HITACHI
Inspire the Next

C22P Probe

INSTRUCTION MANUAL

Notes for operators and responsible maintenance personnel
★ Please read through this Instruction Manual carefully prior to use.
★ Keep this Instruction Manual together with the system with care to make it available anytime.

Hitachi, Ltd.
Tokyo , Japan

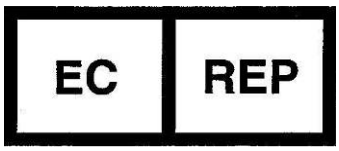
Q1E-EP1457-7

CE 0123

Manufacturer:

Hitachi, Ltd.
2-16-1, Higashi-Ueno, Taito-ku, Tokyo,110-0015, Japan
+81-3-6284-3668
http://www.hitachi.com/businesses/healthcare/index.html

European Representative:



Hitachi Medical Systems GmbH
Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany

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

Local Distributor:

About this manual

This instruction manual shall provide instructions for using, cleaning, and disinfecting and/or sterilizing the HITACHI ultrasound probes.

It also describes safety considerations, maintenance.

For instructions for operating the ultrasound diagnostic scanner, refer to the operation manual for it.

Before using the probe, thoroughly read this manual and keep this book for future reference.

If you have any questions concerning the manual, please contact a service support.

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

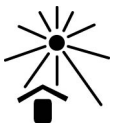
WARNING: "Warning" is used to indicate the presence of a hazard which can cause severe personal injury, death, or substantial property damage if the warning is ignored.

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

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

Graphical Symbols for Use in Labeling of Hitachi Ultrasound Probes

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

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

Definition of symbol

The following symbol is also used for HITACHI Ultrasound Probes.

Location	Symbol	Definition
Probe connector	CE 0123	This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS
Probe connector	IPX7	IPX7 mark See section 1.6.
Probe connector		Type BF APPLIED PART
Probe connector		General warning sign
Probe connector		Warning; dangerous voltage
Probe connector		Caution; Biohazard
Probe connector		Follow the instruction manual to operate this instrument. If not avoided, may result in injury, property damage, or the equipment trouble.
Probe connector		STERRAD sterilization compatibility mark
Probe connector		Do not waste the instrument as general waste. Comply with a local regulation.
Probe connector	Rx Only	By prescription only. U.S. Federal Law restricts this device to sale on order of a physician only.

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1. General

1.1 Features

C22P Probe is a Convex Array type.

The acoustic output of this probe when connected to ultrasound diagnostic scanner was measured according to the IEC60601-2-37 standard.

The table of measured acoustic output data is contained in the operation manual of each ultrasound diagnostic scanner.

This probe is categorized in class IIa according to Directive 93/42/EEC.

According to IEC60601-1 the probe is classified as type BF.

1.2 Principles of operation

This probe and the ultrasound diagnostic scanner enable image diagnosis using ultrasonic waves. This system operates under the principles described below.

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

1.3 Intended Use

C22P Probe is designed for observation and diagnosis mainly of the following regions by connecting with the HITACHI ultrasound diagnostic scanner.

- Biopsy (with Biopsy Attachment)
- General abdominal organs

⚠ WARNING

Never use the probe for following applications.

1) Direct contact to the heart.
2) Biopsy to the heart.
3) Direct contact to the eye.

1.4 Components

The probe components of C22P are as follows:

1) Probe ····· 1 piece
2) Attachment ····· 1 piece
3) Instruction Manual ····· 1 copy

1.5 Option

1.5.1 Needle Guide Bracket EZU-PA7C2

1) Needle guide bracket ····· 1 piece
2) Brush ····· 1 piece
3) Spring (Spare) ····· 2 pieces
4) Instruction manual ····· 1 copy
5) Case ····· 1 piece

1.5.2 Attachment

It becomes easy to have the probe by attaching the attachment to the probe and improves operability.

And the magnetic sensor can be fixed to the probe and it can be used as the Attachment for Real-time Virtual Sonograpy(RVS).

1.5.3 GENERAL PURPOSE Ultra-Pro II™ DISPOSABLE STERILE ULTRASOUND NEEDLE GUIDE/COVER KIT (610-579 or 610-608).

Purchase the Ultra-Pro II™ NEEDLE GUIDE/COVER KIT (610-579 or 610-608) directly from CIVCO MEDICAL INSTRUMENTS or an authorized CIVCO distributor.

1.5.4 GENERAL PURPOSE Ultra-Pro 3™ DISPOSABLE STERILE ULTRASOUND NEEDLE GUIDE/COVER KIT (610-901) (Option).

1.5.5 Purchase the Ultra-Pro 3™ NEEDLE GUIDE/COVER KIT (610-901) directly from CIVCO MEDICAL INSTRUMENTS or an authorized CIVCO distributor.

⚠CAUTION

Sterilization has not been made to the probe, the attachment and the Needle guide bracket shipped from the factory.

Prior to each use, be sure to clean, disinfect and if necessary sterilize them following this instruction manual.

⚠CAUTION

1) Do not attach the devices except for the Ultra-Pro II™ or the Ultra-Pro 3™ NEEDLE GUIDE/COVER KIT to the Needle guide bracket EZU-PA7C2.
2) A biopsy should be performed only by a well-trained physician.

1.6 External View

The external view of C22P is shown in Fig. 1.

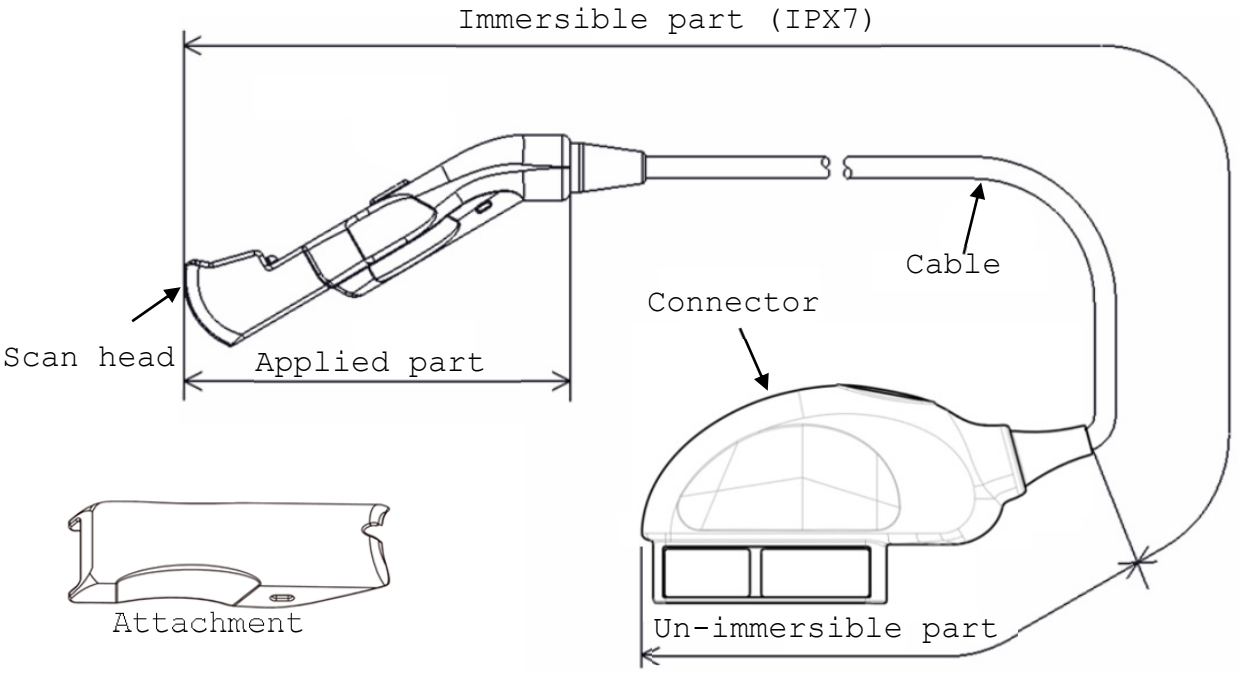
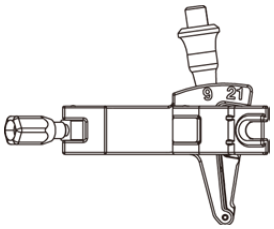


Fig. 1 External View



Needle Guide Bracket EZU-PA7C2

Immersible part: This part can be immersed in disinfectant solution and also can be cleaned by water.

Un-immersible part: This part should not be immersed in disinfectant solution and also cannot be cleaned by water.

2. Inspection before Use

Prior to use, the probe must be carefully inspected that it is appropriate for use. If you find any damage, do not use the probe and immediately contact a service support.

2.1 Inspection for Appropriate Connection

2.1.1 Confirm that the system is correctly operating. Refer to the instruction manual for the ultrasound diagnostic scanner.

2.1.2 Do not attach or connect unauthorized devices or instruments on the probe, such as unauthorized biopsy attachments.

2.2 Inspection for Material Surface

2.2.1 Probe

Visually check the surface of the probe head, the attachment, housing and cable for any crack, scratch or denaturalization. If you find any damage, do not use the probe and contact a service support immediately.

2.2.2 Needle Guide Bracket EZU-PA7C2

1) Visually check the surface of the needle guide bracket for any crack, scratch, denaturalization or deformation.
2) Fill a sterile container with sterile water. Water temperature depends on the type of the ultrasound diagnostic scanner connected to the probe. If the type of the scanner is EUB series, HI VISION series, or Noblus, set water temperature at room temperature. For the other type of the scanner, set it at 40 degrees Celsius.

3) Put the probe in sterile water and confirm that the needle echo at each angle overlaps with the correspondent biopsy guideline (See Fig. 2).

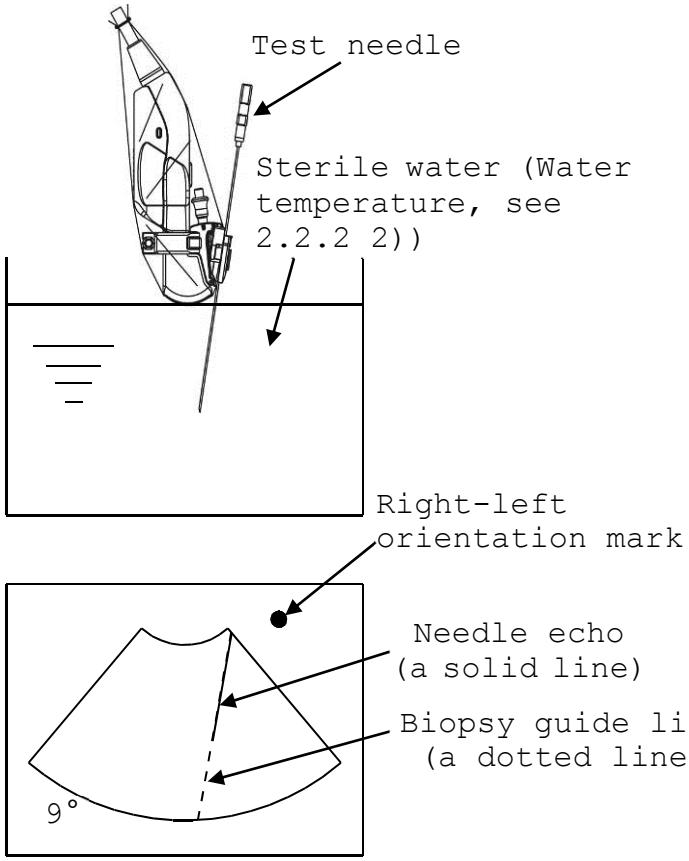


Fig. 2 Echo image of the test needle

⚠ CAUTION

Before use, make sure there is no damage to the surface to which the needle cannula is attached, and the needle guide works properly.

4) Confirm that the needle guide angle corresponds to the angle indicated on the monitor. The needle guide angle is engraved on bracket. (See Fig. 3)

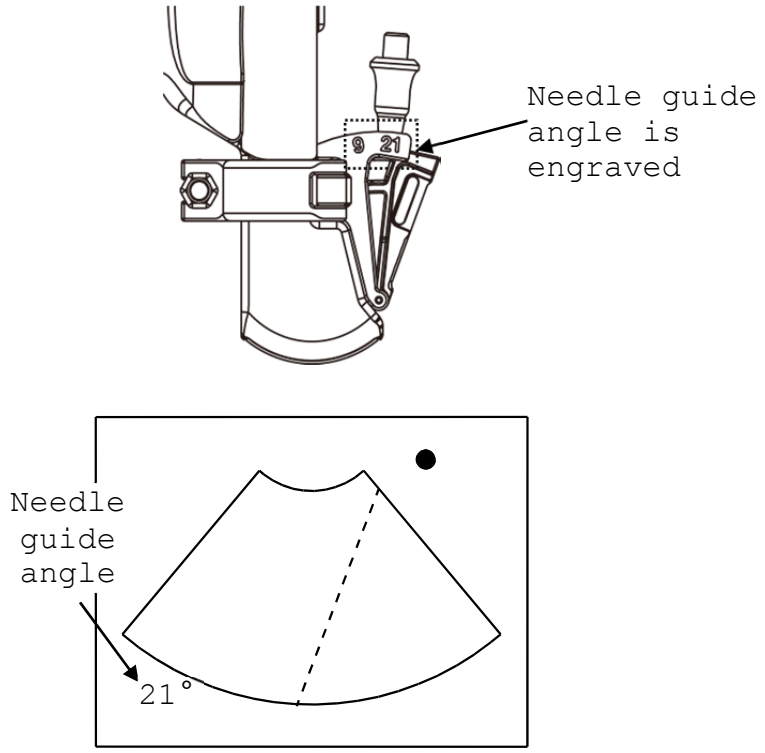


Fig. 3 Needle guide angle

5) Visually inspect the cover to ensure that there are no defects or holes. Do not use cover if it has any holes and tears.

3. Operation Procedure

3.1 Probe

1) Confirm that the probe and the attachment are cleaned, disinfected and if necessary sterilized.

2) Attach the attachment to the probe according to 3.2.

3) Connect the probe to the ultrasound diagnostic scanner, operate the scanner, and adjust the image, all according to the instructions given in the operation manual for the ultrasound diagnostic scanner with which the probe is used as connected.

4) The relationship between the direction of the probe and the image is shown in Fig. 4. The right-left orientation mark on the image indicates the index mark on the probe.

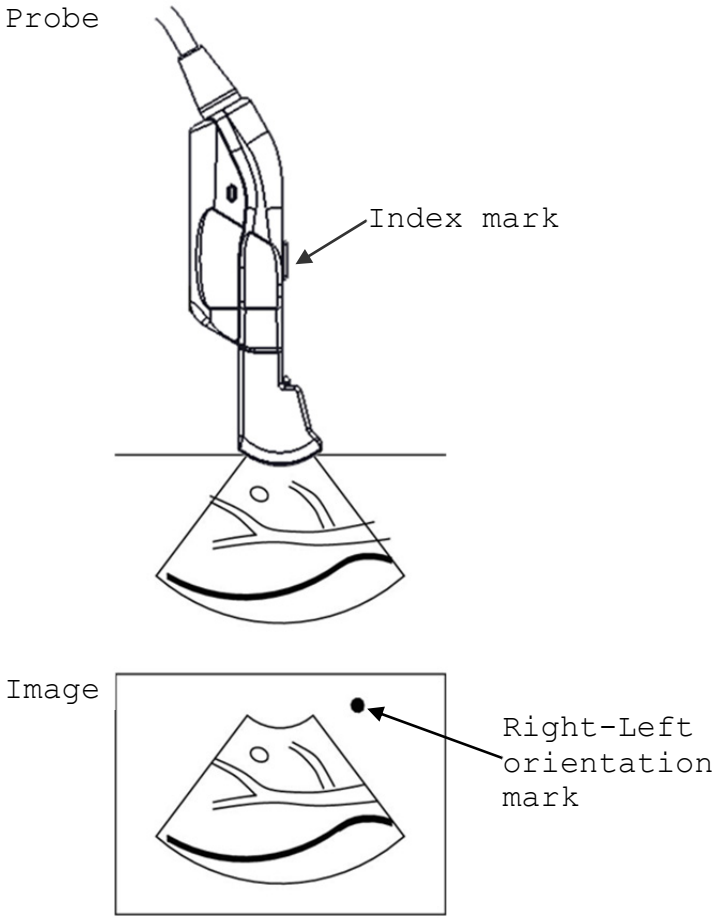


Fig. 4 Relationship between the directions of the probe and the Right-left orientation mark

5) Use a sterile probe cover to protect the probe. The probe cover should be allergy free material to avoid allergic reaction. Between the probe and the probe cover, acoustic coupling gel is required as a couplant.

6) Place the probe on the examination site and adjust the probe's position for a clear view of the desire image.

7) After using the probe, perform the reprocessing procedure in accordance with the procedure stated in "4. Reprocessing Procedure" every time immediately after completing the ultrasound examination.

8) Store the probe and the attachment in the environment indicated in "6. Maintenance and Safety Inspection".

⚠ CAUTION

- Do not use the probe if the image and the frequency do not match the probe. An incorrect acoustic output can result in burns or other injuries to the patient.
- Scan for the minimum length of time necessary for the diagnosis and at the lowest suitable output. There is the possibility that the patient's tissues could be affected. For details about the acoustic output, please refer to the operation manual of the ultrasound diagnostic instrument.

3.2 Attachment

Attach the attachment to the probe as indicated in Fig. 5. The attachment can be released from the probe by sliding the attachment as indicated in Fig. 6.

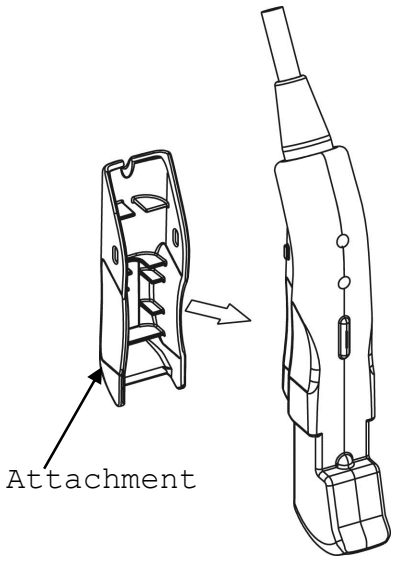


Fig. 5 How to attach the attachment

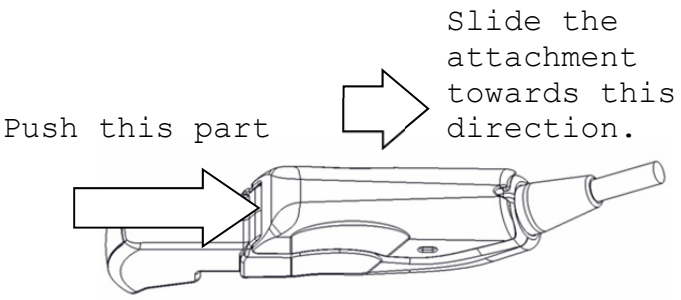


Fig. 6 How to release the attachment

The magnetic sensor enables Real-Time Virtual Sonography (RVS) when it is attached to the probe.

3.2.1 Attaching the Magnetic Sensor

The procedure of attaching the Magnetic sensor is as follows.

1) Attach the Magnetic sensor into the attachment with the correct direction as shown in Fig. 7.
2) Insert the hold of the attachment into the projected part of the probe.

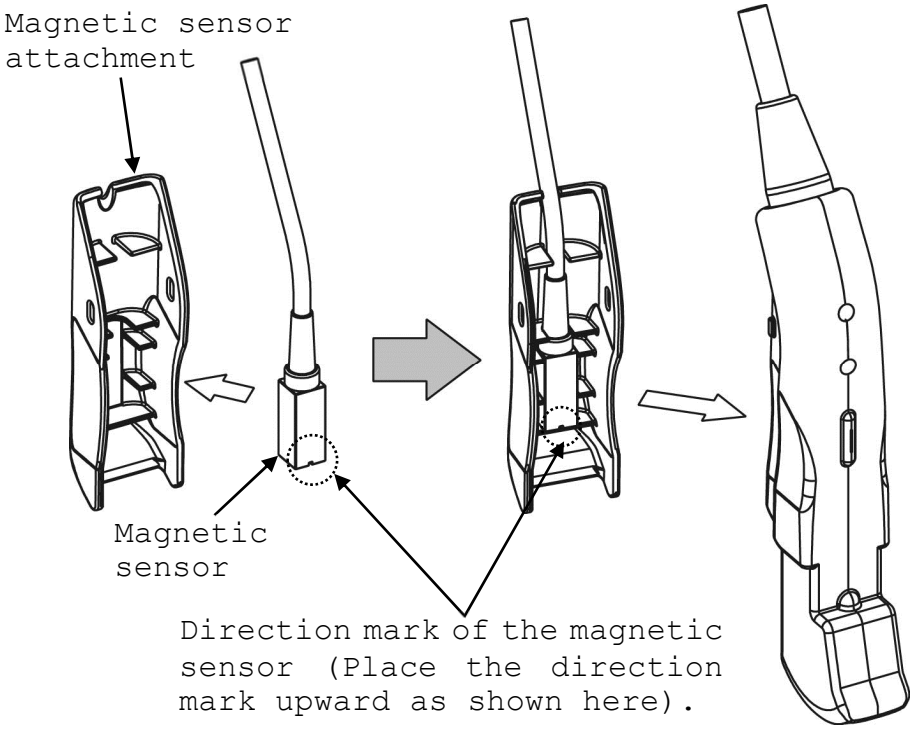


Fig. 7 How to attach the Magnetic Sensor Attachment

⚠ CAUTION

Never attach the Attachment to the probe in the incorrect direction, otherwise it may result in false diagnosis.

3.2.2 Removing the Magnetic Sensor

The procedure of releasing the Magnetic sensor from the probe is as follows.

1) Press the area of the attachment shown with the arrow toward the direction A, and then slide out the attachment toward the direction B as shown in Fig. 8.

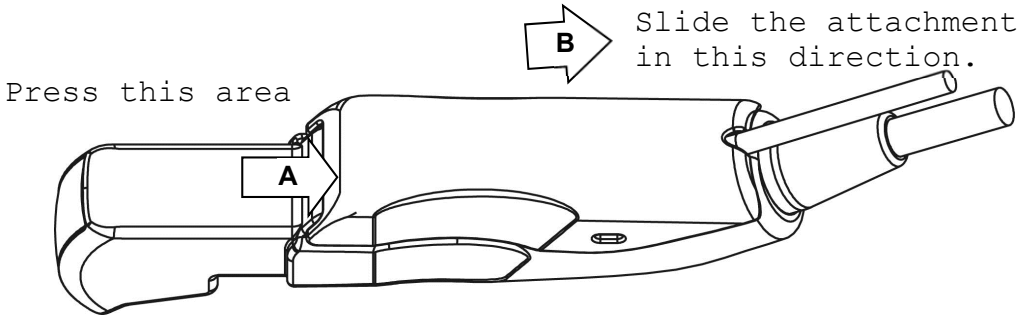


Fig. 8 How to release the attachment from the probe

2) Release the Magnetic sensor from the groove of the attachment as shown in Fig. 9.

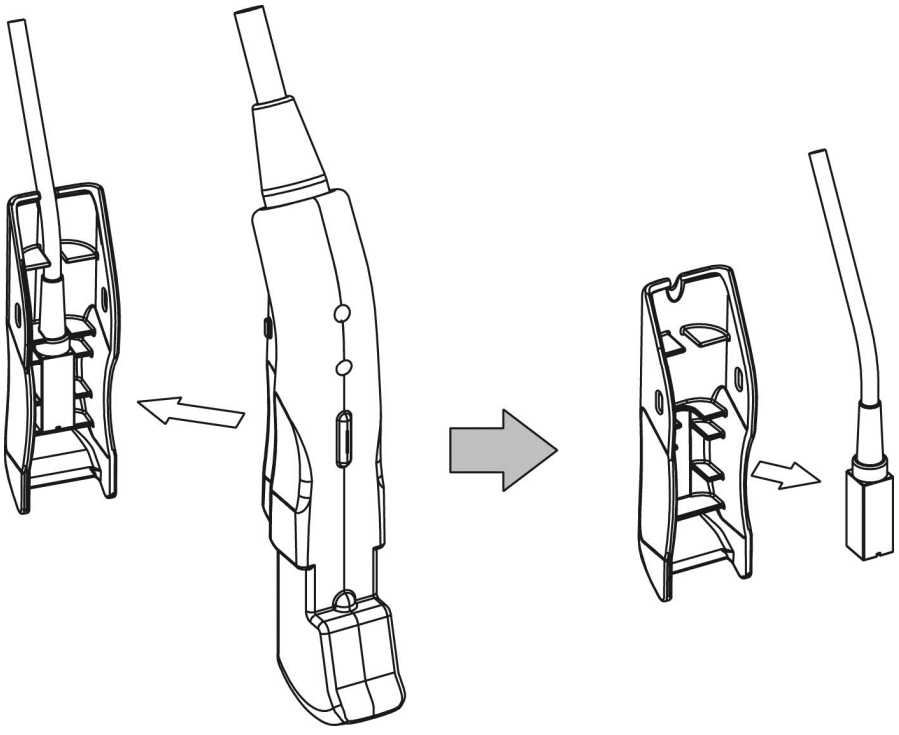


Fig. 9 How to release the Magnetic Sensor from the groove of the probe

⚠ CAUTION

Clean and sterilize the Magnetic sensor before the first use as it is not sterilized in the factory.

3.3 Needle Guide Bracket EZU-PA7C2

1) Confirm that the needle guide bracket is cleaned and disinfected, and the probe is cleaned and disinfected/ sterilized.
2) Fit the needle guide bracket to the probe following "3.3.1 Fitting the needle guide bracket to the probe". Never apply excessive force to attach the needle guide bracket to the wrong position. It may cause a hazard due to unstable biopsy.
3) Fit the CIV-Flex ™ cover to the probe following "3.3.2 Placing the probe and bracket into a transducer cover".
4) Attach the needle guide to the bracket following "3.3.3 Attaching the needle guide to the bracket".
5) Fit the needle insert corresponding to the gauge number of the needle to be used to the needle guide following "3.3.3 Attaching the needle guide to the bracket".
6) Confirm that the needle guide angle corresponds to the angle indicated on the monitor. The needle guide angle is engraved on bracket following "3.3.4 Setting the needle guide angle".
7) In the case of the CIVCO Ultra Pro II, when the needle is released quickly from probe, press the tab on the needle insert toward the bracket. Move bracket and needle guide away from the needle. (See Fig. 10)
8) After the use of the needle guide bracket, it should be cleaned and disinfected, then store it in an adequate place.

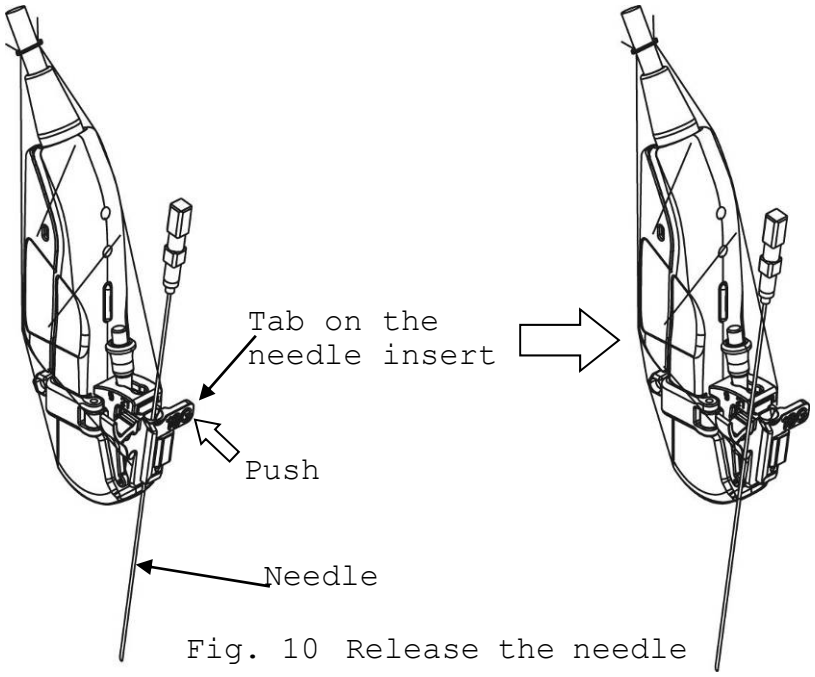


Fig. 10 Release the needle

In the case of the CIVCO Ultra Pro 3™, push the green quick release lever of the needle guide toward the bracket to open the needle insert, and then remove the needle.

For details of the removing procedure of the needle, refer to the Reference Guide each of the Ultra Pro II™ and Ultra Pro 3™.

⚠ CAUTION

1) Since the acoustic jelly accessory to the ultrasound diagnostic scanner is not a sterilized one, never use it.
2) In order to make the dead angle of the needle as short as possible, perform the biopsy operation with full display width. Regarding how to adjust the display width refer to the operating manual of the scanner.
3) Do not hold the needle cannula of the electrosurgical unit with metal tweezers, forceps, and the like.
   [Doing so may damage the insulation section of the needle cannula, and may cause a burn to a non-treated area.]

⚠WARNING

1) Warning in case of using probe covers which latex is contained to. The latex may cause such allergic reactions as itching, rubor, urticaria, swelling, fever, anhelation, wheezing, depression of blood pressure, shock and so on.
   For the patients suspected of latex allergy, do not use the latex-containing medical devices. If you observe any of above mentioned symptoms in your patient during the operation, stop the use of the latex-containing medical devices immediately and take an appropriate treatment to the patient.
2) The Ultra-Pro II™ or the Ultra-Pro3™ NEEDLE GUIDE/COVER KIT is disposable and must not be reused.
3) Sterilize/disinfect the probe and disinfect the needle guide bracket when a cover tears.
4) Confirm that the needle guide angle corresponds to the angle indicated on the monitor. The needle guide angle is engraved on bracket. Otherwise, the biopsy guide line becomes inconsistent with the inserting position of the biopsy needle.
5) When using the needle cannula of the electrosurgical unit while using the needle guide bracket as a guide, be careful not to damage the insulation coating of the needle cannula.
   [When inserting or removing the needle cannula into or from the needle guide, you may damage the insulation coating of the needle cannula, which may cause a burn to tissue contacting the exposed section of the insulation coating.]

3.3.1 Fitting the needle guide bracket to the probe

1) Insert the recess of needle guide bracket to the needle guide bracket mount part. (See Fig. 11)

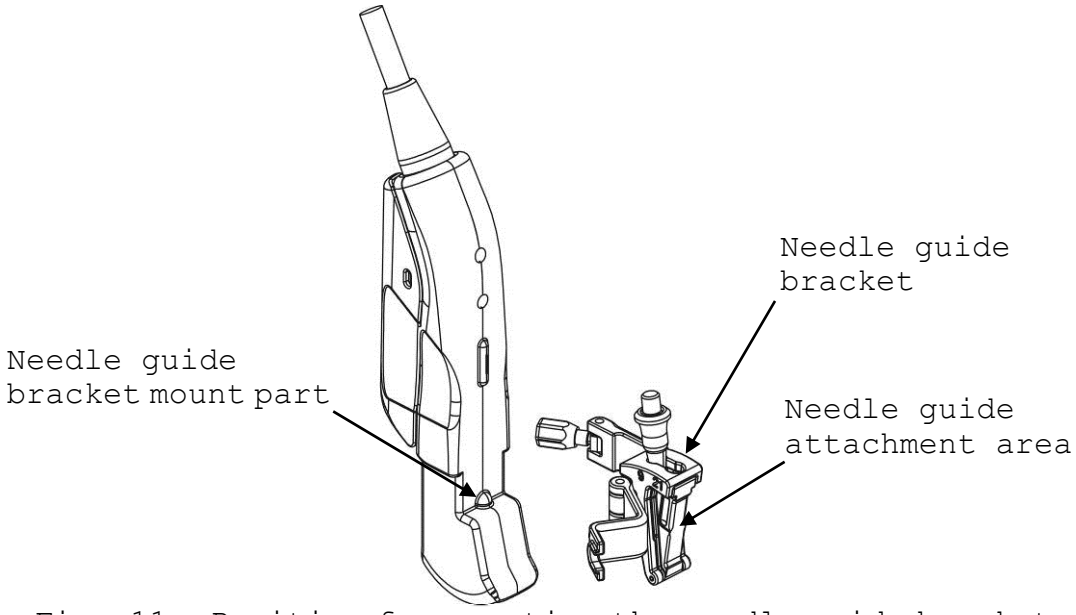


Fig. 11 Position for mounting the needle guide bracket

2) Fit the recess of the bracket to the thumbscrew 1 and tighten the thumbscrew 1. (See Fig. 12) At this time, be sure to attach the needle guide bracket so that the needle guide attachment area is positioned in the same direction as that of the needle guide bracket mount part side.

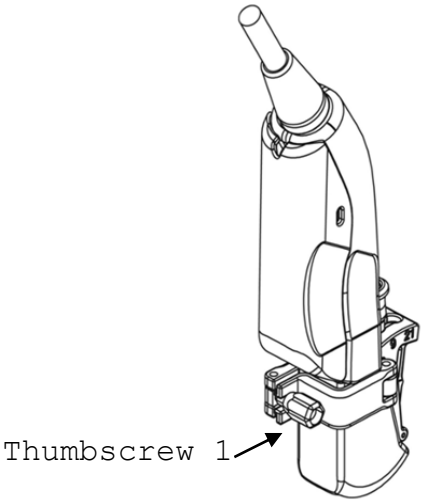


Fig. 12 Fitting the needle guide bracket

⚠CAUTION

Never attach the needle guide attachment area at the reverse side of the needle guide bracket mount part. Otherwise, the biopsy guide line becomes inconsistent with the inserting position of the biopsy needle.

3.3.2 Placing the probe and bracket into a transducer cover

1) Place an appropriate amount of gel inside the cover and/or on the Probe head. (See Fig. 13)

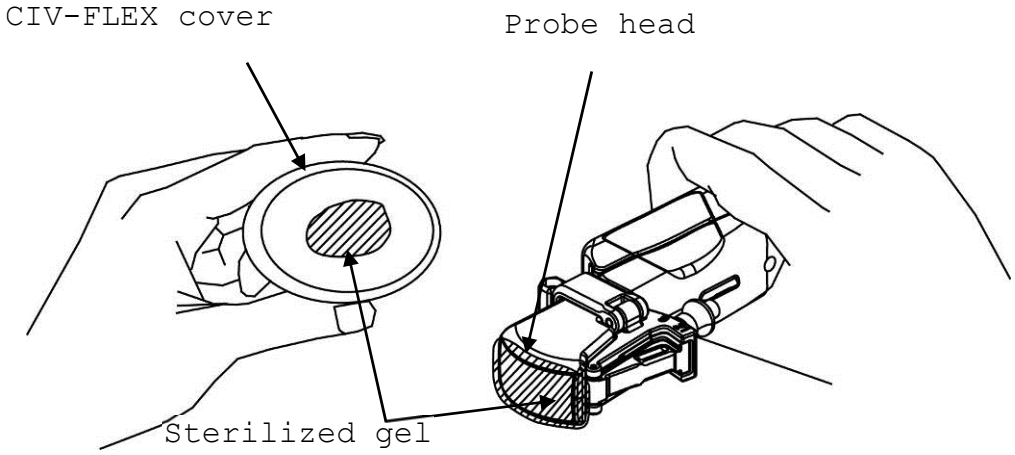


Fig. 13 Placing the gel

2) Insert the probe into the cover.

3) Pull the cover tightly over the probe face to remove wrinkles and air bubbles, taking care to avoid puncturing the cover.

4) Secure cover to the probe housing and cable strain relief with bands as needed.

5) Visually inspect the cover to ensure that there are no defects or holes. Do not uses cover if it has any holes.

⚠ CAUTION

1) Never use the acoustic gel that is enclosed in the main ultrasound system unit because it is not sterilized. Use only sterile acoustic gel that is enclosed in CIVCO Ultra-Pro II™, or Ultra-Pro 3™ Disposable Sterile Ultrasound Needle Guide/Cover Kit. If sterile acoustic gel is not enclosed in the Kit, please use any sterile acoustic gel.

2) Since the acoustic jelly accessory to the ultrasound diagnostic scanner is not a sterilized one, never use it.

3.3.3 Attaching the needle guide to the bracket (Example: In the case of CIVCO Ultra-Pro II™)

1) Attach the unlocked needle guide onto the needle guide attachment area of the bracket. (See Fig. 14)

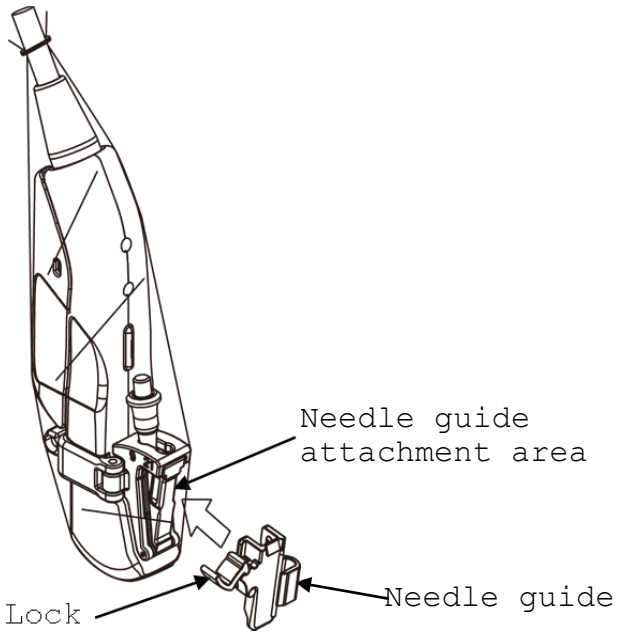


Fig. 14 Attaching the needle guide

2) Push the lock toward the bracket to secure the lock. Make sure the needle guide is firmly attached to the bracket. (See Fig. 15)

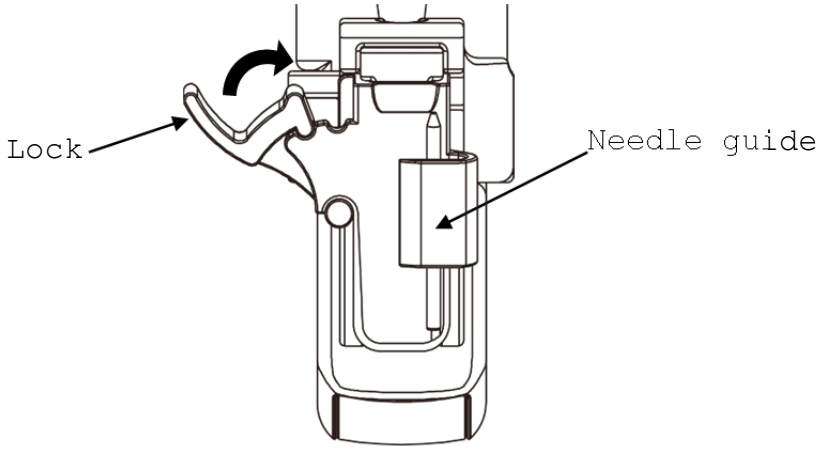


Fig. 15 Attaching the needle guide

3) Select a needle insert to correspond with the needle size intended to be used in the procedure.

4) Slide the needle insert into the needle guide by aligning the arrow tips. (See Fig. 16) Inspect the guide and cover assembly to ensure the needle path is clear of obstructions.

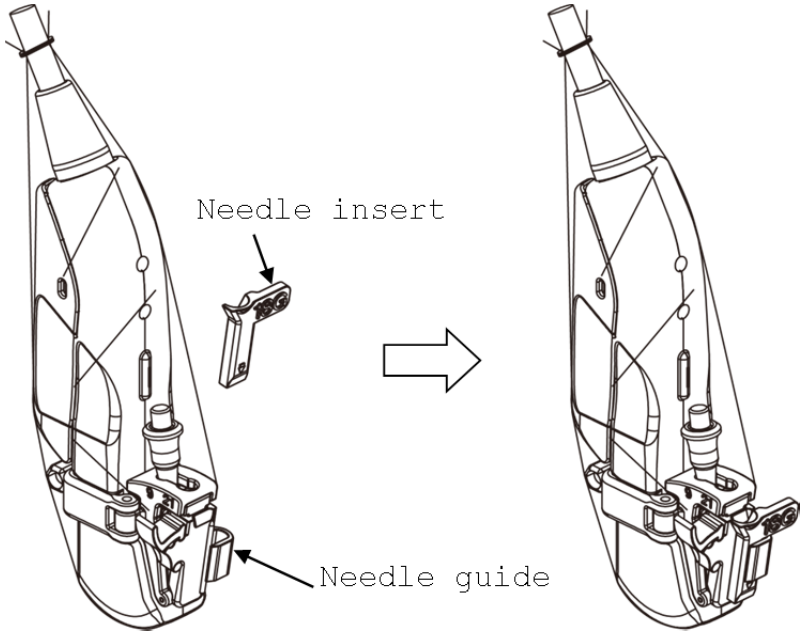


Fig. 16 Attaching the needle insert

⚠CAUTION

In case of bore a hole in the probe cover with a biopsy needle, perform the cleaning and sterilization of the Probe and the attachment, and perform the cleaning and high level disinfection of the needle guide bracket

3.3.4 Setting the needle guide angle

Pull the knob(①) and release it into the recess of appropriate angle of the bracket(②). Needle guide angles are engraved on the bracket. (See Fig. 17)

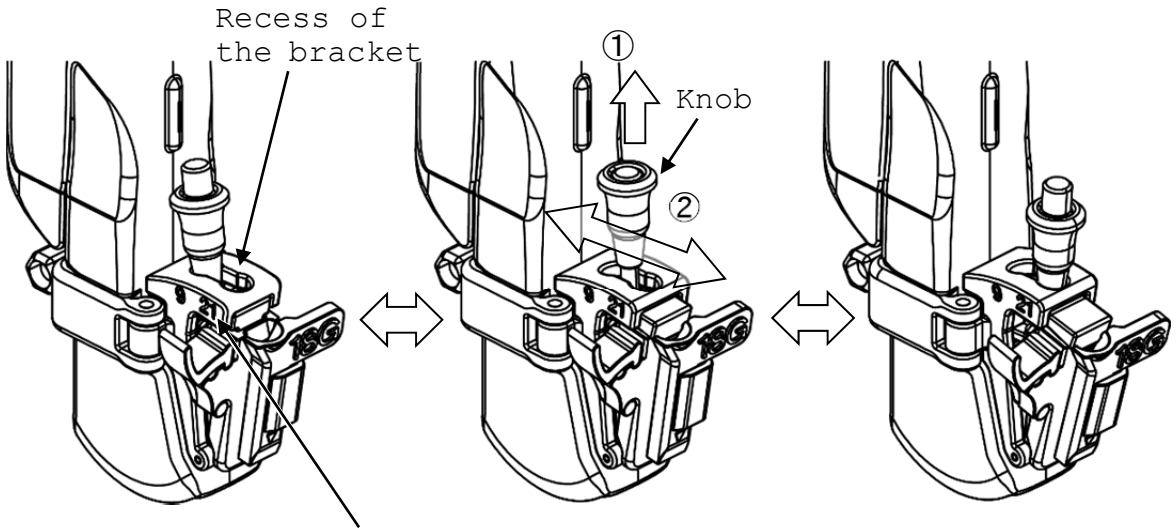


Fig. 17 Setting the needle guide angle

⚠ WARNING

Do not place the knob on any positions between recesses of the bracket. Otherwise, the needle guide angle will be unstable.

4. Reprocessing Procedure

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

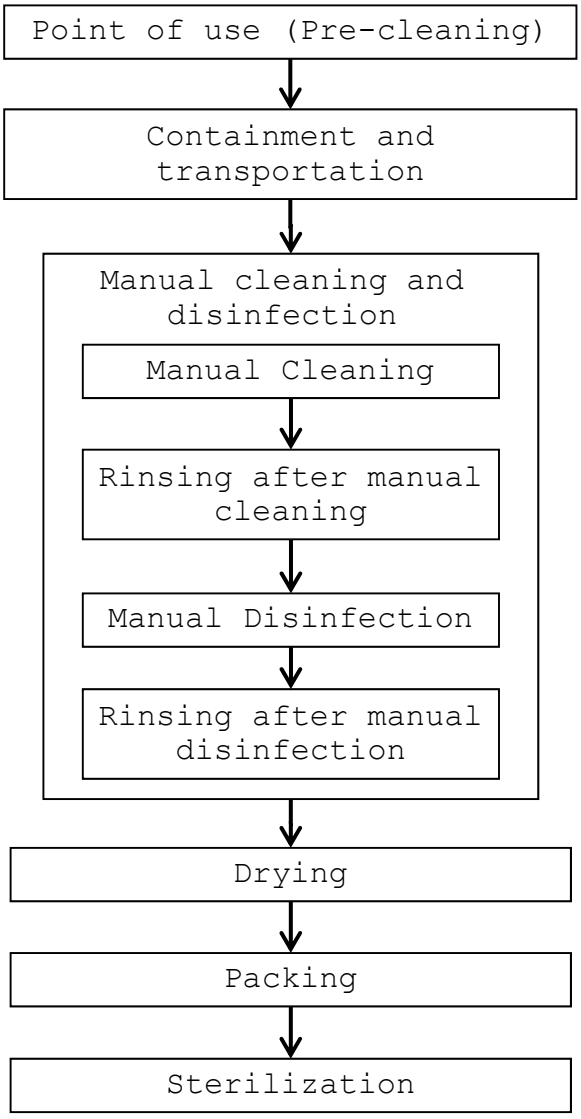
WARNINGS	- The probe is delivered unsterile. Prior to the first use, reprocess the probe. - Temperature should not exceed 60°C during reprocessing. - Probe connector is not water resistant.
Limitations on reprocessing	The probe is not completely submersible. The immersible part is shown in Fig.1. The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

Levels of reprocessing requirements:

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

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

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



4.1 Point of use (Pre-cleaning)

Point of use (Pre-cleaning)

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

A) C22P probe

1) Remove the protective cover.
2) Clean the probe of all patient's blood or fluid with running tap water until the surface of the probe looks visually clean.
3) Wipe the whole surface of the probe with gauze pad and remove superficial visible impurities.

B) Attachment

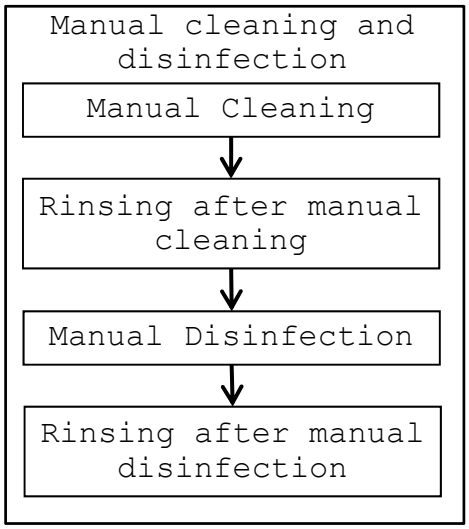
1) Remove the Attachment and the magnetic sensor from the probe.
2) Immerse the Attachment in sufficient amount of high quality tap water. Scrub it using soft cloth to remove all visible soil and from its surface.

4.2 Containment and transportation

Containment and transportation

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

4.3 Manual Cleaning and disinfection



Prepare following items before manual cleaning and disinfection:

a) Detergent: Cidezyme® (Johnson & Johnson, #2258) or another cleaning agent with approved material compatibility for this medical device.
b) Disinfectant: Cidex® OPA (Johnson & Johnson, # 20391) or another disinfectant with approved material compatibility for this medical device.
c) Two tanks, one for cleaning and one for disinfection - optional:
   1 additional tank for rinsing with deionized/tap water (sufficient size for immersion of the submergible part of the probe at full length)
d) Soft, fluff free cloth or single use towel
e) Personal protective equipment (gloves, water repellent protective skirt, face protection mask or protective glasses, see also instructions of the manufacturer for the detergent and the disinfectant)

Manual Cleaning:

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

A) C22P probe

1) The temperature of the detergent solution should be between 15-30 °C, concentration is 1.6%. Please note the minimum contact time of the detergent in the manufacturer's instruction. If a differing detergent is used, please also note the approved material compatibility for the medical device.
2) Immerse the immersible part of the probe without connector into the diluted detergent solution (see Figure 18). Wipe the immersible part of the probe under the surface of the detergent solution with a soft cloth to remove all visible soil. Be sure that all grooves of the probe are implemented during the cleaning process.
3) The immersible part of the probe should be left in the detergent solution according to the specified contact time of the detergent manufacturer.
4) Wipe the un-immergible parts of the probe with a soft cloth dipped with the detergent solution.
5) Rinse the probe with running tap water for 1 minute. (alternatively: immerse the immersible part of the probe in a tray filled with deionized water/tap water (see Fig. 18) for 5 min.)
6) Visually check the outer surface of the probe for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

B) Attachment

1) The temperature of the detergent solution should be between 15-30 °C, concentration is 1.6%. Please note the minimum contact time of the detergent in the manufacturer's instruction. If a differing detergent is used, please also note the approved material compatibility for the medical device.
2) Immerse the Attachment into the diluted detergent solution. Wipe it under the surface of the detergent solution with a soft cloth to remove all visible soil. Be sure that all grooves of the attachment are implemented during the cleaning process.
3) The Attachment should be left in the detergent solution according to the specified contact time of the detergent manufacturer.
4) Rinse the Attachment with running tap water for 1 minute. (alternatively: immerse it in a tray filled with deionized water/tap water (see Fig. 18) for 5 min.)
5) Visually check the outer surface of the Attachment for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

Manual disinfection:

A) C22P probe

1) Prepare the disinfectant solution in a tank with cold water (please follow the instructions of the disinfectant manufacturer regarding application, concentration, microbiological efficiency, service life and contact time).
2) Confirm the concentration of the disinfectant before immersing the probe. Although Cidex® OPA does not need to be diluted, it is recommended to use test strips to verify the concentration. The test strips can indicate whether or not the concentration is above the Minimum Effective Concentration (MEC). Please also note the expiration date of the test stripes. Temperature of disinfectant solution should be minimum 20 °C. The minimum contact time is 5 minutes. If a different disinfectant is used, follow the manufacturer's instructions. Please also consider the material compatibility for the medical device.
3) Immerse the immersible part of the probe into the disinfectant (see Fig. 18). Set a clock to insure the recommended contact time which is 5 minutes.
4) Rinse the immersible part of the probe with deionized water for 1 minute. (alternatively: immerse the immersible part of the probe in a tray filled with deionized water (see Fig.18) for 5 min.)
5) Visually check the outer surface of the probe for leavings of the disinfectant. If necessary, repeat the rinsing.

B) Attachment

1) Prepare the disinfectant solution as stated in the procedure for the probe.
2) Immerse the Attachment into the disinfectant (see Fig. 18). Set a clock to insure the recommended contact time which is 5 minutes.
3) Rinse the Attachment with deionized water for 1 minute. (alternatively: immerse it in a tray filled with deionized water (see Fig.18) for 5 min.)
4) Visually check the outer surface of the Attachment for leavings of the disinfectant. If necessary, repeat the rinsing.

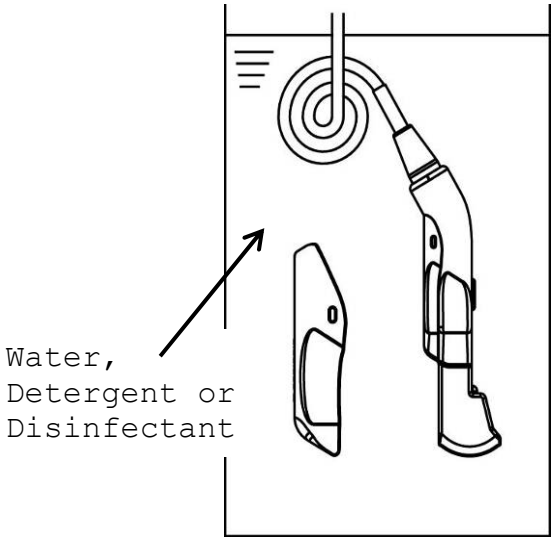


Fig. 18 Immersion of the probe and the Attachment.

4.4 Drying

Drying

1) Wipe the equipment with a single-use, fluff-free wipe or towel to remove moisture from the surface of the equipment.
2) Dry the equipment naturally in an ambient temperature between 15-30°C for a minimum of 4 hours. Alternatively the equipment can be dried using a drying heater at a temperature of less than 55 °C.

4.5 Inspection

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

4.6 Packaging

Packaging

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

Additionally the equipment can be placed on plastic mesh wires supplied for plasma sterilization and then packed as mentioned above.

The equipment can be packed in a simple or double packing.

Please note that the size of a sterile barrier should be large enough to be able to pack the equipment leaving sufficient space to seal it completely.

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

4.7 Sterilization

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

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

The sterilization method and operating conditions are as follows.

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

* STERRAD® systems are manufactured by "Johnson & Johnson"

⚠WARNING

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

The packaging procedure is as follows.

1) Put the probe into TYVEK pouch.

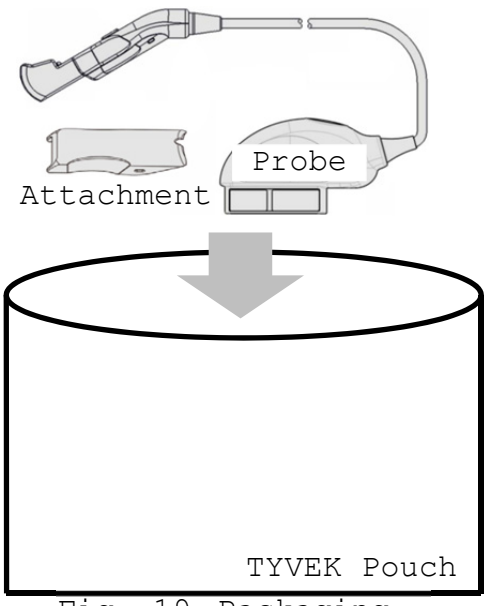


Fig. 19 Packaging in the pouch

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

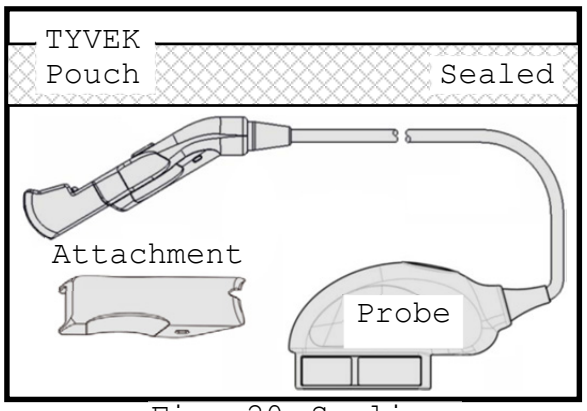


Fig. 20 Sealing

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

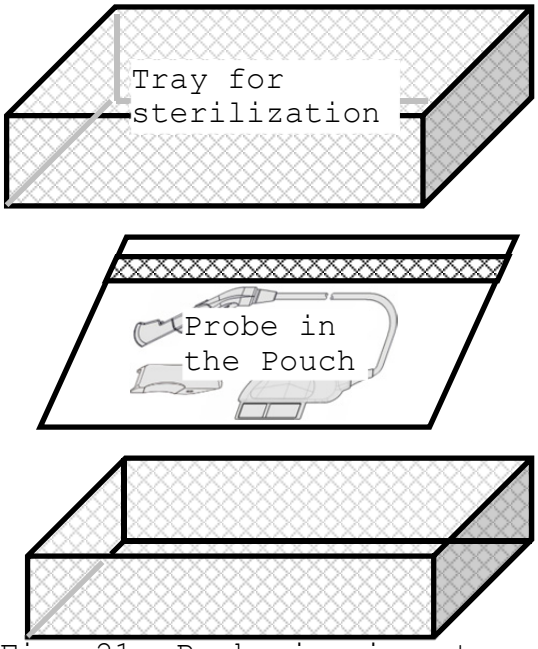


Fig. 21 Packaging in a tray

4.8 Storage

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

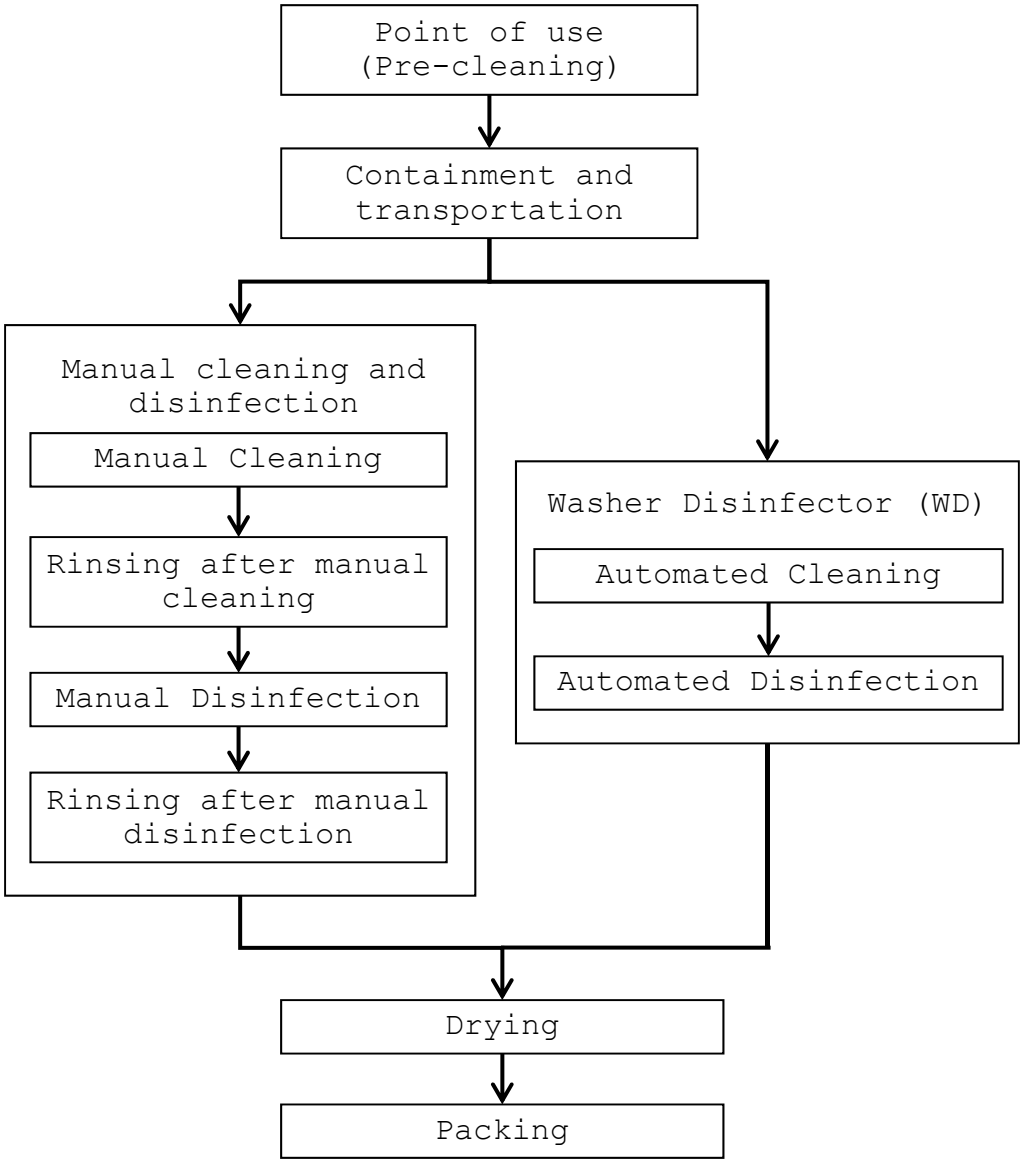
5. Cleaning and Disinfection of EZU-PA7C2

EZU-PA7C2 must be reprocessed after each use. Refer to the reprocessing instruction in this chapter.

WARNINGS	- EZU-PA7C2 is delivered unsterile. Prior to the first use, reprocess it. - The cavities and the spiral spring of the EZU-PA7C2 require particular attentions during all processes. The needle guide bracket must be manually pre-cleaned using ultrasound prior manual reprocessing as well as automated reprocessing and must be dismantled into single parts (shown in Figure 22).
Transportation before using	EZU-PA7C2 should be packed in a sterile pouch or container to transport from Central Sterile Supply Department (CSSD) to an operating room. Be careful not to damage the sterile pouch or container during transportation.

Levels of reprocessing requirements: Refer to the chapter 4.

The flowchart of the reprocessing process of EZU-PA7C2 is as follows.



5.1 Point of use (Pre-cleaning)

Point of use (Pre-cleaning)

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

1) Remove contaminated needle guide and probe cover from the probe with needle guide bracket and dispose them appropriately.
2) Remove the needle guide bracket from the probe.
3) Flush patient's blood or fluid by tap water from the needle guide bracket directly after use, until the surface looks visually clean
4) Immerse the needle guide bracket in sufficient amount of high quality tap water. Scrub it using soft cloth to remove all visible soil and from its surface.
5) Prepare following items before manual pre-cleaning of the puncture adapter using ultrasound:
   a) Ultrasound bath: i.e. Euronda, Eurosonic 4D
   b) Detergent: Cidezyme® (Johnson & Johnson, #2258) or another cleaning agent with approved material compatibility for this medical device
   c) Personal protective equipment (gloves, water repellent protective skirt, face protection mask or protective glasses, see also instructions of the manufacturer for the detergent and the disinfectant)

Pre-Cleaning:

1) Fill the ultrasound bath with the detergent. The temperature of the detergent solution should be between 15-30 °C, concentration is 1.6%. If a different detergent is used, follow the manufacturer's instructions. Please also consider the material compatibility for the medical device.
2) Immerge the needle guide bracket into the diluted detergent in the ultrasound bath and switch on the ultrasound bath for a time of 20 minutes at 25°C.
3) Remove the needle guide bracket and continue with the manual or automated cleaning and disinfection.

5.2 Containment and transportation

Containment and transportation

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

5.3 Manual Cleaning and disinfection

Prepare following items before manual cleaning and disinfection:

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

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

c) Cleaning brushes if applicable

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

e) Soft, fluff free cloth or single use towel

f) 50 ml syringe

g) Personal protective equipment (gloves, water repellent protective skirt, face protection mask or protective glasses, see also instructions of the manufacturer for the detergent and the disinfectant)

Manual Cleaning:

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

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

2) Separate the needle guide bracket to thumbscrew #1, thumbscrew #2, spring, knob, and the body of the needle guide bracket (see Figure 22).

3) Immerse all parts of the needle guide bracket into the diluted detergent solution.

4) Using a syringe flush the cavity and the spiral spring of the needle guide bracket 5 times under the surface of the detergent solution with 50 ml diluted detergent. Brush the whole length of the cavity and the spiral spring of the needle guide bracket at least 5 times by using an applicable brush.

5) Wipe the parts of the needle guide bracket under the surface of the detergent solution with a single-use fluff free soft cloth to remove all visible soil. Be sure that all grooves of the needle guide bracket are implemented during the cleaning process.

6) All parts of the needle guide bracket should be left in the detergent solution according to the specified contact time of the detergent manufacturer.

7) Rinse all parts of the needle guide bracket with running tap water for 1 minute. (alternatively: immerse them in a tray filled with deionized water/tap water (see Fig. 22) for 5 min.)

8) Visually check the outer surface of all parts of the needle guide bracket for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

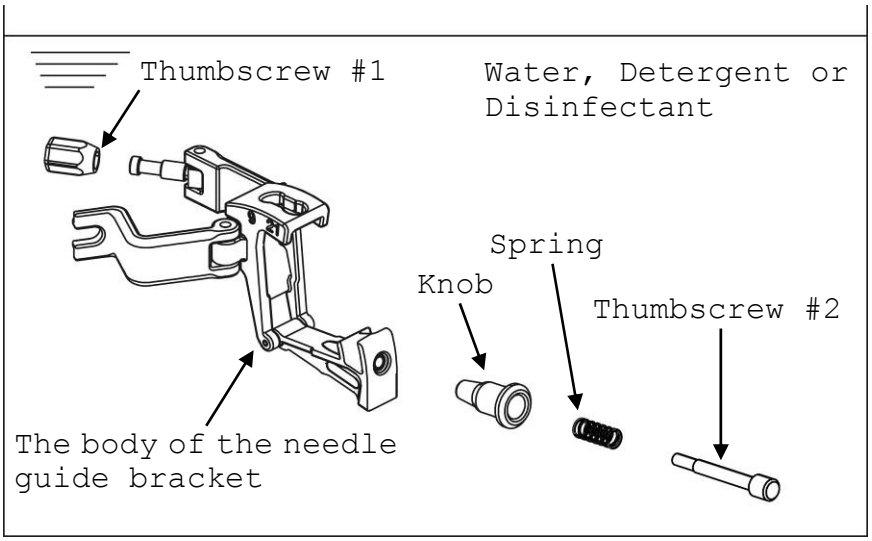


Fig. 22 Immersion of the Needle Guide Bracket

Manual disinfection:

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

2) Immerse all parts of the needle guide bracket into the disinfectant (see Fig. 22). Rinse the cavity of the needle guide bracket with 50 ml disinfectant solution. Repeat this 4 times. Set a clock to insure the recommended contact time which is 5 minutes.

3) Rinse all parts of the needle guide bracket with deionized water for 1 minute. (alternatively: immerse them in a tray filled with deionized water (see Fig. 22) for 5 min.)

4) Visually check the outer surface of all parts of the needle guide bracket for leavings of the disinfectant. If necessary, repeat the rinsing.

5.4 Automated cleaning and disinfection

The following items must be provided prior to automated cleaning and disinfection:

a) Washer disinfector: according to DIN EN ISO 15883 with chemo-thermal program (temperature: max. 60°C)

b) Detergent: Korsolex® Endo-Cleaner (Bode Chemie; #972020) or another cleaning agent with approved material compatibility for this medical device

c) Disinfectant: Korsolex® Endo-Disinfectant (Bode Chemie; #972030) or another disinfectant with approved material compatibility for this medical device

d) Washer disinfector accessories
basket for holding the needle guide bracket
basket with lid for holding the dismantled small parts (screws, spring) of the needle guide bracket

1) The parameter of the cleaning and disinfection of the device are as follows:

Program step	**water (40 l)**	**Dosage (ml/l)**	**Temp. (°C)**	**time (min)**
Pre- Rinse	Cold water			5
Cleaning	Deionized water	5 (0,5 %)	50	10
Rinse	Deionized water			1
Disinfection	Deionized water	10 (1 %)	55	5
Rinse	Deionized water			1
Rinse	Deionized water		55	1
Drying			55	15

Table 2: Parameters for automated process

2) Place the pre-cleaned and dismantled needle guide bracket and the dismantled parts (srews, spring) into the basket. Small parts must be placed in a strainer basket with lid.
3) After closing the door, start the chemo-thermal program.
4) After end of the program, open the door.
5) Remove the dismantled needle guide bracket and check whether it is dry. If not, proceed as described under drying.

5.5 Drying

Drying

1) Wipe all parts of the needle guide bracket with a single-use, fluff-free wipe or towel to remove moisture from the surface of them.
2) Dry all parts of the needle guide bracket naturally in an ambient temperature between 15-30°C for a minimum of 4 hours. Alternatively they can be dried using a drying heater at a temperature of less than 55°C.

5.6 Packaging

Packing the device into the sterile bag is recommended until using it for keeping cleaned and disinfected condition.

5.7 Assembly and Inspection

Assemble the needle guide bracket and inspect it for any damage such as crack, scratch or deformation. Do not use it if any damage is found.

5.8 Storage

Store the equipment in a cool, dustproof and dark space to avoid high temperature, humidity and direct sunlight.

⚠WARNING

Do not perform any sterilization procedure to the needle guide bracket. The needle guide bracket is not applied to any sterilization procedure. If sterilization procedure is performed to it, it may suffer serious damage and become unusable.

6. Maintenance and Safety Inspection

1) After using the probe and the attachment, they should be cleaned and disinfected or sterilized according to "4. Reprocessing Procedure", then store them in a cool and dark place avoid high temperature and humidity, direct sunlight.
2) After using the Needle guide bracket, it should be cleaned and high level disinfected according to "4. Reprocessing Procedure", then store it in a cool and dark place avoid high temperature and humidity, direct sunlight.
3) Visually inspect the surface of the probe head, housing, cable connector and the attachment for any crack, scratch or denaturalization. If you find any damage, do not use the probe and contact a service support immediately.
4) Visually inspect the surface of the Needle guide bracket for any crack, deformation or denaturalization. If you find any damage, do not use it and contact a service support immediately.

7. Safety Precautions

⚠WARNING

- Never use the probe if the probe head, housing or cable are cracked or damaged.
- When use this Probe (C22P) for biopsy purpose, use Needle Guide Bracket EZU-PA7C2 (Option) certainly.
- Do not attempt to disassemble, modify, or repair the probe. Electric shock or other unforeseen accidents could result.
- Wear medical gloves during examination. Conducting examinations with the bare hands can expose the operator to a risk of infection.
- Do not use the probe fallen on to floor. Otherwise, there is a risk of infection. Stop the operation and perform the inspection, cleaning, and disinfection or sterilization according to section 2 "Inspection before Use" and section 4 “Reprocessing Procedure".
- When using ultrasound contrast agent, follow the supplied documentation. Unexpected accidents could result. Check the state of the patient and take appropriate precautions to avoid side effects.
- During a biopsy, use sterilized physiological saline for the acoustic medium. Using an unsterilized ultrasound medium can cause an infection on the patient.
- For details about the reuse and disposal of puncturing needles, follow the instructions in the documentation supplied with the puncturing needles. Reuse of puncturing needles that are not reusable or improper disposal could result in an infection.

⚠ CAUTION

- By examination of an early pregnancy the exposure time shall be as short as possible. Start examination with acoustic output power set to L (Low).
- The probe connector is not waterproof. Do not allow liquid to contact the connector.
- Do not drop, hit or bend the probe.
- Use only water, detergents and disinfectants in the suppliers list.
- Under sterile condition, use appropriate protection for probe and cable. Some Latex material may create allergic reactions.
- The probe and the attachment are not delivered disinfected or sterilized.
- The acoustic lens of the probe is manufactured very thin and delicate to get the high resolution.
  Therefore, in case of wiping out the ultrasound jelly or cleaning the surface of the acoustic lens, please use the soft cloth or tissue paper and handle with care.
- Do not use this probe with other equipment except for those specifically approved in the manual. Use with unapproved equipment can result in an electric shock, burn, or other injury to the patient or operator and damage to the probe and the other equipment.
- Do not wash, disinfect or sterilize using procedures other than those specified in this manual. Infection could result due to incomplete washing disinfection or sterilization. It can also result in damage to the probe or reduced performance.

8. Specifications

8.1 Probe

Type:	C22P Probe
Acoustic working Frequency:	3.0MHz
Technology:	Convex Array Probe
Dimensions:	See Fig. 23 and Fig. 24.
Weight:	Approx. 0.70kg (Including cable and connector)
Probe materials:	Biocompatible allergy free components
Acoustic output:	According to IEC60601-2-37 (See Main Unit manual)
Applicable systems:	Depending on production and upgrade status for detailed information, contact a service support.
Classification:	MDD classification IIa.
Cleaning:	Applicable detergents are listed in the supplier list
Disinfection:	Applicable disinfectants are listed in the suppliers list
Sterilization:	ETO gas sterilization Plasma sterilization

Operating conditions:

Ambient temperature:	+10 - +40°C
Contact surface temperature:	max. 42°C (Temperature of examinee)
Relative humidity:	30-75% (subject to no condensation)

Storage/Transportation conditions:

Temperature:	-10 - +50°C
Relative humidity:	10-90% (subject to no condensation)

8.2 Suppliers List of the Probe

The products listed below are seriously tested and approved for use with C22P.

Product name	manufacturer	purpose
Cidezyme®	Johnson & Johnson	Enzymatic detergent
STERANIOS 2%	ANIOS	Disinfectant
ANIOXYDE1000	ANIOS	Disinfectant
CIDEX	Johnson & Johnson	Disinfectant
CIDEX® plus™ 28	Johnson & Johnson	Disinfectant
CIDEX® OPA	Johnson & Johnson	Disinfectant
HYAMINE SOLUTION	RICCA CHEMICAL COMPANY	Disinfectant
STERIHYDE®	Maruishi Pharmaceutical	Disinfectant/ sterilize
WAVICIDE-01	Mediacal Chemical Corp	Disinfectant/ sterilize

Please contact your local distributor for a current version of the "Disinfectant/Sterilization Method Compatibility for Ultrasound Probe and Accessory List

8.3 Needle Guide Bracket EZU-PA7C2

Dimensions: See Fig. 25 and Fig. 26

Applicable probe: C22P Probe

Needle angle: 9 and 21 degree

8.4 Suppliers list of the Needle Guide Bracket EZU-PA7C2

Product name	Manufacturer	Purpose
GENERAL PURPOSE Ultra-Pro II™ DISPOSABLE STERILE ULTRASOUND NEEDLE GUIDE/COVER KIT (610-579 or 610-608)	CIVCO MEDICAL INSTRUMENTS	Needle Guide and Cover
GENERAL PURPOSE Ultra-Pro 3™ DISPOSABLE STERILE ULTRASOUND NEEDLE GUIDE/COVER KIT (610-901)	CIVCO MEDICAL INSTRUMENTS	Needle Guide and Cover
Cidezyme™	Johnson & Johnson	Enzymatic detergent
Cidex OPA™	Johnson & Johnson	Disinfectant
Cidex Plus™ 28day solution	Johnson & Johnson	Disinfectant
Cidex™	Johnson & Johnson	Disinfectant

9. Disposal of the probe

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

⚠ CAUTION

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

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

Waste Electrical and Electronic Equipment (WEEE) Directive

The illustration on the right is required by the EU WEEE Directive to appear on all electrical and electronic equipment.
For proper disposal of this product in an EU nation, contact an EU office or agency and observe appropriate local and national regulations and laws.

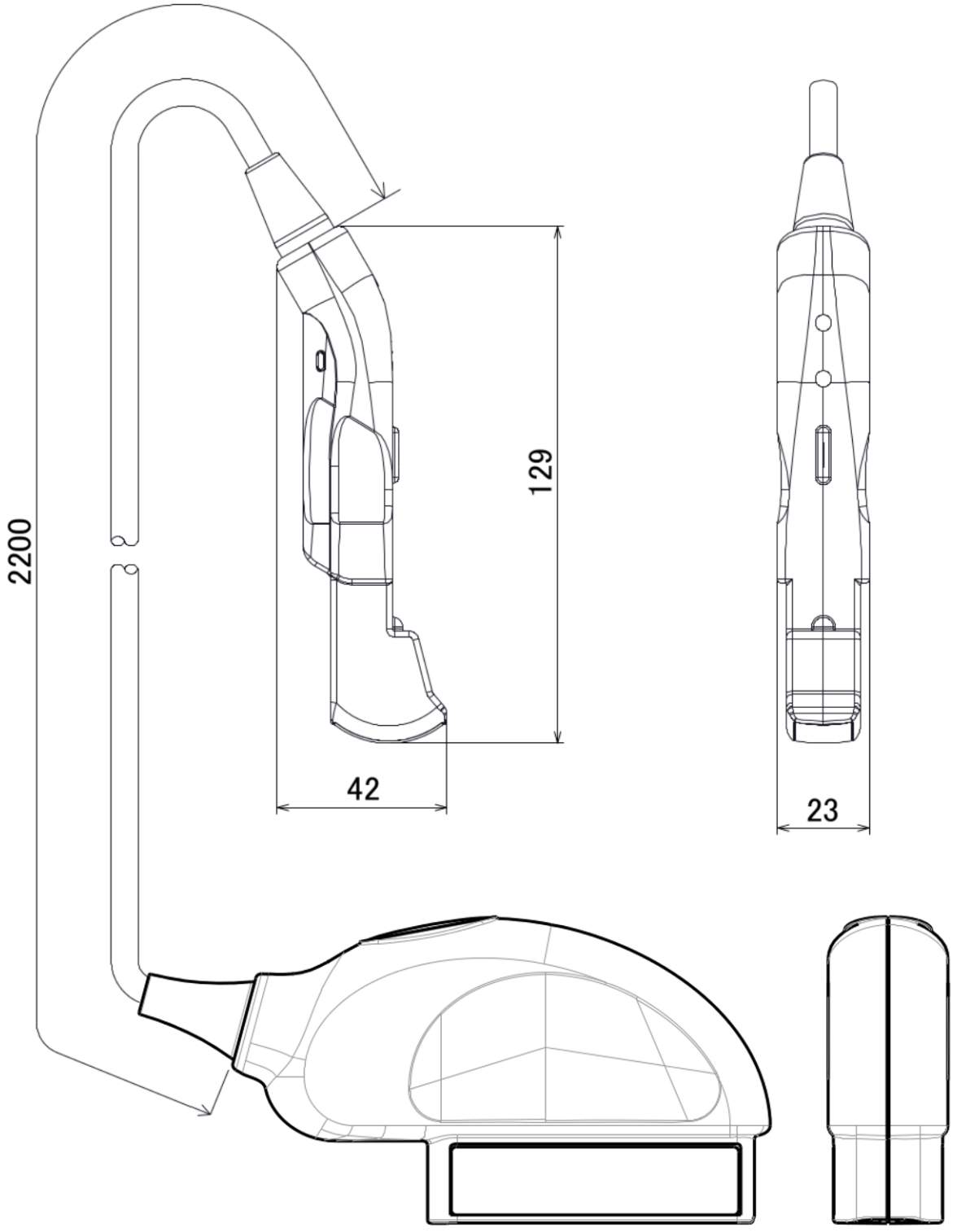
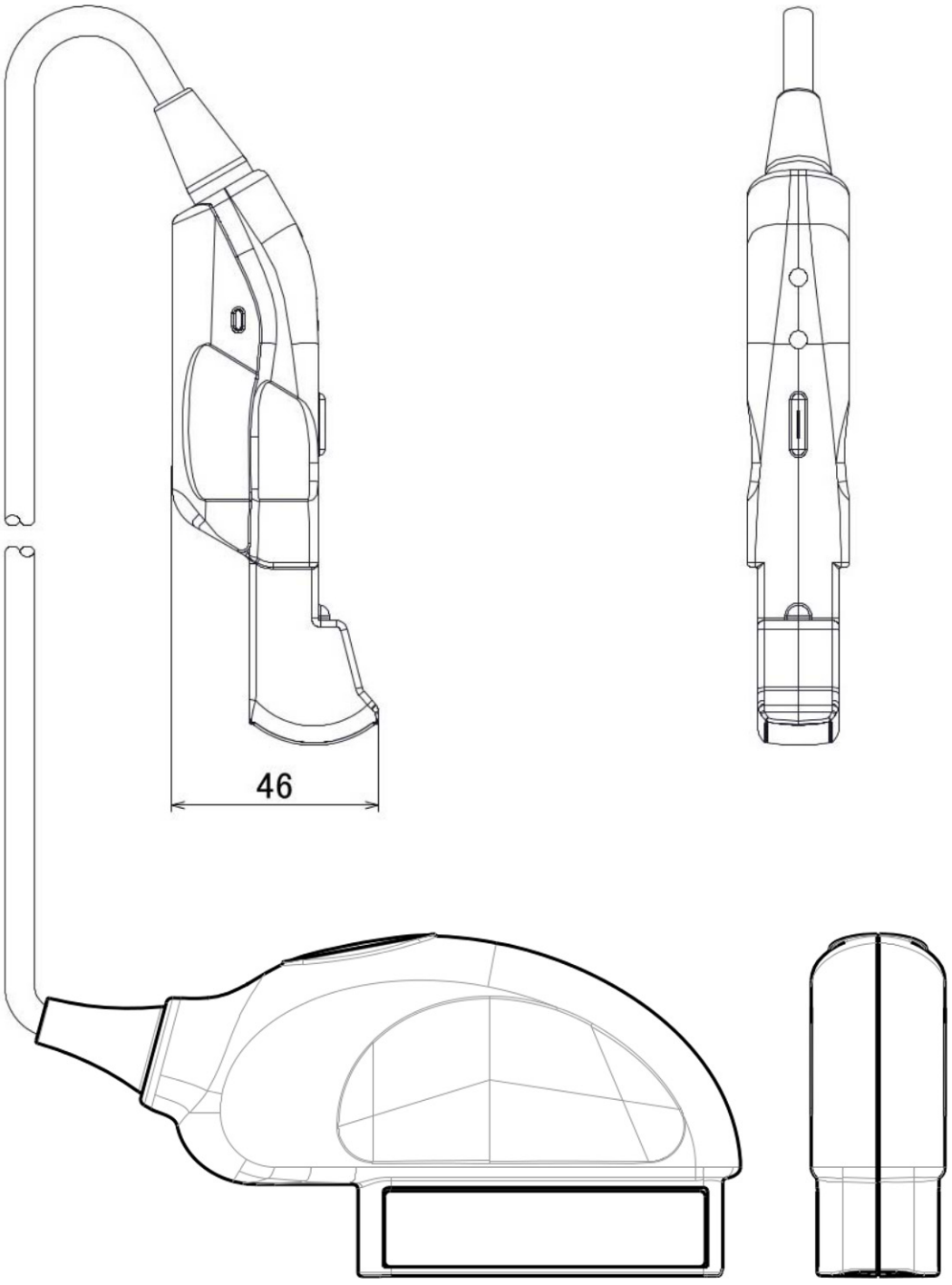


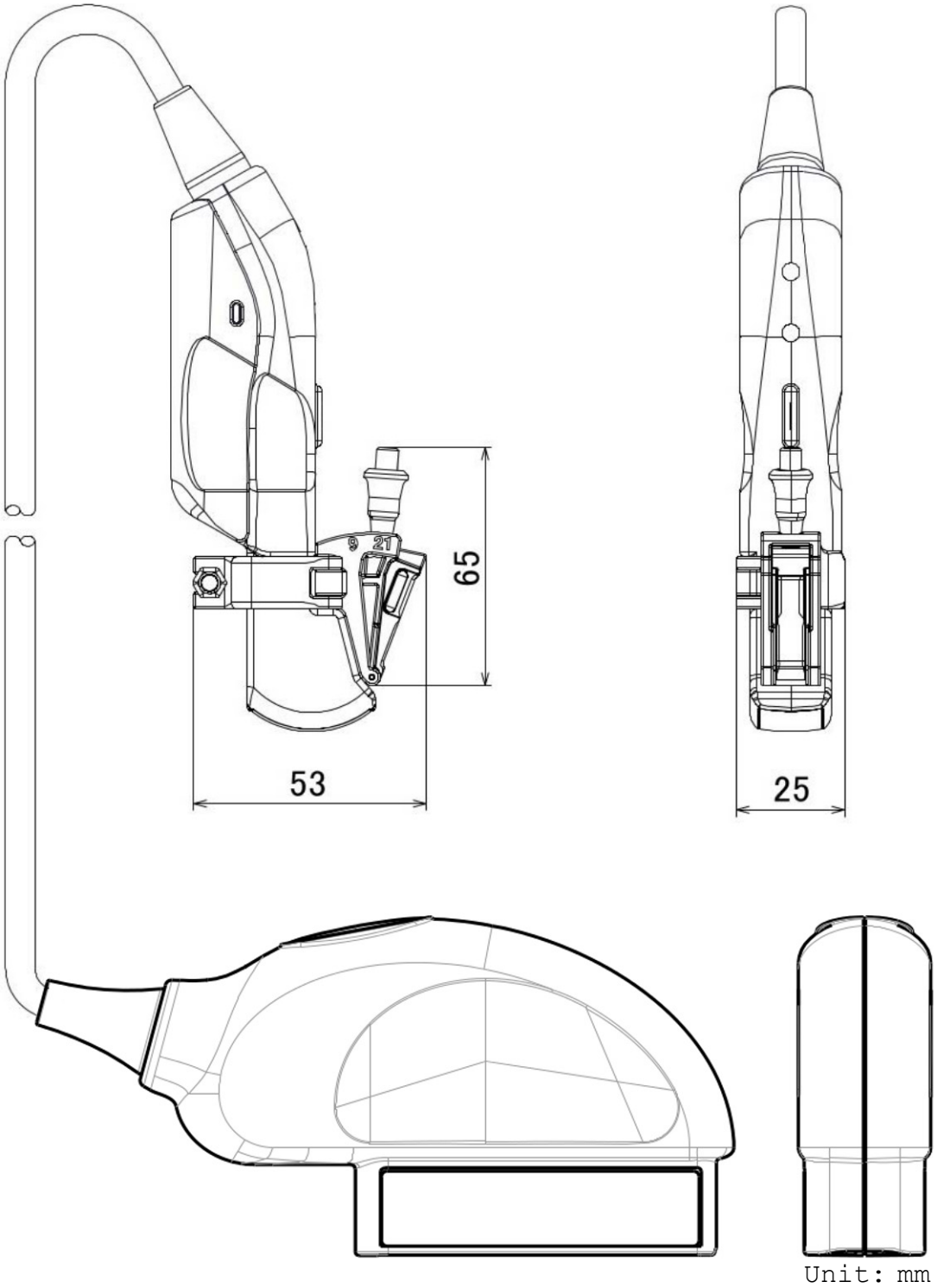
Fig. 23 Dimensions

Unit: mm



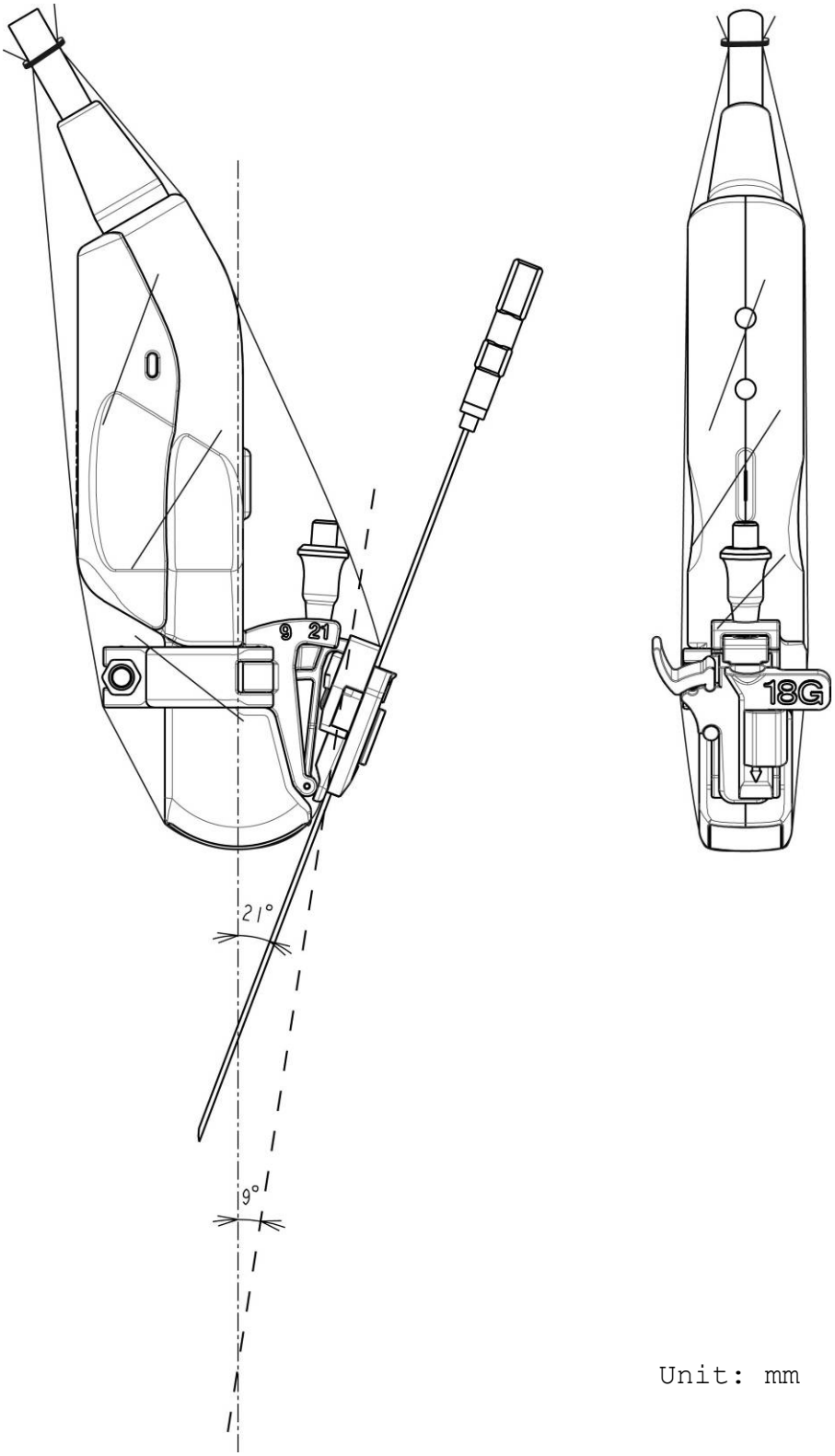
Unit: mm

Fig. 24 External view (with the attachment)



Unit: mm

Fig. 25 Dimensions (with the Needle Guide Bracket)



Unit: mm

Fig. 26 External view (with Ultra-Pro II Needle Guide / cover kit)