gynesonics®

Sonata® SYSTEM

Instructions for Use
Sonata Intrauterine Ultrasound (IUUS) Probe

IUUS Probe REF: IUSP-002

Manual Catalog #: REF-003.
LS 05928-008 Rev 005, Instructions for Use Sonata Intrauterine Ultrasound (IUUS) Probe, September 2025
Release Date: 19NOV2025

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Notice

Sonata® Intrauterine Ultrasound (IUUS) Probe Instructions for Use

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If you have any questions regarding the appropriate use of this device or concerning any safety or operating instructions described in this manual, please contact your local Gynesonics Representative or the service department of Gynesonics at:

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About this Instruction Manual

This Instruction Manual covers the Intrauterine Ultrasound (IUUS) Probe, an accessory of the Sonata System for Transcervical Fibroid Ablation. Refer to Sonata System Instructions for Use for Sonata System 2.2 (REF-009) for full operational description of the IUUS Probe with the Sonata System.

This manual includes reprocessing at healthcare facilities that support low temperature sterilization using specified sterilization methods. Reprocessing Staff must be trained in the handling of biohazardous medical devices in addition to having reviewed this procedure thoroughly. Supplemental training may be provided by Gynesonics upon request. Pre-sterilized IUUS Probes and third-party reprocessing options may be available for healthcare providers who do not have access to sterilization methods specified within this manual; contact Gynesonics for further information.

Contact Gynesonics for additional copies of this manual, any additional questions or technical support required for training, service, and maintenance. Manual originally issued in English.

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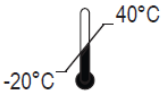
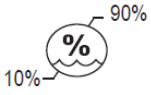
Symbols Glossary

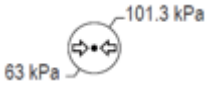
The following tables show the safety symbols that are used on the Sonata System and throughout this manual.

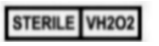
SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1 #5.1.1	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.12	Symbols for use in the labeling of medical devices.
			ISO 7000 - 3082	Graphical symbols for use on equipment.
	Importer	To indicate the entity importing the medical device into the locale	ISO 7000-3725	Graphical symbols for use on equipment
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1 #5.1.3	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.6	Symbols for use in the labeling of medical devices.
			ISO 7000-2497	Graphical symbols for use on equipment.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1 #5.1.6	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.10	Symbols for use in the labeling of medical devices.
			ISO 7000-2493	Graphical symbols for use on equipment.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1 #5.1.7	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.5	Symbols for use in the labeling of medical devices.
			ISO 7000-2498	Graphical symbols for use on equipment.
	Medical Device	Indicates that a device is a Medical Device	ISO 15223-1:20 21 #5.7.7	Medical devices – Symbols to be used with medical

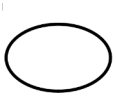
				device labels, labeling, and information to be supplied.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1 #5.1.2	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.13	Symbols for use in the labeling of medical devices.
	Follow instructions for use	Refer to instruction manual/booklet.	IEC 60601-1 Table D.2, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			ISO 7010-M002	Graphical symbols – Safety colours and safety signs – Registered safety signs.
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 #5.2.3	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.8.2	Symbols for use in the labeling of medical devices.
			ISO 7000-2501	Graphical symbols for use on equipment.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1 5.2.7	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.23	Symbols for use in the labeling of medical devices.
			ISO 7000-2609	Graphical symbols for use on equipment.
	DO NOT use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 #5.2.8	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #6.3	Symbols for use in the labeling of medical devices.
			ISO 7000-2606	Graphical symbols for use on equipment.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
IPX7	Degree of Ingress Protection Provided by Enclosure	Protected against the effects of temporary immersion in water. The handle and device shaft and tip are IPX 7 rated.	IEC 60601-1 Table D.3, Symbol 2	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC 60529 section 6	Degrees of Protection Provided by Enclosures.
	General warning sign	To signify a general warning.	IEC 60601-1 Table D.2 symbol 2	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			ISO 7010 W001	Graphical symbols – Safety colours and safety signs – Registered safety signs.
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	ISO 15223-1 #5.3.1	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-0621	Graphical symbols for use on equipment.
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1 #5.3.4	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-2626	Graphical symbols for use on equipment.
			EN 980 #5.21	Symbols for use in the labeling of medical devices.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1 #5.3.7	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-0632	Graphical symbols for use on equipment.
			EN 980 #5.17.3	Symbols for use in the labeling of medical devices.
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1 #5.3.8	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-2620	Graphical symbols for use on equipment.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	ISO 15223-1 #5.3.9	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-2621	Graphical symbols for use on equipment.
	Type BF applied part	To identify a Type BF applied part complying with IEC 60601-1. Type BF refers to classification of the nature of patient contact and degree of patient protection from risk of electrical shock.	IEC 60601-1 Table D.1. Symbol 20	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC 60417 #5333	Graphical Symbols for Use on Equipment.
	Linear or curved array probe	To identify the control or the indicator to activate a linear array or curved array probe for the electronic generation of a sound field and to identify the corresponding connector.	TR 60878 #5710	Graphical Symbols for electrical equipment in medical practice.
CE	CE marking	Signifies European technical conformity.	MDR (EU) 2017/745	Medical Device Regulation
UK CA	UKCA Marking	Signifies technical conformity with medical device regulations of the United Kingdom.	2002 No. 618 with 2019 No. 791 and 2020 No. 1478	UK Medical Devices Regulations 2002 as amended

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	TUV Mark	Indicates that the product was tested and met the certification requirements for electrical, and/or mechanical products.	N/A	N/A
	Recycle: electronic equipment	DO NOT dispose of electronic equipment in normal trash.	Directive 2012/19/EU Annex IX	Marking of Electrical and Electronic Equipment in accordance with Article 15 (2) of Directive 2012/19/EU
	Sterilized using hydrogen peroxide	Indicates a medical device that has been sterilized using hydrogen peroxide	N/A	N/A
	Sterilized using plasma (e.g., STERRAD®)	Indicates a medical device that has been sterilized using plasma (e.g., STERRAD®)	N/A	N/A
	Sterilized using vaporized hydrogen peroxide	Indicates a medical device that has been sterilized using vaporized hydrogen peroxide	MedTech Europe Guidance May 2019	Use of Symbols to Indicate Compliance with the MDR
	Product is not made with natural rubber latex	Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.	ISO 15223-1 #5.4.5 Reference Annex B for the general prohibition symbol and negation symbol	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 #5.4.3	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.
	Single sterile barrier system	Indicates a single sterile barrier system	ISO 15223-1 #5.2.11	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside	ISO 15223-1 #5.2.14	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.

Symbols Not from Standards

SYMBOL	SYMBOL TITLE	EXPLANAORY TEXT	REFERENCE	REFERENCE TITLE
	Quantity	Indicates net quantity of package contents, expressed in terms of weight or volume, numerical count, or any combination thereof, or other terms which accurately reflect the contents of the package.	None	None

Glossary of Terms, Acronyms, and Definitions

TERM	DEFINITION
Articulation Lever	The self-locking control arm used to pivot the Articulating Tip on the IUUS Probe.
Articulating Tip	The three-position articulating Imaging Surface of the IUUS Probe, controlled by the Articulation Lever.
Cable	The data and power cord from the proximal side of the IUUS Probe handle to the connector.
Cleaning	Physical removal of soil and contaminants to the extent necessary for further processing.

Connector	A multipin connector that interfaces with the Sonata SMART Tablet.
Disinfection	The destruction of pathogens and other microorganisms by physical or chemical means.
EMC	Electromagnetic Compatibility
EMI	Electromagnetic Interference
Enzymatic detergent	A solution for medical device cleaning designed for removal of biological soil such as blood, tissue, and biofilms.
Gynesonics	Sonata System manufacturer
Imaging Surface	The transducer surface at the tip of the Intrauterine Ultrasound Probe
Intrauterine Ultrasound (IUUS) Probe	A reusable device that connects to the single-use RFA Handpiece to create the Sonata Treatment Device. The IUUS Probe images the uterus from within the endometrial cavity.
Operator	The clinician or supporting staff operating the Sonata System.
Point-of-Use	The location and time where the device is used.
Reprocessing	The entire procedure of cleaning, disinfecting (if required), and sterilizing the IUUS Probe for the first time or after a procedure in preparation for the next use.
Sterilization	A process that renders product free from viable microorganisms.
Strain Relief	The flexible tapered elastomer portions at the ends of the cable.
WEEE	Waste Electronic and Electrical Equipment (WEEE) Regulations for proper disposal within European Union.

Chapter 1 General Information

CAUTION	
⚠	SALE AND USE Federal law restricts this device to sale by or on the order of a physician.

1.1 Device Description and the Sonata System Instructions for Use

The Sonata Intrauterine Ultrasound (IUUS) Probe is a reusable device that connects to the single-use Sonata Radiofrequency Ablation (RFA) Handpiece to create the Sonata Treatment Device. The IUUS Probe images the uterus from within the endometrial cavity. The IUUS Probe is an accessory of the Sonata Transcervical Fibroid Ablation System. The Sonata System provides radiofrequency (RF) ablation of uterine fibroids (myomata; leiomyomata uteri) using a transcervical approach without incisions or material uterine distension.

The IUUS Probe should only be used in conjunction with the Sonata System for radiofrequency ablation of fibroids. The Sonata System is comprised of durable medical equipment, software, and various single-use and reusable instruments. The system enables a clinician to deliver radiofrequency energy to fibroid tissue resulting in thermal fixation and coagulative necrosis of the tissue.

For the operation of the Sonata System as well as general warnings and cautions, refer to:

Sonata System Instructions for Use REF-009 (Sonata System 2.2)

1.2 Sonata System Intended Use and Clinical Trial Results

The Sonata System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

Refer to Sonata System Instructions for Use REF-009 (Sonata System 2.2) for Sonata System pivotal clinical trial results.

1.3 Safety Information

Read all General Warnings (Section 1.6) and Cautions (Section 1.7) and note that additional Warnings and Cautions are placed on product labels and located in pertinent sections of this Instructions for Use (IFU). Refer to the Symbols Glossary, in the front of this IFU, for an explanation of symbols.

Refer to Sonata System IFU REF-009 (Sonata System 2.2) for details on contraindications, patient selection, potential postoperative events, procedure setup, risks, warnings, cautions, anesthesia, and other required materials associated with the use of the IUUS Probe with the Sonata System.

In the event of a serious incident related to use of the Sonata System, notify Gynesonics. If located within the European Union, also notify the competent authority of the EU Member State in which the user and/or patient is established.

The Sonata IUUS Probe, as a part of the Sonata System, has been tested to the following standards:

- EN/IEC 60601-1, Medical Electrical Equipment: General Requirements for Safety and Essential Performance.
- EN/IEC 60601-1-2, Medical Electrical Equipment: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – requirements and tests.
- EN/IEC 60601-1-6, Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN/IEC 60601-2-37, Medical Electrical Equipment: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

1.4 Sterile Status of IUUS Probe as Provided

The Sonata IUUS Probe is provided non-sterile, requiring cleaning and sterilization per Chapter 2 of this manual prior to use and between each subsequent use.

Pre-sterilized IUUS Probes and third-party reprocessing options may be available for healthcare providers who do not have access to sterilization methods identified in this manual; contact Gynesonics for further information. Pre-sterilized IUUS Probes are provided sterile either by ethylene oxide or vaporized hydrogen peroxide gas plasma as indicated on the sterile packaging.

1.5 Intended Operators and Support Staff

1.5.1 Operator

Operators should be a licensed and board eligible/board certified clinician, such as an obstetrician/gynecologist, proficient with hysteroscopic and/or laparoscopic surgery, electrosurgery, and sonography. Only clinicians who have completed a Gynesonics-approved training program and understand the contents of this IFU should treat patients using the Sonata System.

1.5.2 Support Personnel

Support personnel should be trained in the operation of electrosurgical instruments and management of sterile surgical environments. Only support personnel who have read and understood the Sonata Instructions for Use and received instruction and relevant training from a Gynesonics Representative should support the treatment of patients using the Sonata System.

1.5.3 Reprocessing Personnel

Personnel involved in reprocessing of the reusable IUUS Probe should be knowledgeable in general principles and risks associated with the reprocessing of reusable medical devices and be competent in common practices and safety procedures used in reprocessing. Reprocessing personnel are expected to have adequate understanding and skills with regard to hazards associated with contaminated medical devices and reprocessing chemical exposure.

1.6 General Warnings and Reporting

The following warnings identify known operations, procedures, or practices that should be heeded immediately or risk injury or death to patient or operator.

WARNINGS		
1		READ INSTRUCTIONS FOR USE BEFORE USE Read this Instructions for Use and the Sonata System Instructions for Use in its entirety before use or reprocessing. Safe and effective electrosurgery is dependent not only on equipment design, but also on factors under control of the Operator. It is important that the instructions supplied with this system be read, understood, and followed in order to enhance safety and effectiveness. This includes following the indications and contraindications for use.
2		FOR USE ONLY BY QUALIFIED CLINICIAN To reduce the possibility of patient or operator injury, products covered in this Operator's Manual are intended for use only by qualified healthcare professionals trained in the safe use of electrosurgery and in the Sonata System. Contact Gynesonics for information regarding approved training programs.
3		RISK OF UTERINE PERFORATION The Sonata System requires device insertion via a transcervical approach. As with similar procedures, risks include uterine perforation, cervical laceration, and other injuries; the probabilities of such risks may be reduced, but not eliminated, through attention to uterine size and position, as well as to any undue resistance during cervical and uterine instrumentation. A false passage within the cervical stroma or frank uterine perforation can occur during any procedure in which the uterus is instrumented, especially in cases of severe uterine anteversion, retroversion, or lateral displacement of the uterus.
4		DO NOT MODIFY SYSTEM DO NOT make any modifications to Gynesonics instruments or hardware as any changes may compromise safety and performance. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNINGS		
5		INSPECT STERILE BARRIER AND DATE Prior to use, inspect sterile barrier and expiration date of the IUUS Probe. Use of expired product or device with breached sterile barrier may lead to increased risk of infection.
6		CHECK CORD AND CABLE CONDITION Periodically check power cords and cables for damage, including damage to metal blades, cut or frayed rubber jackets, or crushed connectors. Replace cords if their blades are bent. DO NOT re-straighten and DO NOT attempt to repair abnormal cables. If damage has occurred to the insulation, replace the cord or cable immediately, as electric shock and/or equipment damage may result. To prevent damage to plugs (on the hospital grade cords, for example), properly connect/disconnect wall plugs by grasping the plug body, not the cord. In applications involving frequent connections and disconnections, inspect wall plugs, the flexible cable, and connectors frequently for potential damage. If safety of a cord is in doubt, cord replacement is strongly recommended to maintain safety against electric shock.
7		LIMIT ULTRASOUND USE Ultrasound procedures should be used for valid reasons and for the shortest period of time. For systems distributed in the United States of America, refer to the Medical Ultrasound Safety Education Program brochure produced by the AIUM.
8		INFECTION CONTROL To avoid cross-contamination, follow all infection control policies (including for reprocessing, packing, and storage) for personnel and equipment that have been established for your office, department, or hospital.
9		WEAR PERSONAL PROTECTIVE EQUIPMENT The used IUUS Probe has been directly exposed to blood and tissue. Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices, and equipment. PPE includes gown, mask, goggles or face shield, gloves, and shoe covers. Follow standard procedures for handling soiled equipment.

1.7 Cautions

The following cautions identify known operations, procedures, or practices which should be addressed promptly or risk undesired outcomes or material damage.

CAUTIONS		
1	⚠	OPEN CONNECTORS DO NOT immerse electrical connectors on any device cables, especially during cleaning. Damage may result to the instruments. Refer to Reprocessing Instructions for immersion limitations.
2	⚠	CLEANING PROCEDURES Always follow proper cleaning procedures. Failure to adhere to cleaning, disinfection, and sterilization procedures outlined in this manual could result in transmission of disease and cause infection, endangering operators and patients.
3	⚠	SALE AND USE Federal law restricts this device to sale by or on the order of a physician.

1.8 Intrauterine Ultrasound (IUUS) Probe

The IUUS Probe, see Figure 1-1, is reusable and must be reprocessed (cleaned and sterilized) prior to use and between treatments as described in Chapter 2 through Chapter 6 of this manual. DO NOT use if there is damage to the sterile packaging of the IUUS Probe. If there is damage to the sterile packaging, the affected IUUS Probe requires repeat cleaning and sterilization. Obtain a replacement sterile IUUS Probe for use.

The IUUS Probe includes the following parts (see Figure 1-2):

- Articulation Tip – Articulates to 45° and 60° with a 114° field of view,
- Articulation Lever – Press down to unlock and move forward to adjust angle,
- Release Latches,
- Handle,
- Shaft – 8.5 mm diameter (Diameter of Treatment Device is 8.75mm diameter), and
- A 3-m Connector Cable.

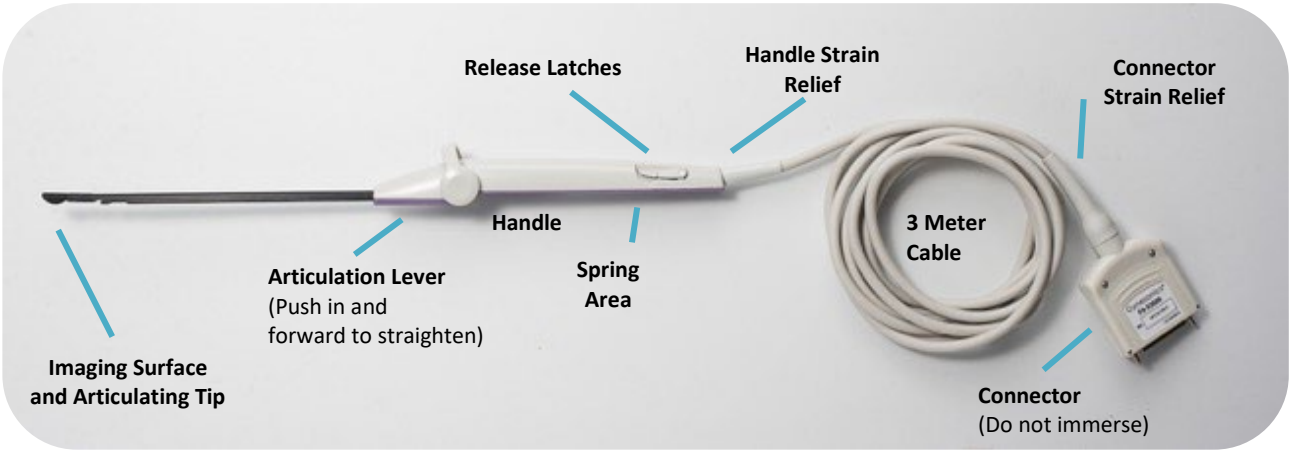


Figure 1-1 Relevant components of the IUUS Probe.

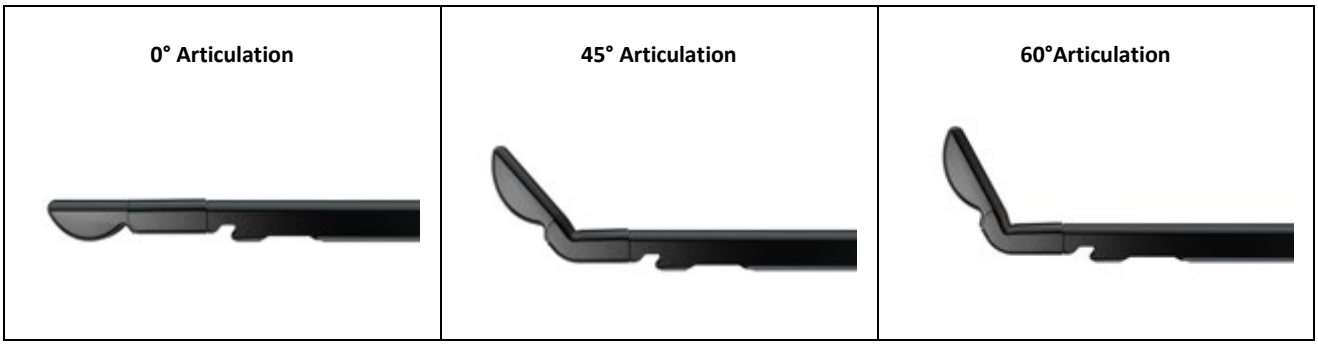


Figure 1-2 Examples of Articulating Tip angle at 0°, 45° and 60°.

CAUTIONS	
⚠	PROTECT IMAGING SURFACE The Imaging Surface of the IUUS Probe is fragile. Damage to the Imaging Surface can result in poor imaging or safety hazard.
⚠	CLEAN AND STERILIZE AFTER USE, DO NOT AUTOCLAVE The IUUS Probe should be cleaned and sterilized following each procedure. Steam sterilization (autoclave) of the IUUS Probe will result in device damage.
⚠	FOR INTRAUTERINE USE ONLY The IUUS Probe has an Articulating Tip with ultrasonic Imaging Surface. DO NOT attempt to use the IUUS Probe Tip in any application other than intrauterine. DO NOT apply force on the Tip while trying to articulate or the Tip may become permanently misaligned.

1.8.1 IUUS Probe Storage

Following cleaning and sterilization, store per treatment facility protocols for sterile products.

1.8.2 Ultrasound-Related Safety

The Sonata System SMART Tablet complies with the international standard IEC 60601-2-37 for real-time display of Thermal and Mechanical Acoustic Output Indices. When operating in any mode with the Freeze function disabled, the window displays the acoustic output indices relevant to the currently-active probe. The acoustic power indices are constant at each imaging frequency/depth setting; there are no operator-accessible adjustments. The Mechanical Index (MI) and Thermal Index Soft Tissue (TIS) are displayed to allow you to monitor the amount of ultrasound energy that is transferred to the patient.

With respect to use of the Sonata System, practice of the ALARA principle (exposure of the patient to ultrasound energy at a level that is as low as reasonably achievable) includes performing ultrasound procedures only for valid reasons, and for the shortest period of time practicable.

Refer to the Sonata System Instructions for Use for information on the Ultrasound Tablet Acoustic Output Indices including limits and compliance information to the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (NEMA UD 3).

Note: For systems distributed in the United States of America, refer to the Medical Ultrasound Safety ultrasound education program brochure produced by the AIUM.

1.9 IUUS Probe Pre-Cleaning Overview

A Point-of-Use pre-cleaning is conducted immediately after using the IUUS Probe. The IUUS Probe is prepared and transferred to reprocessing. Repeat the procedure if Point-of-Use Pre-Cleaning was not adequately completed (see Section 5.5 of the Sonata System Instructions for Use).

Reprocessing should be performed within 24 hours unless the IUUS Probe is packaged in the IUUS Probe Return Kit for shipment.

WARNINGS	
	WEAR PERSONAL PROTECTIVE EQUIPMENT Wear protective equipment including gloves and follow procedures for handling soiled equipment.

CAUTIONS	
	PROTECT THE IUUS PROBE ARTICULATING TIP When transporting, handling, and reprocessing, take measures to protect the IUUS Probe Tip from damage.
	DO NOT WET OPEN CONNECTOR When wiping down or cleaning, DO NOT wet the open end of the electronic connector. This may lead to device damage.

1.9.1 Pre-Cleaning IUUS Probe to Remove Visible Soil from IUUS Probe and Cable

Materials needed:

- IUUS Probe (separated from RFA Handpiece and unplugged from SMART Tablet, see Section 5.4 of the Sonata System Instructions for Use),
- Enzymatic detergent spray or water, and
- Surgical towel or sponge

Pre-Cleaning Procedure

1. Set the IUUS Probe Articulating Tip to a 0° angle (straight, unarticulated).
2. Use enzymatic detergent spray or water and a sponge or towel to remove visible soil from the IUUS Probe and the Cable.
    1. Follow manufacturer's instructions when using enzymatic detergent and solutions.
    2. Protect the connector opening from liquid contact.

3. DO NOT use strong force on the Imaging Surface or Articulating Tip. Apply the minimum force needed to avoid damaging surfaces.

3. Dispose of cloth or sponge after use in a biohazard container.

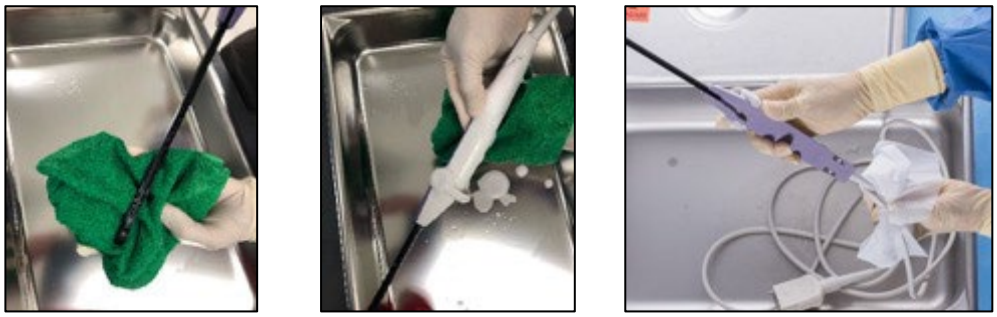


Figure 1-3 Use enzymatic spray or water and a sponge or towel to remove visible soil.

1.9.2 In-House Reprocessing

Validated reprocessing is referenced in Chapter 2. Contact Gynesonics Representative for Central/Sterile Processing Inservice training as required.

1. Ensure the IUUS Probe Tip is set to 0°.
2. Place the IUUS Probe into a container that has a lid, is puncture proof, and is labeled as containing biohazard. Make sure the IUUS Probe Tip is protected during transport to the reprocessing area, see Figure 1-4.
3. Transfer used IUUS Probes to the reprocessing area as soon as possible.

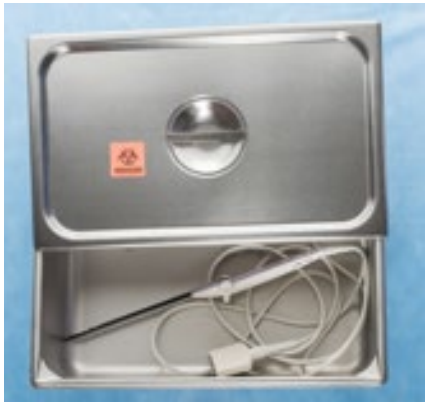


Figure 1-4 Utilize leak proof container with a lid to transport the IUUS Probe to Central Processing

1.9.3 Third-Party Reprocessing Option

1. Facilities without sterilization options listed in Chapter 2 may elect to utilize a third-party reprocessing option in which IUUS Probes are reprocessed remotely and returned ready to use.
2. Used IUUS Probes should be sent to the third-party service provider of reprocessing services using the Sonata IUUS Probe Return Kit (RTN-001).

3. Contact Gynesonics representative for information regarding third-party reprocessing arrangements.

Chapter 2 Reprocessing Introduction

2.1 IUUS Probe Reprocessing Overview (Cleaning, Disinfection, and Sterilization)

A Point-of-Use pre-cleaning is conducted immediately after using the IUUS Probe. Gynesonics recommends that the IUUS Probe be thoroughly cleaned as soon as possible following use and then sterilized, see Table 1. The sterile IUUS Probe should then be stored in sterile containment between uses. Information regarding compatibility with disinfectants is also provided for reference when interim disinfection is required by local or national guidelines.

Facilities with sterilization options listed in section 2.3 may perform in-house reprocessing per Chapter 2 through Chapter 56 of this manual. Contact Gynesonics Representative for Central/Sterile Processing Inservice training as required.

For the list of materials needed for reprocessing the IUUS Probe see Section 2.3 through 2.6.

REPROCESSING OVERVIEW	LOCATION
1. **IUUS Probe Point-of-Use Pre-Cleaning**	Section 1.9
2. **Inspect the IUUS Probe for Damage**	Section 3.1
3. **Clean the IUUS Probe** Option 1: Manually Clean with disinfection option	Chapter 4
4. **Clean the IUUS Probe** Option 2: Automated Washing with disinfection option	**Chapter 5**
5. **Package and Sterilize the IUUS Probe**	**Chapter 6**

Table 1 Reprocessing Overview

2.2 Reprocessing Warnings and Cautions

Caution is required when cleaning and sterilizing the IUUS Probe. Follow the reprocessing instructions as outlined in this Instructions for Use.

The IUUS Probe has no serviceable components.

WARNINGS	
	WEAR PERSONAL PROTECTIVE EQUIPMENT Wear protective equipment including gloves and follow procedures for handling soiled equipment.

CAUTION	
	OPEN CONNECTORS DO NOT immerse electrical connectors on any device cables, especially during cleaning. Damage may result to the instruments. Refer to reprocessing instructions for immersion limitations.
	TEMPERATURE LIMITS DO NOT steam sterilize. If exposed to temperatures exceeding 140°F (60°C), there may be damage to the IUUS Probe. If the IUUS Probe appears damaged from exposure to high temperature, contact Gynesonics for guidance.
	PROTECT THE IUUS PROBE ARTICULATING TIP When transporting, handling, and reprocessing, take measures to protect the IUUS Probe Tip from damage.
	CLEANING PROCEDURES Always follow proper cleaning procedures. Failure to adhere to cleaning, disinfection, and sterilization procedures outlined in this manual could result in transmission of disease and cause infection, endangering operators and patients.

2.3 Validated Sterilization Methods

VALIDATED SYSTEM	USE CYCLE	VALIDATED STERILIZATION TRAY	VALIDATED STERILIZATION WRAP & ACCESSORIES (AS APPLICABLE)
Hydrogen Peroxide (H_2O_2) Based Sterilization Options			
+STERRAD® 100NX®	Standard Cycle	Sonata® IUUS Probe Reprocessing Tray OM-1000-GS APTIMAX® #13837 [58 cm x 28 cm x 10 cm) by ASP®	Halyard® Sequential Sterilization Wrap #68248 [H400, 121 x 121 cm] Double-wrap technique
+STERRAD NX™		No Tray required	
STERIS V-PRO® maX	Lumen, Non-Lumen or Flexible Cycle	Sonata® IUUS Probe Reprocessing Tray OM-1000-GS STERIS Sterilization Tray #vP0004	H600 OneStep® Sterilization Wrap [121 x 121 cm] Double-wrap technique
STERIS V-PRO® maX 2	Lumen, Non-Lumen or Flexible Cycle		
STERIS V-PRO® 60	Lumen, Non-Lumen or Flexible Cycle		
STERIS V-PRO® s2	Lumen, Non Lumen, Flexible or Fast Cycle		
STERIS V-PRO® 1	Standard Cycle		
STERIS V-PRO® 1 Plus	Lumen & Non-Lumen Cycle		
Liquid Chemical Sterilization Options			
STERIS SYSTEM 1E®	Standard Cycle	C1220E Tray	IUUS Probe Connector Protector (ACCY-018)
*STERIS SYSTEM 1® EXPRESS			

Table 2 Sterilization settings and packaging for sterilization of the IUUS Probe

* Not available for use in the United States

+ Includes AllClear™ Technology

2.4 Compatible Reprocessing Materials and Chemicals

	CHEMICAL DESCRIPTION	COMPATIBLE FOR AUTOMATED PROCESS	COMPATIBLE FOR MANUAL PROCESS
Materials Used for Cleaning	pH-neutral to mildly alkaline (pH 7-11) medical grade enzymatic detergent Follow detergent manufacturer's instructions regarding concentration and other conditions.	Yes	Yes
Materials Used for Disinfection	neoDisher Septo DN (Dr. Weigert GmbH & Co.)	Yes	No
	ASP® Cidex® OPA Ortho-Phthaladehyde Solution	No	Yes
	CaviWipes™ by Metrex™	No	Yes

Table 3 Compatible materials and chemicals effective in cleaning the IUUS Probe.

For a full list of reprocessing agents used during validation, refer to section T4.1.

2.5 Materials Needed for Manual Cleaning & Disinfection

All compatible reprocessing agents are referenced in section 2.4.

- Enzymatic detergent
- Soft nylon brush
- A tray for soaking and manual cleaning of the IUUS Probe. An approximate tray size that will fit measures: 48 x 25 x 6 cm (19 x 10 x 2.5 inches).
- Water for use in final rinsing. Recommend using purified, distilled, or demineralized water
- Medical grade, low alcohol surface disinfectant wipes
- Clean, soft, lint-free cloth, or drying cabinet
- Timer

2.6 Materials Needed for Automated Cleaning & Disinfection

All compatible reprocessing agents are referenced in section 2.4.

- Washer-disinfector, ISO 15883 compliant
- Enzymatic detergent
- Disinfectant

- Sonata IUUS Probe Reprocessing Tray (OM-1000-GS)
- Sonata IUUS Probe Connector Protector (ACCY-018)

2.7 Maintenance and Service

The IUUS Probe is not user serviceable. User should inspect the IUUS Probe thoroughly before and after each use and at point of reprocessing. If any damage or defect is observed, do not continue to use the device and notify Gynesonics for evaluation and possible replacement.

2.8 Conditions for Storage and Transport and Usage

Storage and Transport: -20 °C to 40 °C, 10% to 90% relative, non-condensing

Usage: 10 °C to 35 °C, 30% to 75% relative, non-condensing

Chapter 3 IUUS Probe Inspection

3.1 Inspect the IUUS Probe for Damage

1. Inspect the IUUS Probe for any damage to any of the following areas, see Figure 3-1:
    1. Articulating Tip should be straight.
    2. Imaging face should have no cracks or chips.
    3. Handle should have no cracks in the plastic or separation of parts.
    4. Cable should have no cracks or cuts in the insulation.
    5. Connector should not be cracked or have broken housing.
    6. Rubber cover of the IUUS Probe tip appears intact all around.
2. DO NOT reprocess or use if there is any damage to the IUUS Probe. Replace the IUUS Probe if there is any damage and contact your Gynesonics Representative.

AREAS TO INSPECT ON THE IUUS PROBE	
 The tip should be straight. The rubber cover around the articulating tip should be intact and free of damage or adhesive peeling.	 There should be no cracks or chips on the Imaging Surface. Inspect rubber cover all around.
 There should be no cracks in the plastic or separation of any parts on the handle.	 There should be no cracks or cuts in the cable insulation. Connector should not be cracked or have a broken housing.

Figure 3-1 Inspection points of the IUUS Probe.

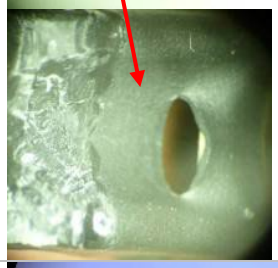
REJECTION EXAMPLES	
Reject: *Probe has broken tip. At 0 degree position the distal tip must be straight.* *Note: Check that the probe can switch to 2 positions: 45° and 60°.*	
Reject: *Probe has Hinge cover tear. Torn hinge cover looks like a slit when straight and opens up when articulated as shown on the right.* *Note: Inspect cover at 0° and at 45° to check for tears.*	 
Reject: *Reject probes with damage on the imaging surface as shown. Also reject if damage to material surface or adhesives is visible.*	

Figure 3-2 Examples of reject probes.

Chapter 4 Option 1: Manual Cleaning and Disinfection

4.1 Prepare Enzymatic detergent Solution

1. Prepare fresh enzymatic detergent solution (use at least 1 gallon or 3.8 L for ease of mixing) according to the manufacturer's instructions. Prepared enzymatic detergent solution will be needed for both soaking and cleaning steps.
2. The temperature of the enzymatic detergent solution should be lukewarm (95°F to 104°F [35°C to 40°C]).
3. Always use fresh solution for each IUUS Probe.

4.2 Soak the IUUS Probe for at Least 12 Minutes

CAUTIONS	
⚠	SOAK LIMIT Be sure to soak the IUUS Probe and cable up to the Connector as shown by the red line in Figure 4-1. The Connector must not get wet.
⚠	SET TIP ARTICULATING TIP STRAIGHT To prevent damage, maintain proper orientation with the Articulating Tip set to 0° (straight) when placing the IUUS Probe in the tray and when storing the IUUS Probe.
⚠	PREVENTING FLUID DAMAGE DO NOT soak or allow the connector to get wet. Allowing fluid to enter the electrical connector may result in damage to the electronics.

Figure 4-1 Areas of IUUS Probe to soak.

1. Use a clean tray on a flat surface. A tray approx. 48 x 25 x 6 cm (19 x 10 x 2.5 inches) will fit one probe.
2. Gently place the IUUS Probe into container.
    1. Be careful with the Articulating Tip to avoid damaging the tip.
    2. DO NOT place the connector into the soaking container.
3. Fill the tray or container with enough enzymatic detergent solution to soak the IUUS Probe to fully cover all parts.
    1. DO NOT soak the IUUS Probe connector (see Figure 4-1).
    2. Set aside the remaining enzymatic detergent solution for Manual Cleaning (see Section 4.3).
4. Soak the IUUS Probe in the enzymatic detergent solution for at least 12 minutes, see Figure 4-2.

Figure 4-2 Fill with sufficient solution to cover the device.

4.3 Manually Clean the IUUS Probe

CAUTION	
⚠	AVOID DAMAGE TO ARTICULATING TIP Clean the Imaging Surface and Articulating Tip of the IUUS Probe cautiously to avoid damaging the Imaging Surface or the rubber cover over the articulation hinge. To avoid damage to the IUUS Probe, DO NOT apply strong force with the brush.

1. With fresh enzymatic solution, saturate a soft nylon brush and remove visible soil from the IUUS Probe. Focus on cleaning the following parts where blood and tissue can accumulate, see Figure 4-3:
   1. IUUS Probe handle.
   2. Articulation Lever.
   3. Release latches and spring area. Move the mechanisms to improve access.
   4. Imaging Surface and Articulating Tip.

   DO NOT use strong force on the Imaging Surface or Articulating Tip. Apply the minimum force needed to avoid damaging surfaces.

Figure 4-3 Areas of IUUS Probe to manually clean.

2. If any soil is difficult to remove, soften the soil with enzymatic detergent solution.

3. Use running water to help remove soil as needed.
4. When you are finished manually cleaning the IUUS Probe, visually inspect all parts for any remaining soil. If clean, proceed with rinsing as outlined in Section 4.4. Otherwise repeat the Manual Cleaning process until all visible soil is removed.

4.4 Rinse Off Cleaning Solution

1. Thoroughly rinse off the enzymatic detergent solution from the IUUS Probe with lukewarm (95°F to 104°F [35°C to 40°C]) water (purified, distilled, or demineralized is recommended). Rinse all parts of the IUUS Probe that were exposed to enzymatic detergent solution including mechanisms, see Figure 4-4.
    1. Release latches,
    2. Spring area,
    3. Articulation lever, and
    4. Imaging Surface and Articulating Tip.

    DO NOT allow the connector to get wet when rinsing.
2. Rinse for at least 2 minutes at approximately 4 L/min or for as long as needed.

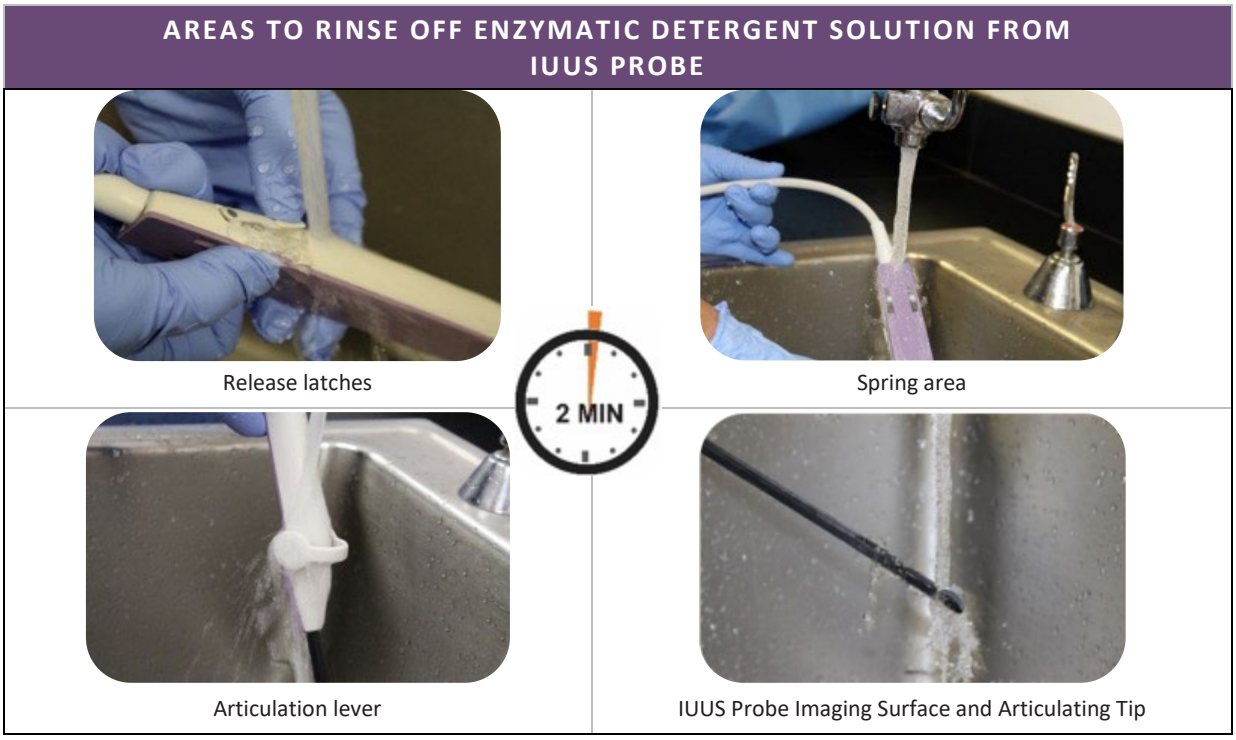


Figure 4-4 Rinse off the release latches, spring area, articulation lever, and tip. Use of purified, distilled, or demineralized water is recommended.

4.5 Wipe Cable with Medical Grade Low Alcohol Surface Disinfection Wipes a Minimum of Two (2) Times

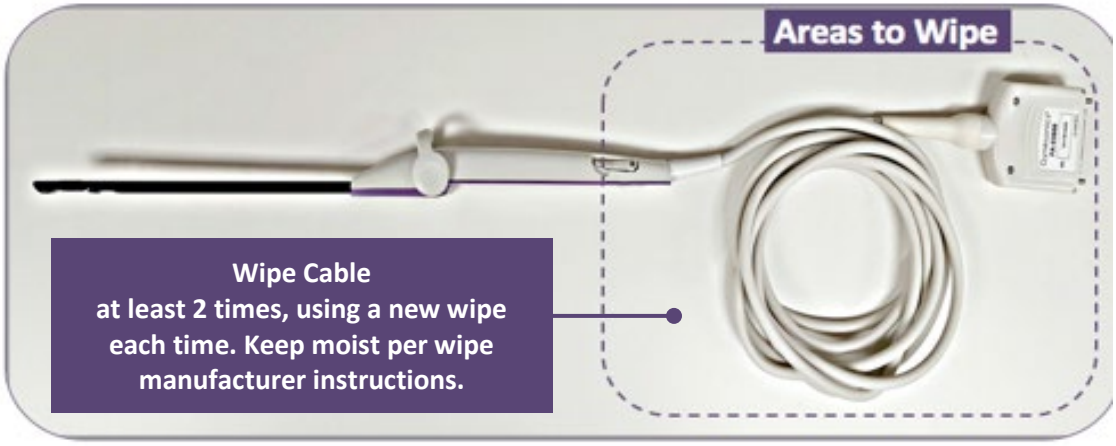
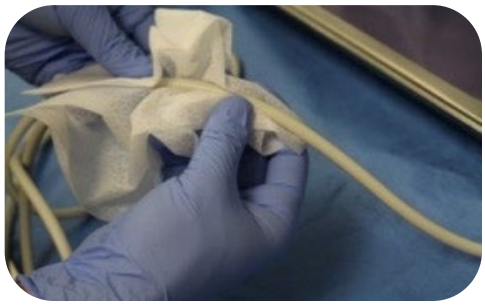


Figure 4-5 Areas to wipe with medical grade low alcohol surface disinfectant wipes.

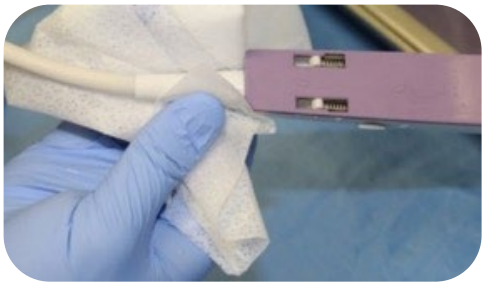
CAUTIONS	
⚠	PREVENTING FLUID DAMAGE DO NOT allow the IUUS Probe electrical connector to get wet. Allowing fluid to enter the electrical connector may result in damage to the electronics.
⚠	USE LOW ALCOHOL SURFACE DISINFECTION WIPES DO NOT wipe the IUUS Probe with household surface cleaners. Only use approved medical grade, low alcohol surface disinfection wipes.

1. Wipe the entire length of the cable and handle strain relief using medical grade, low alcohol surface disinfectant wipes (see Figure 4-6). Follow the manufacturer's instructions.
    1. Pay close attention to the area where the strain relief joins the handle. Soil may accumulate in that area.
    2. Wipe beyond the area that had been soaked to be sure that no part of the device has visible soil.
2. Dispose of the soiled wipe in a biohazard waste container.
3. Use a fresh wipe to re-wipe the cable and handle strain relief a second time. **Wipe at least two (2) times using a new wipe each time**.
4. Continue wiping the cable using new wipes until all visible soil is removed and the IUUS Probe is visibly clean.
5. Continue to keep the surfaces moist with medical grade low alcohol surface disinfectant wipes for the duration specified by the surface disinfectant wipe manufacturer.

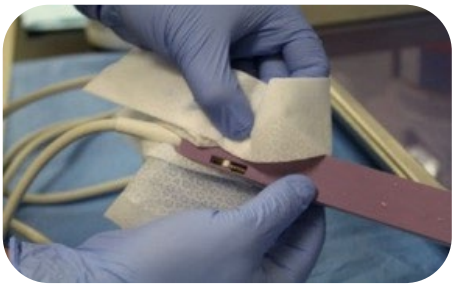
WIPE CABLE



Wipe entire length of cable



Wipe the handle strain relief



Wipe beyond the soaking area

Figure 4-6 Wipe with medical grade low alcohol surface disinfectant wipe at least 2 times using a new wipe each time.

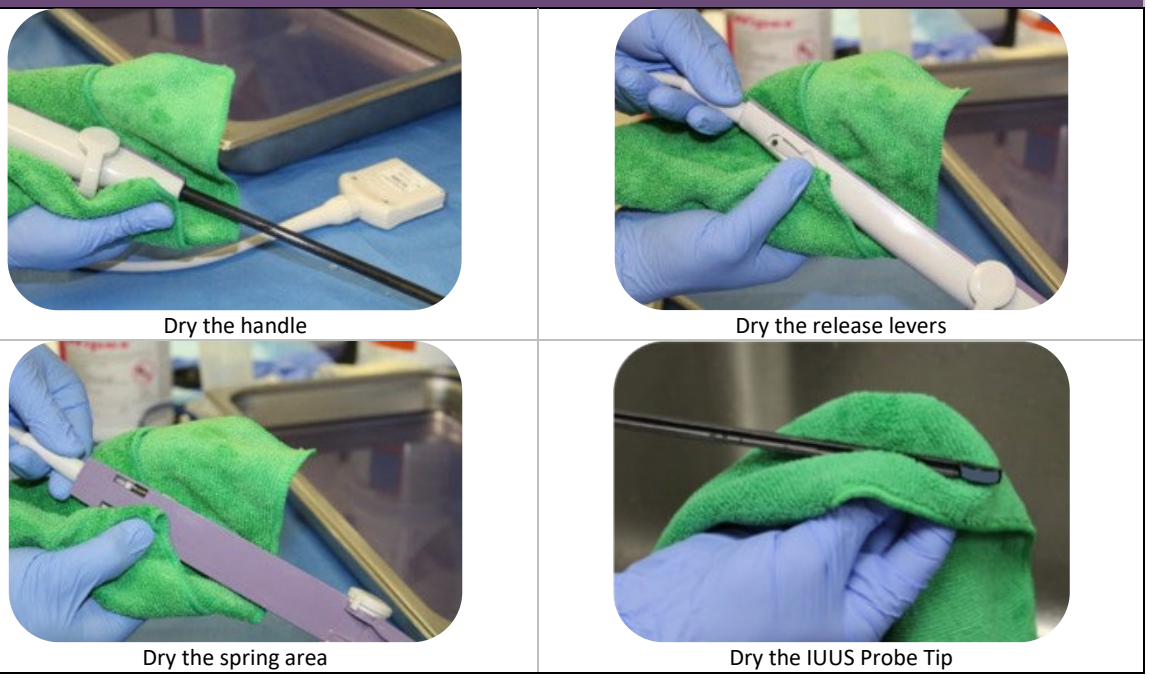
4.6 Dry the IUUS Probe

CAUTION	
⚠	SET THE ARTICULATING TIP STRAIGHT To prevent damage, maintain proper orientation with the Articulating Tip set to 0° (straight) when placing the IUUS Probe in the tray and when storing the IUUS Probe.

1. Completely dry the IUUS Probe, including the mechanisms on the handle, with a clean, soft, lint-free cloth, air dry, or use a drying cabinet, see Figure 4-7.

   If using a drying cabinet, DO NOT exceed 140°F (60°C).

MECHANISMS TO DRY ON IUUS PROBE



Dry the handle | Dry the release levers | Dry the spring area | Dry the IUUS Probe Tip

Figure 4-7 Dry the IUUS Probe with a lint-free cloth.

2. When the IUUS Probe is completely dry proceed to disinfecting and sterilizing, see Chapters 4 through 6.

4.7 Disinfect the IUUS Probe

If disinfection is desired or required per local or institutional policies prior to sterilization, the IUUS Probe is compatible with disinfectants per Section 2.4. Refer to the disinfectant manufacturer's instruction for immersion and rinse procedures.

Following disinfection, dry the IUUS Probe per Section 4.6.

4.8 Compatible Materials and Chemicals

See Section 2.4 for materials and chemicals compatible for manual cleaning of the IUUS Probe.

Chapter 5 Option 2: Automated Cleaning and Disinfection

Automated cleaning using an ISO 15883-compliant automated washer-disinfector has been validated for the Sonata IUUS Probe (IUSP-002) as described in this chapter.

WARNING	
⚠	DO NOT PLACE LID ON TRAY DURING AUTOMATED CLEANING & DISINFECTION Validation of automated cleaning was performed with the lid removed. Leaving the lid on may result in insufficient cleaning of the IUUS Probe.

CAUTIONS	
⚠	SET THE ARTICULATING TIP STRAIGHT To prevent damage, maintain proper orientation with the Articulating Tip set to 0° (straight) when placing the IUUS Probe in the tray and when storing the IUUS Probe.
⚠	TEMPERATURE LIMITS DO NOT steam sterilize. If exposed to temperatures exceeding 140°F (60°C) there may be damage to the IUUS Probe. If the IUUS Probe appears damaged from exposure to high temperature, contact Gynesonics for guidance.
⚠	PLACE IUUS PROBE CONNECTOR INTO CONNECTOR PROTECTOR Place the IUUS Probe's Connector into the IUUS Probe Connector Protector and close securely. Ensure that the pins of the probe connector are seated in the recessed portion of the Connector Protector and not on the silicone seal.

5.1 Prepare the IUUS Probe for Automated Reprocessing

Using the Sonata Reprocessing Tray (OM-1000-GS) and Sonata IUUS Probe Connector Protector (ACCY-018), prepare the IUUS Probe for automated reprocessing:

a. The tray silicone device mounts must be placed to secure the device, see Figure 5-1.The IUUS Probe should be positioned on top of the silicone mounts, but not pushed in.

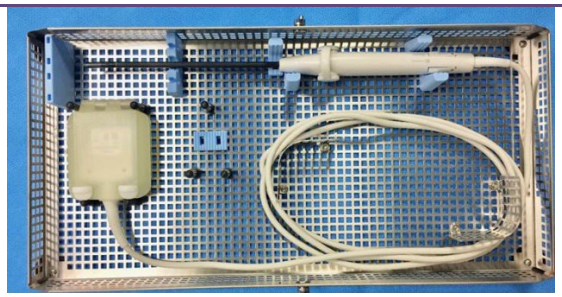


Figure 5-1 Representative of IUUS Probe in reprocessing tray. Tray in photo is Sonata® IUUS Probe Reprocessing Tray OM-1000-GS with Connector Protector ACCY-018

b. Place the IUUS Probe within the tray with the articulation angle set to 0°. Ensure that the articulation lever is facing up, such that the IUUS Probe transducer surface is facing down, see Figure 5-2.

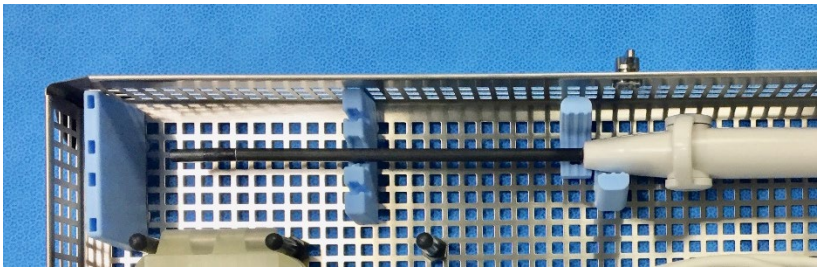


Figure 5-2 Proper storage of the IUUS Probe with its Articulating Tip set to 0°.

c. Wipe the IUUS Probe Connector and Connector relief using medical grade, low alcohol surface disinfectant wipes.

d. Confirm the IUUS Probe Connector is placed inside the Sonata Connector Protector (ACCY-018) and that the cover is closed and secure with both latches.

e. Place the tray without lid on the rack of the automated washer-disinfector.

f. Follow automated washer-disinfector manufacturer's instructions for setting parameters, based on Section 5.1.1 below.

5.1.1 Automated Cleaning and Disinfection Programming

The washer-disinfector should be ISO 15883 compliant. The compatible chemicals used for automated washing and disinfecting are in Section 2.4.

The following parameters shall be used for automated cleaning and disinfection cycles:

STEP	MINIMUM TIME SETTING	MINIMUM TEMPERATURE SETTING	CHEMICAL
Pre-cleaning rinse	5 minutes	~20°C	Tap water or deionized water

Cleaning	10 minutes	45°C	Enzymatic detergent prepared per manufacturer's instructions
Rinse	5 minutes	35°C +/- 5°C	Tap water
Disinfection	5 minutes	55°C Do NOT exceed 60°C	Disinfectant prepared per manufacturer's instructions
Rinse	5 minutes	35°C +/- 5°C	Deionized or tap water (deionized water reduces water stains)
Air Dry	5 minutes	60°C	N/A

Once automated cleaning has been completed, proceed to the device sterilization process in Chapter 6.

Chapter 6 Sterilization

6.1 Package and Sterilize the IUUS Probe

Sterilization of the IUUS Probe has been validated using various low temperature sterilization methods. All compatible sterilization methods are found in section 2.3.
NOTE: Not all the validated sterilization methods may be authorized for commercial distribution by local governments. Ensure use of only locally authorized sterilization systems.

Before sterilizing the IUUS Probe, ensure the IUUS Probe is free of all soil and has been properly cleaned per the instructions in Chapter 4 or Chapter 5.

CAUTIONS	
⚠	DO NOT STEAM STERILIZE (AUTOCLAVE) ULTRASOUND PROBES Doing so will destroy them.
⚠	SET THE ARTICULATING TIP STRAIGHT To prevent damage, maintain proper orientation with the Articulating Tip set to 0° (straight) when placing the IUUS Probe in the tray and when storing the IUUS Probe.
⚠	USE ONLY THE APPROVED CYCLES The IUUS Probe has not been shown to be compatible with sterilization systems or cycles other than those listed in the table below. To preserve the life of the IUUS Probe, DO NOT expose it to non-specified sterilization cycles.
⚠	INFECTION CONTROL To avoid cross-contamination, follow all infection control policies (including for reprocessing, packing, and storage) for personnel and equipment that have been established for your office, department, or hospital.

6.2 Packaging and Sterilization for H_2O_2

6.2.1 Sterilization with STERRAD® 100NX® or STERIS V-PRO®

1. Use a clean sterilization tray, see Figure 6-1. Refer to sterilization tray manufacturer's Instructions for Use for information regarding cleaning and disinfection between use.
2. The tray silicone device mounts must be placed to secure the device, see Figure 6-1.

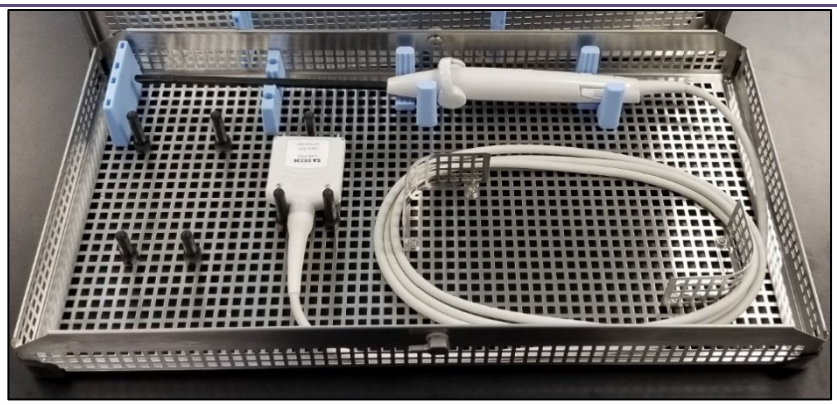


Figure 6-1 Representative of IUUS Probe in sterilization tray. Tray in photo is Sonata® IUUS Probe Reprocessing Tray OM-1000-GS.

3. The IUUS Probe must be dried thoroughly before loading in the sterilization chamber in order to avoid cycle cancellation.
4. Place the IUUS Probe within the tray with the articulation angle set to 0°, see Figure 6-2.

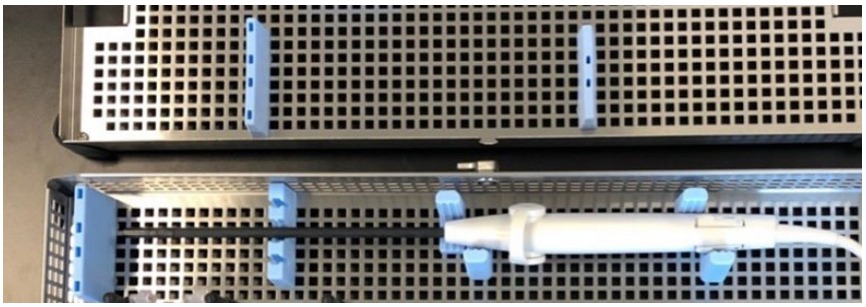


Figure 6-2 Proper storage of the IUUS Probe with its Articulating Tip set to 0°.

5. Ensure the Connector Protector is removed prior to placing in the tray.
6. Place the lid on top of tray and secure.
    1. Tray OM-1000-GS: In order to successfully align the lid and close the tray, the blue silicone pieces on the inside of the lid must be on top of the IUUS Probe seated inside of the tray base. Rotate the latches at each side of the tray lid to secure, see Figure 6-1.
7. Fully envelope the sterilization tray with sterilization wrap (121 x 121 cm, double-wrap technique). For compatible material, reference Section 2.3.
8. Sterilize the prepared IUUS Probe by cycle listed in Section 2.3.

NOTE: Ensure the IUUS Probe Connector Protector is **not** connected to the IUUS Probe Connector prior to sterilization.

6.2.2 Sterilization with STERRAD NX™

1. Place the IUUS Probe on a sterilization wrap with the articulation angle set to 0° and the cable coiled neatly in place.

2. Wrap the IUUS Probe with sterilization wrap using simultaneous envelope fold method or per your facility procedure.
3. Sterilize the prepared IUUS Probe by cycle listed in Section 2.3.

NOTE: Ensure the IUUS Probe Connector Protector is **not** connected to the IUUS Probe Connector prior to sterilization.

6.3 Sterilization with Liquid Chemical Sterilant Processing Systems

CAUTION	
⚠	PLACE IUUS PROBE CONNECTOR INTO CONNECTOR PROTECTOR Place the IUUS Probe's Connector into the IUUS Probe Connector Protector and close securely. Ensure that the pins of the probe connector are seated in the recessed portion of the Connector Protector and not on the silicone seal.

Preparation

1. Cover the IUUS Probe Connecter using the Sonata IUUS Probe Connector Protector (ACCY-018)
2. Place the IUUS Probe into the tray of the validated liquid chemical sterilant processing system – see Section 2.3 for all validated Liquid Chemical Sterilization options.
3. Load the single-use S40 Concentrate cup and start the cycle
    i. STERIS SYSTEM 1E and 1EXPRESS “standard cycle” is defined by:
        a. Exposure time: 6 minutes
        b. Temperature: 45.5° – 60°C
        c. Concentration: ≥175 (measurement of the actual equivalent units of conductivity of the use dilution, not the concentration of peracetic acid)

Once a cycle is in process, the control screen will show the remaining time of the entire cycle, as well as what phase the processor is currently in.

Evidence that liquid chemical sterilization conditions have been achieved and maintained is provided in the cycle monitoring section of the printout from the STERIS SYSTEM 1E and 1EXPRESS processors. The processing cycle parameters should be verified to ensure proper conditions were achieved.

Sterilization

The sterilization process cycle runs automatically as a part of the liquid chemical sterilization systems. Operate the system per the manufacturer’s instructions.

After the cycle completed, open the system and following aseptic techniques, place the IUUS Probe into the sterile field for immediate use. If IUUS Probe is not used immediately, the IUUS Probe must be processed again before use.

WARNING	
	NON-STERILE IUUS PROBE CONNECTOR If the IUUS Probe is received with a Connector Protector on the IUUS Probe Connector, the Probe Connector is **non-sterile** and should be treated as such.

Appendix A Technical Manual

Technical Manual Table of Contents

Technical Chapter 1 Maintenance and Service

Refer to the Sonata System Instructions for Use for full system technical information.

T1.1 Operator-Serviceable Components

Operators or treatment facility should inspect the IUUS Probe after each use as described in Section 3.1 of this manual. All other service should be performed only by Gynesonics authorized personnel. There are no maintenance tasks required on the IUUS Probe.

T1.2 Service Life

IUUS Probe: use limit determined by operator inspection between use.

Validation performed for up to 50 cycles using H_2O_2 sterilization methods and for 12 cycles for liquid chemical sterilization methods. The number of validated cycles does not specify the maximum number of uses a device can be used, provided the device is properly inspected between uses.

T1.3 Calibration

The IUUS Probe does not require calibration or adjustment.

Technical Chapter 2 Environmental Considerations of Used Materials

The Intrauterine Ultrasound Probes are multi-use, medical grade electronics. Should they become obsolete, they should be handled per facility procedures. The IUUS Probe may contain environmentally hazardous materials such as, but not limited to: heavy metals, general recyclable metals, and plastics.

Technical Chapter 3 Technical Specifications

T3.1 Range of Settings and Defaults for Operator-Accessible Controls and Limits

Table T-4. Operator-Accessible Settings, Defaults, and Limits

OPERATOR-ACCESSIBLE SETTINGS	SPECIFICATION
IUUS Tip Angle	0°, 45°, 60°

T3.2 Probe Specifications

Table T-5. IUUS Probe Specifications

IUUS PROBE SPECIFICATIONS	SPECIFICATION
Usage Type	Reusable
Sterilization	Refer to Section 2.3
Transducer Type	Curved linear
Center Frequency	7.2 MHz
Probe Dimensions	Working Diameter: 8.5 mm
Transport and Storage Environment (non-sterile)	-20 °C to 40 °C 10% to 90% relative, non-condensing
Operating Environment	10 °C to 35 °C 30% to 75% relative, non-condensing
Fluid Immersion Rating	IPX7 (except the cable connector) Submergible section protected from the ingress of water during temporary immersion. The cable connector should never be immersed in fluid.

T3.3 Ultrasound Technical Features and Safety Information

T3.3.1 Exposure to Ultrasound

According to the American Institute of Ultrasound in Medicine (AIUM) Official Statement of the Clinical Safety of Diagnostic Ultrasound (March 1993): Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use: No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.

T3.3.2 Prudent Use Statement and Control of Acoustic Power Output

The following is a Prudent Use Statement regarding the use of ultrasound: Use diagnostic ultrasound only when there is a good medical reason. The Sonata System SMART Tablet does not provide explicit control of acoustic power output. Frequency and Depth Controls do affect acoustic outputs within the limits specified in the acoustic output tables provided in the Sonata System Instructions for Use. In general, to minimize the exposure to ultrasound energy, limit the duration of ultrasound exposure.

T3.3.3 Electrical Safety

The Sonata System conforms to the IEC/EN 60601-1 electrical safety standard. The IUUS Probe is insulated from the patient to minimize patient exposure in the presence of a system fault or a fault in other patient-connected equipment. The type of protection against electric shock is Class I. The degree of protection is Type BF, per safety standard IEC 60601-1.

T3.3.4 Surface Heating of Invasive Probes

The average and peak radiated acoustic powers of the IUUS Probe is limited to ensure that the surface heating of the probe array is less than 43 °C. The self-heating is a function of how many elements are being fired, how often they are being fired, the output (excitation) voltage and the transmit frequency. A software model has been developed to predict the surface heating under various operating conditions. To limit the temperature rise, the software first lowers the output voltage to limit, and then reduces the frame rate to keep the temperature rise below 6 °C. Starting at body temperature (37 °C) this means the maximum temperature will be 43 °C when the IUUS Probe is touching a patient. The peak acoustic power is constrained by the maximum voltage applied to the probe array elements.

Technical Chapter 4 Reprocessing Validations

T4.1 Reprocessing Agents Used for Validations

The Table below indicates chemicals that have been validated for cleaning and disinfection of the Sonata® IUUS Probe.

	CHEMICAL DESCRIPTION	USED IN VALIDATION FOR AUTOMATED PROCESS	USED IN VALIDATION FOR MANUAL PROCESS
Materials Used for Cleaning	Enzol ® by ASP ®	No	Yes
	neoDisher® Mediclean Forte (Dr. Weigert GmbH & Co.)	Yes	No
Materials Used for Disinfection	neoDisher Septo DN (Dr. Weigert GmbH & Co.)	Yes	No
	ASP® Cidex® OPA Ortho-Phthaladehyde Solution	No	Yes
	CaviWipes™ by Metrex™	No	Yes

Table 6 Validated materials and chemicals effective in cleaning the IUUS Probe.

Index of Terms

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REF-003 LS 05928-008.005 September 2025