FUJIFILM

CC41R2 Probe

Instruction Manual
Specifications

Requests to operators and maintenance managers:

- Read this document “Instruction Manual”.
- After reading “Instruction Manual”, store it near the system so that it is accessible at all times.

FUJIFILM Healthcare Corporation

MN1-6825 Rev. 1

DOC-0057090-A

Introduction

Introduction

Thank you for purchasing the probe.
This is the instruction manual for CC41R2 probe.
This document is intended for doctors and other qualified persons. The separate instruction manual “Cleaning, Disinfection and Sterilization (MN1-7016)” is intended for the persons handling the devices.
Before use, read this manual as well as the separate instruction manual “Safety (MN1-6840)” in which information for safe use is provided. In particular, be sure to read chapter 1 “Safety Precautions” in the separate instruction manual “Safety”.
Keep this manual securely for future reference.
The probe bears the CE mark but the mark is valid only when the probe is connected to the ultrasound diagnostic instrument bearing the CE mark. This instrument complies with Medical Device Regulation (EU) 2017/745 and Directive 2011/65/EU and (EU) 2015/863 relating to RoHS.

Revision history

Revision No.: 1
Revision date: 2022-10-14

Symbols used in this document

This manual uses the following terms to describe the safety precautions that must be observed to prevent danger or injury to operators and patients.
The severity of risks and injuries that might occur if safety precautions are not observed is classified into three levels: DANGER, WARNING, and CAUTION. In addition, NOTICE indicates precautions that operators must observe.

DANGER

Indicates an imminently hazardous situation that, if not avoided, might result in death or serious injury. This symbol also indicates an immediate danger that might result in the total destruction of devices or a fire.
(Symbols used: ISO 7010 - W001)

WARNING

Indicates a potentially hazardous situation that, if not avoided, might result in death or serious injury. This symbol also indicates a potential (latent) danger that might result in the total destruction of devices or a fire.
(Symbols used: ISO 7010 - W001)

⚠ CAUTION	Indicates a situation that, if not avoided, might result in light or moderate injury. This symbol also indicates a situation that might result in damage to a device or to part of a device or in the loss of computer data. (Symbols used: ISO 7010 - W001)
NOTICE	Indicates a precaution that we strongly urge operators to observe to prevent damage to or deterioration of devices during operation, as well as to ensure a that the devices are used efficiently. Alternatively, this symbol indicates a recommended procedure, condition, or action that requires careful attention.

Safety precautions are categorized as follows and indicated by the following symbols.
This symbol means that the described action requires caution.

	Indicates prohibited conditions or actions. Safety precautions accompanied by this symbol describe conditions or actions that are prohibited. (Symbols used: ISO 7010 - P001)
	Indicates required actions that the operator must perform. (Symbols used: ISO 7010 - M001)

Contents

1 General Information

General information for the probe is provided below.

1.1 Intended use

This probe is intended for use by doctors observing the following application areas for the purpose of performing tomography and hemodynamic diagnosis of blood flow in the human body.
In addition, the combination of puncture tools allows doctors to perform ultrasound-guided puncture operations.

- Urology areas (Transrectal approach)
- Obstetrics/Gynecology areas (Transvaginal approach)

For details on the connectable instrument, please refer to section *2.1 Specifications* on page 8 of this manual.

⚠ WARNING

⃠ Do not use this probe for other than its intended use.
Otherwise, it could cause burns or other injuries to the operator or the patient.

1.2 Classification of ME equipment

This equipment is classified as follows according to IEC 60601-1.
Please refer to the section *2.1 Specifications* on page 8 for the applied part, the part treated as the applied part, and the range of IPX7.

- Classification based on the degree of protection against electric shock: Type BF applied part
- Classification for protection against ingress of liquids: IPX7 (Watertight equipment)
- Operation mode: Continuous operation
- Method of sterilization: Refer to the separate instruction manual “Cleaning, Disinfection and Sterilization”

1.3 Standard components

The standard components of this probe are as follows.

CC41R2 Probe	:	1 set
Storage case	:	1 set
Gap adapter OP-001	:	1 piece

Instruction Manual

- Specifications (MN1-6825) : 1 copy
- Safety (MN1-6840) : 1 copy
- Cleaning, Disinfection and Sterilization (MN1-7016) : 1 copy

1.4 Option

The following options are available for this probe.
It does not suggest that CIVCO product(s) described in this manual are commercially available in all countries and regions.
Intended uses of approved products vary by country and region.

- Puncture
  To perform a puncture, use the products listed in *Table 1-1 Option for puncture* on page 7. Refer to the document provided with each product for instructions and precautions for use.

  Table 1-1 Option for puncture

Product Name	Product No.
Disposable Endocavity Needle Guides <Configuration> Needle guide Needle guide insert (16/18/20G)	644-101
Disposable Endocavity Needle Guides <Configuration> Needle guide Needle guide insert (16/18/20G) Latex cover Bands Gel	644-102

- Probe cover
  Please use the option listed in *Table 1-2 Option for probe cover* on page 7 for probe cover. Please refer to the *Chapter 4, Operation* on page 13 for how to mount/remove the probe cover.

  Table 1-2 Option for probe cover

Product Name	Product No.	Remarks
Rubber Boot	RB-945BP-NS	Non-sterilized
CIV-Flex™ Endocavity Probe Covers	610-006	sterilized
PROcovers™	610-076	sterilized

- Reprocessing by liquid detergent, disinfectant or sterilant
  Whole the probe is able to immerge into the liquids by putting the connector of the ultrasound probe to the waterproof case WP-001 as below *Table 1-3 Accessory for reprocessing by liquid detergent, disinfectant or sterilant* on page 8.
  Precautions about the waterproof case, please refer to the instruction manual.

Table 1-3 Accessory for reprocessing by liquid detergent, disinfectant or sterilant

Product Name	Product No.
Waterproof case	WP-001

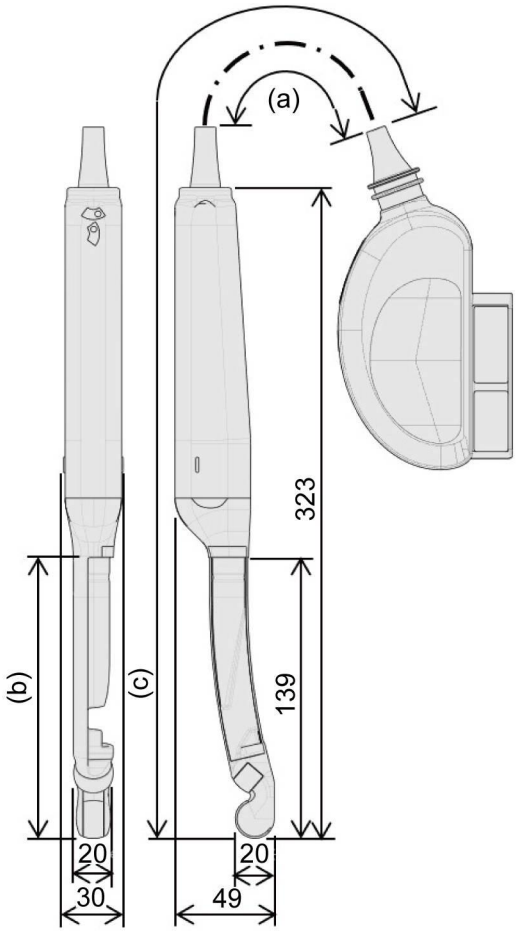
2 Specifications and Part Names

The specifications and the name of each part are provided below.

2.1 Specifications

2.1.1 Specifications of the Probe

Application	:	Urology areas, Obstetrics/Gynecology areas
Patient target group	:	Urology areas (mainly male), Obstetrics/Gynecology areas (female)
Type of patient contact	:	Transrectal, Transvaginal
Connectable instruments	:	ARIETTA 65 NOTE: At the time of publication of this manual, the connectable diagnostic ultrasound instrument or instrument software version available with this probe is different for each country. Please refer to the instrument instruction manual or contact our company written on the back cover.
Field of view	:	180° (Sagittal plane), 180° (Axial plane)
Frequency	:	6.5 MHz (Sagittal plane), 6.5 MHz (Axial plane)
Cable length	:	2.5 m (See (a) in *Figure 2-1 External View* on page 9.)
Service life	:	3 years
Applied part	:	139 mm (See (b) in *Figure 2-1 External View* on page 9.)
Part treated as applied part	:	139 mm (See (b) in *Figure 2-1 External View* on page 9.)
IPX7 range	:	In case that not putting the waterproof case to the ultrasound probe connector, see (c) in *Figure 2-1 External View* on page 9. In case that putting the waterproof case to the ultrasound probe connector, whole the probe from the tip of the ultrasound probe to the connector with Waterproof Case WP-001 is IPX7 range.
Accuracy	:	For the measurement accuracy and calculation accuracy, refer to the instruction manual of the ultrasound diagnostic instrument.
External dimensions	:	See *Figure 2-1 External View* on page 9.



Unit: mm

Remark:

The tolerance for the dimensions is ±10%.

Figure 2-1 External View

2.2 Name of each part

The name of each part is shown in *Figure 2-2 Name of each part* on page 10 and the description of each part is listed in *Table 2-1 Name of each part and its description* on page 10.

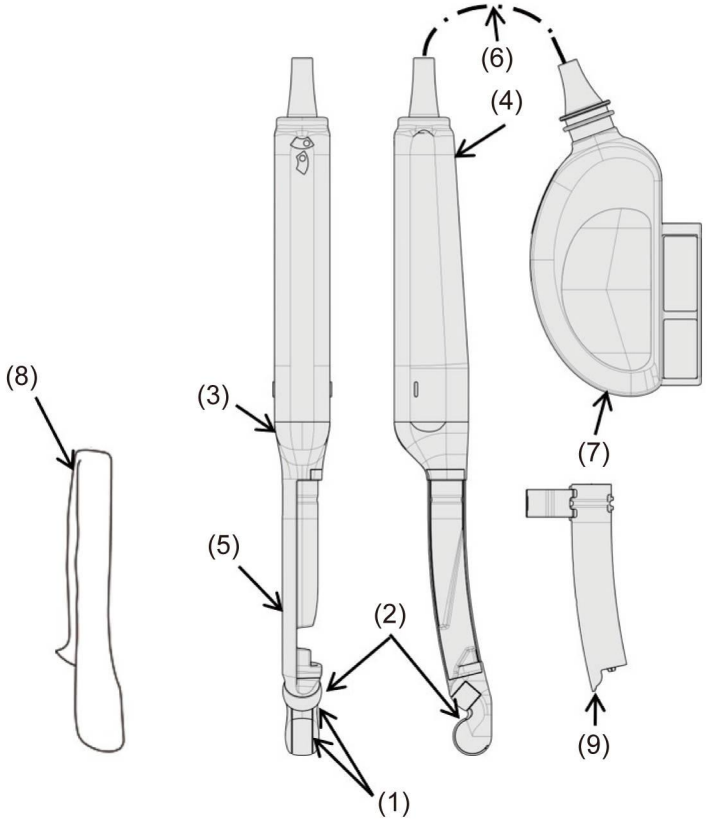


Figure 2-2 Name of each part

Table 2-1 Name of each part and its description

No.	Name	Description
(1)	Ultrasonic radiation part	Ultrasound is radiated from this part. The electronic convex transducer is integrated underneath this part.
(2)	Orientation mark side	The side of the orientation mark corresponds to the side of the orientation mark on the image. See *4.2 Relationship between the direction of the probe and the orientation mark* on page 14.
(3)	Probe tip	This part is gripped during operation.
(4)	Handle	This part is held during operation.
(5)	Insertion portion	This part is inserted into the patient.
(6)	Cable	Cable transfers electric input/output signals.
(7)	Connector	The connector is the part which is connected to the diagnostic ultrasound system.
(8)	Probe cover	This covers the insertion portion for preventing infection. See *4.3 How to mount/remove the probe cover* on page 15.
(9)	Gap adapter	This is an adapter to be attached when the needle guide is not used. See *4.1 How to attach the gap adapter and operation* on page 13.

⚠ CAUTION

	Do not pull, bend, twist, or apply excessive force to the cable. The probe may malfunction due to cable disconnection.
	Do not subject the ultrasonic radiation part to impact. The impact may damage the transducer, resulting in noise or no echo in the image. In most cases, the ultrasonic radiation part itself is not damaged because the part is made of elastic material.

3 Preparations before Use

This chapter describes preparations needed to use the probe safely. Please prepare the probe prior to each use by following the instructions below.

3.1 Visual check

Check the appearance of the probe before use.
Visually check the probe tip, ultrasonic radiation part, cable, and connector.
If any holes, indentations, abrasion, cracks, deformation, looseness, discoloration, or other abnormalities are found, do not use the probe.
Check also the options as necessary.
In addition, the boundary of the probe tip is sealed with an adhesive. Do not use if peeled or cracked.

⚠ WARNING

	Check the appearance of the probe before use. The patient may be injured if the equipment has any abnormality. If any abnormality is found in the equipment, stop using it and contact our company written on the back cover.

3.2 Confirmation of cleaning, disinfection, and sterilization

Confirm that the probe is certainly cleaned, disinfected, and sterilized. The degree of reprocessing depends on the intended use.
Confirm also that options are properly cleaned, disinfected, and sterilized.
Refer to the separate instruction manual “Cleaning, Disinfection and Sterilization” for cleaning, disinfection, and sterilization procedure.
Please keep this instruction in the room where the probe is actually cleaned and sterilized.

⚠ WARNING

Check the appearance of the probe before use.
The patient may be injured if the equipment has any abnormality. If any abnormality is found in the equipment, stop using it and contact our company written on the back cover.

3.3 Operation check

Connect the probe to the ultrasound diagnostic instrument and check that the displayed scan type and frequency correspond to those of the probe. Check also that there is no abnormality in the image.

Remark:

Please refer to the instruction manual of the ultrasound diagnostic instrument for how to connect the probe and information displayed on the monitor.
If the probe is operated in air, brightness on the top of the image may be non-uniform, but this does not affect the performance of the probe unless no echo is generated or other abnormalities occur in the image.

⚠ WARNING

Make preparations prior to each use.
The operator and the patient may be injured if the equipment has any abnormality. If any abnormality is found in the equipment, stop using it and contact our company written on the back cover.

⚠ CAUTION

Do not use the probe if the displayed scan type and frequency do not correspond to those of the probe.
Incorrect acoustic output can result in burns or other injuries to the patient. Stop using the equipment and contact our company written on the back cover.

3.4 Visual check for the disposable endocavity needle guides (644-101, 644-102)

Visually inspect the envelope of the sterile needle guide for any break, deformation, crack, or denaturalization. If you find any damage, do not use them and contact a service support immediately.

4 Operation

This section describes how to operate this probe.

4.1 How to attach the gap adapter and operation

Attach the gap adapter to the probe as shown in *Figure 4-1 How to attach the Gap adapter - 1* on page 13 to *Figure 4-3 How to attach the Gap adapter - 3* on page 14 and mount a probe cover on the probe. Insert the probe into the body cavity. An image of the region of interest is displayed on the monitor of the diagnostic ultrasound system. For details on displaying and adjusting the image, refer to the documentation supplied with the diagnostic ultrasound system.

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1. Put a protrusion of the tip of the adapter into a dent of the tip of the probe.
   See *Figure 4-1 How to attach the Gap adapter - 1* on page 13.

   a. A protrusion of the tip of the adapter

   b. A dent of the tip of the probe

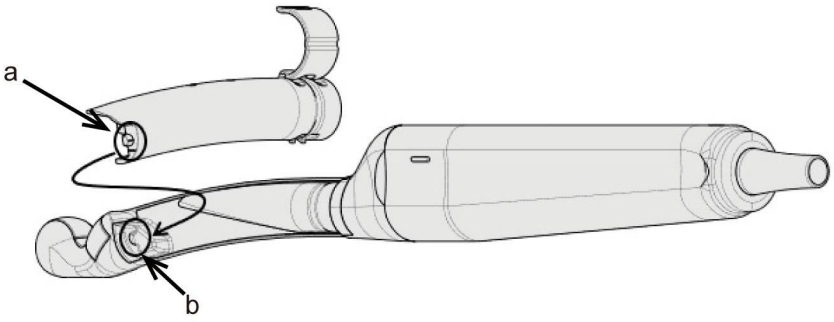

Figure 4-1 How to attach the Gap adapter - 1

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2. Cover the Gap adapter to the probe shaft.
   See *Figure 4-2 How to attach the Gap adapter - 2* on page 13.

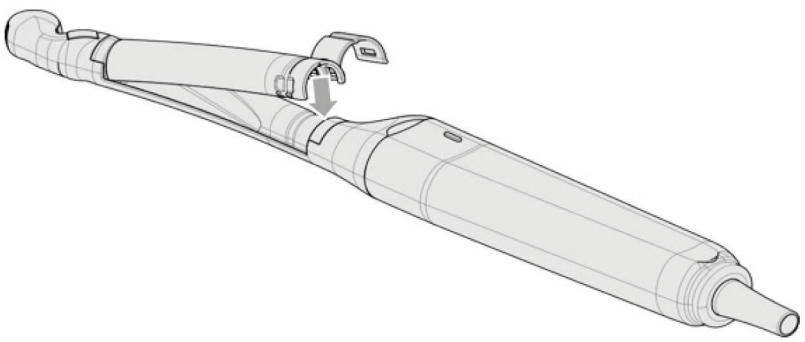

Figure 4-2 How to attach the Gap adapter - 2

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3. Clip the latch of the Gap adapter
   See *Figure 4-3 How to attach the Gap adapter - 3* on page 14.

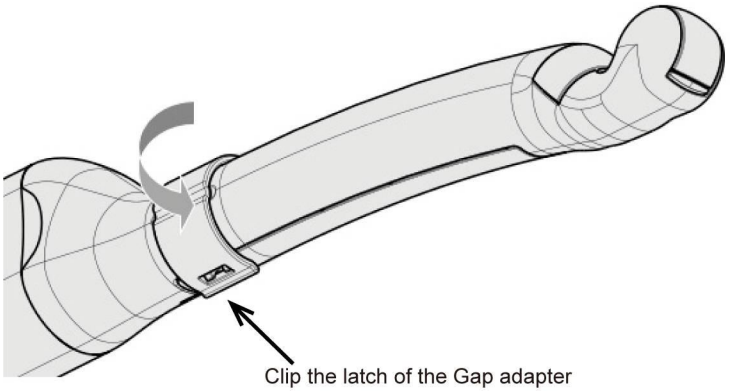
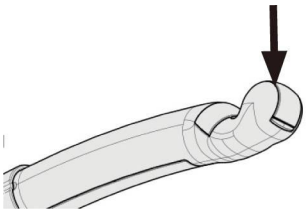


Figure 4-3 How to attach the Gap adapter - 3

CAUTION

Do not operate the probe with excessive force.
Use with excessive force could result in injury to the patient.

Do not apply excessive force to the ultrasonic radiation surface.
Applying more force than necessary may damage the sealing part of the probe.



Scan for minimum time necessary at the lowest possible acoustic output.
Acoustic output may affect the patient's internal tissues.
For details about the acoustic output, please refer to the documentation supplied with the diagnostic ultrasound system.

Do not touch the connector terminal pin of the probe.
Electrostatic discharge may result in malfunction of the probe.

Do not touch the probe connector of the diagnostic ultrasound system and the patient at the same time.
It can cause electric shock to the patient.

4.2 Relationship between the direction of the probe and the orientation mark

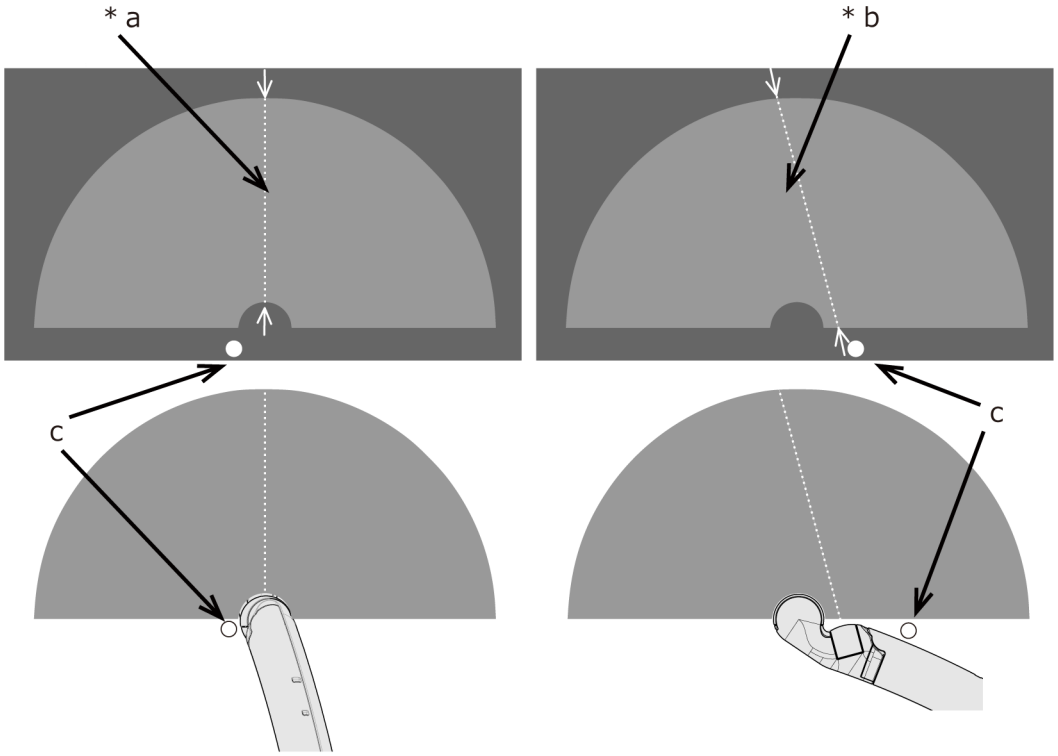
This probe has two ultrasound radiation parts, one for Sagittal image and the other for axial image. *Figure 4-4 Relationship between the direction of the probe and orientation mark* on

page 15 shows the relationship between the direction of the probe and the orientation mark in the image.

a. Sagital Plane

b. Axial Plane

c. Orientation mark



* The two-dot chain line in the figure is not displayed in the images.

Figure 4-4 Relationship between the direction of the probe and orientation mark

4.3 How to mount/remove the probe cover

4.3.1 How to mount the probe cover

Apply a suitable amount of sterile ultrasound gel on the ultrasound radiation part and then mount the probe cover on the probe.
See *Figure 4-5 How to attach the probe cover* on page 16.

Remove air bubbles in the ultrasound gel or wrinkles of the probe cover on the ultrasound radiation part.

a. Probe cover

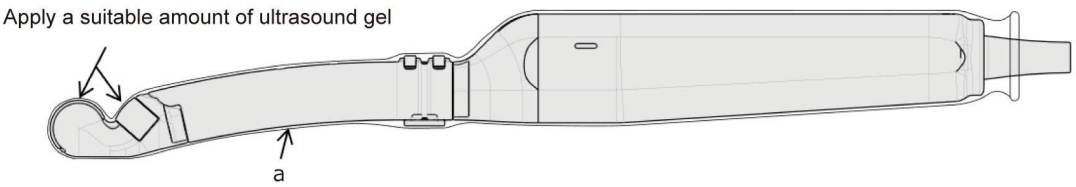


Figure 4-5 How to attach the probe cover

WARNING

- Mount the probe cover on the insertion portion.
  If the probe cover is not mounted, residual pathogens on the probe could infect the patient.
- Use our company probe covers only.
  Use of non biocompatible probe covers can cause an adverse reaction.
- Use only sterile probe covers.
  Use of non sterile probe covers could cause infection to the patient.
- Do not reuse the probe cover.
  Reuse of probe covers may cause infection to the patient.
- Do not apply non sterile acoustic medium.
  Use of non sterile acoustic medium can cause infection to the patient.
- Do not use latex probe covers for patient who may have an allergic reaction.
  Use of the latex probe covers could result in anaphylactic shock. Ask the patient about allergy history before diagnosis.

CAUTION

- Confirm the storage condition and the expiration date of the probe cover.
  Store the probe cover according to its instruction. Do not use the probe cover if the expiration date has passed, if it is discolored or if there is visible damage such as a tear.
- Confirm that there is no air bubbles in the ultrasound gel on the ultrasound radiation part.
  Air bubbles on the ultrasound radiation part can result in misdiagnosis due to poor image quality or improper rendering.

4.3.2 How to remove the probe cover

1. Wrap the probe cover in tissue and remove the probe cover from the probe.
2. Wipe off the acoustic medium adhering to the probe with tissue.
3. Dispose tissue and the probe cover according to the infection prevention procedures of your facility.

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.

4.4 How to remove the Gap adapter

Remove the Gap adapter from the probe in the reverse order of *4.1 How to attach the gap adapter and operation* on page 13.

4.5 How to attach the disposable endocavity needle guides (644-101, 644-102)

When attaching the needle guide, do not use the Gap adapter.
Follow the steps below to attach the needle guide to the probe.

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1. Select the needle guide insert according to the thickness of the needle to be used and attach it to the needle guide.
   See *Figure 4-6 How to attach the needle guide - 1* on page 17.

   a. Needle guide

   b. Needle guide insert

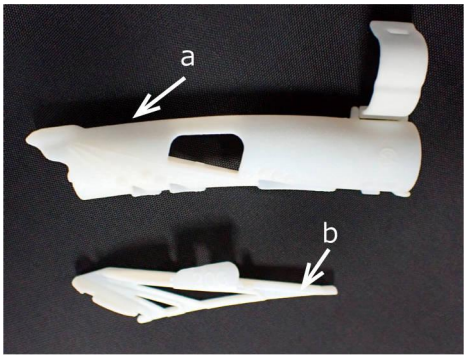

Figure 4-6 How to attach the needle guide - 1

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   a. Attach by combining unevenness.
      See *Figure 4-7 How to attach the needle guide - 2* on page 17.

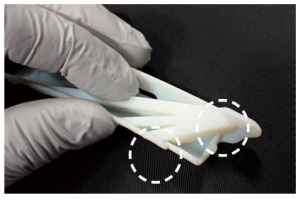

Figure 4-7 How to attach the needle guide - 2

Figure 4-8 After attaching the needle guide

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2. Attach the probe cover to the probe in the same procedure as in *4.3.1 How to mount the probe cover* on page 15.
   See *Figure 4-9 How to attach the needle guide - 3* on page 18.

Figure 4-9 How to attach the needle guide - 3

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3. Align the protrusion of the needle guide with the dent on the probe tip.
   See *Figure 4-10 How to attach the needle guide - 4* on page 18.

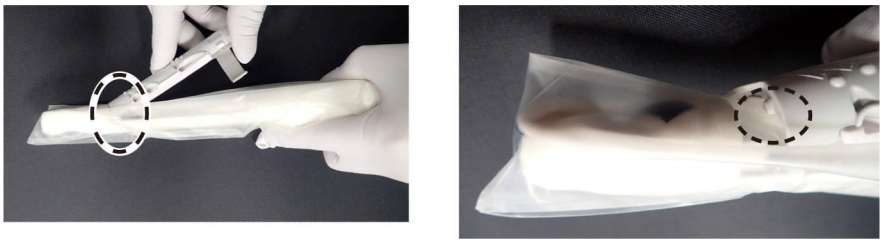

Figure 4-10 How to attach the needle guide - 4

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4. Cover the probe with the needle guide, and clip the latch.
   See *Figure 4-11 How to attach the needle guide - 5* on page 18.

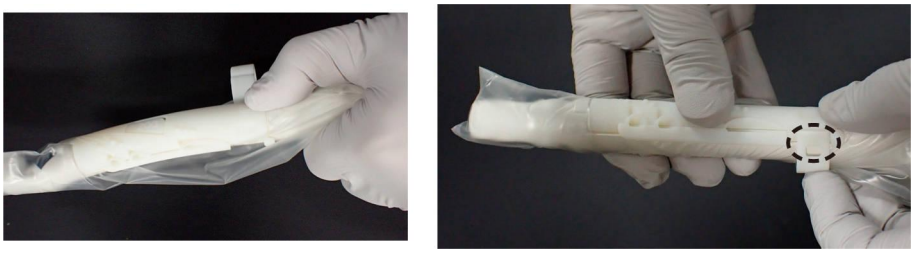

Figure 4-11 How to attach the needle guide - 5

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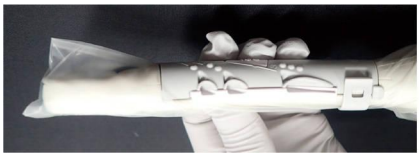
5. Make sure that the needle guide is attached correctly.
   See *Figure 4-12 How to attach the needle guide - 6* on page 19.

The needle guide is attached correctly.



Examples of incorrect conditions
(The protrusion does not fit with the dent)

Figure 4-12 How to attach the needle guide - 6

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6. Insert the puncture needle and perform puncture. Pay attention to the needle tip on the screen, and if the needle tip echo becomes small, rotate the puncture needle so that you do not lose sight of it.

4.6 Display of Puncture Guideline

The puncture guideline can be displayed by dot marks. Please refer to the documentation supplied with the diagnostic ultrasound system for how to display the puncture guideline on the image.

See *Figure 4-13 Puncture Guideline 1* on page 19.

a. Guideline

b. Sagittal plane

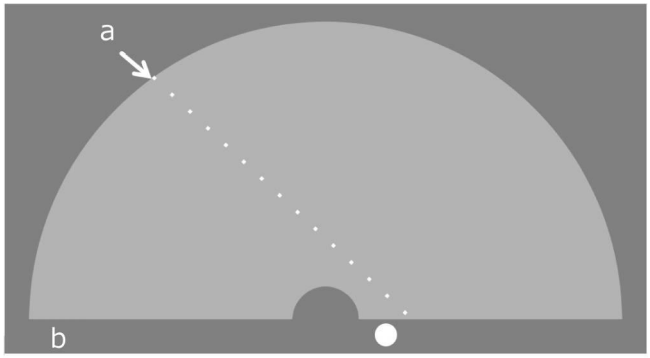


Figure 4-13 Puncture Guideline 1

When Puncture Disp.Pattern” is “Multi”, multiple puncture guidelines are displayed at the same time.Perform puncture by matching the number indicated in the puncture guideline with the number of the puncture route of the needle guide and the number of protrusions.
See *Figure 4-14 Puncture Guideline 2* on page 20.

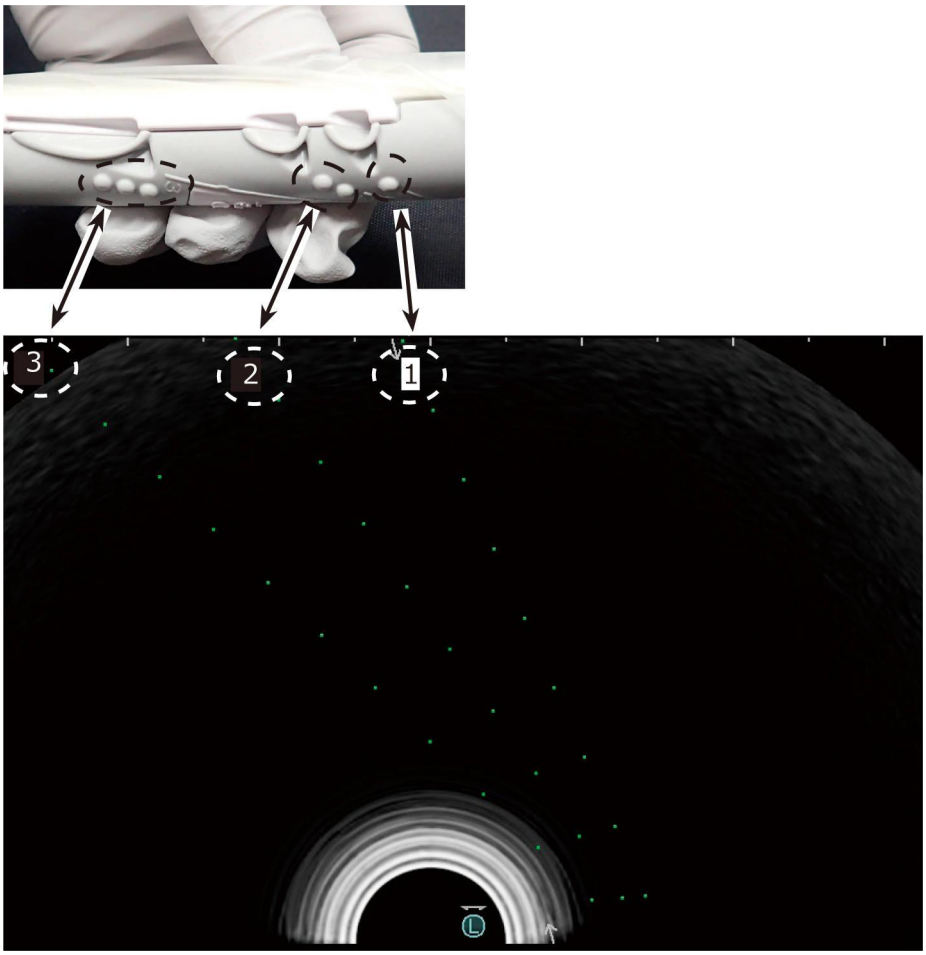
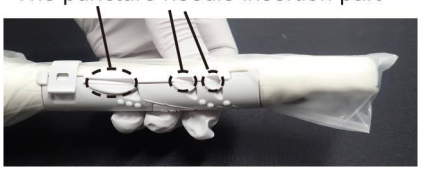


Figure 4-14 Puncture Guideline 2

WARNING

Puncture is performed with the puncture needle insertion part of the needle guide visible.
Depending on the insertion depth of the probe, the puncture needle insertion part may be inserted into the body and may not be visible.
Select the puncture route of the visible puncture needle insertion part and perform puncture.

The puncture needle insertion part



CAUTION

Maximize the scanning angle to minimize the blind area of puncture. Please refer to the instruction manual of the diagnostic ultrasound system for setting the scanning angle.

4.7 Operation

Place the ultrasonic radiation part of the probe in the body cavity. An image of the region of interest is displayed on the monitor of the ultrasound diagnostic instrument. For details on displaying and adjusting the image, refer to the instruction manual of the ultrasound diagnostic instrument.

⚠ WARNING

- Clean and sterilize the probe if blood is adhered to the probe, otherwise there is a risk of infection.

⚠ CAUTION

- Do not operate the probe with excessive force.
  Use with excessive force could result in injury to the patient.
- Scan for the minimum time necessary at the lowest possible acoustic output.
  Acoustic output may affect the patient's internal tissues.
  For details about the acoustic output, please refer to the instruction manual of the ultrasound diagnostic instrument.
- Do not touch the connector terminal pin of the probe.
  Electrostatic discharge may result in malfunction of the probe.
- Do not touch the probe connector of the ultrasound diagnostic instrument and the patient at the same time.
  It can cause electric shock to the patient.

4.8 Post-operation checks

After operation, check the external appearance of the probe.
Visually inspect the probe tip, the ultrasonic radiation part, the cable, and the connector.
If there are any abnormalities such as holes, dimples, abrasion, cracking, deformation, loosening, or discoloration, discontinue use and perform the necessary actions.

⚠ WARNING

- Check the appearance of the probe after use.
  The patient may be injured if the equipment has any abnormality. If any abnormality is found in the equipment, stop using it and contact our company written on the back cover. In particular, always check the external appearance if the probe has been knocked against something or has received a physical shock.
- Clean and sterilize the probe if blood is adhered to the probe, otherwise there is a risk of infection.

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