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Sonata® SYSTEM

Sonata® RFA Handpiece Cable, Reusable (ACCY-008) Instructions for Use

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Manual Catalog #: REF-008
LS 06305, Rev F, September 2025 RFA Handpiece Cable, Cable Instructions for Use

Notice

Sonata® ACCY-008 RFA Handpiece Cable, Reusable Instructions for Use

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About this Instruction Manual

This Instruction Manual covers the Sonata Reusable RFA Handpiece Cable. The Reusable RFA Handpiece Cable is an accessory of the Sonata® Transcervical Fibroid Ablation System 2.2. For use of the cable with the system refer to the Sonata® Transcervical Fibroid Ablation System 2.2 Instructions for Use REF-009. This manual is intended for healthcare facilities that support steam sterilization. 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.

Contact Gynesonics for additional copies of this manual, any additional questions or support required for training, service, and maintenance.

Refer to the Sonata System 2.2 Instructions for Use for information regarding intended use and operation of the Reusable Sonata RFA Handpiece Cable, and for detailed technical, maintenance and service information.

Manual originally issued in English.

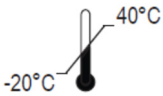
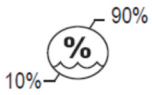
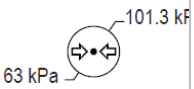
Table of Contents

Symbols Glossary

The following tables show the safety symbols that are used on the Sonata System devices and accessories 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.
	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.
	Importer	To indicate the entity importing the medical device into the locale	ISO 7000-3725	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.
	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 information 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.
	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.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	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.
 www.gynesonics.com/manuals	Operator's manual; operating instructions	Consult instructions for use. Indicates the need to consult the instructions for use (IFU). An electronic instructions for use (eIFU) indicator (website address) may accompany the symbol when used to indicate an instruction to consult an eIFU.	ISO 7000-1641	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.
	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.
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator 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
	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.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	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.
	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.
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
	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
IPX6	Degree of Ingress Protection Provided by Enclosure	Protected against powerful water jets	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.
Rx Only	Prescription Only	Requires a prescription in the United States.	21 CFR 801.15(c)(1)(i)F	Labeling-Medical devices; prominence of required label statements.
			21 CFR 801.109	Labeling-Prescription devices.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Medical Device	Indicates that the device is a Medical Device	MedTech Europe Guidance May 2019	Use of Symbols to Indicate Compliance with the MDR
	Autoclave symbol	Sterilizable in a steam sterilizer (autoclave) at temperature specified	ISO 7000-2868	Graphical symbols for use on equipment.

Glossary of Terms, Acronyms, and Definitions

TERM	DEFINITION
Cleaning	Physical removal of soil and contaminants to the extent necessary for further processing.
Connector	A multipin connector that interfaces with the RF Generator or the RFA Handpiece
Disinfection	The destruction of pathogens and other microorganisms by physical or chemical means.
Gynesonics	Manufacturer of the Sonata Transcervical Fibroid Ablation System 2.2, including ACCY-008 RFA Handpiece Cable, Reusable
Operator	The clinician or supporting staff operating the Sonata System.
Point-of-Use	The location and time where the device is used.
RF	Radiofrequency
Radiofrequency Ablation (RFA)	The process of destroying a volume of tissue using radiofrequency energy to sufficiently elevate temperatures for a period of time, which results in thermal fixation and coagulative necrosis.
Reusable RFA Handpiece Cable	A reusable data and power cable that connects the RFA Handpiece to the RF Generator. Refers to ACCY-008.
RFA Handpiece	A single-use component of the Treatment Device with deployable electrodes used to deliver thermal energy to fibroids. The RFA Handpiece attaches to the IUUS Probe.
Radiofrequency (RF) Generator	Controls the delivery of energy to the RFA Handpiece.
Reprocessing	The entire procedure of cleaning, disinfecting (if required), and sterilizing (if required) Sonata accessories when being used for the first time or after a procedure in preparation for the next use.
SMART Tablet	Unit on top of the System Cart that provides ultrasound imaging, ablation planning, and communications with the RF Generator.
Steam sterilizer	A machine that can expose items to direct steam contact at a required temperature and pressure for a specified time. Also known as an Autoclave machine or sterilizer.
Sterilization	A process that renders product free from viable microorganisms.
Washer-disinfector	A machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice
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

The Sonata® RFA Handpiece Cable, Reusable (Figure 2-1) is an accessory to the Sonata® Transcervical Fibroid Ablation System 2.2. The Sonata System 2.2 is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding. The Cable connects the Sonata® Radiofrequency Ablation Handpiece to the Sonata® Radiofrequency Generator. The 3-m cable conducts power, thermal data, and control data. The Cable is reusable and is provided non-sterile.

1.2 Maintenance and Service

The Reusable RFA Handpiece Cable is not user serviceable. Inspect the Reusable RFA Handpiece Cable thoroughly at start of reprocessing and prior to packaging for sterilization. If any damage or defect is observed, do not continue to use the device and notify Gynesonics for evaluation and possible replacement.

1.3 Conditions for Storage and Transport and Usage

Between uses, the Reusable RFA Handpiece Cable should be reprocessed per Chapter 3 and stored as sterile product per local and facility requirements.

Storage and Transport Conditions:	-20 °C to 45°C, 10% to 90% relative humidity, non-condensing
Operating Conditions:	10 °C to 35 °C, 30% to 75% relative humidity, non-condensing

1.4 Environmental Considerations

The RFA Reusable Cable is a multi-use, medical grade electronic device. At the end of its useful life, it should be cleaned and disinfected per Chapter 3 and disposed per facility procedures. The equipment comprising the System may contain environmentally hazardous materials such as, but not limited to heavy metals, general recyclable metals, and plastics. Contact Gynesonics for recovery of equipment.

Packaging of the reusable RFA Handpiece Cable includes recyclable materials. Observe plastics packaging recycling symbols and recycle all paper materials such as chipboard boxes and over shippers.

1.5 European Union Environmental Considerations

WARNING	
	Waste Electronic and Electrical Equipment (WEEE) Please follow the guidelines as outlined by WEEE Regulations for proper disposal within European Union

Equipment marked with the WEEE symbol shall not be disposed of as unsorted municipal waste but should be collected separately for proper recycling.

1.6 Safety Information

Read all Warnings and Cautions that 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.

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 System including the RFA Handpiece Cable 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 60601-1-8, Medical electrical equipment Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
- EN/IEC 60601-2-2, Medical Electrical Equipment: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.
- EN/IEC 60601-2-37, Medical Electrical Equipment: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

1.7 Intended Reprocessing Personnel

Personnel involved in reprocessing of the reusable RFA Handpiece Cable 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.

Chapter 2 Using the RFA Handpiece Cable

2.1 Refer to Sonata System 2.2 Instructions for Use for full usage instructions of the Reusable RFA Handpiece Cable

WARNING	
⚠	READ INSTRUCTIONS BEFORE USE Read this Instructions for Use (IFU) and the Sonata System 2.2 IFU 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.
⚠	CLEAN AND STERILIZE AFTER USE The RFA Handpiece Cable should be cleaned and sterilized following each procedure.

The Reusable RFA Handpiece Cable is used to connect the RFA Handpiece to the RF Generator. The Cable must be cleaned and sterilized per the instructions in Chapter 3 of this manual prior to first use and between uses.

Refer to Sonata System 2.2 Instructions for Use REF-009 for full instructions regarding use, contraindications, patient selection, potential postoperative events, procedure setup, risks, warnings, cautions, anesthesia, and electrical test data associated with the use of the ACCY-008 Reusable RFA Handpiece Cable with the Sonata System 2.2.

To connect to the RFA Handpiece to the RF Generator, connect the correct ends of the Cable to each device as shown below.

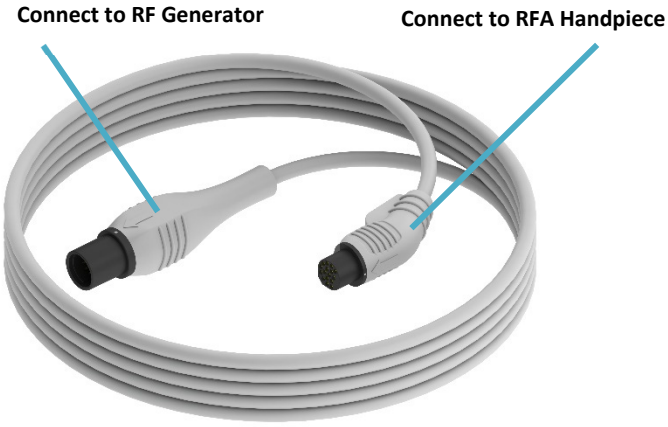


Figure 2-1. Cable Connectors

Each connector is marked with a white orientation indicator and is keyed for insertion in one position. Rotate the connectors until the angle allows for it to be pushed in. Push into the sockets fully.

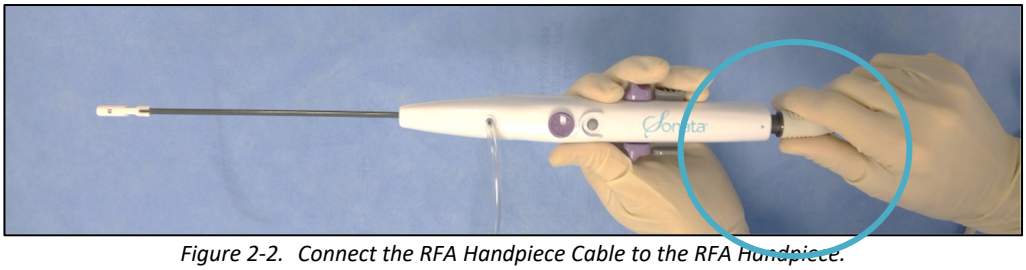


Figure 2-2. Connect the RFA Handpiece Cable to the RFA Handpiece.

Figure 2-3. Connect RFA Handpiece to front of RF Generator.

Confirm that proper connections are made by referring to indicators on the Sonata SMART Tablet display as described in the Sonata System 2.2 Instructions for Use.

Disconnect after use and DO NOT DISPOSE.

CAUTION	
⚠	DO NOT PULL ON THE CABLE TO DISCONNECT When removing the connectors, grasp the cable at the connectors to prevent damage.

Following the procedure, disconnect the Cable from both ends.

DO NOT dispose! This Cable is intended for reprocessing before next use. Proceed to Chapter 3 below for reprocessing instructions.

2.2 Point-of-Use Pre-cleaning

A Point-of-Use pre-cleaning is conducted immediately after using the Reusable RFA Handpiece Cable and prior to transferring to reprocessing to remove visible soil.

1. Use gauze or surgical towel wetted with water. Use of a pre-moistened, low alcohol surface wipe appropriate for medical instruments is also acceptable. Follow manufacturer instructions for use.
2. Wipe from one end of the connector to the other and visually inspect for remaining contaminants.
3. If blood or tissue is on the connector openings, remove to prevent drying of contaminants on the connectors. Low pressure liquid directed at the connectors is acceptable.
4. Dispose of the gauze or towel after use in a biohazard container.
5. Place the Reusable RFA Handpiece Cable into a container that has a lid, is puncture proof, and is labeled as containing biohazard. Use of a damp cloth to prevent surface drying of remaining contaminants is acceptable.
6. Transport to the reprocessing area as soon as possible.

Chapter 3 RFA Reusable Cable Reprocessing

REPROCESSING OVERVIEW	LOCATION
1. **Point-of-Use Pre-Cleaning**	Section 2.2
2. **Material Needed**	Section 0
3. **Inspect for Damage**	Section 3.2
4. **Automated Cleaning and Disinfection**	Section 3.3
5. **Manual Cleaning and Disinfection Option**	Section 3.4
6. **Package and Steam Sterilization**	Section 3.5

Table 1 Reprocessing Overview

WARNINGS	
	WEAR PERSONAL PROTECTIVE EQUIPMENT The used RFA Handpiece Cable 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.
	HANDLE CONTAMINATED CABLE WITH CARE The used Reusable RFA Handpiece Cable has been indirectly exposed to blood and tissue. Follow local and facility guidelines for handling of biohazardous used medical equipment including use of PPE.

CAUTION	
	DO NOT IMMERSE OPEN CONNECTORS The connectors of the Cable are not designed for immersion in liquids for extended periods. If the connectors become wet during any processes, rinse with deionized water and then shake out as much as possible from the connectors. Rinse of the connectors under running water is acceptable.
	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.
	TEMPERATURE LIMITS The Reusable RFA Handpiece Cable may be damaged if exposed to temperatures exceeding 275°F (135°C). If the Reusable RFA Handpiece Cable appears damaged from exposure to high temperature, contact Gynesonics for guidance.

3.1 Materials Needed

- Soft nylon brush
- Medical grade, low alcohol surface disinfectant wipes
- Clean, soft, lint-free cloth, or drying cabinet
- Washer-Disinfector machine (optional)
  - Mild pH detergent (MediClean Forte)
- Gravity or Vacuum pulse steam sterilization machine

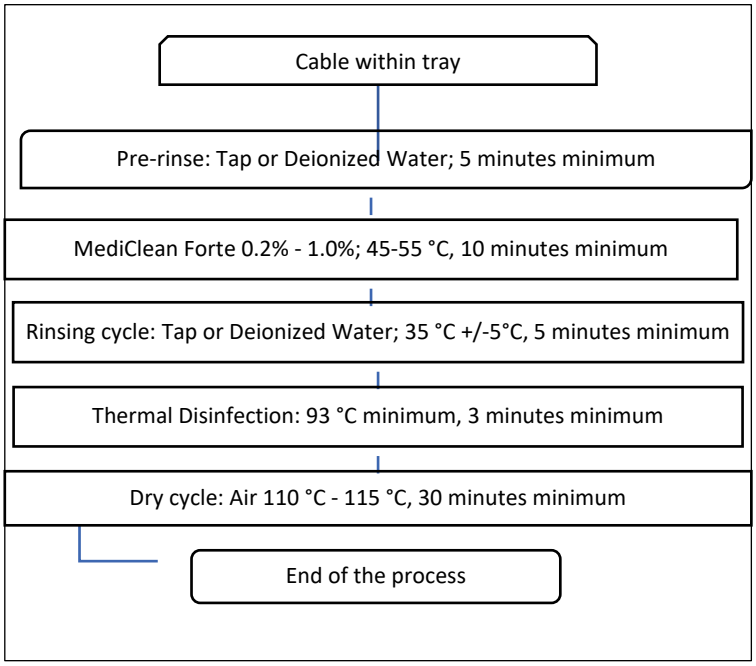
- Sterilization pouch indicated for steam sterilization

3.2 Inspect for Damage

1. Prior to reprocessing, inspect the Reusable RFA Handpiece Cable for any damage to any of the following areas:
   a. Cable should have no cracks or cuts in the insulation.
   b. Connectors should not be cracked.
2. DO NOT reprocess or use if there is any damage to the Reusable RFA Handpiece Cable. Contact your Gynesonics Representative.

3.3 Cleaning and Disinfection – Automated Washer-Disinfector Option

1. Coil the RFA Handpiece Cable and place in a tray intended for use in automated washer-disinfectors.
2. Place tray within a washer-disinfector machine. Follow machine manufacturer's instructions.
3. The following automated cleaning and disinfection process is validated by Gynesonics.



4. Upon completion unload the washer-disinfector. Visually inspect for dryness. Remaining wetness may be removed with medical grade compressed air or with clean and lint free single use wipes.
5. When the Reusable RFA Handpiece Cable is completely dry proceed to packaging Section 3.5.

3.4 Cleaning and Disinfection – Manual Option

CAUTIONS	
⚠	PREVENTING FLUID DAMAGE DO NOT submerge connectors or run water directly into the end of the connectors.
⚠	USE LOW ALCOHOL SURFACE DISINFECTION WIPES Use approved medical grade, low alcohol surface disinfection wipes for removal of contaminants or decontamination.

1. Clean Reusable RFA Handpiece Cable under running tap water with soft wet cloth or soft brush. Keep connectors facing down to reduce fluid entry.
2. Continue process until all visible soil is removed and the Reusable RFA Handpiece Cable is visibly clean.
3. Dry with a clean, soft, lint-free cloth.
4. Wipe the two connectors and cable using medical grade, low alcohol surface disinfectant wipes. Follow the manufacturer's instructions.
    a. Wipe both connectors.
    b. Wipe entire length of cable.
    c. Wet all surfaces with the disinfectant.
5. Dispose of the soiled wipe in a biohazard waste container.
6. Use a fresh wipe to re-wipe the connectors and cable a second time. **Wipe at least two (2) times using a new wipe each time.**
7. Continue to keep the surfaces moist with medical grade low alcohol surface disinfectant wipes for the duration specified by the surface disinfectant wipe manufacturer.
8. Completely dry the Reusable RFA Handpiece Cable with a clean, soft, lint-free cloth, air dry, or use a drying cabinet.
9. When the Reusable RFA Handpiece Cable is completely dry proceed to packaging Section 3.5.

3.5 Packaging and Steam Sterilization

CAUTIONS	
⚠	USE ONLY THE APPROVED CYCLES The RFA Reusable Cable has not been shown to be compatible with steam sterilization cycles other than those listed in the table 2 below.
⚠	VALIDATED PACKAGING The sterilization effectiveness of alternate pouches not listed in these instructions has not been established. Follow manufacturer instructions when using any sterilization pouch.

1. Coil Reusable RFA Handpiece Cable and place into a sterilization pouch intended for use for steam sterilization.
2. Seal the pouch per pouch manufacturer instructions.
3. Place sealed pouch into a steam sterilizer intended for use in health care facilities per pouch & steam sterilizer manufacturer instructions.
4. Sterilization using steam (moist heat) has been validated for the Reusable RFA Handpiece Cable. See Table 2 for reprocessing within the health care facility.

STERILIZATION CYCLE	TEMPERATURE	EXPOSURE TIME	DRYING TIME	PACKAGING
Pre-Vacuum (Pre-Vac) Steam	135 °C (275°F)	3 minutes minimum	16 minutes minimum	Steam Sterilization pouch. See Section 3.7.
Gravity Displacement	135 °C (275°F)	10 minutes minimum	30 minutes minimum	Steam Sterilization pouch. See Section 3.7.

Table 2 Steam sterilization cycles and packaging for sterilization of the Reusable RFA Handpiece Cable

3.6 Storage before Use

1. After sterilization, store pouch in a dry and dust-free location appropriate for sterile storage per facility practices.
2. For shelf life see Instructions For Use of the sterilization pouch used.

3.7 Validated Materials and Chemicals

MATERIAL	MANUFACTURER AND PART NUMBER
Steam Sterilization pouch	Steriking Heat Seal Pouch #16 (10in x 15in)
Medical Grade Low Alcohol Surface Disinfection Wipes	CaviWipes™ by Metrex™
Cleaner for washer-disinfector machine	NeoDisher MedClean Forte
Automatic washer Processing Tray	OM-1000-GS Sonata IUUS Probe Reprocessing Tray

Table 3 Validated materials and chemicals effective in reprocessing the Reusable RFA Handpiece Cable.

Appendix A Technical Manual

Technical Chapter 1 Technical Specifications

T1.1 RFA Handpiece Cable

Refer to the Sonata System 2.2 Instructions for Use for full system technical information.

Table T-4. Reusable RFA Handpiece Cable Specifications

REUSABLE RFA HANDPIECE CABLE SPECIFICATIONS	SPECIFICATION
Usage Type	Reusable
Sterilization	Moist Heat (steam)
Length	3m
Transport and Storage Environment	-20 °C to 45°C 10% to 90% relative humidity, non-condensing
Operating Environment	10 °C to 35 °C 30% to 75% relative humidity, non-condensing
Fluid Rating	IPX6 Protected against powerful water jets. The cable connectors should never be immersed in fluid.
Service Life	Use limit determined by inspection between use. Validated for up to 50 use cycles.

T1.2 Technical Support and Product Return Information

Service Returns

Read these instructions prior to returning any used/unused potentially defective product to Hologic. Contact Technical Support if the RFA Reusable Cable fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and biohazard/return kit if applicable. Return the RFA Reusable Cable according to the instructions provided by Technical Support. Be sure to clean the device before returning it and include all accessories in the box with the returned unit. Return used or opened disposable devices according to the instructions provided with the Hologic-supplied Biohazard kit.

Index of Terms

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The Sonata® Transcervical Fibroid Ablation System 2.2 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 logos are trademarks and registered trademarks of Gynesonics, Inc. All other trademarks are properties of their respective owners. Gynesonics products are covered by US and foreign patents.

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