and should always be kept dry.
- Before inserting the probe, **do not rub or spray the tip** of the probe with an **anesthetic agent**.
- When not in use, store the probe as specified in the next paragraph.

After use, clean and disinfect the probe as specified in this manual.

Control of the Endocavity Probe

The endocavity probe must be checked before every examination.

- Perform both a visual and manual check to ensure that there are no holes, bulges, abrasions or dents.
- Perform a visual and manual check of the probe cable; cuts or holes in the cable may jeopardize electrical safety.
- The connector pins are not bent. If the pins are damaged, do not use the probe and have it repaired.

WARNING

Breaks in the probe casing or in the cable could expose the patient and/or operator to an electrical safety risk.

Do not use a probe if it has been dropped. A leakage current test (see Appendix C for further details) must be performed prior to re-use to ensure that no electrical damage to the probe has occurred.

Physical damage to the probe may cause electric shock or mechanical injury to the patient. Protective sheaths **DO NOT** provide protection against such damage nor do they guarantee that the probe is insulated electrically. **DO NOT USE** the probe if it is known or suspected that it has been damaged; contact ESAOTE immediately.

CAUTION

Do not attempt to dismantle the probe; any attempt to dismantle the probe may result in damage to the probe and will void the warranty and could compromise its safety.

In order to minimize the probability of damaging the probe, the following operations are suggested:

- ***Do not touch the lens*** at the front of the probe. Never exert force on the lens.
- The connector is not waterproof and should always be kept dry.

After use, clean and disinfect the probe as specified in this manual.

Control of the Intraoperative Probe

The Intraoperative probe must be carefully inspected before every examination.

- Perform a manual and visual check to ensure that there are no holes, bulges, tears or dents along the entire surface of the probe.
- Check the cable manually and visually; there must be no cuts or irregularities.
- The connector pins are not bent. If the pins are damaged, do not use the probe and have it repaired.
- When not in use, store the probe as specified in the next paragraph.

WARNING

Breaks in the probe casing or in the cable could expose the patient and/or the operator to an electrical safety risk.

Do not use a probe if it has been dropped. A leakage current test (see Appendix C for further details) must be performed prior to re-use to ensure that no electrical damage to the probe has occurred.

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if it is known or suspected that it has been damaged; contact ESAOTE immediately.

CAUTION

Do not try to dismantle the probe; any attempt to dismantle the probe may damage it and will void the warranty.

In order to minimize the probability of damaging the probe, the following operations are suggested:

- ***Do not touch the lens*** at the front of the probe. Never exert force on the lens.
- The connector is not waterproof and should always be kept dry.
- When not in use, store the probe in its case.

After use, clean and sterilize the probe as specified in this manual.

Control of the Laparoscopic Probe

The laparoscopic probe must be carefully inspected before every examination.

- Perform a manual and visual check to ensure that there are no holes, bulges, tears or dents along the entire surface of the probe.
- Perform a manual and visual check of the endoscope while bending the tip in all possible directions; deflection must function according to characteristics and the guides must not protrude during these movements.
- Check the cable manually and visually; there must be no cuts or irregularities.
- The connector pins are not bent. If the pins are damaged, do not use the probe and have it repaired.

WARNING

Breaks in the probe casing or in the cable could expose the patient and/or the operator to an electrical safety risk.

Do not use a probe if it has been dropped. A leakage current test (see Appendix C for further details) must be performed prior to re-use to ensure that no electrical damage to the probe has occurred.

In case of incorrect operation of the flexion, do not use the probe and call Esaote Service Assistance.

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if it is known or suspected that it has been damaged; contact ESAOTE immediately.

CAUTION

Do not try to dismantle the probe; any attempt to dismantle the probe may damage it and will annul the guarantee.

In order to minimize the probability of damaging the probe, the following operations are suggested:

- ***Do not touch the lens*** at the front of the probe. Never exert force on the lens.
- The connector is not waterproof and should always be kept dry.
- When not in use, store the probe in its case.

After use, clean and sterilize the probe as specified in this manual.

Storing and Protecting the Transducers

Daily Storage and Protection

Non-Invasive Transducers

When not in use, the transducer must be stored in the special probes slot on the machine. If all the available slots are full, place the probe in its case. All gel must always be cleaned off the probe (see the next chapter for the relative instructions).

CAUTION

Always keep the probe in its case. Otherwise it could be accidentally dropped or damaged.

Storing and Protecting the Transesophageal Probe

The probe must always be cleaned following the instructions provided in the next chapter. The probe must be kept in a clean environment and with the endoscope straight. In particular, we recommend using:

- Wall-mounted supports
- A storage drawer that is large enough to house the endoscope, bending it as little as possible

Storing and Protecting the Endocavity Probe

The probe must always be cleaned following the instructions provided in the next chapter. When not in use, the transducer must be stored in the special probes slot on the machine. If all the available slots are full, place the probe in its case.

CAUTION

Always keep the probe in its case. Otherwise it could be accidentally dropped or damaged.

Storing and Protecting the Intraoperative and Laparoscopic Probe

The probe must always be cleaned following the instructions provided in the next chapter. When not in use, place the probe in its case.

CAUTION

Always keep the probe in its case. Otherwise it could be accidentally dropped or damaged.

Transport or Long-Term Storage and Protection

All transducers are supplied with their own case that must always be used both when transporting the probe and for long-term storage. Clean the transducer carefully, following the procedures described in the following chapter before putting the probe away in its case.

For long-term storage, check that the environmental requirements indicated on the label of the case are observed.

CAUTION

Always use the original case to store the transesophageal probe. The special shape of this case prevents damage to the gastroscope due to excessive bending.

Dispatching the Transducer

Contact Esaote personnel to ensure that the transducer is correctly packed before dispatching it.

Needle Guide Kit Control

Always check that:

- The socket is not bent. Do not use the socket if it has been damaged.
- The needle guide is not bent. Do not use the guide if it has been damaged.

Storing and Protecting Needle Guide Kits

All biopsy kits are supplied with their own case. We recommend leaving any unused needle guides in the case. The kits must always be sterilized after use (see the next chapter for procedures). Please refer to the procedures used on-site for storing sterile parts.

2 - Cleaning and Disinfecting Transducers and Biopsy Kits

Periodic Cleaning and Disinfecting Schedule

The following table describes the periodic maintenance to be carried out on transducers and biopsy kits depending on their application. The risk of infection establishes the type of application.

Device	Application	Operation	Frequency
Non-invasive probes	Non-critical ^[1]	Cleaning	Before the first use and after each exam.
		Disinfection	When necessary
Transesophageal and Endocavity probes	Semi-critical ^[2]	Cleaning and Disinfection	Before the first use and after each exam.
Intraoperative and Laparoscopic probes	Critical ^[3]	Cleaning and Sterilization	Before the first use and after each exam.
Needle Guide kits	Critical ^[3]	Cleaning and Sterilization	Before the first use and after each exam.

[1] The application is considered non-critical when the device is used on intact skin.

[2] The application is considered semi-critical when the device is used on the mucous membranes.

[3] The application is considered critical when the device comes into contact with blood or compromised tissue.

If non-invasive probes are used in semi-critical/critical applications and in a sterile field, apply protective sheaths during the examination. These sheaths are usually composed of latex (natural rubber).

WARNING

Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

ESAOTE recommends disinfecting the probe, if the probe has not been used for an extended period.

Do not immerse the probe cable or connector in water or other liquid. Immersion may compromise the electrical safety features. The probe can be inserted in water up to the Maximum Immersion Level. (see Appendix A).

Note

Probes and needle guides supplied by ESAOTE are neither disinfected nor sterilized.

Agents

Refer to **Appendix B** for a list of recommended cleaning, disinfection and sterilization agents.

Note

Damage caused by the use of not recommended agents is not covered by the warranty.

WARNING

The disinfection/sterilization agents listed are recommended because of chemical compatibility with the probe materials, and not related to biological effectiveness. For information related to the biological effectiveness of a disinfectant, refer to the guidelines and recommendations of the disinfectant manufacturer.

Use of solutions other than those referenced is not recommended. They may damage the probe housing or acoustic lens.

Follow the instructions provided by the manufacturer of the agent for proper use.

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (i.e. gloves, protective glasses ...).

Never attempt to clean or disinfect the probes while they are connected to the unit.

Probes Tightness to Liquids

See Appendix A for description of probes Maximum Immersion Level.

Do not immerse the probe cable or connector in water or other liquid. The probes can be inserted in water up to the **Maximum Immersion Level** that will not compromise a probe's integrity:

WARNING

Connector immersion in water or other liquid can compromise the safety feature of the probe. Damage caused by the probe immersion is not covered under the warranty.

Cleaning Probes Used in Non-Critical Applications

The cleaning procedures described in this paragraph apply to all the probes used in non-critical applications. An application is considered non-critical when the device is used on intact skin.

Cleaning Procedure

Probes must be cleaned at regular intervals to ensure that they work properly. Esaote recommends removing the gel from the probe between one examination and the other; this keeps the probes clean between one complete cleaning procedure and the next.

- Disconnect the probe from the unit
- Remove all residues of ultrasound gel from the probe using a soft cloth.
- Clean the probe by rubbing it lightly with a soft cloth soaked in a solution of water and mild soap.
- Rub the probe with a soft damp cloth to remove any soap residue.
- Dry the probe by rubbing it with a soft dry cloth.

Disinfecting Probes Used in Non-Critical Applications

The disinfection procedures described in this paragraph apply to all probes used in non-critical applications. The application is considered non critical when the device is used on intact skin. Low-level disinfection is sufficient for these applications. The probes can be disinfected using the recommended agents, following the manufacturer's instructions.

Disinfection Procedure

- Disconnect the probe from the system.
- Clean the probe as described in the previous paragraph.
- Immerse the probe casing in the recommended agent, following the manufacturer's instructions very carefully.

WARNING

Do not immerse the entire body of the probe. The probe is not waterproof and immersion may compromise the electrical safety characteristics (see Appendix A for Maximum Immersion Level).

Do not soak the probe in the disinfection solution for periods beyond the time required to achieve a disinfection.

CAUTION

Do not try to sterilize probes using the autoclave, ultra-violet rays, gamma rays or gas, steam or heat sterilization techniques. These sterilization methods can permanently damage the probe. Any damage to the probe caused by substances or methods not approved by ESAOTE is not covered by the guarantee.

- Extract the probe, rinse it with sterile water and clean the probe handle and cable using the recommended agents or with a mild detergent solution.
- Dry the probe carefully using a soft cloth or leave it to air dry for at least 30 minutes.

Cleaning and Disinfecting Probes Used in Semi-Critical Applications

The procedures described in this paragraph apply to all probes used in semi-critical applications. The application is considered semi-critical when the device is used on the mucous membranes. The use of sterile sheaths for this type of application is recommended, and high-level disinfection is necessary. Wearing gloves is recommended during probe cleaning and disinfecting operations. The probe must be disinfected before it is used for the first time. The probe must be cleaned and disinfected after every examination.

Esaote recommends disinfecting the probe before it is used for the first time after prolonged storage periods

- Disconnect the probe from the system.
- Remove the protective sheath; clean the probe handle, the transducer and the endoscope with the recommended agent.

Note

Handle any examination waste (protective sheath, gloves...) as if potentially infected and treat it accordingly.

- If the probe is contaminated by body fluids, disinfect it before and after cleaning.
- Immerse the probe casing into the recommended agents, following the manufacturer's instructions very carefully.

WARNING

Do not leave the probe immersed in the disinfectant for longer than the time indicated by the manufacturer for high-level disinfection.

Do not immerse the entire body of the probe. The probe is not waterproof and immersion may compromise the electrical safety characteristics (see Appendix A for Maximum Immersion Level).

- Extract the probe, rinse it with sterile water and clean the probe handle and cable with a soft cloth dampened with a mild detergent solution.
- Dry the probe carefully using a soft cloth or leave it to air dry for at least 30 minutes.

CAUTION

Any damage to the probe caused by substances or methods not approved by ESAOTE, such as steam (autoclave), ethylene oxide or radiation, are not covered by the guarantee. These sterilization methods can permanently damage the probe.

For information on how to store disinfected parts, refer to the locally applicable procedures.

Cleaning and Sterilization of Intraoperative, Laparoscopic probes and Needle Guide Kits

Please refer to next chapters for more information on the accessories of the intraoperative probe.

The procedures described in this paragraph apply to the intraoperative probe and its accessories, to the laparoscopic probes and all the kits used in critical applications. The application is considered critical when the device comes into contact with blood or compromised tissue. Sterilization is stipulated for this type of procedure.

Wearing gloves is recommended during cleaning and sterilization operations.

WARNING

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (i.e. gloves, protective glasses ...).

The probe, eventual accessories and the kit must be sterilized before it is used for the first time. They must be cleaned and sterilized after every examination.

Esaote recommends sterilizing the probe and the kit before they are used for the first time after prolonged storage periods.

- Dismantle the kit or the accessories from the probe.
- Clean the kit, the accessories or the probe carefully with mild soap.
- Follow the instructions of the manufacturer of the sterilization agent.

Note

The material used for needle guide kits can undergo all the sterilization methods used for surgical instruments.

The type of tissue the transducer comes into contact with establishes the disinfection level.

For information on how to store sterilized parts, refer to the locally applicable procedures.

Cleaning and Sterilizing the Biopsy Attachment of CAB411A Probe

Wearing gloves is recommended during cleaning and sterilization operations.

Clean the attachment with a mild soap solution; make sure that no residuals are left.

Sterilization Procedure

Place the attachment in an appropriate bag and use Ethylene Oxide Gas, at following conditions:

- Temperature: below 55°C
- Gas pressurization: 1~2 kg/cm²
- Gas depressurization : 760 ~ 60 Torr
- Aeration : below 55°C

Note

Regard any exam waste (i.e., protective cover, etc.) as potentially infectious material and dispose of it accordingly.

3 - The Transesophageal Probes

The transesophageal probes (**TEE022**, **TEE122** and **TEE132**) are a Type BF part. The probe must be physically intact and the system correctly grounded for the electrical safety of the patient and operator.



Read the Safety and Standards Manual carefully: all the safety characteristics, cautions and warnings listed also apply to the use of this probe.

In particular, remember that:

WARNING

The system must be correctly grounded: it must be supplied from a socket equipped with a protective earth connection .

Mobile configurations are fitted with insulated supply sockets for supplying documentation systems without increasing the current leakage. Incorrect connections or failure to use insulated sockets may compromise electrical safety.

In case of doubts about the protective earth connection, DO NOT use the probe and contact ESAOTE immediately.

Characteristics and Components

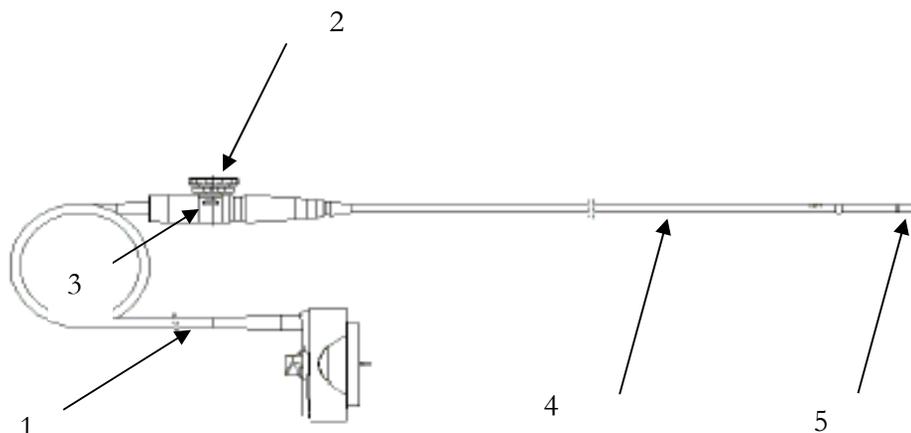
The **TEE022**, **TEE122** and **TEE132** transesophageal probes are designed for transesophageal imaging of the heart in adult and pediatric patients respectively. The transesophageal probe incorporates an array transducer which can be rotated 180° to easily obtain all imaging planes. The probe tip can also be deflected for optimal coupling.

These probes are equipped with a temperature sensor; **MyLab** models are designed to use these sensor thermal data to prevent probe tip overheating.

Components

- 1.** Probe cable and system connector
- 2.** Probe handle with the probe tip deflection control and the transducer rotational knob

3. Locking device
4. Probe shaft; this shaft has a length of 100 cm and is labelled in 10 cm increments
5. Probe tip with the ultrasound transducer



TEE probes are delivered with a carrying case.

Examination Safety

The user must know how to recognize contraindications to the examination and any possible complications, such as tip buckling.

The transesophageal examination is to be carried out by operators who have been specially trained to insert the probe and interpret the images. Carefully review current medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

Before the Examination

Before each examination :

- Perform a manual and visual inspection of the entire probe (see Chapter 2 of this manual). DO NOT use the probe if it has been damaged or if damage is suspected.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if you know or suspect that it has been damaged.

- Check that the probe deflection controls function correctly in all directions and that they have not jammed.
- Make sure that the probe tip is free to move; the probe handle provides a locking device which must be set to “loose” position.
- Use protective sheaths during the examination. These sheaths are mainly composed of latex (natural rubber).

WARNING

Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

If the protective cover is damaged during the transesophageal exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).

- Always use a bite-proof mouthpiece to protect the probe from the patient's teeth.

WARNING

Physical damage to the probe can cause electrical or mechanical injury to the patient.

CAUTION

Damage caused to the probe due to failure to use a protective mouthpiece is not covered by the guarantee.



Be familiar with the mechanical and thermal indices display and the **ALARA** principle (As Low As Reasonably Achievable) before using the probe. The patient must be exposed to ultrasound for as short a time as possible and only for as long as it takes to achieve the diagnostic information.

During the Examination**WARNING**

Before probe use, check to be sure that the probe name shown on the monitor is correct.

Esaote recommends the Operator to:

- Never force the probe during manipulation and extraction; if there is any resistance in introducing the probe, interrupt the examination. Make sure that the tip is straight and released before inserting or removing the probe.

WARNING

Insertion, manipulation or forced removal can seriously damage the patient's esophagus.

- Do not leave the probe against the esophagus wall for prolonged periods.
- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.
- If it is necessary to use the defibrillator, disconnect and remove the probe from the patient.

Electric scalpels used during the TEE examination interfere with the 2D and make it impossible to use Doppler procedures.

Electric scalpels and other devices that introduce radio frequency or electromagnetic current fields into the patient interfere with ultrasound images.

High frequency signals used by ultrasound can interfere with the functioning of pacemakers.

WARNING

Even if the possibility of interference is remote, interrupt the examination immediately if interference with a pacemaker is noticed.

While using the system in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to the transducer lens can cause electro-surgical currents that can burn the patient. Thoroughly check the system and the probe before applying HF surgical currents to the patient. Disconnect the probe when not imaging.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Esaote recommends the Operator to:

- Clean and disinfect the probe, according to the instructions provided in Chapter 2 of this manual.
- Store the probe as indicated in Chapter 1 of this manual.

Temperature Control

Transesophageal probes are equipped with a temperature sensor, to provide continuous feed-back on the temperature of the probe tip; the ultrasound scanner constantly samples and displays the probe temperature.

Once the probe is connected, the temperature is displayed on the screen.

To ensure patient safety, the ultrasound scanner “allows” a maximum temperature of **42.5°C (108.5°F)**; if the probe reaches this limit, the system automatically de-activates and displays a warning message.

As soon as the temperature goes down below the thermal limit, the message disappears and the probe starts working again. The Operator should either wait for the probe to cool down or interrupt the procedure and remove the probe from the patient.

In normal conditions, the probe does not reach the thermal limit; the limit may be reached in patients with fever or due to breakage of the thermal sensor. A list of recommendations follows to prevent the probe from over-heating:

- Set the B-Mode angle at maximum



*The Advanced
Operation manual
indicates specific
information
applicable to your
MyLab model.*

**How to Minimize
Probe Heating**

- The CFM mode is the greatest heat “generator”; limit the use of the CFM as much as possible in patients with a high body temperature.
- Trans-gastric projections reduce heat dissipation; repositioning the probe in the esophagus may make the probe cool down quickly.

Preparation of the Transesophageal Probe

Follow the instructions below to prepare the transesophageal probe.

Note

The Operator is recommended to wear gloves during the probe preparation procedure.

See Chapter on Consumables for selecting these accessory kits

The use of latex transducer covers is strongly recommended, along with a bite guard to protect the probe shaft. These items are available as accessory kits, which also contain items that facilitate placement of the probe cover on the transducer.

- Place the tip of the probe in a straight position and release it.
- Apply a sufficient quantity of ultrasound gel inside the sheath.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.
- Secure the sheath with the rubber band provided.

Transducer Orientation

The probe handle wheels can be used to rotate the transducer inside the tip or to change the tip position.

The rotation of the transducer is controlled by the smallest knob and is adjustable from 0° to 180°. In the zero position, the transducer will scan the transversal plane. The zero, 90° and 180° positions are marked on the knob.

The MyLab system screen displays the transducer’s current orientation.

Transducer Rotation



Tip Position

The probe tip can be oriented to optimize tissue contact. The articulation of the flexible part of the probe is controlled by the largest knob; up- and back-wards adjustments are feasible:

- 120° upwards (clockwise rotation of the knob)
- 90° backwards (counter- clockwise rotation of the knob)

The zero position is marked on the knob. This knob can be locked into position by engaging the locking device, located next to the knob. This locking device has two color coded positions: on red, the tip is locked, on grey the tip is loose.

During probe insertion, make sure that the tip is unlocked (grey locking device)



4 - The Endocavity Probes

The endocavity (**EC123**, **EC1123**, **E8-5 R10P** and **BE1123**) and transrectal (**TRT33**) probes are Type BF parts. As per directive EN60601-1, the probe must be physically intact and the system correctly grounded for the electrical safety of the patient and operator.



Read the Safety and Standards Manual carefully: all the safety characteristics, cautions and warnings listed also apply to the use of this probe.

In particular, remember that:

WARNINGS

The system must be correctly grounded: it must be supplied from a socket equipped with a protective earth connection.

Mobile configurations are fitted with insulated supply sockets for supplying documentation systems without increasing the leakage current. Incorrect connections or failure to use insulated sockets may compromise electrical safety.

In case of doubts about the protective earth connection, DO NOT use the probe and contact ESAOTE immediately.

Characteristics and Components

The **EC123**, **EC1123**, **E8-5 R10P** and **BE1123** probes incorporate a high frequency convex transducer for sagittal (transverse) endorectal or endovaginal scanning.

The **TRT33** incorporates both a convex transducer and a linear transducer for longitudinal and transversal scanning.

The **EC123** and **TRT33** probes are delivered with the following accessories:

- Storage case
- Tubing kit (60 cc syringe with IV extension tubing and stopcock)

Examination Safety

Endocavity probes must be used by operators who have been specially trained to insert the probe and interpret the images. Carefully review current medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

Before the Examination

Before each examination Esaote recommends the Operator to:

- Perform a manual and visual inspection of the entire probe before using it (see Chapter 2 of this manual). DO NOT use the probe if it has been damaged or if you suspect damage.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against these damages nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if you know or suspect that it has been damaged.

- Use protective sheaths during the examination. These sheaths are mainly composed of latex (natural rubber).

Note

The use of sterile covers is mandatory for all endocavity scans.

WARNING

Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

If the protective cover is damaged during the transesophageal exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).



The Operator should be familiar with the mechanical and thermal indices display and the **ALARA** principle (As Low As Reasonably Achievable) before using the probe. The patient must be exposed to ultrasound for as short a time as possible and only for as long as it takes to achieve the diagnostic information.

During the Examination

Before probe use, check to be sure that the probe name shown on the monitor is correct

WARNING

During the examination Esaote recommended the Operator to:

- Never force the probe during insertion or removal.

WARNING

Electric scalpels used during the examination may interfere with the 2D and make it impossible to use Doppler procedures.

Forced insertion or removal may wound the patient.

- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.

Electric scalpels, and other devices that introduce radio frequency or electromagnetic current fields into the patient, interfere with ultrasound images.

While using the system in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to the transducer lens can cause electro-surgical currents that can burn the patient. Thoroughly check the system and the probe before applying HF surgical currents to the patient. Disconnect the probe when not imaging.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Esaote recommends the Operator to:

- Clean and disinfect the probe, according to the instructions provided in Chapter 2 of this manual.
- Store the probe as indicated in Chapter 1 of this manual.

Preparation of the Endocavity Probes

Follow the instructions below for preparing the endocavity probe.

Note

The Operator is recommended to wear gloves during the probe preparation procedure

- Apply a sufficient quantity of ultrasound gel inside the sheath.

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.
- Secure the sheath with the rubber band provided.

See Chapter on consumables for selecting the gel and sheathes.

WARNING

- To make it easier to insert the endocavity probe, apply some water-based lubricating gel on the tip of the transducer.

Water Stand-Off for EC123, EC1123 and TRT33 Probes

Both **EC123**, **EC1123** and **TRT33** endocavity probes have two communicating holes, one at the tip and one at the base, that make it possible to use water stand-off to optimize probe adherence in transrectal examinations. The probes are equipped with a 60 cc syringe with tubes that allow water to be injected.

- Cover the part of the probe that can be immersed with the stand-off cap and attach it with the rubber band provided at about 5 cm. from the tip; make sure the water intake hole is below the band.
- Fill a 60 cc syringe with sterile water.
- Apply the tap valve to the syringe.
- Connect a section of the IV tube to one end of the tap; the other end of the IV tube must be inserted into the probe-filling hole.
- Open the tap; inject about 30 cc of water into the probe.
- To eliminate air bubbles, turn the probe upwards holding it by the handle; the bubbles will rise towards the water intake hole.
- Suck air back into the syringe; close the tap to remove the syringe and expel the air.
- Repeat this procedure until all the air bubbles have been eliminated.
- Replace water, without air, back into the syringe and close the valve; leave the tube and the syringe connected.
- Apply ultrasound examination gel to the tip of the stand-off.
- Cover the portion of the probe that is to be inserted with the protection cap.

Eliminate the air bubbles between the transducer and the sheath; air bubbles impede the transmission of ultrasound.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

- To make insertion easier, apply some lubricating gel to the tip of the probe.

Once the probe is in the correct position, fill the stand-off with water again. To optimize image quality, use enough water to ensure that the probe adheres as well as possible to the rectal wall.

Do not remove the probe from the rectum if the probe tip is still full of water.

5 - The Intraoperative Probe

The intraoperative probe (**IOE323**) is a Type BF part. The probe must be physically intact and the system properly grounded for the electrical safety of the patient and operator.



Carefully read the Safety and Standards Manual: all safety characteristics, cautions and warnings listed also apply to the use of this probe.

In particular, remember that:

WARNING

The system must be properly grounded: it must be supplied from a socket equipped with a protective ground connection.

Mobile configurations are equipped with insulated sockets to supply power without increasing the leakage current. Incorrect connections or failure to use insulated sockets may compromise the electrical safety.

If in doubt about the protective ground connection, **DO NOT** use the probe and contact ESAOTE immediately.

Characteristics and Components

The **IOE323** probe incorporates a high frequency linear transducer for intraoperative scanning.

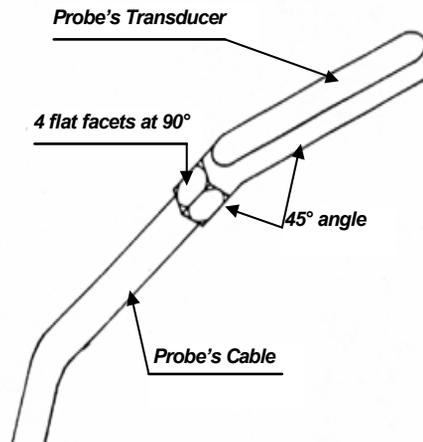
The probe is delivered with the following accessories:

- Storage case
- Handle attachment
- Finger attachment
- Sled attachment
- Biopsy attachment.

The IOE323 probe is designed to form an angle of 45° between the head, which houses the transducer and the terminal portion where the cable is connected.

The terminal portion of the probe has a square shape to accommodate accessories available for use with the probe, offering maximum comfort during surgical ultrasonography.

The probe accessories are shaped in a manner to prevent rotation and to improve patient safety.



Examination Safety

The intraoperative examination is to be carried out by operators who have been specially trained to use the probe and interpret the images. Carefully review current medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

WARNING

Do not use the intraoperative probe in direct contact with the heart, the central circulatory system and the central nervous system.

Before the Examination

Before each examination :

- Perform a manual and visual inspection of the entire probe prior to use (see Chapter 2 of this manual). DO NOT use the probe if it has been damaged or if damage is suspected.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against these damages nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if damage is known or suspected.

- Use protective sheaths during the examination. These sheaths are usually composed of latex (natural rubber).

Note

See Chapter 8 on consumables for choosing gel and sheaths.

During the probe preparation procedure the operator is recommended to wear gloves

- Apply enough ultrasound gel inside the sheath.

WARNING

The probe sheaths may contain natural rubber latex which may cause allergic reactions. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

Note

Esaote recommends the use of sterile sheaths in intraoperative examinations.

- Completely unroll the sheath along the transducer body, fitting it tightly so to avoid air pockets.
- Secure the sheath with the rubber band.

WARNING

If the protective cover is damaged during the transesophageal exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).

Note

Esaote recommends use of sterile sheaths in intraoperative examinations.



The operator must be familiar with the mechanical and thermal indices display and the **ALARA** principle (As Low As Reasonably Achievable) before using the probe. The patient must be exposed to ultrasound for as short a time as possible and only for as long as necessary to achieve the diagnostic information.

During the Examination

WARNING

Before probe use, check to be sure that the probe name shown on the monitor is correct.

During the examination, Esaote recommends that the Operator:

- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.

Electric scalpels used during the IOE examination interfere with the 2D and make it impossible to use Doppler procedures.

Electric scalpels and other devices that introduce radio frequency or electromagnetic current fields into the patient interfere with ultrasound images.

While using the system in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to the transducer lens can cause electro-surgical currents that can burn the patient. Thoroughly check the system and the probe before applying HF surgical currents to the patient. Disconnect the probe when not imaging.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Esaote recommends that the Operator:

- Clean and sterilize the probe, according to the instructions provided in Chapter 2 of this manual.
- Store the probe as indicated in Chapter 1 of this manual.

Using the IOE323 Intraoperative Probe

Follow the instructions given above to prepare the intraoperative probe.

Note

The operator is recommended to wear gloves during the probe preparation procedure

- Apply enough ultrasound gel inside the sheath.

See Chapter 8 on consumables for selecting the gel and sheaths.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

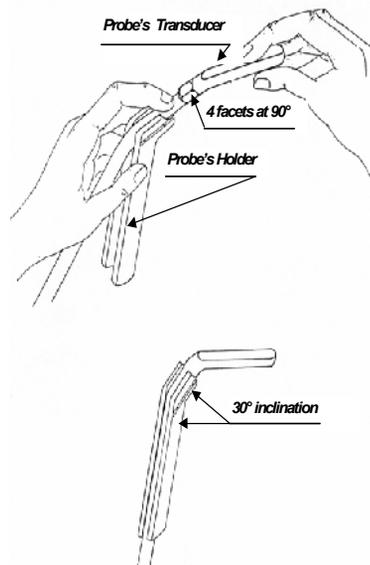
Note

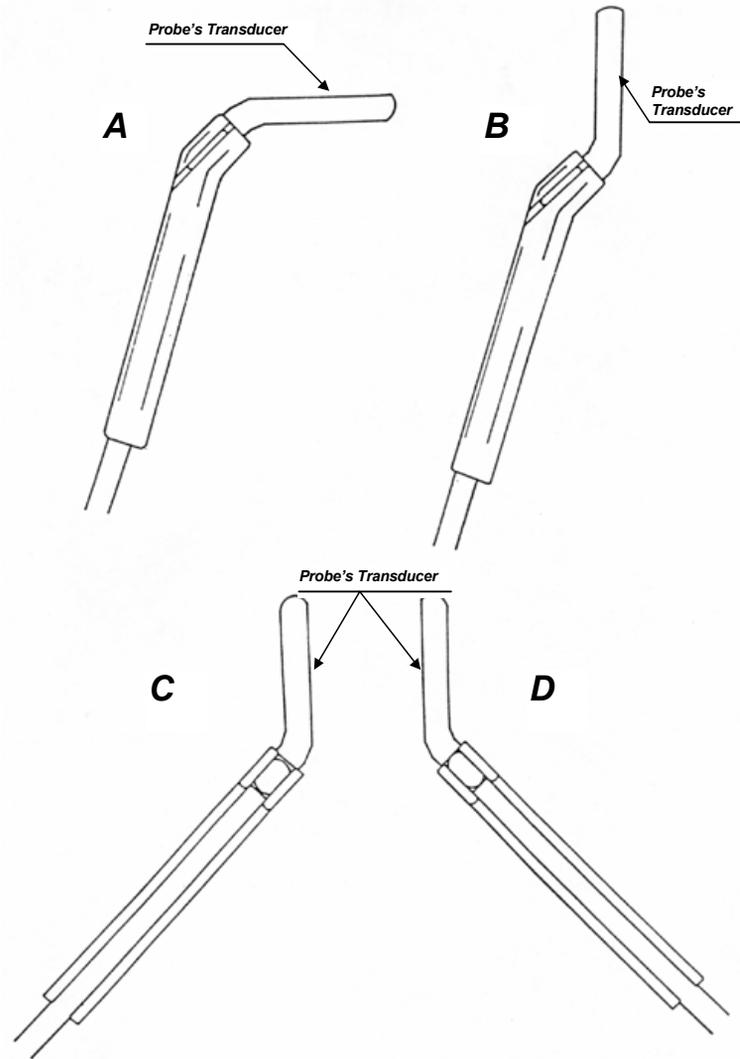
Esaote recommends use of sterile sheaths in intraoperative examinations.

- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.
- Secure the sheath with the rubber band provided.

Handle Attachment

The handle attachment, is inclined 30 degrees, and can be placed on the probe in four different positions to form four different shapes (profiles) A, B, C and D as shown below and on the following pages:

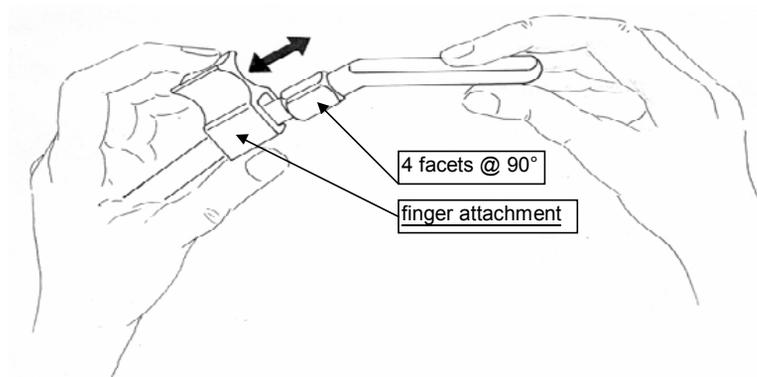


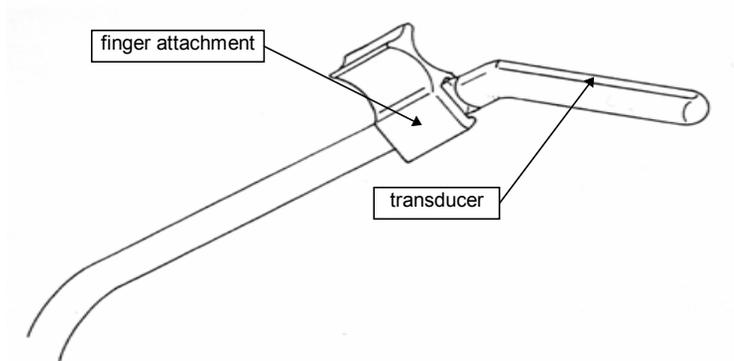


Finger Attachment

The Finger Attachment allows manipulation of the Intraoperative IOE323 probe for use with only two fingers.

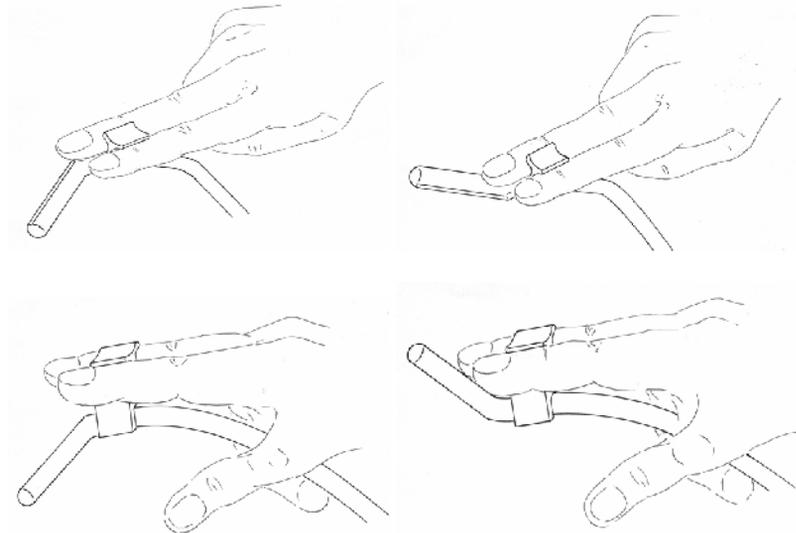
The 4 facets, at 90 degrees, allow the user to obtain four different insertion methods with the probe.





The finger attachment can be used in four different configurations in order to more closely adapt to the surface being evaluated. In intraoperative applications, it is possible to insert the probe below, adjacent to, or on top of the structure of interest.

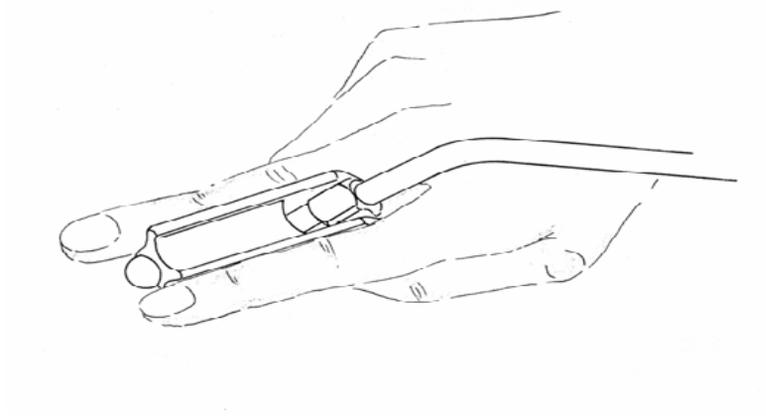
Following are the four different IOE323 probe attachment designs.



Sled Attachment

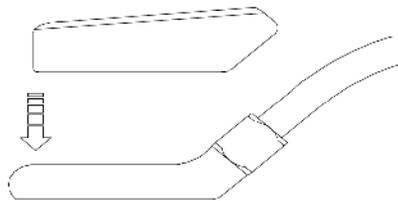
The sled attachment has been developed to provide easier manipulation of the probe during both intraoperative and superficial scanning. The attachment corresponds to the ergonomics of the probe, and is the same length as the transducer.

The correct position of the SLED attachment is shown below.

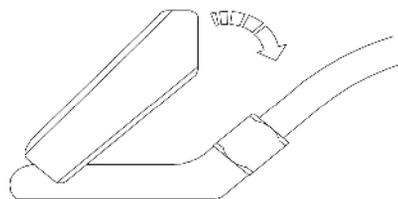


To place the attachment on the probe, follow the procedure described below. The sequence is also shown in the following design.

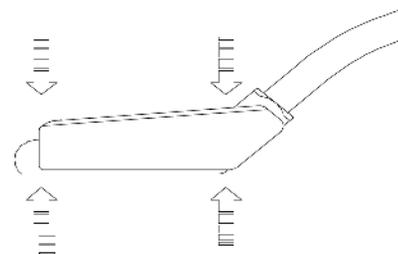
1. Place the sled attachment at the tip of the transducer.



2. Rotate the sled attachment around the probe until it is safely in place between the two lateral extensions of the attachment.



3. Press the transducer inside the holder, hearing a click, to assure secure and complete insertion.



4. To remove the sled attachment, reverse the procedure.

6 - The Laparoscopic Probe

The laparoscopic probe (LP323) is a Type BF part. The probe must be physically intact and the system properly grounded for the electrical safety of the patient and operator.

Read the Safety and Standards Manual carefully: all the safety characteristics, cautions and warnings listed also apply to the use of this probe.

In particular, remember that:

WARNING

The system must be properly grounded: it must be supplied from a socket equipped with a protective ground connection.

Mobile configurations are fitted with insulated supply sockets for supplying electricity to the systems without increasing the leakage current. Incorrect connections or failure to use insulated sockets may compromise electrical safety.

If in doubt about the protective ground connection, DO NOT use the probe and contact ESAOTE immediately.

Characteristics and Components

The LP323 incorporates a high frequency linear transducer for laparoscopic scanning.

The probe is delivered with the following accessories:

- Storage case
- Sterilization bowl

LP323 Probe

The LP323 probe has an articulation that allows a double movement of its extremity in order to position the transducer directly on to the surface of the organ under evaluation. This movement is adjustable by two control levers located on the probe handle.

Examination Safety

The laparoscopic examination is to be carried out by operators who have been specially trained to use the probe and interpret the images. Carefully review current medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

WARNING

Do not use the laparoscopic probe in direct contact with the heart, the central circulatory system and the central nervous system.

Before the Examination

Before each examination :

- Perform a manual and visual inspection of the entire probe prior to use (see Chapter 2 of this manual). **DO NOT** use the probe if it has been damaged or if damage is suspected.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against these damages nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if damage is known or suspected.

- Use protective sheaths during the examination. These sheaths are usually composed of latex (natural rubber).

Note

Esaote recommends use of sterile sheaths in laparoscopic examinations.

WARNING

Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

If the protective cover is damaged during the transesophageal exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).



Be familiar with the mechanical and thermal indices display and the **ALARA** principle (As Low As Reasonably Achievable) before using the probe. The patient must be exposed to ultrasound for as short a time as possible and only for as long as necessary to achieve the diagnostic information.

During the Examination**WARNING**

Before probe use, check to be sure that the probe name shown on the monitor is correct

During the examination, Esaote recommends that the Operator:

- Never force the probe during insertion or removal.

WARNING

Before introducing the LP323 probe into the Trocar verify that there is no mechanical play of the tip of the probe.

While inserting the LP323 probe into the Trocar, the tip of the probe should be in a straight position.

Forced insertion or removal may harm the patient.

- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.

Electric scalpels used during the LP examination interfere with the 2D and make it impossible to use Doppler procedures.

Electric scalpels and other devices that introduce radio frequency or electromagnetic current fields into the patient interfere with ultrasound images.

While using the system in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to the transducer lens can cause electro-surgical currents that can burn the patient. Thoroughly check the system and the probe before applying HF surgical currents to the patient. Disconnect the probe when not imaging.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths **DO NOT** provide protection against such damage nor do they guarantee that the probe is insulated electrically. Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Esaote recommends that the Operator:

- Clean and disinfect the probe, according to the instructions provided in Chapter 2 of this manual.
- Store the probe as indicated in Chapter 1 of this manual.

Preparation of the Laparoscopic Probe

Follow the instructions below for preparing the laparoscopic probe.

Note

The Operator is recommended to wear gloves during the probe preparation procedure

See Chapter 8 on consumables for selecting the gel and sheathes.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

Note

Esaote recommends use of sterile sheaths in intraoperative examinations.

- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.
- Secure the sheath with the rubber band provided.

7 - Needle Guide Kits



See the **MyLab** “Advanced Operations” manual for correct use of the needle guide.

ESAOTE supplies a series of optional adaptors for the biopsy needle guide, fitted with special couplings for connection to the probe. The following table lists the available kits.

Biopsy adaptor	Probe	Kit contents
ABS421	CA421 CA430 CA431	1 20° coupling, 1 30° coupling+ 5 needle guides
ABS621	CA621 CA631	1 25° coupling, 1 35° coupling + 5 needle guides
Type T/ABS1421 ABS523	CA1421 LA523 LA522 LA523P LA532	1 36.3° coupling 1 coupling (45° angle) + 5 needle guides
ABS424	LA424 LA435	1 coupling (45° angle) + 5 needle guides
WBSL33X	LA332	1 35° coupling
ABS123 ABS15	EC123 IOE323	1 coupling (3.8° angle) + 1 needle guide 1 coupling (45° angle) + 5 needle guides

See Appendix A in this manual for probes characteristics. The ABS kits for LA, CA and Intraoperative probes include 14, 18, 20, 21, and 22 gauge needles; the ABS kit for the endocavity probe has a guide for a 16 gauge needle; the ABS kit for the transrectal probe includes 14, 16, 18 and 20 gauge needles.

G12 and G19 needle guides are available for the CA, LA and intraoperative probe ABS kit.

WARNING

Do not use needle guides other than those described in this manual.

ABS421, ABS424, ABS1421/Type T, ABS523, ABS621, ABS15 and WBSL33X kits are composed of stainless steel; the ABS123 needle guide kits is composed of titanium.

Disposable needle guides for CA and LA probes

In addition to the above mentioned biopsy adaptors, the CA and LA probes are equipped with biopsy kits composed of sterilizable mounting brackets and disposable needle guides¹. The following table lists the available kits:

Biopsy adaptor	Manufacturer's kit code	Probe	Kit contents
DBS421/431	7352	CA421 CA430 CA431	1 20° coupling, 1 30° coupling+ set of needle guides
DBS621/631	7354	CA621 CA631	1 25° coupling, 1 35° coupling + set of needle guides
DBSC12X	7356	CA123	1 coupling (15° angle) +set of needle guides
DBS523	7351	LA523 LA522 LA532	1 coupling (45° angle), 1 coupling (60° angle), 1 coupling (75° angle) + set of needle guides
DBS424/435	7350	LA424 LA435	1 coupling (45° angle) + set of needle guides

The following needle guides are sterilized single-use kits:

Biopsy adaptor	Probe	Kit contents
Type X	EC123 / EC1123	25 disposable biopsy kits (3.8° angle)
Type O	E8-5 R10P	25 disposable biopsy kits (3° angle)

Each kit contains sterile probe cover, sterile needle guides, sterile gel and sterile elastic bands plus non-sterile mounting bracket and non-sterile verification kit. The sterile needle guides are of different colour to match the needle to be used. The needle guides are sterile but cannot be re-sterilized.

The biopsy adaptors must be attached to the probes using the alignment pivots, as below described. Follow the instructions provided by the Manufacturer with these kits to properly use them and to clean, disinfect and sterilize them.

Examination Safety



All safety information related to the use of the needle guide kits is in addition to the safety procedures described for the system and for the probes. Consult your MyLab "Safety & Standard" manual for additional safety information.

Before the Examination

Before each examination, Esaote recommends that the Operator:

- Handle the biopsy kit and the probe with sterile gloves.

¹ Manufactured by Protek Medical, www.protekmedical.com

- Perform a visual check of the adaptor and needle guides: do not use them if any damage or distortion is found.
- Use protective sheaths during the examination. These sheaths are primarily composed of latex (natural rubber).

Note

Using sterile sheaths is recommended for intraoperative and biopsy procedures.

WARNING

Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such a reaction.

During the Examination

Pay particular attention to the ultrasound image during the insertion of the needle into the body, checking that the needle follows the displayed line.

WARNING

The lines displayed on the monitor only provides an indication of the needle direction, according to the selected guide. Pay particular attention to the ultrasound image during the insertion of the needle into the body and be sure that the needle always stays within the displayed area.

Before performing the biopsy-test, check for the correct assembly and positioning of the biopsy kit. Also, check that the insertion angle is equal to the angle selected via the user interface software.

Needle insertion in a guide with an insertion angle other than that of the selected angle involves risks to patient safety.

At the End of the Examination

At the end of the examination Esaote recommends that the Operator:

- clean and sterilize the kit,
- clean and disinfect the probe used during the biopsy.

Chapter 2 provides cleaning, disinfection and sterilization instructions.

Mounting the ABS Needle Guide for LA and CA Probes

The ABS adaptors for LA and CA biopsy probes are composed of two parts: the coupling to be connected to the relative probe and the needle guide device.

- Make sure that the probe has been disinfected.
- Apply ultrasound examination gel to the probe or to the tip of the protection cap.

- Cover the probe with the protective cap securing it with the rubber band provided.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such a reaction.

If the protective cover is damaged during the exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).

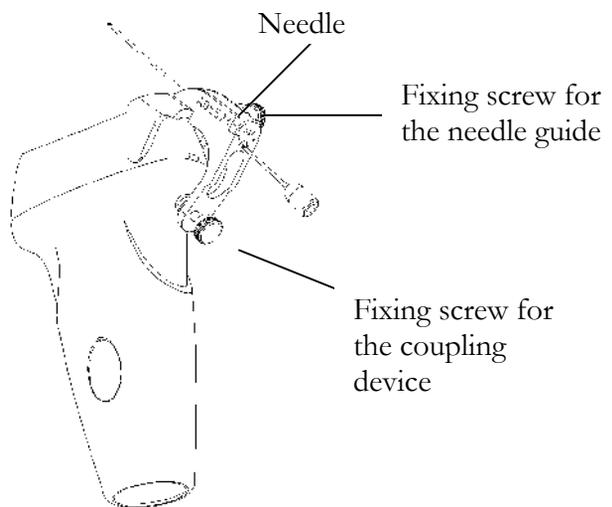
- Connect the kit to the probe, positioning the two alignment pins on the special notches on the probe.

Notes

The guiding device for needle insertion must be on the same probe side of the LED. The coupling must click into the special notch on the probe.

When using the disposable biopsy adaptors and with the ABS1421, the coupling device has to be mounted before inserting the protective cap; this will allow to safely use the same coupling device in different exams.

The following figures show an example of how the ABS523 is assembled on the LA523.



WARNING

Make sure the bottom cone shaped part (at the bottom of the bracket) is screwed into the indentation at the bottom of the top curved portion of the

probe. If the user does not perform this operation correctly, the insertion angle can be wrong causing a risk to patient safety.

For disassembly of the biopsy kit, reverse the previous procedure.

Disposable Biopsy Kit for CA1421 Probe

The CA1421 probe is available with a disposable biopsy kit with 36.3° coupling angle. The kit includes a guide for 14, 16, 18, 20, 22 and 25 gauge needles. The kit can be ordered from CIVCO.

Manufacturer	Manufacturer's kit code	Contents
CIVCO ² Medical Instruments, Inc, Kalona, IA (USA)	610-137	Disposable sterile kit with needle guides, 8x45cm sheath, seal and gel.

The plastic disposable guide is sterile, but cannot be re-sterilized. For a correct use of the disposable biopsy kit, please refer to the manufacturer's instruction.

Mounting the WBSL Needle Guide on LA Probes

The WBSL adaptors for LA biopsy probes are composed of two parts: the coupling device to be connected to the probe and the needle guide.

- Make sure that the probe has been disinfected.
- Apply ultrasound examination gel to the probe or to the tip of the protection cap.
- Cover the probe with the protective cap securing it with the rubber band provided.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such a reaction.

If the protective cover is damaged during the exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).

- Connect the coupling device to the probe, by placing its grooved side on the probe's ridge.
- Close the coupling device by hitching it to the opposite side of the probe.

² Civo Medical Instruments, Kalona IOWA; www.civcomedical.com



Notes

The guiding device for needle insertion must be on the same probe side of the LED. The coupling device must click into the special notch on the probe.



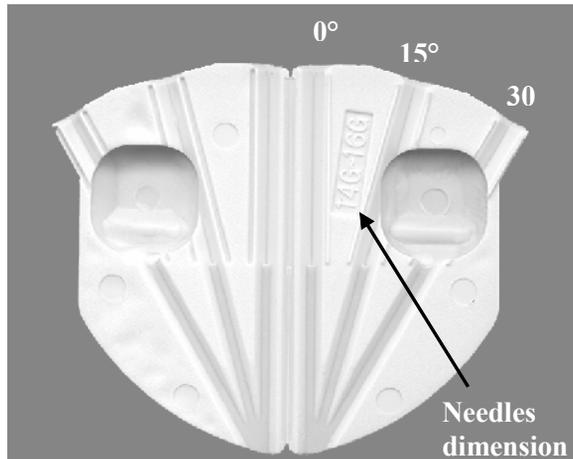
WARNING

If the user does not perform this operation correctly, the insertion angle can be wrong causing a risk to patient safety.

To disassemble the biopsy kit, reverse the previous procedure.

Mounting the Needle Guide for CAB411A Probes

CAB411A is a special probe designed for biopsy. The bracket for CAB411A biopsy probe consists of only one plastic part with three different insertion angles (0° , 15° and 30° degrees). Each bracket has imprinted the dimension of supported needles: 14, 16, 17, 19, 20 and 23 gauge needles.



The innovative design allows easy removal of the biopsy attachment while the needle is inserted in the tissue.

Note

Brackets supplied by ESAOTE are neither disinfected nor sterilized.

- Make sure that the probe has been disinfected
- Apply ultrasound examination gel to the probe or to the tip of the protection cap.
- Cover the probe with the protective cap; secure with the rubber band provided.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such a reaction.

If the protective cover is damaged during the exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).

- Close the bracket by folding in half.
- Insert the bracket into the gap on the scan head paying attention to push it into the special safety catch on the probe.
- Insert the needle guide in one of the three holes formed between the wings of the bracket paying attention to choose the correct insertion angle.

The figure shows an example of how the needle guide is assembled on the CAB411A.

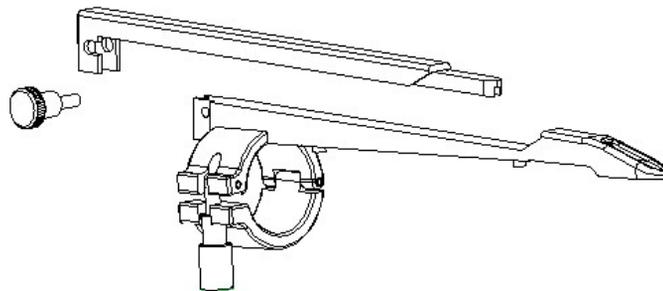


For disassembly of the biopsy kit, reverse the previous procedure.

Mounting the ABS Needle Guide on the EC123 Endocavity Probe

The **ABS123** endocavity biopsy kit is composed of two parts: the coupling to be connected to the probe and the needle guide device.

ABS123 Biopsy kit for the EC123 probe



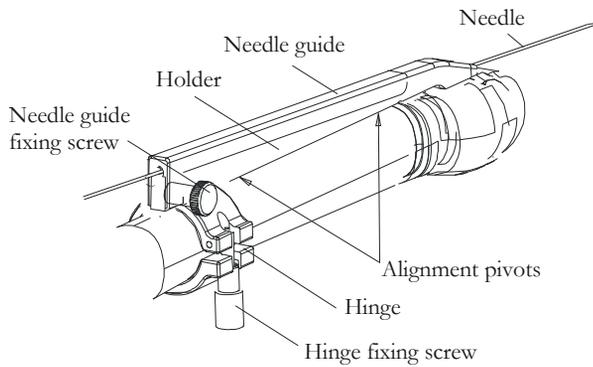
- Make sure that the probe has been disinfected.
- Apply ultrasound examination gel to the probe or to the tip of the protection cap.
- Cover the probe with the protective cap securing it with the rubber band provided.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such a reaction.

If the protective cover is damaged during the exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).

- Connect the kit to the probe, positioning the two alignment pins on the special notches on the probe.



- Close the clamp and tighten it using the special ratchet.
- Insert the needle guide and tighten it onto the coupling.

The EC123 probe is also available with Type X disposable biopsy kit. The kit can also be ordered from CIVCO.

Manufacturer	Manufacturer's kit code	Contents
CIVCO ³ Medical Instruments, Inc, Kalona, IA (USA)	610-693	Disposable sterile kit with needle guide, 2x20cm sheath, 3.5x20cm sheath, seal and gel

The assembly procedure for this kit is identical to that of the metal biopsy kit; the biopsy kit must be attached to the probe using the alignment pivots. The plastic disposable guide is sterile, but cannot be re-sterilized. For a correct use of the disposable biopsy kit, please refer to the manufacturer's instruction.

Note

- The use of sterile covers is mandatory for all endocavity scans.

³ Civco Medical Instruments, Kalona Iowa; www.civco.com

- Please pay attention not to have gel on the shaft of the probe where the holes for biopsy kit connection are.

E8-5 R10P Endocavity Probe

The **E8-5 R10P** probe is available with Type O disposable biopsy kit with 3° coupling angle. The kit can be ordered from CIVCO.

Manufacturer	Manufacturer's kit code	Contents
CIVCO ³ Medical Instruments, Inc, Kalona, IA (USA)	610-543	Disposable sterile kit with needle guide, 2x20cm sheath, seal and gel.

The assembly procedure for this kit is identical to the one described for the metal needle guide; the needle guide must be attached to the probe using the alignment pivots. The plastic disposable guide is sterile, but cannot be re-sterilized. For a correct use of the disposable biopsy kit, please refer to the manufacturer's instruction.

Note

- The use of sterile covers is mandatory for all endocavity scans.
- Please pay attention not to have gel on the shaft of the probe where the holes for biopsy kit connection are.

EC1123 Endocavity Probe

The **EC1123** probe is available with Type X disposable biopsy kit with 3.8° coupling angle. The kit can also be ordered from CIVCO.

Manufacturer	Manufacturer's kit code	Contents
CIVCO ³ Medical Instruments, Inc, Kalona, IA (USA)	610-693	Disposable sterile kit with needle guide, 2x20cm sheath, 3.5x20cm sheath, seal and gel

The assembly procedure for this kit is identical to the one described for the metal needle guide; the needle guide must be attached to the probe using the alignment pivots. The plastic disposable guide is sterile, but cannot be re-sterilized. For a correct use of the disposable biopsy kit, please refer to the manufacturer's instruction.

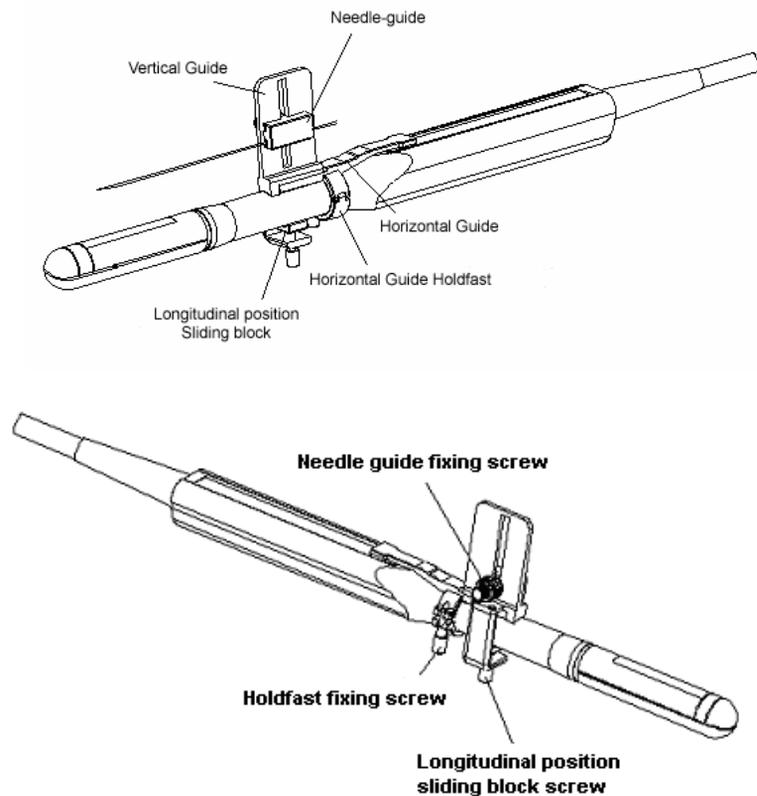
Note

- The use of sterile covers is mandatory for all endocavity scans.
- Please pay attention not to have gel on the shaft of the probe where the holes for biopsy kit connection are.

Mounting the ABS Trans-rectal Probe Needle Guide

The trans-rectal biopsy kit is composed of two parts: the coupling to be connected to the probe and the needle guide device.

Biopsy kit for the TRT33 probe



The position of the needle-guide is adjustable both in length and in depth.

The longitudinal adjustment is performed by the horizontal sliding of the vertical guide onto the horizontal guide. The attachment is made by the “longitudinal position sliding block”.

The vertical adjustment allows the user to change the needle depth in the linear transducer field of view and is performed by sliding the needle guide along the vertical track. To guarantee the precision of the adjustment, the vertical guide has a scale in centimeters (1cm to 5cm) corresponding to the depth shown in the ultrasound image; the needle guide has two notches to indicate each of the two guides for the supported needles. By rotating the needle guide the user can select the gauge. The “Needle guide fixing pawl” holds the guide in place.

- Make sure that the probe has been disinfected.
- Apply ultrasound examination gel to the probe or to the tip of the protection cap.
- Cover the probe with the protective cap; secure with the rubber band provided.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such a reaction.

If the protective cover is damaged during the exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).

- Connect the horizontal guide to the probe, positioning it on the groove on the probe and screwing the attachment system.
- Adjust the needle guide on the vertical guide to choose the correct depth for the exam.
- Slide the vertical guide on the horizontal one so that it fits in the desired position.
- Attach the vertical guide with the “longitudinal position sliding screw”.
- Insert the needle into the guide paying particular attention to choose the correct needle guide hole.

To disassemble the biopsy kit, reverse the previous procedure.

Mounting the ABS Intraoperative Probe Needle Guide

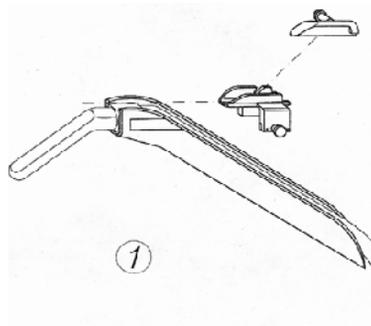
The ABS15 needle guide kit consists of two components: one bracket to hook the needle guide to the probe handle attachment and a needle guide to attach to the bracket. These two components can be disassembled to enable easier cleaning and sterilization.

Kit assembling

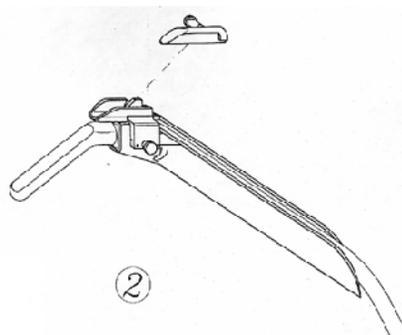
The ABS15 biopsy kit can only be placed on the probe handle attachment as shown below.

Check the integrity of the probe and needle guide and assemble the biopsy kit as follow:

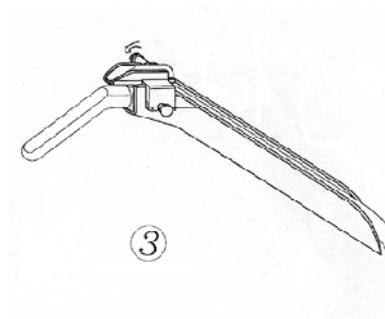
- Once the biopsy kit has been positioned on the handle attachment as shown in picture 1, insert the biopsy bracket into the grooves on the handle attachment by sliding the biopsy bracket to the end of the groove. Attach the bracket with the screw provided.



- Choose the needle guide acceptable for the diameter of the needle to be used and insert it into the bracket.



- Attach the needle guide to the bracket with the screw provided.



- The needle can then be inserted into the hole formed between the bracket and the attached needle guide.

If necessary, the needle guide attachment can be removed from the handle attachment without removing the needle.

To disassemble the biopsy kit reverse the previous procedure.

8 - Accessories and Consumables

ECG Cable

The leads on the ECG cable supplied by Esaote are equipped with a pliers terminal. Any button electrode can be used with the ECG cable. We recommend using disposable Ag/AgCl electrodes. Read the manufacturer's instructions carefully for correct use of the electrodes.

Checking the ECG Cable

A periodic check should be made of the ECG cable.

Disconnect the cable from the system and check that there are no breaks or slits.

ECG Cable Inspection

Note

Esaote recommends replacing the ECG cable if there are any breaks or slits.

Cleaning and Disinfecting the ECG Cable

Periodically clean the ECG cable and electrodes so that they remain in optimal working order.

Never try to clean or disinfect the ECG cable when it is still connected to the unit.

WARNING

Equipment

The equipment listed in the following table will be necessary for periodic maintenance procedures.

CIDEX OPA® is a Johnson&Johnson Ltd. Registered brand.

Agent	Destined for
Solution of mild soap and water	Cleaning the ECG cable and electrodes
CIDEX OPA	Disinfecting the ECG cable
Indicated by the manufacturer	Disinfecting the electrodes

Cleaning Procedure

- Disconnect the cable from the system.
- Dust the cable coupling with a soft cloth.
- Clean the cable by rubbing it gently with a soft cloth dampened with water and a mild detergent.

CAUTION

Do not immerse the ECG cable further than the start of the leads. The cable is not waterproof.

- Rub the cable gently with a soft cloth slightly dampened with a mild detergent solution or alcohol.
- Dry the cable by rubbing it gently with a soft, dry cloth.

Disinfection Procedure

The ECG cable can be disinfected using CIDEX OPA, following the manufacturer's instructions.

- Disconnect the cable from the system.
- Clean the cable as explained in the previous paragraph.
- Immerse the ECG cable leads in CIDEX OPA. When using the disinfectant substance, carefully follow the manufacturer's instructions.

Stand Off for Linear Probes

The stand off part number 9650030000 allows to keep some distance between the probe head and the skin, thus moving the focus area of the probe. The use of a stand off is therefore valuable when studying the tissue surface in musculo-skeletal and vascular applications.

The stand off can be mounted on all MyLab linear probes with size 4 e 5 cm (LA 4XX and LA5XX probe families).



To get the desired distance the operator has to fill with water (preferably sterile) or ultrasound gel the contact pocket equipped with a cock. The pocket can be filled and emptied using a syringe which perfectly suits into the cock opening.

CAUTION

During the exam, check that the cock is perfectly closed and correctly mounted on its case, to avoid fluid leaks or air bubbles.

Using the Stand-Off

- Immerse the stand off into water before each use.
- Apply ultrasound gel on the probe.
- Place the stand off on the probe sliding it till some gel comes out from the lower part of the pocket, on the base of the filling tube.
- Apply ultrasound gel on the stand off (between the contact pocket and the patient).

CAUTION

When the stand off is not used, it is recommended to store it far from light sources, to avoid early ageing of the rubber.

Cleaning and Disinfecting

The stand off is made of natural rubber and can be cleaned with a mild soap. Thoroughly rinse it with water, especially after each contact with disinfectant agents.

CAUTION

The use of germicidal lamps and/or disinfectant agents containing quaternary ammonium compound is not recommended as they could damage the stand-off.

To dry the stand off, use warm air at 60° or a clean cloth.

Sterilizing

Sterilization can be performed in autoclave at 134°C for 20 minutes, if the contact pocket doesn't contain ultrasound gel.

Gel

Transmission gel must always be applied to probes to obtain correct probe-patient contact. Esaote recommends only using water or glycerine-based ultrasound gel.

CAUTION

Do not use gels containing the substances listed below. The transducer could be damaged if such gels are used.

Always check the gel composition before using it.

Note

Any damage caused by the use of gels containing the below listed components is not covered by the warranty.

Substances to Be Excluded

- acetone
- methanol, ethanol, isopropyl alcohol
- denatured ethyl alcohol
- mineral oil
- iodine
- any lotion or gel containing perfume
- glycol

The following table indicates ultrasound gels that have tested compatibility with MyLab.

Product	Supplier
Aquasonic® Scan®	Parker Laboratories, Inc. New Jersey, USA

Sheaths

The use of protective sheaths is recommended in all clinical situations where there is a risk of infection. Specific sheaths are available on the market for most types of Esaote probes. The sheaths listed below are produced by CIVCO Medical Instruments Inc., Kalona, IA (USA). Refer to the manufacturer’s instructions for the characteristics and use of the protective sheaths.

See later for sheaths included in accessory kits.

LA, CA and BC431 Probes

Probes	Manufacturer’s kit code	Measurements	Sterile	Latex
LA332, LA424, LA435, LA522, LA523, LA523P, LA532	610-001	8.9 x 61 cm	Yes	No
CA421, CA541, CA1421, CA621, CA430, CA431, CA631, BC431, CA123, C5-2 R13	610-002	14 x 61 cm	Yes	No

EC123, EC1123, BE1123 and TRT33 Probes

Manufacturer’s code	Measurements	Sterile	Latex
610-006	Can be reduced from 11.9 to 4.6 x 61 cm	Yes	No
610-007	Can be reduced from 11.9 to 4.6 x 61 cm	No	No
610-214	3.5 x 20 cm	Yes	Yes
610-010	3.5 x 20 cm	No	Yes
610-075	2 x 20 cm	Yes	Yes
610-039	2 x 20 cm	No	Yes

IOE323 Probe

The IOE323 intraoperative probe uses the Esaote sterilized sheath Ref.1000000065.

LP323 Probe

The Laparoscopic probe uses the Esaote sterilized sheath Ref.7900000210.

Accessory Kits for Transesophageal Probes

The kits listed below are produced by CIVCO Medical Instruments Inc., Kalona, IA (USA). Refer to the manufacturer’s instructions for the characteristics and use of the kits.

TEE022 Probe

Manufacturer’s code	Content	Sterile	Latex
610-840	Bite-guard and sheath with application kit	No	No

A

Appendix A - MyLab Probes



GS

Probes Denomination

This chapter provides a list of **MyLab** probes with their main characteristics; system dependent features are described in your model documentation.

The name of ESAOTE probes includes:

- a prefix indicating the technology used (ex. PA = Phased Array, CA = convex transducer etc)
- a number indicating the transducer type
- when applicable, a letter indicating the production site

The user manual and the display always identifies the probe, by using the prefix and the number only.

Phased Array Probes

Probe ID	Maximum immersion level
PA240	Up to 3 cm from transducer head
PA230	Up to 3 cm from transducer head
PA121	Up to 3 cm from transducer head
PA122	Up to 3 cm from transducer head
PA023	Up to 3 cm from transducer head

Linear Probes

Probe ID	Maximum immersion level
LA332	Up to 3 cm from transducer head
LA424	Up to 3 cm from transducer head
LA435	Up to 3 cm from transducer head
LA522	Up to 3 cm from transducer head
LA523P	Up to 3 cm from transducer head
LA523	Up to 3 cm from transducer head
LA532	Up to 3 cm from transducer head
LA923	Up to 3 cm from transducer head

Convex Probes

Probe ID	Maximum immersion level
CA123	Up to 3 cm from transducer head
C5-2 R13	Up to 3 cm from transducer head
CA421	Up to 3 cm from transducer head
CA1421	Up to 3 cm from transducer head
CA430	Up to 3 cm from transducer head
CA541	Up to 3 cm from transducer head
CA431	Up to 3 cm from transducer head
CA621	Up to 3 cm from transducer head
CA631	Up to 3 cm from transducer head
CAB411A	Up to 4 cm from transducer head

Specialty Probes

Transesophageal (Adults)

Probe ID	TEE022
Technology	Phased Array
Imaging plane	0-180°
Maximum immersion level	Up to 1 m from transducer head

Transesophageal (Pediatric)

Probe ID	TEE122 / TEE132
Technology	Phased Array
Imaging plane	0-180°
Maximum immersion level	Up to 70 cm from transducer head

Endocavity

Probe ID	EC123
Technology	Convex Array
Imaging plane	Sagittal
Maximum immersion level	Up to 25 cm from transducer head

Probe ID	E8-5 R10P
Technology	Convex Array
Imaging plane	Sagittal
Maximum immersion level	Up to 25 cm from transducer head

Probe ID	EC1123
Technology	Convex Array
Imaging plane	Sagittal
Maximum immersion level	Up to 28 cm from transducer head

Transrectal

Probe ID	TRT33
Technology	Convex + Linear Array
Imaging planes	Transversal and Longitudinal
Maximum immersion level	Up to 25 cm from transducer head

Intraoperative

Probe ID	IOE323
Technology	Linear Array
Maximum immersion level	Up to 10 cm from transducer head

Laparoscopic

Probe ID	LP323
Technology	Linear Array
Maximum immersion level	Up to 50 cm from transducer head

BIScan Convex

Probe ID	BC431
Technology	Convex Array
Maximum immersion level	Up to 9.5 cm from transducer head

BIScan Endocavity

Probe ID	BE1123
Technology	Convex Array
Imaging plane	Sagittal
Maximum immersion level	Up to 17,5 cm from transducer head

Doppler Probes

Continuous Wave

Probe ID	Maximum immersion level
2 CW	Up to 6 cm from transducer surface
5 CW	Up to 6 cm from transducer surface
HF CW	Up to 6 cm from transducer surface

Appendix B - Cables and Consumables

ECG Cables



This chapter provides a list of **MyLab** ECG cables with their main characteristics; refer to your system documentation for ECG capabilities.

Reference	Description
9630028000	3-Leads ECG Cable - IEC Colours
9630028010	3-Leads ECG Cable - AHA Colours

Recommended Consumables

Below is the recommended single use electrodes; the product has been tested for compatibility with the ESAOTE **MyLab** systems.

Type	Product	Manufacturer
Single Use Electrodes	Excel 3040.050	Ludlow Technical Products Massachusetts, USA

Cleaning, Disinfection and Sterilization Agents

The following tables list the MyLab probes and the recommended cleaning (C), disinfection (D) and sterilization (S) agents. X means “Do Not Use”.

Note

Damage caused by the use of not recommended agents is not covered by the warranty.

WARNING

Follow the instructions provided by the manufacturer of the agent for proper use.

Convex Probes

	CA123	C5-2 R13	CA421	CA1421	CA430	CA541	CA431	CA621	CA631
Accel RTU	C	C	C	C	C	C	C	C	C
Alkazyme	X	X	X	X	X	C	X	C	X
Anioxyde 1000	X	X	X	X	X	X	X	S	X
Anios Detergent Desinfectant	C	C	C	C	C	C	C	C	C
Assepti Wipes II	X	X	X	X	X	C	X	X	X
CaviWipes	X	X	X	X	X	C	X	X	X
Cidex® OPA	D	D	D	D	D	D	D	D	D
Cidexplus®	D/S	D/S	D/S	D/S	D/S	D	D/S	D/S	D/S
Compliance™	X	X	X	X	X	X	X	D/S	X
Enzol/Cydezime	C	C	C	C	C	C	C	C	X
Gigasept (10% vol.)	D	D	D	D	D	X	D	D	X
Gigasept® FF	D	D	D	D	D	X	D	D	D
Hexanios G+R	C	C	C	C	C	C	C	C	C
Klenzyme	X	X	X	X	X	C	X	C	X
Medi-Prep	C	C	C	C	C	C	C	C	X
Medister	S	X	S	X	S	X	S	S	X
Metricide®	S	S	S	S	S	D	S	S	X
Milton	C	X	C	X	C	X	C	C	C
NuCidex	X	X	X	X	X	X	X	S	X
Omnicide™ (2.25%)	D/S	D/S	D/S	D/S	D/S	X	D/S	D/S	X
Perasafe®	X	X	X	X	X	X	X	S	X
PreCept RTU	C	C	C	C	C	C	C	C	C
Salvanios	X	X	X	X	X	X	X	C	X
Sani-cloth Active	C	C	C	C	C	C	C	C	X
SeptiWipes	X	X	X	X	X	C	X	X	X
Ster-Bac Blu	X	X	X	X	X	D	X	X	X
Super Sani-cloth	X	X	X	X	X	X	X	X	C
Resert HLD (ex Secure HLD)	X	X	X	X	X	X	X	D/S	X
Sporox II	X	X	X	X	X	X	X	X	D
Steranios	D	D	D	D	D	D	D	D	X
Transeptic Spray	C	C	C	C	C	C	C	C	C
T-Spray	C	C	C	C	C	C	C	C	C
T-Spray II	C	C	C	C	C	C	C	C	C
Virkon®	D	D	D	D	D	D	D	D	D
Wavicide-01®	D/S	D/S	D/S	D/S	D/S	D	D/S	D/S	D

Linear Probes

	LA332	LA424	LA435	LA522	LA523	LA532
Accel RTU	C	C	C	C	C	C
Alkazyme	X	X	X	X	X	X
Anioxyde 1000	X	X	X	X	X	X
Anios Detergent Desinfectant	C	C	C	C	C	C
Cidex®	D	D	D	D	D	D
Cidex Activated Dialdehyde Solution	S	S	S	S	S	S
Cidex® OPA	D	D	D	D	D	D
Cidexplus®	D/S	D/S	D/S	D/S	D/S	D/S
Compliance™	X	X	X	X	X	X
Enzol/Cydezime	C	C	C	C	C	C
Gigasept (10% vol.)	D	D	D	D	D	D
Gigasept® FF	D	D	D	D	D	D
Hexanios G+R	C	C	C	C	C	C
Klenzyme	X	X	X	X	X	X
Medi-Prep	C	C	C	C	C	C
Medister	S	S	S	S	S	S
Metricide®	S	S	S	S	S	S
Milton	C	C	C	C	C	C
NuCidex	X	X	X	X	X	X
Omnicide™ (2.25%)	D/S	D/S	D/S	D/S	D/S	D/S
Perasafe®	S	X	X	X	X	X
PerCept RTU	C	C	C	C	C	C
Salvanios	X	X	X	X	X	X
Sani-Cloth Active	C	C	C	C	C	C
Sani-Cloth HB	X	X	X	X	X	X
Resert HLD (ex Secure HLD)	X	X	X	X	X	X
Steranios	D	D	D	D	D	D
Transeptic	C	C	C	C	C	C
T-Spray	C	C	C	C	C	C
T-Spray II	C	C	C	C	C	C
Virkon®	D	D	D	D	D	D
Wavicide-01®	D/S	D/S	D/S	D/S	D/S	D/S

Phased Array Probes

	PA023	PA121	PA122	PA240	PA230
Accel RTU	C	C	C	C	C
Anios Detergent Desinfectant	C	C	C	C	C
Cidex®	D	D	D	D	D
Cidex Activated Dialdehyde Solution	S	S	S	S	S
Cidex® OPA	D	D	D	D	D
Cidexplus®	D/S	D/S	D/S	D/S	D/S
Enzol/Cydezime	C	C	C	C	C
Gigasept (10% vol.)	D	D	D	D	D
Gigasept® FF	D	D	D	D	D
Hexanios G+R	C	C	C	C	C
Medi-Prep	C	C	C	C	C
Medister	S	S	S	S	S
Metricide®	S	S	S	S	S
Milton	C	C	C	C	C
Omnicide™ (2.25%)	D/S	D/S	D/S	D/S	D/S
PreCept RTU	C	C	C	C	C
Sani-cloth Active	C	C	C	C	C
Steranios	D	D	D	D	D
Transeptic	C	C	C	C	C
T-Spray	C	C	C	C	C
T-Spray II	C	C	C	C	C
Virkon®	D	D	D	D	D
Wavicide-01®	D/S	D/S	D/S	D/S	D/S

Specialty Probes

	BC431	CAB411A	E8-5 R10P	EC123	EC1123	BE1123
Accel RTU	C	X	C	C	C	C
Alkazyme	X	C	C	X	X	X
Anios Detergent Desinfectant	C	C	C	C	C	C
Anioxyde 1000	X	X	S	X	X	X
Cidex®	D	D	D	D	D	D
Cidex Activated Dialdehyde Solution	S	X	X	X	S	D/S
Cidex® OPA	D	D	D	D	D	D
Cidexplus®	D/S	D/S	D/S	D/S	D/S	D/S
Compliance™	X	X	X	D/S	X	X
Enzol/Cydezime	C	C	C	C	C	C
Ethylene Oxide	X	S	X	X	X	X
Gigasept (10% vol.)	D	D	D	D	D	D
Gigasept® FF	D	D	D	D	D	D
Hexanios G+R	C	C	C	C	C	C
Klenzyme	X	X	C	X	X	X
Medi-Prep	C	X	C	C	C	C
Medister	S	S	X	S	S	X
Metricide®	S	S	S	S	S	S
Milton	X	C	X	C	X	X
NuCidex	X	X	S	X	X	X
Omnicide™ (2.25%)	D/S	X	D/S	D	D/S	D/S
Perasafe®	X	X	S	S	S	X
PreCept RTU	C	X	C	C	C	C
Salvanios	X	C	C	X	X	X
Sani-cloth Active	C	X	C	C	C	C
Resert HLD (ex Secure HLD)	X	X	D/S	D/S	X	X
Steranios	D	D	D	D	D	D
STERRAD®100	X	S	X	X	X	X
Transeptic	C	C	C	C	C	C
T-Spray	C	C	C	C	C	C
T-Spray II	C	C	C	C	C	C
Virkon®	D	X	D	D	D	D
Wavicide-01®	D/S	D/S	D/S	D/S	D/S	D/S

MyLab - TRANSDUCERS AND CONSUMABLES

	IOE323	LP323	TEE022 TEE122 TEE132	TRT33
Accel RTU	X	X	X	C
Alkazyme	C	C	X	X
Anioxyde 1000	D	D	X	S
Anios Detergent Desinfectant	X	X	X	C
Cidex®	D	D	D	D
Cidex Activated Dialdehyde Solution	X	X	X	S
Cidex® OPA	D	D	D	D
Cidexplus®	X	X	X	D/S
Compliance™	X	X	X	D/S
Enzol/Cydezime	C	C	C	C
Ethylene Oxide	S	S	X	X
Gigasept (10% vol.)	D	D	D	D
Gigasept® FF	D	D	D	D
Hexanios G+R	X	X	X	C
Klenzyme	C	C	X	X
Medi-Prep	C	C	X	C
Medister	S	S	X	S
Metricide®	X	X	S	S
Milton	X	X	C	C
NuCidex	S	S	X	S
Omnicide™ (2.25%)	X	X	D/S	D/S
Perasafe®	S	S	X	S
PreCept RTU	X	X	X	C
Salvanios	C	C	X	X
Sani-cloth Active	C	C	X	C
Resert HLD (ex Secure HLD)	D/S	D/S	X	D/S
Steranios	D	D	D	D
STERRAD®100	S	S	X	X
Transeptic Spray	X	X	X	C
T-Spray	C	C	C	C
T-Spray II	C	C	C	C
Virkon®	D	D	D	D
Wavicide-01®	X	X	X	D/S

Doppler Probes

	2CW	5CW	HF CW
Accel RTU	C	C	X
Anios Detergent Desinfectant	C	C	X
Cidex®	D	D	D
Cidex Activated Dialdehyde Solution	S	S	X
Cidex® OPA	D	D	X
Cidexplus®	D/S	D/S	X
Enzol/Cydezime	C	C	X
Gigasept (10% vol.)	D	D	X
Gigasept® FF	D	D	X
Hexanios G+R	C	C	C
Medi-Prep	C	C	X
Metricide®	S	S	X
Milton	C	C	X
Omnicide™ (2.25%)	D/S	D/S	X
PreCept RTU	C	C	X
Sani-cloth Active	C	C	X
Steranios	D	D	X
Transeptic Spray	C	C	X
T-Spray	C	C	X
T-Spray II	C	C	X
Virkon®	D	D	X
Wavicide-01®	D/S	D/S	X

Needle Guides

	ABS421	ABS621	ABS523	ABS424	ABS123	ABS15
Accel RTU	C	C	C	C	C	C
Anios Detergent Desinfectant	C	C	C	C	C	C
Cidex®	D	D	D	X	D	D
Cidex® OPA	D	D	D	X	D	D
Cidexplus®	D/S	D/S	D/S	X	D/S	D/S
Compliance™	D/S	D/S	D/S	D/S	D/S	D/S
Enzol/Cydezime	C	C	C	C	C	C
Gigasept (10% vol.)	D	D	D	X	D	D
Gigasept® FF	D	D	D	X	D	D
Hexanios G+R	C	C	C	C	C	C
Medi-Prep	C	C	C	C	C	C
Metricide®	X	S	S	X	X	S
Milton	C	C	C	C	C	C
Omnicide™ (2.25%)	D/S	D/S	D/S	X	D/S	D/S
Perasafe®	S	S	S	X	S	S
PreCept RTU	C	C	C	C	C	C
Sani-cloth Active	C	C	C	C	C	C
Steam (autoclave)	S	S	S	S	S	S
Steranios	D	D	D	X	D	D
Steris	S	S	S	X	X	X
Transeptic Spray	C	C	C	C	C	C
T-Spray	C	C	C	C	C	C
T-Spray II	C	C	C	C	C	C
Virkon®	D	D	D	X	D	D
Wavicide-01®	D/S	D/S	D/S	X	D/S	D/S

Besides the agents indicated in the table, all compatible sterilization methods for surgical instruments can be applied to the ABS15, ABS123, ABS424, ABS523, ABS1421/Type T, ABS 421, ABS621 and WBSL33X kits.

Manufacturers of Recommended Agents

Agent	FDA Approved	Presentation	Main ingredients	Country of manufacture	Manufacturer
Cidex®	No	Liquid	Glutaraldehyde	USA	Advanced Sterilization Products (www.sterrad.com/about_asp/locations/index.asp)
Cidex Activated Dialdehyde Solution	No	Liquid	Alkaline glutaraldehyde solution		
Cidex® OPA	Yes	Liquid	Ortho-phthalaldehyde		
Cidexplus®	No	Liquid	Glutaraldehyde		
Enzol/Cydezime	No	Liquid	Enzymatic detergent		
NuCidex	No	Liquid	Peracetic acid		
STERRAD®100	No	System	Low-temperature hydrogen peroxide gas plasma		
Ethylene Oxide	No	System	Ethylene Oxide	Various	Various manufacturers
Omnicide™ (2.25%)	Yes	Liquid	Glutaraldehyde	USA	COTTRELL LTD
Gigasept (10% vol.)	No	Liquid	Succindialdehyde	Germany	Schülke&Mayr GmbH, (www.schuelkemayr.com/int/en/contact/smi044_adresses.htm)
Gigasept® FF	No	Liquid	Succindialdehyde		
Perasafe®	No	Powder	In aqueous solution-hydrogen peroxide and peracetic acid	UK	Day-Impex Ltd, (http://www.day-impex.co.uk/lab_products.asp)
Virkon®	No	Liquid	Potassium peroximonosulphate	USA	Metrex Research Corporation, (www.metrex.com/company/contact/index.cfm)
CaviWipes	No	Wipes	14.3% IPA		
Compliance™	No	Liquid	Hydrogen Peroxide and peracetic acid		
Metricide™	Yes	Liquid	Glutaraldehyde	USA	Wave Energy Systems INC
Wavicide-01®	Yes	Liquid	Glutaraldehyde		
Steris	Yes	System	Peracetic acid+lowtemperature+biocidal agent	USA	STERIS Corporation, (www.steris.com)
Resert HLD (ex Secure HLD)	No	Liquid	Hydrogen peroxide; phosphoric acid		
Klenzyme	No	Liquid	Enzymatic detergent		
Medister	No	Powder	In aqueous solution-hydrogen peroxide +peracetic acid	Italy	Euro Trading S.r.l.
Steam (autoclave)	No	System	Steam	Various	Various manufacturers
Hexanios G+R	No	Powder	Polyhexanide, quaternary ammonium chloride	France	Laboratoires Anios, (www.anios.com)
Steranios	No	Liquid	Glutaraldehyde		
Salvanios	No	Powder	Quaternary ammonium propionate, guanidinium acetate		
Anioxyde 1000	No	Liquid	Peracetic acid		
Anios Detergent Disinfectant	No	Liquid	Quaternary ammonium propionate, guanidinium acetate	USA	Professional Disposables International, (www.nicepak.com/divisions/pdi/default.asp)
Sani Cloth Active	No	Wipes	Quaternary ammonium compound; monoethanolamine		
Super Sani Cloth	No		Quaternary ammonium compound; Isopropyl alcohol		
Sani-cloth HB	No		Quaternary ammonium compounds		
Medi-Prep	No	Wipes	1% cetrimide BP	UK	Seton
Milton	No	Liquid	Sodium hypochlorite	France	Milton Pharmaceutical Ltd, (www.milton-tm.com/milton-baby-hygiene-products-contact.htm) or Laboratoires RIVADIS
Alkazyme	No	Powder	IPA, quaternary ammonium chloride	France	Alkapharm UK. Ltd, (www.alkapharm.co.uk)
Sporox II	Yes	Liquid	Hydrogen peroxide	USA	Sultan Healthcare, Inc., (www.sultanhealthcare.com)
Transeptic	Yes	Spray	Isopropyl alcohol	USA	Parker Laboratories Inc. (www.parkerlabs.com)
T-Spray	No	Spray	IPA, quaternary ammonium	USA	Pharmaceutical Innovations Inc (www.pharminnovations.com)
T-Spray II	No	Spray	chloride		
Accel RTU	No	Wipes	Hydrogen peroxide	Canada	Virox Technologies (www.virox.com)

Appendix C - Probes

Electrical Safety

The transesophageal, endocavitary, intraoperative and laparoscopic probes, produced by Esaote, are classified as Type BF applied parts. To ensure electrical safety both to the patient and the operator, it is necessary to check the physical integrity of the probe and to have the system correctly grounded.

It is important to check on a regular basis the electrical safety of probes used in semi-critical (such as transesophageal, endocavitary) and critical (intraoperative, laparoscopic) applications, according to what stated by the EN60601-1 standard. This means that the procedures adopted to check probes must also include a leakage current measurement.

WARNING

Do not use a probe which underwent any kind of shock or whose integrity has been compromised (carefully read Chapter 1 of this manual), until its electrical integrity has been defined by a leakage current measurement. Contact your local ESAOTE representative.

The leakage current measurement must be performed by a qualified person, using some test equipment complying with the standards.

Note

Before performing the measurement, make sure that the test equipment is correctly calibrated.

The below described procedure refers to ULT800 (www.flukebiomedical.com) measurement device: for further details on its use, please refer to the manufacturer's user manual. Any other equipment complying with the standards can be used, referring to the corresponding user manuals.

WARNING

During the test do not touch either the electrodes or the liquid where the probe is immersed. During the test a high voltage is applied on the electrodes..

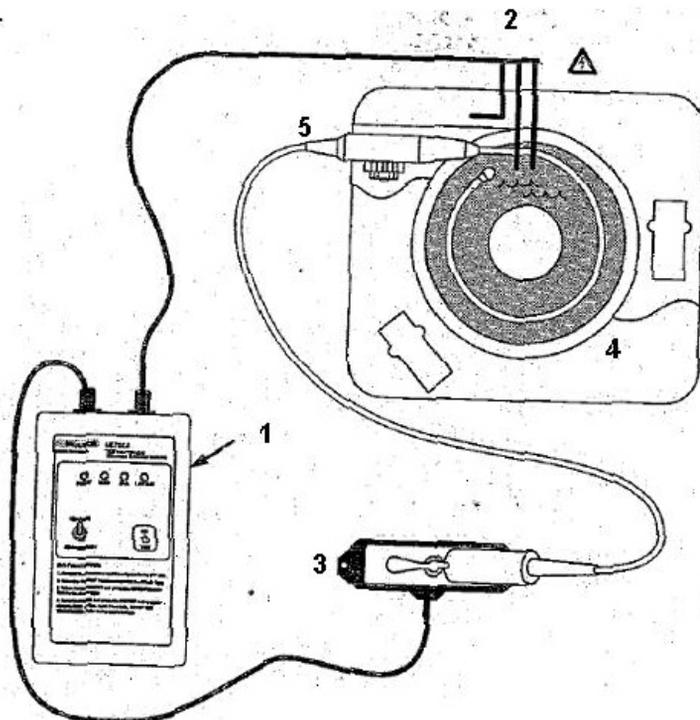
Do not immerse the probe cable or connector into water or other liquids. Immersion may compromise the electrical safety features. The probe can be inserted into water up to its Maximum Immersion Level. (see Appendix A).

Procedure

- Connect the probe to the adapter available on the measurement device.
- Turn the measurement device on and wait till it's ready to work.
- Immerse the probe into a saline solution or Cidex®.
- Place the electrodes into the saline solution.
- Connect both the electrodes and the probe adaptor to the tester.
- Run first the conductivity test and then the leakage current test.

WARNING

If the leakage current test gives a negative result, do not use the probe and contact your local ESAOTE representative.



Legenda

- 1: Measuring device
- 2: Conductivity sensor
- 3: Probe adapter
- 4: Water tank filled with Cidex® or saline solution
- 5: Probe to be examined