HITACHI
Inspire the Next

C22P Probe

INSTRUCTION MANUAL
--- For USA ---

Hitachi, Ltd.
Tokyo, Japan

Q1E-EP1458-2

DM 120926 v2

CONTENTS

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 5.
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.

1. Foreword

Before using the probe, carefully read this instruction manual for correct and safe handling of the probe as well as for making the most of the performances of the probe and the ultrasound scanner with which the probe is to be used.

Notes to Users
To ensure safe operation, it is essential that you fully understand the function, operating and maintenance instructions by thoroughly reading and understanding this manual and the manuals that accompany probes and accessories before operating this equipment, paying particular attention to all warnings, cautions, and notes incorporated herein. Please contact a service support if you have any questions concerning the operation of equipment.
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.

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

2. General caution

For safe use of the ultrasound scanner and probe, it is advisable to strictly observe the following:

⚠WARNING

1) Never use the probe for following regions.
   a) Direct contact to the heart.
   b) Biopsy to the heart.
   c) Direct contact to the eye.
2) When use this Probe (C22P) for biopsy purpose, use Needle Guide Bracket EZU-PA7C2 (Option) or Puncture Adapter MP-2824* certainly.

*Puncture Adapter MP-2824: Hitachi

⚠CAUTION

1) Federal law restricts this device to use by or on the order of a physician.
2) Be sure to read and observe the "General Cautions in Operation" stated in the operation manual for the ultrasound scanner with which the probe is to be used.
3) The probe and ultrasound scanner with which it is used should never be operated in an environment at a higher or lower temperature, under a higher or lower pressure and a higher humidity, than the specified operating ambient conditions. (Also see the paragraph "10. Specifications".)
4) Never try to remodel the probe and ultrasound scanner; if they are remodeled, a fault will possibly be caused.
5) Do not use chemicals or organic solvents such as thinner for wiping the probe. (See the paragraph "11. Supplier's List".)
6) Do not hit or drop the probe because the inside of the probe head is easily broken by mechanical shocks.
7) Keep the probe head off substances containing fatty acid (hydrocarbon of methane series, paraffin). Because it soaks into the inside of the probe head through the surface of the probe head and cause a fault.
8) If the ultrasound scanner and probe malfunction, contact our service personnel.
9) The use of a sterile probe sheath is recommended with this probe.
10) Use only sterilized acoustic gel during examinations in which sterile techniques are used.

NOTE: 1) The warranty period of the probes is one year from their delivery to the user. If they become faulty within this period and it is evident that Hitachi is responsible for the fault, they will be repaired or replaced with normal ones free of charge.

2) This warranty does not cover accidental damage on your site or improper handling, such as wear, extreme temperature, damages caused by chemical acids and solvents.

⚠WARNING

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA is now advising health-care professionals to screen their latex-sensitive patients, and be prepared to treat allergic reactions promptly. Please read and become familiar with the FDA Medical Alert report of March 29, 1991, titled, "Allergic Reactions to Latex-Containing Medical Devices", reprinted on the following pages.
In certain applications, the use of a protective sheath is recommended. Because of the possibility of latex-sensitive patients, Hitachi and HAMA are now recommending the use of non-latex covers. Specifically, we are recommending that the end user utilize the following devices:

Device: CIVCO PRO/Covers™
Manufacturer: CIVCO Medical Instruments Company, Inc.

We recommend that the end user contact CIVCO directly for obtaining sizing and pricing information, samples, and local distribution information.

FDA

Medical Alert

March 29, 1991
MDA91-1

Lenore Gelb
(301) 443-3220

Allergic Reactions to Latex-Containing Medical Devices

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), FDA is advising health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly. Patient reactions to latex have ranged from contact urticaria to systemic anaphylaxis. Latex is a component of many medical devices, including surgical and examination gloves, catheters, intubation tubes, anesthesia masks, and dental dams.

Reports to FDA of allergic reactions to latex-containing medical devices have increased lately. One brand of latex-cuffed enema tips was recently recalled after several patients died as a result of anaphylactoid reactions during barium enema procedures. More reports of latex sensitivity have also been found in the medical literature. Repeated exposure to latex both in medical devices and in other consumer products may be part of the reason that the prevalence of latex sensitivity appears to be increasing. For example, it has been reported that 6% to 7% of surgical personnel and 18% to 40% of spina bifida patients are latex-sensitive.

Proteins in the latex itself appear to be the primary source of the allergic reactions. Although it is not now known how much protein is likely to cause severe reactions, FDA is working with manufacturers of latex-containing medical devices to make protein levels in their products as low as possible.

FOOD AND DRUG ADMINISTRATION
U.S. Department of Health and Human Services
Public Health Service
5600 Fishers Lane, Rockville, Md. 20857

FDA's recommendations to health professionals in regard to this problem are:

• When taking general histories of all patients, include questions about latex sensitivity. For surgical and radiology patients, spina bifida patients, and health-care workers, this recommendation is especially important. Questions about itching, rash or wheezing after wearing latex gloves or inflating a toy balloon may be useful. Patients with positive histories should have their charts flagged.

• If latex sensitivity is suspected, consider using devices made with alternative materials, such as plastic. For example, a health professional could wear a non-latex glove over the latex glove if the patient is sensitive. If both the health professional and patient are sensitive, a latex middle glove could be used. (Latex gloves labeled "hypoallergenic" may not always prevent adverse reactions.)

• Whenever latex-containing medical devices are used, especially when the latex comes in contact with mucous membranes, be alert to the possibility of an allergic reaction.

• If an allergic reaction does occur and latex is suspected, advise the patient of a possible latex sensitivity and consider an immunologic evaluation.

• Advise patients to tell health professionals and emergency personnel about any known latex sensitivity before undergoing medical procedures. Consider advising patients with severe latex sensitivity to wear a medical identification bracelet.

FDA is asking health professionals to report incidents of adverse reactions to latex or other materials used in medical devices. (See the October 1990 *FDA Drug Bulletin*.) To report an incident, call the FDA Problem Reporting Program, operated through the U.S. Pharmacopeia toll-free number: 800-638-6725. (In Maryland, call collect 301-881-0256.) For further information on the clinical aspects of latex sensitivity, call Claudia Gaffey, M.D., Office of Health Affairs, Center for Devices and Radiological Health, at (301) 427-1060.

For a single copy of a reference list on latex sensitivity, write to: LATEX, FDA, HFZ-220, Rockville, MD 20857.

☆☆☆

3. General

C22P Probe is of Convex array electronic scanning. This is designed for use as connected with Hitachi Ultrasound scanner.

Clinical Intended Use

Please refer to the Instruction Manual (Supplement – Safety and Effectiveness) of the scanner with which this probe is combined.

NOTE: Do not use this probe for a purpose out of the specified intended use, and the intended use of this probe is limited each device. Please contact your local Hitachi representative with any question on this probe availabilities and intended uses.

Acoustic output

Please refer to the Instruction Manual (Supplement – Safety and Effectiveness) of the scanner with which this probe is combined.

Clinical Measurement Accuracy

In case of using measurement function with this probe, please refer to the Instruction Manual (Supplement – Safety and Effectiveness) of the scanner with this probe is combined with regard to the clinical measurement accuracy.

4. Probe Components and Accessories

4.1 The components list

Table.1 Probe component list

	Component	Note
1	Probe	1 piece
2	Attachment	1 piece
3	Instruction Manual	1 copy

4.2 Accessories

1) Needle guide bracket EZU-PA7C2

2) Puncture Adapter MP-2824(Hitachi)

3) GENERAL PURPOSE Ultra- ProII™ DISPOSABLE STERILE ULTRASOUND NEEDLE GUIDE/COVER KIT (610-579 or 610-608) (Option)

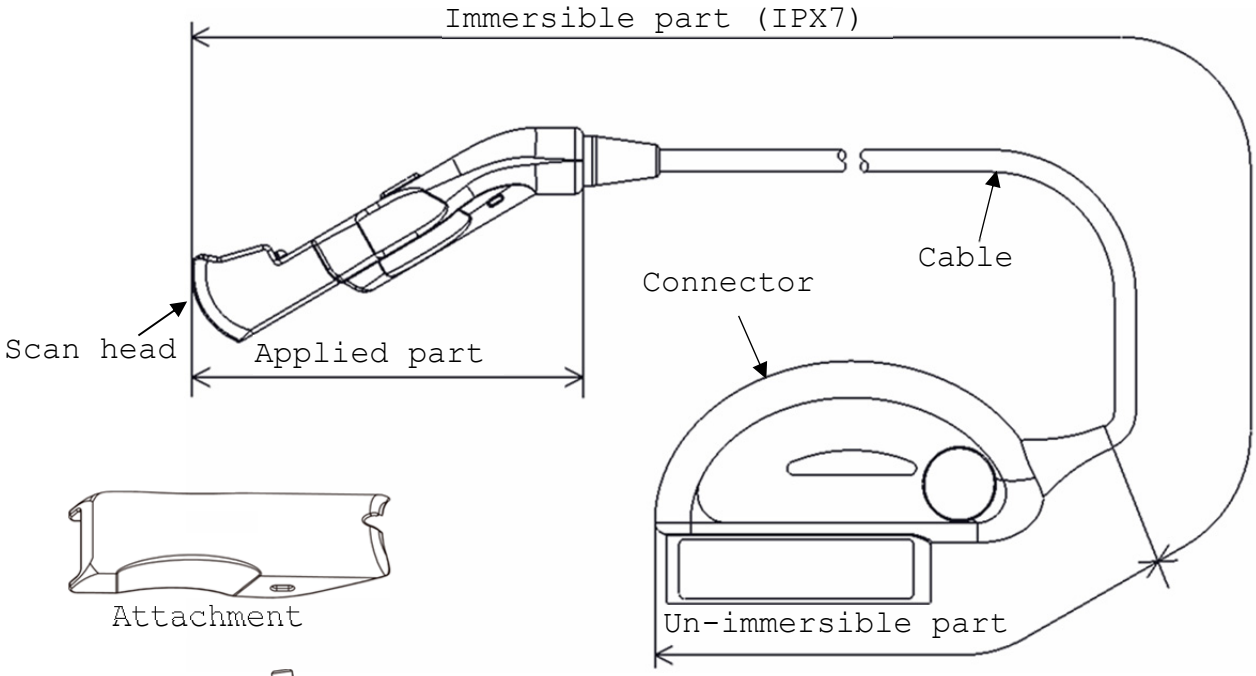
   Purchase the Ultra-ProII™ NEEDLE GUIDE/COVER KIT (610-579 or 610-608) directly from CIVCO MEDICAL INSTRUMENTS or an authorized CIVCO distributor.

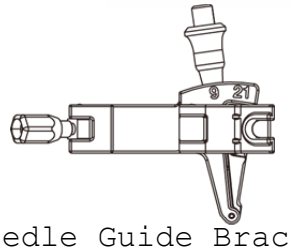
4) GENERAL PURPOSE Ultra-Pro3™ DISPOSABLE STERILE ULTRASOUND NEEDLE GUIDE/COVER KIT (610-901) (Option)

   Purchase the Ultra-Pro3TM NEEDLE GUIDE/COVER KIT (610-901) directly from CIVCO MEDICAL INSTRUMENTS or an authorized CIVCO distributor.

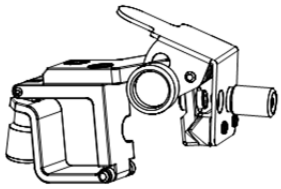
5. External View

The external view of C22P Probe is given in Fig.1.





Needle Guide Bracket
EZU-PA7C2



Puncture Adapter
MP-2824

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 can not be cleaned by water.

Fig.1 External View

6. Cleaning and sterilization/high level disinfection of the probe and the attachment

The probe and the attachment are not sterilized, but must be sterilized or disinfected before the initial use, and after each subsequent use, following the directions given below and working in accordance with standard hospital practice. (For reference, consult "Good Hospital Practice: Handling and Biological Decontamination of Reusable Medical Devices: ANSI/AAMI ST35-1991", published by the Association for the Advancement of Medical Instrumentation.)

6.1 Levels of Disinfection Requirement

To choose an appropriate disinfectant, the user must determine the required level of disinfection, based on the following classification (See Table.2) and the regulation of each country

Table.2 Levels of Disinfection Requirements

Classification	Definition	Levels of disinfection
Critical	Device directly contacts tissue (Intraoperative applications)	Sterilization
Semi-critical	Device contacts mucous membranes (Intracavity applications)	Sterilization or minimally High
Non-critical	Device contacts intact skin	Intermediate or low

⚠CAUTION

Do not clean, disinfect or sterilize by the procedures other than those specified in this manual. Infection could result due to incomplete cleaning, disinfection or sterilization. It can also result in damage to the probe or reduced performance.

6.2 Reprocessing Procedure

After each use of the probe, the reprocessing procedure including cleaning, disinfection, and sterilization must be performed immediately. A flow diagram showing the steps of the reprocessing procedure is given in Fig.2. The reprocessing procedure must be performed even after the probe was used with a probe sheath.

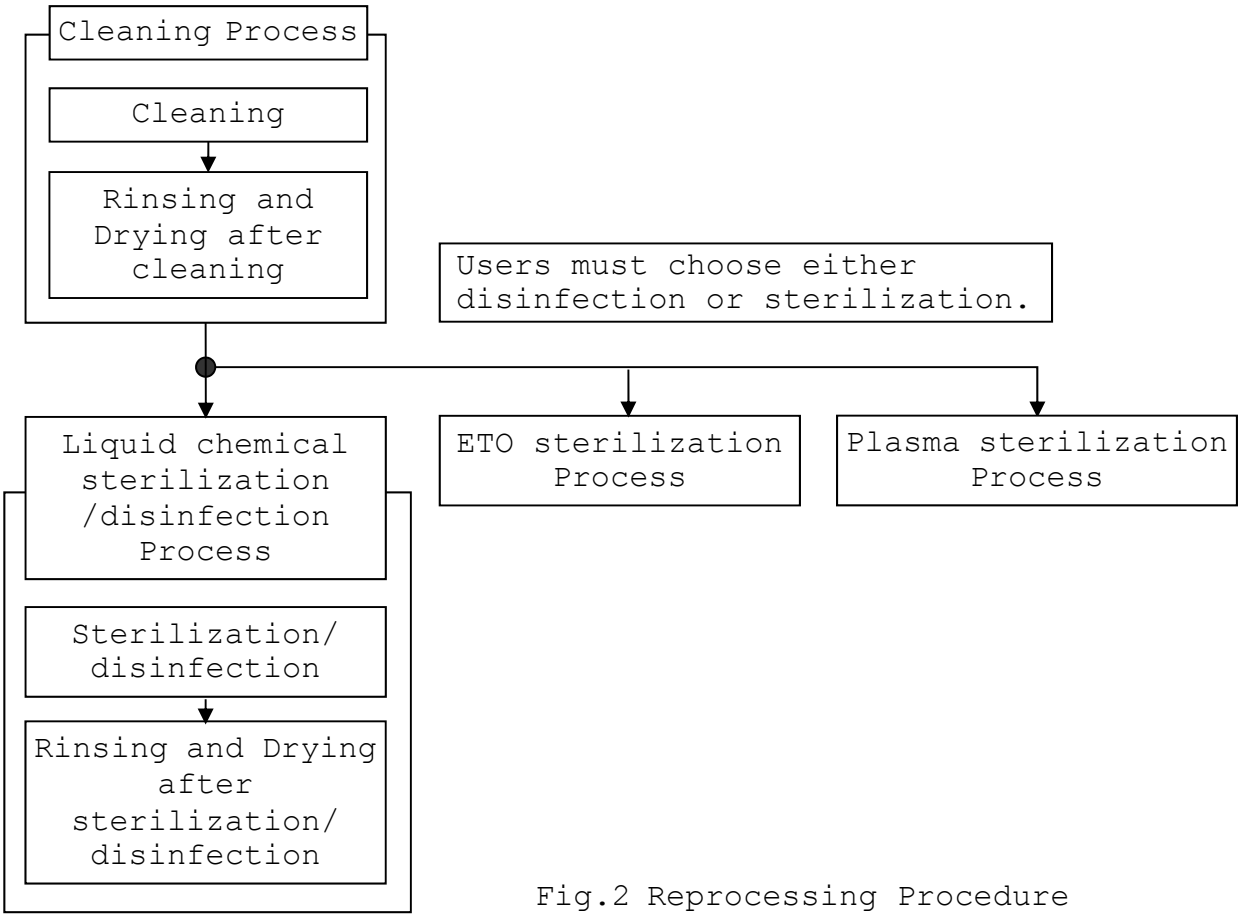


Fig.2 Reprocessing Procedure

⚠WARNING

Do not sterilize the probe by Autoclave. Autoclave sterilization causes the probe to malfunction.

6.3 Cleaning Process

Prior to liquid chemical sterilization/high level disinfection process, the probe and the attachment must be cleaned.

6.3.1 Cleaning

Immerse the probe and the attachment in an enzymatic detergent (Enzol®) solution (as shown in Fig.3) for more than 30 minutes or until the visible residue is removed. If needed, scrub the probe and the attachment using a soft sponge, gauze, or cloth to remove visible residue from the surface of the probe and the attachment.

⚠WARNING

Follow the instructions of the enzymatic detergent manufacturer regarding recommended dilution, temperature and soak time. Using insufficiently diluted detergent may damage the probe.

6.3.2 Rinsing and Drying after Cleaning

After cleaning and prior to liquid chemical sterilization/high level disinfection, the probe and the attachment must be thoroughly rinsed with high quality tap water or sterile water for more than 10 minutes to remove all residue of the detergent solution (See Fig.4). After rinsing the probe and the attachment, air-dry it completely.

⚠WARNING

Remove all debris and residue of sterilant/detergent solution from the surface of the probe and the attachment sufficiently.
Debris and residue of sterilant/detergent solution on the surface of the probe may affect patient health.

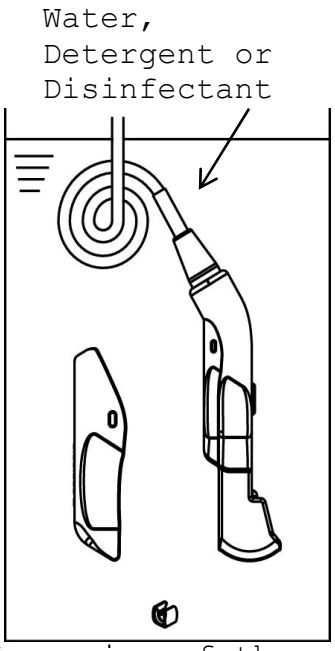


Fig.3 Immersion of the probe and the attachment in detergent or disinfectant solution

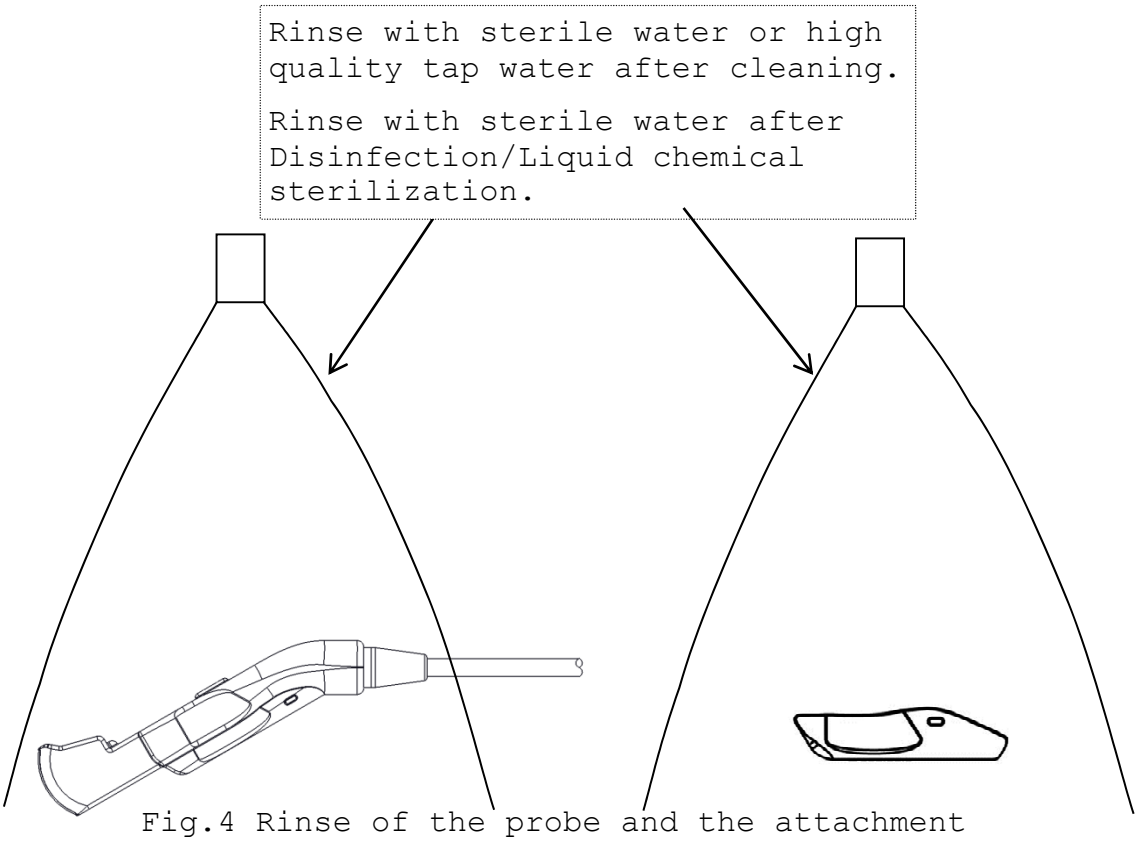


Fig.4 Rinse of the probe and the attachment

6.4 Liquid Chemical Sterilization/Disinfection Process

For sterilization/high level disinfection of C22P Probe and the attachment using liquid chemicals, follow the procedures as indicated in this paragraph. (For reference, consult "Chemical Sterilants and sterilization Methods - A Guide to Selection and Use: AAMI TIR7-113", published by the Association for the Advancement of Medical Instrumentation).

6.4.1 Sterilization / High Level Disinfection

Immerse the probe and the attachment in a sterilant/high level disinfectant (Refer to 11. Supplier's List) following the manufacturer's directions regarding preparation and soak time (Fig.3). The contact condition of recommended solutions is given in Table 3.

Table.3 Contact condition of sterilant/disinfectant

Solution	Contact condition	Purpose
Cidex®	10 hours at 25°C	Sterilization
Cidex plus®	10 hours at 20-25°C	Sterilization
Cidex® OPA	12 minutes at 20°C	Disinfection

⚠CAUTION

1) Do not mix any solution into a disinfectant unless otherwise indicated by the manufacturer.
2) Do not use activated disinfectant solution beyond the expiration date.
3) Do not immerse the probe in liquid disinfectant more than 15 hours.
4) Do not immerse the probe in disinfectant solution exceeding 30°C in temperature.

6.4.2 Rinsing and drying

Use sterile technique when removing the probe and the attachment from high level disinfectant solution and rinse the probe and the attachment thoroughly by soaking in sterile water for more than 10 minutes (See Fig.4). After rinsing the probe and the attachment, air-dry it completely.

⚠WARNING

1) Remove all debris and residue of sterilant/disinfectant solution from the surface of the probe and the attachment sufficiently. Debris and residue of sterilant/disinfectant may affect patient health.
2) The probe connector is not waterproof. Do not allow liquid to contact the connector.

6.5 ETO Sterilization Process

C22P Probe and the attachment are compatible with Ethylene Oxide (ETO) Sterilization. This manual does not describe the instructions of ETO sterilizer, therefore, follow the instructions of your sterilizer regarding the operation.

6.5.1 ETO Sterilization

Ensure that the probe and the attachment are cleaned in accordance with the procedure stated in "6.3 Cleaning Process" before the sterilization. Perform sterilization operations with the condition given in Table4.

Table.4 ETO Sterilization condition

Preconditioning:	none
Conditioning in Chamber (Dwell):	
Temperature:	122.0-131.0°F (equivalent of 50-55°C)
Humidity:	40-90 % RH
Prevacuum:	1.93-3.89 PSIA (22-26" Hg, 13.26-26.73kPa)
Time:	30-45 minutes
Exposure:	
Temperature:	122.0-131.0°F (equivalent of 50-55°C)
Sterilant gas:	10% E0/90% HCFC
Gas Concentration	600±30 mg/L
Exposure time:	125 minutes
Post-vacuum:	1.93-3.89 PSIA (22-26" Hg, 13.26-26. 73kPa), 2 times
Aeration:	
Temperature:	53°C
Time:	11 hours and 30 minutes to 12 hours

6.6 Plasma Sterilization Process

C22P Probe and the attachment are compatible with STERRAD® Plasma Sterilization (STERRAD®50, 100S, 200, NX and 100NX). This manual does not describe the instructions of STERRAD® system, therefore, follow the instructions of your STERRAD® system regarding the operation.

6.6.1 STERRAD® Sterilization (Johnson & Johnson Product)

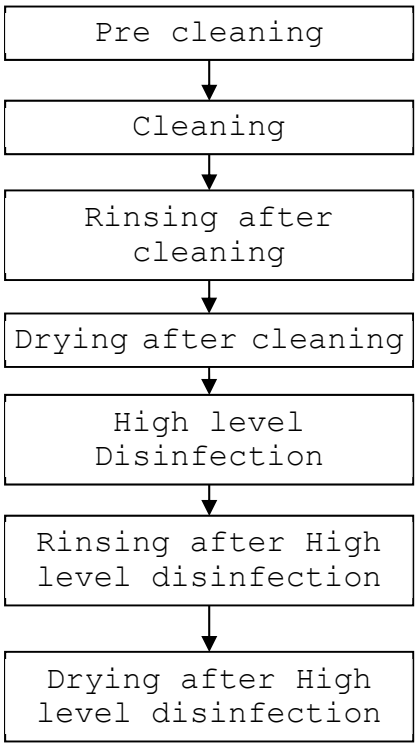
Ensure that the probe is cleaned in accordance with the procedure stated in "6.3 Cleaning Process" before the sterilization. Perform sterilization operations by following the instructions of the manufacturer.

⚠WARNING

Confirm the sterilization condition before performing sterilization. The sterilization by other than the specified condition causes the probe to malfunction.

7. Cleaning and High level disinfection of the Needle Guide Bracket EZU-PA7C2

Before the first use of the needle guide bracket and every time after the use, perform the cleaning and high level disinfection of the needle guide bracket. In prior to the high level disinfection perform cleaning thoroughly. Handling should be according to the operation manual of the enzymatic detergent or each disinfectant.



⚠CAUTION

To choose an appropriate disinfectant, users must determine the required level of disinfection, based on the following classification (See the following table) and the regulation of each countries.

Levels of Disinfection Requirements

Classification	Definition	Levels of disinfection
Critical	Device directly contacts tissue (Intraoperative applications)	Sterilization
Semi-critical	Device contacts mucous membranes (Intracavity applications)	High
Non-critical	Device contacts intact skin	Intermediate or low

7.1 Cleaning of the Needle Guide Bracket EZU-PA7C2

Pre cleaning
↓
Cleaning
↓
Rinsing after cleaning
↓
Drying after cleaning

Before disinfection process, clean the needle guide bracket as follows.

1) Remove the needle guide bracket from the probe.
2) Remove the thumbscrew 1, thumbscrew 2, spring and knob of the needle guide bracket.
3) Immerse the needle guide bracket and thumbscrew 1, thumbscrew 2, spring and knob in the enzymatic detergent solution. (See Fig.5) Follow the instructions of the detergent manufacturer regarding usage, dilution and contact-time of the detergent solution. In the enzymatic detergent remove foreign matters with soft cloth or sponge. Clean the groove and hole of the guide bracket with attached brush.
4) After the cleaning, wash the needle guide bracket with high-quality tap water or sterile water at least two times in order to remove the detergent and other remains.
5) Thoroughly dry the needle guide bracket with soft cloth or towel.

⚠CAUTION

1) Follow the instructions of the detergent manufacturer regarding usage, dilution, concentration, temperature and contact-time of the detergent solution.
2) Remove all debris and residue of the detergent solution from surface of the needle guide bracket sufficiently. If the detergent solution stays on the surface of the needle guide bracket, it may affect to the patient health.

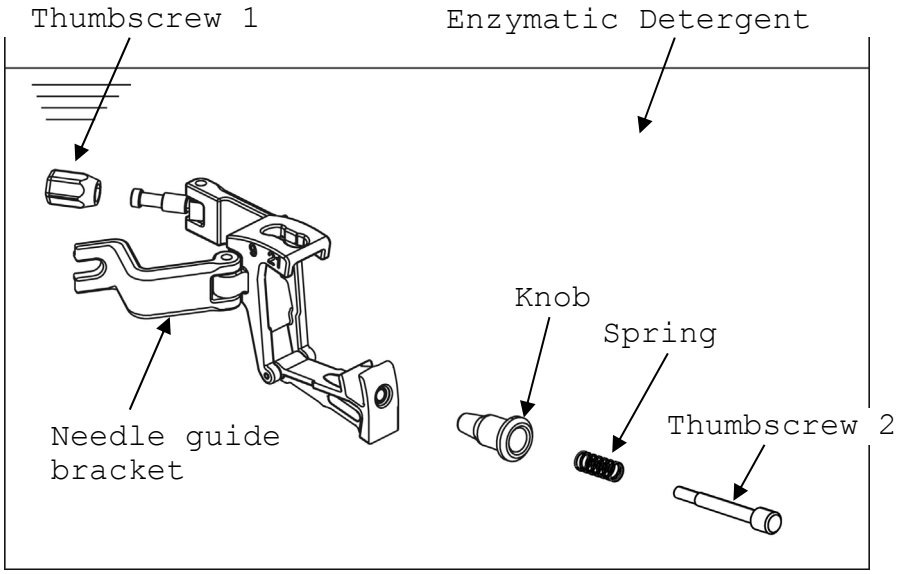


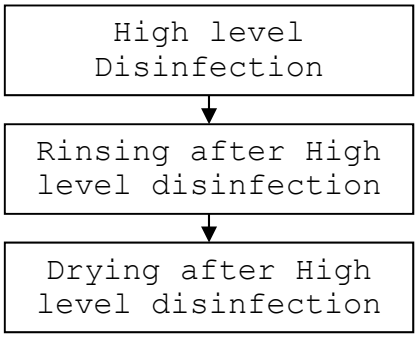
Fig.5 Immersion of the Needle Guide Bracket

⚠CAUTION

1) Never use any organic solvent such as a chemical or thinner for the cleaning of the needle guide bracket.
2) Never wash the needle guide bracket kept attached to the probe.
3) Never try to rub off any solid stains using any hard or sharp-edged thing.

7.2 High level disinfection of the needle guide bracket EZU-PA7C2

7.2.1 Immersion method



1) Prepare a disinfectant solution. The needle guide bracket can be disinfected by following method. Handling should be according to the operation manual of the disinfectant.
   a) Cidex OPA™
   b) Cidex Plus™ 28 day solution
   c) Cidex™
2) Follow the instructions of the disinfectant manufacturer regarding use-life, concentration, microbiological effectiveness and contact-time etc.
3) Immerse the needle guide bracket in the disinfectant for a time period of the contact-time (See Fig.5).
4) Rinse the needle guide bracket with sterile water to remove all residues of the disinfectants.
5) Thoroughly dry the needle guide bracket.

⚠CAUTION

1) Never perform not specified disinfection or sterilization to this needle guide bracket, otherwise the needle guide bracket may suffer serious damages such as deformation or crack. Especially, never perform Autoclave sterilization to this needle guide bracket because main material of this bracket is general engineering plastic and it cannot withstand high temperature of the autoclave.
2) Do not perform high level disinfection while attaching the needle guide bracket to the probe, otherwise high level disinfection may not be achieved.

8. Operating Procedure

8.1 Probe

8.1.1 Operation of the ultrasound diagnostic scanner

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.

⚠WARNING

1) Set the ultrasound diagnostic scanner to “FREEZE ON” mode when replacing the probe.
2) Wear medical gloves during examination. Conducting examinations with the bare hands can expose the operator to a risk of infection.
3) Do not use the probe fallen onto the floor. Otherwise, there is a risk of infection. Stop the operation and perform the cleaning and disinfection or sterilization according to paragraph 6 "Cleaning and sterilization/high level disinfection of the probe and the attachment".

⚠CAUTION

1) Prior to each use, ensure that the probe is cleaned and sterilized/ disinfected in accordance with the procedure stated in “6.2 Reprocessing Procedure”.
2) Do not use the probe if the image and the frequency of the probe are not correctly displayed. An incorrect acoustic output can result in burns or other injuries to the patient.
3) 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.
4) 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.

8.1.2 Orientation of the image

The Relationship between the direction of the probe and the B-Mode image is shown in Fig.6. The mark of right-left orientation on the image indicates the direction of the index mark of the probe. (For detail of the right-left orientation mark, refer to the instruction manual of the device to be connected.)

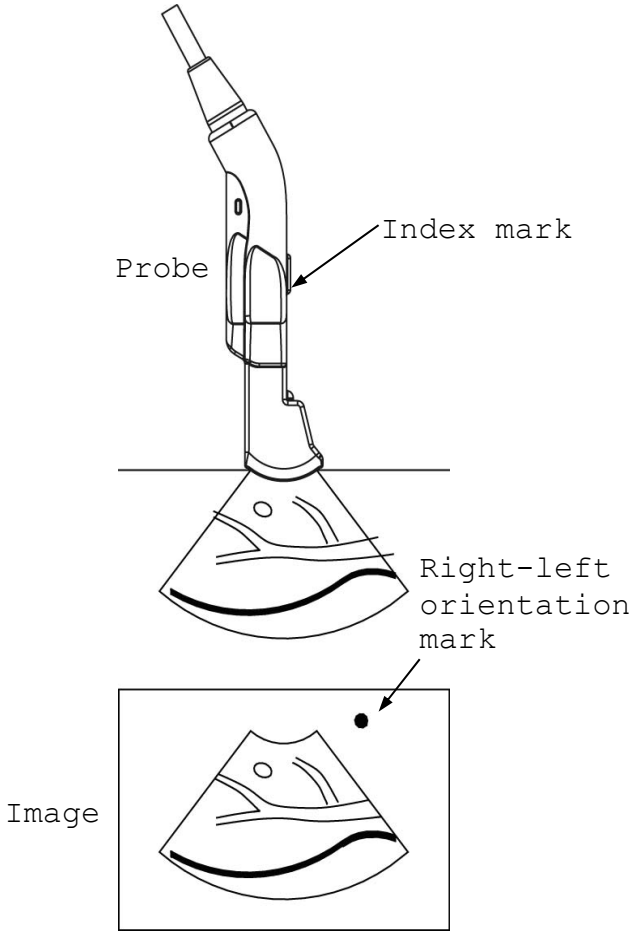


Fig.6 Orientation of the B-Mode Image

8.1.3 Probe Sheath

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

⚠WARNING

1) Some Latex material may create allergic reaction. See "2. General Caution" for more detail.
2) Use a biocompatible probe cover. Use of a non-biocompatible probe cover can cause the patient an adverse reaction.

8.1.4 Diagnosis

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

⚠WARNING

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.

8.1.5 Care after use

Perform the reprocessing procedure in accordance with the procedure stated in "6.2 Reprocessing procedure" every time immediately after completing the ultrasound examination.

8.2 Attachment

It becomes easy to have the probe by attaching the attachment to the probe. And it improves operability. Attach the attachment to the probe as indicated in Fig.7. The attachment can be released from the probe by sliding the attachment as indicated in Fig.8.

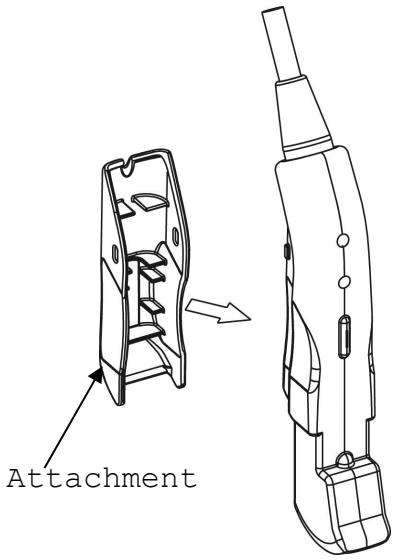


Fig.7 How to attach the attachment

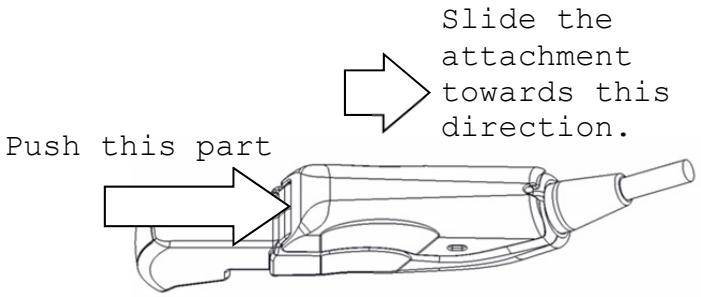


Fig.8 How to release the attachment

8.3 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 “8.3.1 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 TM cover to the probe following “8.3.2 Placing the probe and bracket into a transducer cover”.
4) Attach the needle guide to the bracket following “8.3.3 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 “8.3.3 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 “8.3.4 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.9)
8) After the use of the needle guide bracket, it should be cleaned and disinfected, then store it in an adequate place.

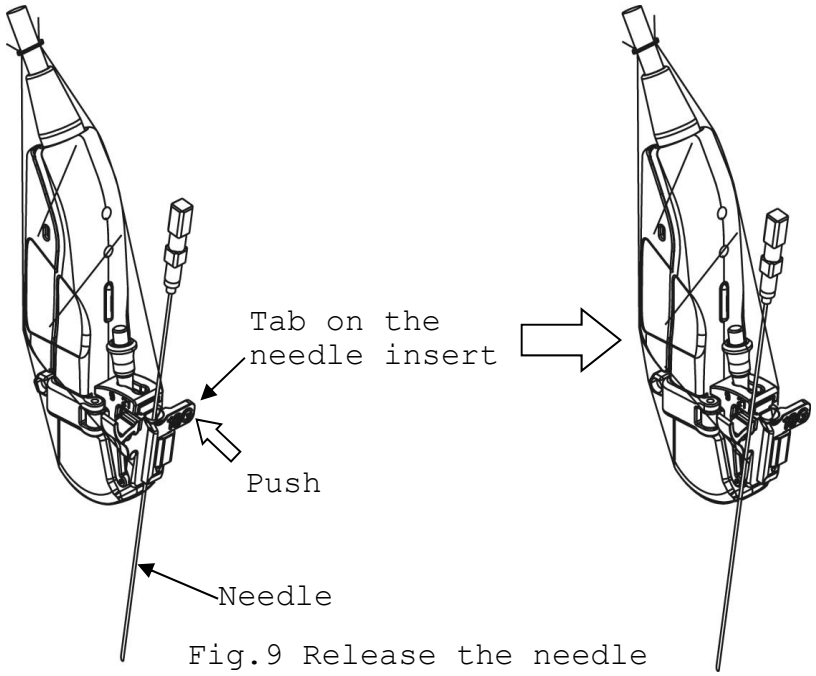


Fig.9 Release the needle

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.]

8.3.1 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.10)

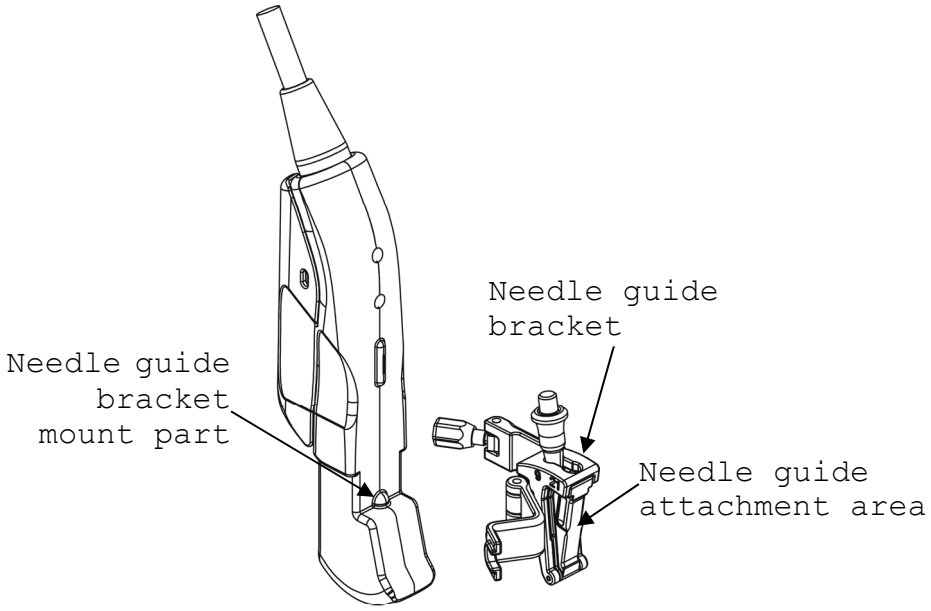


Fig.10 Position for mounting the needle guide bracket

2) Fit the recess of the bracket to the thumbscrew 1 and tighten the thumbscrew 1. (See Fig.11) 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.

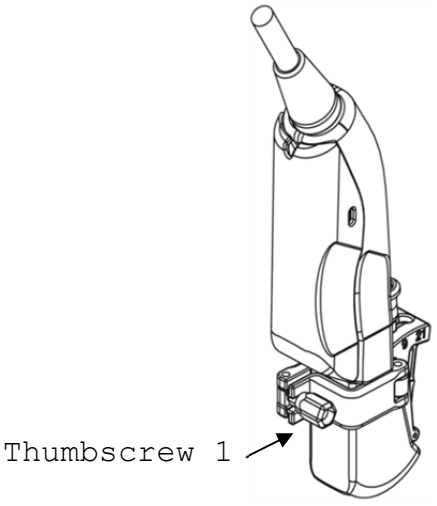


Fig.11 Fitting the needle guide bracket

8.3.2 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.12)

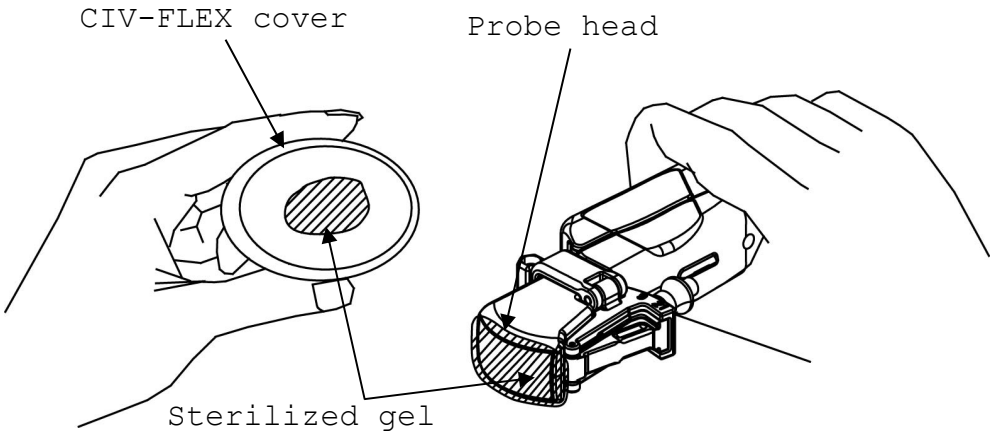


Fig.12 Placing the gel

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.

8.3.3 Attaching the needle guide to the bracket (Example: In the case of CIVCO Ultra-ProII™)

1) Attach the unlocked needle guide onto the needle guide attachment area of the bracket. (See Fig.13)

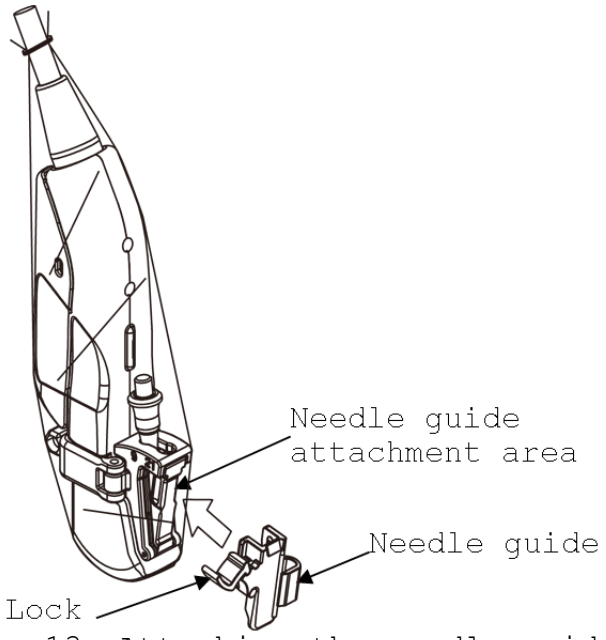


Fig.13 Attaching the needle guide

2) Push the lock toward the bracket to secure the lock. Make sure the needle guide is firmly attached to the bracket. (See Fig.14)

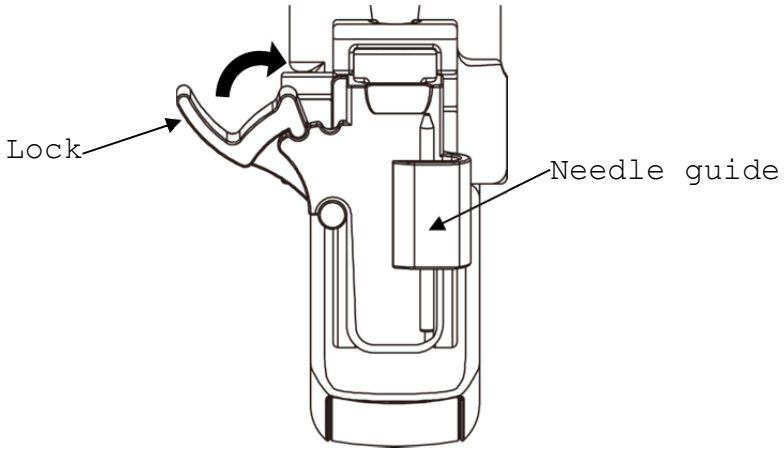


Fig.14 Attaching the needle guide

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.15) Inspect the guide and cover assembly to ensure the needle path is clear of obstructions.

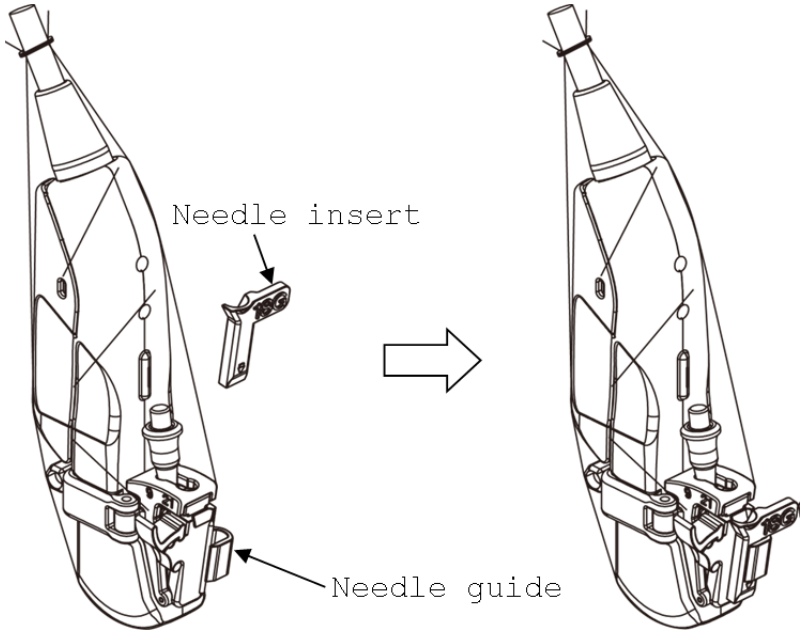


Fig.15 Attaching the needle insert

⚠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.

8.3.4 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.16)

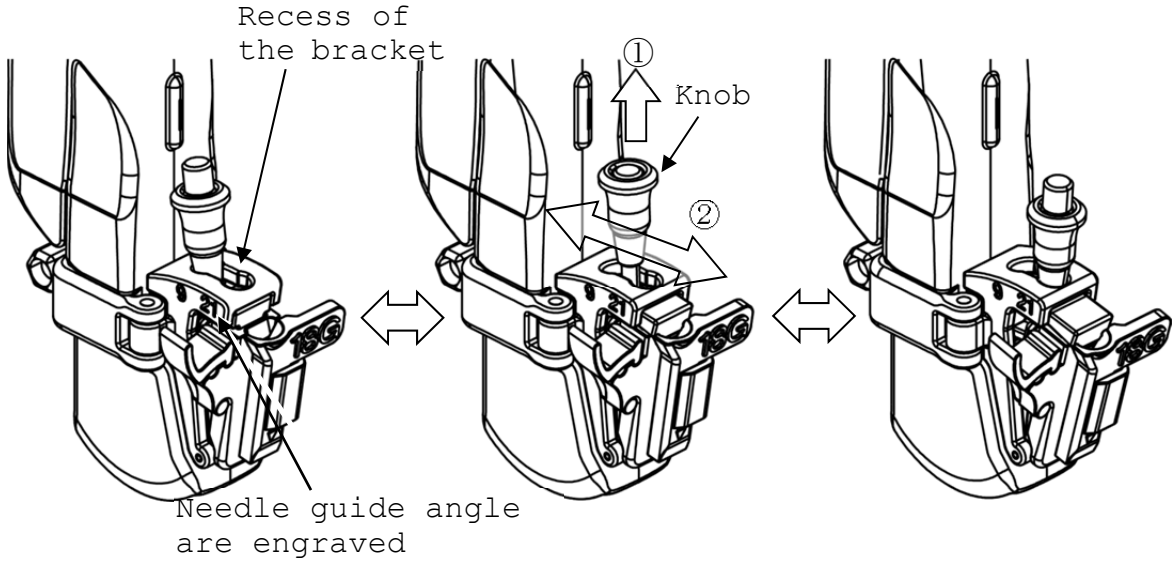


Fig.16 Setting the needle guide angle

⚠WARNING

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

9. Maintenance and Safety Inspection

9.1 Probe Care

Use gauze soaked in water or in ethyl alcohol to clean the dirt on the surface of the probe.

⚠CAUTION

1) Do not attempt to scrape away caked dust on the probe with a hard cloth or knife.
2) Do not allow liquid to contact/enter the probe connector, as the probe connector is not waterproof.
3) Do not use Ethyl alcohol other than cleaning. Ethyl alcohol is not effective as a disinfectant/sterilant.

9.2 Daily Inspection

1) Visually inspect the surface of the probe head, the housing, and the cable for any crack, scratch or denaturalization. If you find damage, do not use the probe, and immediately contact our service personnel.
2) Visually inspect the ultrasound image for abnormality or major change from initial state. If you find abnormality or major change, do not use the probe, and immediately contact our service personnel.

10. Specifications

10.1 C22P Probe

Type:	C22P Probe
Acoustic working Frequency:	3.0MHz
Technology:	Convex Array Probe
Dimensions:	See Fig.17
Weight:	Approx. 0.70kg (Including cable and connector)
Probe materials:	Biocompatible allergy free components
Applicable systems:	Depending on production and upgrade status for detailed information, contact a service support.
Cleaning:	Applicable detergents are listed in the suppliers list
Disinfection:	Applicable disinfectants are listed in the suppliers list
Sterilization:	ETO gas sterilization or Plasma sterilization
Operating conditions:	
Ambient temperature:	+10 - +40℃
Contact surface temperature (Temperature of examinee):	Max. 42℃
Relative humidity:	30 - 75% (subject to no condensation)
Storage/Transportation conditions:	
Temperature:	-10 - +50℃
Relative humidity:	10 - 90% (subject to no condensation)

10.2 Needle Guide Bracket EZU-PA7C2

Dimensions:	See Fig.19 and Fig.20
Applicable probe:	C22P Probe
Needle angle:	9 or 21 degrees

10.3 Puncture Adapter MP-2824

Dimensions:	See the Instruction Manual of MP-2824
Applicable probe:	C22P Probe
Needle angle:	15 degrees

11. Supplier's List

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

Product name	manufacturer	purpose
Enzol®	Johnson & Johnson	Enzymatic detergent
Cidex®	Johnson & Johnson	Sterilant
Cidex Plus®	Johnson & Johnson	Sterilant
Cidex® OPA	Johnson & Johnson	disinfectant
Transducer covers	CIVCO Medical	Covers

12. Disposal of the probe

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

⚠CAUTION

Before disposing of the equipment, disinfect or take other infection-prevention measures. Disposal of the equipment without taking the proper preventative measures can lead to infection.

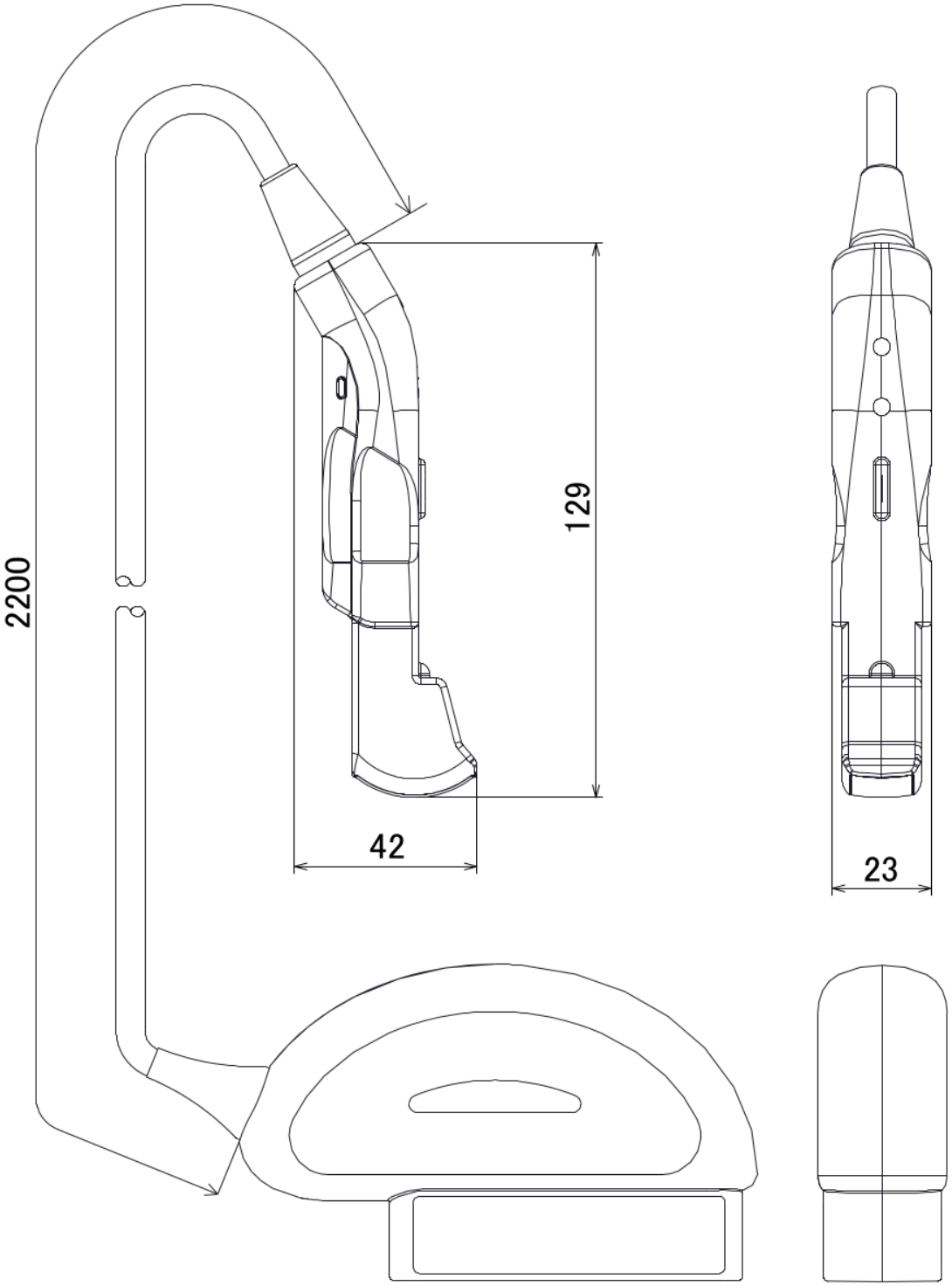


Fig.17 Dimensions Unit: mm

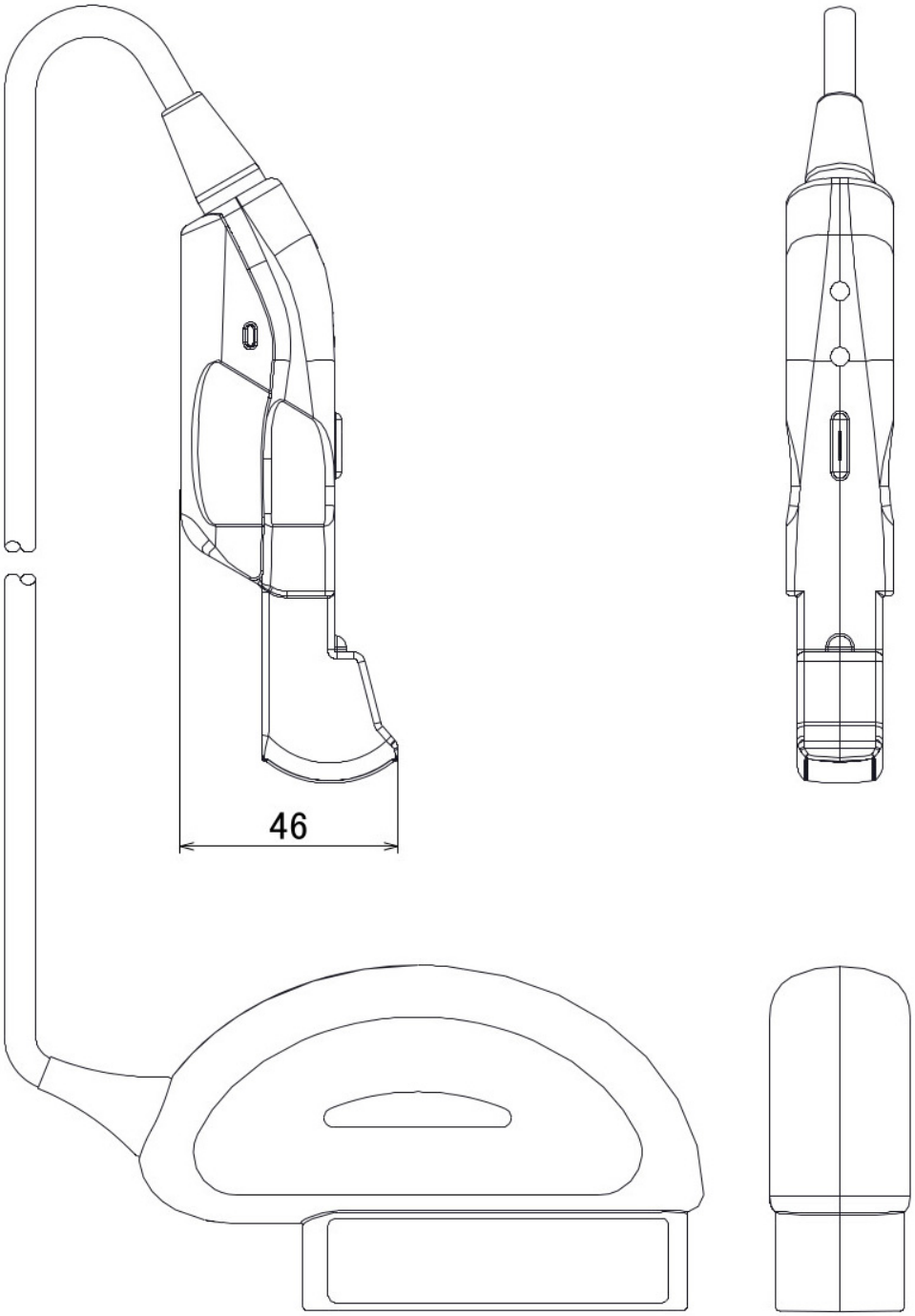


Fig.18 Dimensions (with the attachment) Unit: mm

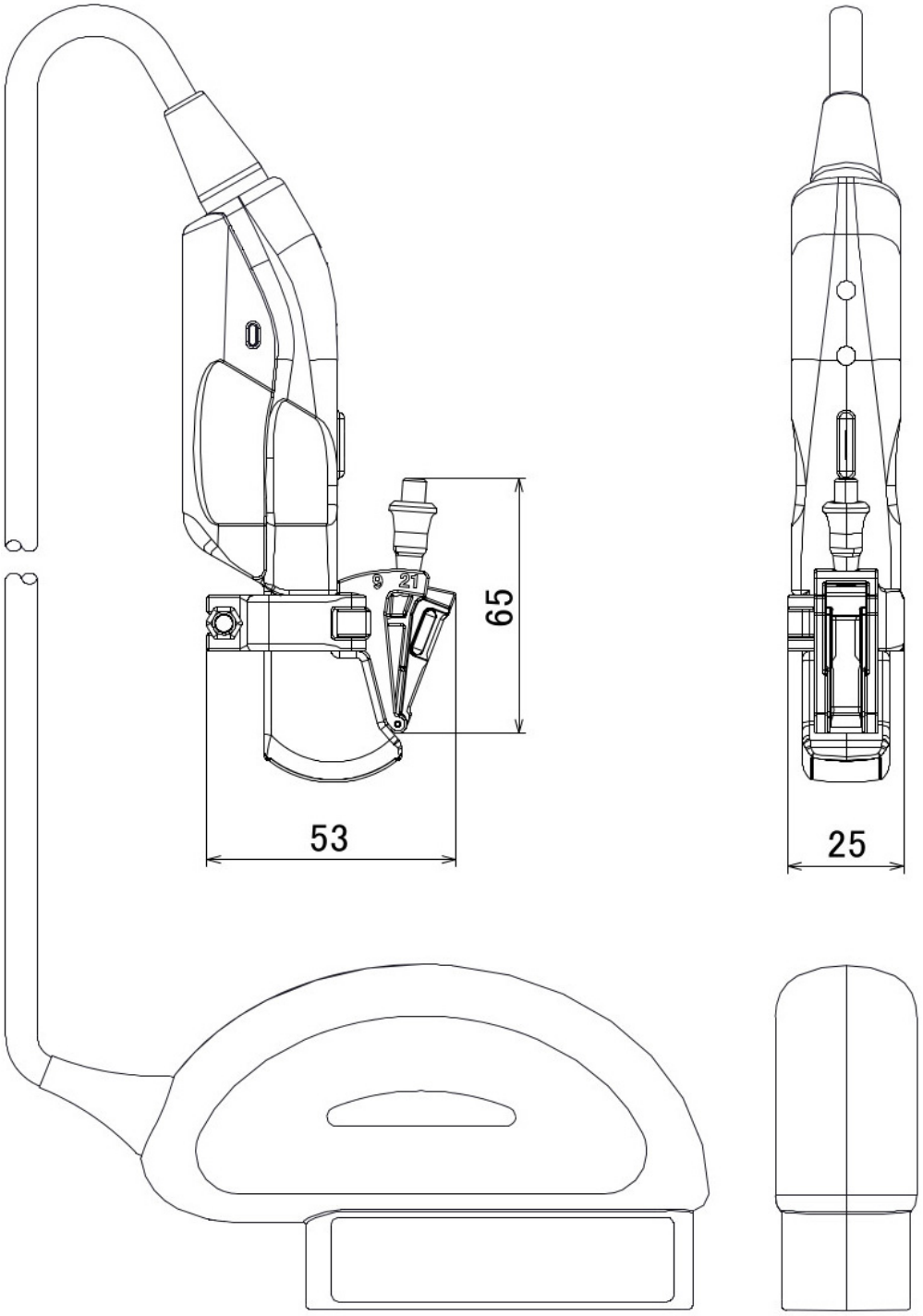
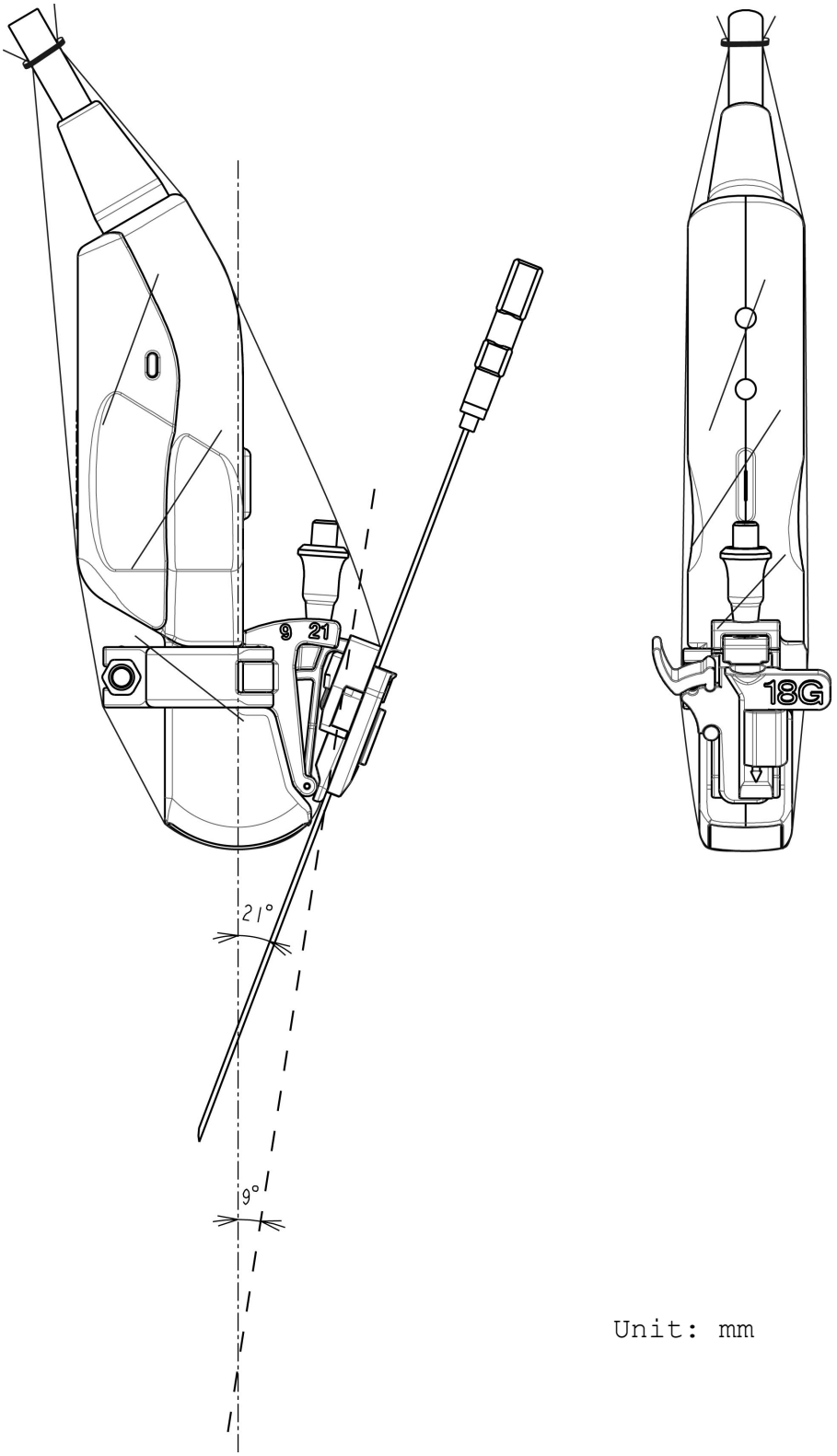


Fig.19 External view (with the Needle Guide Bracket)

Unit: mm



Unit: mm

Fig.20 External view (with transducer covers / CIVCO)

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

Representative
Hitachi Aloka Medical America, Inc.
10 Fairfield Boulevard, Wallingford, CT 06492 U.S.A.