SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
EC REP	Authorized repre-sentative 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 instruc-tions for use	Refer to instruction manual/ booklet	IEC 6060-1 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.
-20°C -40°C	Tempera-ture 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.
10% 90%	Humidity limitation	Indicates the range of humid-ity 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.
	Caution	To indicate that caution is necessary when operating the device or control close to where the sym-bol is placed, or to indicate that the current situation needs operator aware-ness or oper-ator action in order to avoid undesirable consequences	IEC 60601-1 Table D.1, Symbol 10	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
			ISO 7000-0434A	Graphical symbols for use on equipment.
	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 colors and safety signs – Registered safety signs.

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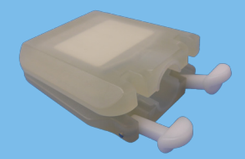

Sonata® IUUS Probe Connector Protector

The Sonata System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding. To learn more, visit www.gynesonics.com/sonata-system. Gynesonics, Sonata, and the logo are trademarks and registered trademarks of Gynesonics, Inc. ©2025 Gynesonics, Inc.

Sonata® SYSTEM

Instructions for Use
Sonata Intrauterine Ultrasound (IUUS) Probe Connector Protector

REF-016 LS 06534 Rev D September 2025

CE UKCA

gynesonics®
Gynesonics, Inc.
200 Cardinal Way #250
Redwood City, CA 94063
gynesonics.com

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Symbols Glossary

The following tables show the safety symbols that are used on the Connector Protector and throughout this IFU.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Importer	To indicate the entity import-ing the medical device into the locale	ISO 7000-3725	Graphical symbols for use on equipment.
	Manufac-turer	Indicates the medical device manufacturer	ISO 15223-1 #5.1.1	Medical devices – Symbols to be used with medical device labels, labeling, and informa-tion to be supplied.
			EN 980 #5.12	Symbols for use in the labeling of medical devices.
			ISO 15223-1	Graphical symbols for use on equipment.
	Date of Manufac-ture	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 informa-tion 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.
REF	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 informa-tion 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.
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1 #5.1.5	Medical devices – Symbols to be used with medical device labels, labeling, and informa-tion to be supplied.
			EN 980 #5.4	Symbols for use in the labeling of medical devices.
			ISO 7000-2492	Graphical symbols for use on equipment.
MD	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 informa-tion to be supplied.
CE	CE Marking	Signifies Euro-pean 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.

Notice

Sonata® Intrauterine Ultrasound (IUUS) Probe Connector Protector Instructions for Use (IFU)

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:

Gynesonics, Inc.
200 Cardinal Way #250
Redwood City, CA 94063 USA
www.gynesonics.com
For service and support:
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US: USCustomerService@gynesonics.com

EC REP
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Trademark and Patent Information

About this Instruction Manual

This Instruction for Use covers the Intrauterine Ultrasound (IUUS) Probe Connector Protector (ACCY-018), an accessory of the Sonata System for Transcervical Fibroid Ablation. Refer to Instructions for Use, Sonata IUUS Probe (REF-003) for full description of the Sonata IUUS Probe and Reprocessing Instructions.

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

Chapter 1
General Information & Technical Specifications

1.1 Device Description

The Sonata® IUUS Probe Connector Protector is an accessory to the Sonata Intrauterine Ultrasound (IUUS) Probe, IUSP-002. The Connector Protector Provides water-tight cover for the electrical connector for the IUUS Probe during reprocessing.

The Connector Protector is only for use with the Sonata IUUS Probe. The Sonata 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.

For the Instructions for Use and Reprocessing information for the IUUS Probe, as well as general warnings and cautions, refer to the IUUS Probe Instructions for Use, REF-003.

1.2 Intended Users

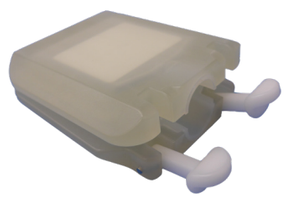

Figure 1-2: Sonata IUUS Probe Connector Protector

The Connector Protector is intended to be used by IUUS Probe 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 regards to hazards associated with contaminated medical devices and reprocessing chemical exposure.

1.3 Important Safety Information

Read all General Cautions 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 Instructions for Use, Sonata Intrauterine Ultrasound (IUUS) Probe REF-003 for details on cleaning, reprocessing, and disinfection of the IUUS Probe.

In the event of a serious incident related to use of the IUUS Probe Connector Protector, 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.

1.3.1 Cautions and Warning

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

CAUTIONS		
1	⚠	READ INSTRUCTIONS BEFORE USE Read this Instructions for Use in its entirety before use.
2	⚠	CLEANING PROCEDURES Always follow proper cleaning procedures. Failure to adhere to cleaning, disinfection, and sterilization procedures outlined in this Instructions for Use could result in transmission of disease and cause infection, endangering Operators and patients.

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

1.3.2 Latex Allergies

None of the user-contacting components of the Sonata IUUS Probe Connector Protector are manufactured with natural rubber latex.

1.4 Technical Specifications

CONNECTOR PROTECTOR SPECIFICATIONS	SPECIFICATION
Transport and Storage Environment	-20°C to 60°C 15% to 80% relative humidity (non-condensing)
Operating Environment	10°C to 60°C 10% to 85% relative humidity (non-condensing)
Service Life	Use limit determined by operator inspection between use. Validated for up to 50 uses.

1.5 Environmental Considerations

At the end of their life, Connector Protectors should be disposed of by way of the facility's established procedure for contaminated or infected product.

1.6 Clean / Disinfect the Connector Protector

Thoroughly clean and disinfect the IUUS Probe Connector Protector (refer to Figure 1-6) prior to use by wiping the inside and outside with medical grade low alcohol surface disinfection wipes (e.g., Incidin wipe or CaviWipe).

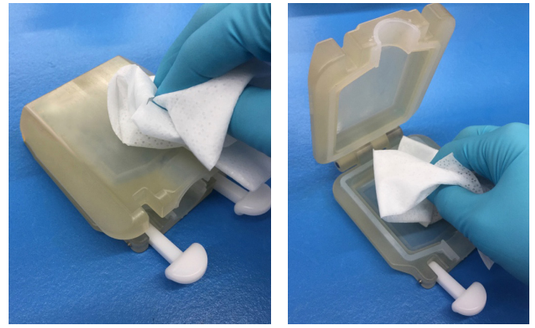

Figure 1-6: Clean the outside and inside of the IUUS Probe Connector Protector

1.7 Using the Connector Protector

1. Prior to using the Connector Protector, ensure that the silicone seals are intact and there is no cracking. If any sign of degradation is identified, replace the Connector Protector.
2. Prior to using the Connector Protector, ensure the IUUS Probe (IUSP-002) is cleaned per the IUUS Probe IFU, REF-003.
3. **Place the IUUS Probe 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 on not on the silicone seal.
4. **Press down and engage both latches fully, Figure 1-7.**

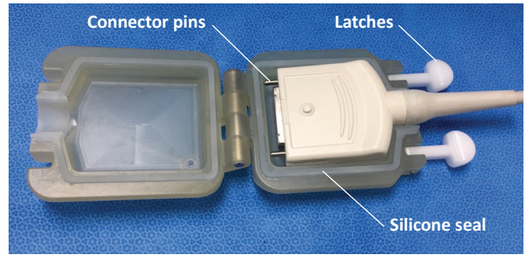

Figure 1-7: Sonata IUUS Probe Connector Protector securely closed over the IUUS Probe Connector