**Manufacturer**: Gynesonics, Inc.
**Methods**: Hydrogen peroxide gas plasma or Ethylene Oxide

CE UK CA

**Symbol Glossary**

| SYMBOL | SYMBOL TITLE | EXPLANATORY TEXT | STANDARD REFERENCE | STANDARD TITLE |
|---|---|---|---|---|
|  | Use by date | Indicates the date after which the medical device is not to be used. | ISO 15223-1 #5.1.4 | Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied. |
|  | 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. |
|  | 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. |
|  | 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. |
| CE | CE marking | Signifies European technical conformity. | 2017/745 | Medical Device Regulation (EU) |
| 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 |
|  | Follow instructions for use | Refer to instruction manual/booklet. | ISO 7010-M002 | Graphical symbols – Safety colours and safety signs – Registered safety signs. |
|  | Importer | To indicate the entity importing the medical device into the locale | ISO 7000-3725 | Graphical symbols for use on equipment |
| EC REP | 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. |

| DESCRIPTION | |
|---|---|
| **Name of Product** | Sonata® IUUS Probe Sterile Shipper Kit SHPR-001 |
| **Indication for Use** | The Sonata® IUUS Probe Sterile Shipper Kit is intended to be used to enclose the Sonata® Intrauterine Ultrasound (IUUS) Probe for terminal sterilization by ethylene oxide or STERRAD® hydrogen peroxide gas plasma. After completion of the sterilization process, the Sterile Shipper Kit maintains sterility through transit by common carrier and storage until the seal of the pouch is opened. |
| **Contents of Kit, SHPR-001** | • IUUS Probe Tyvek Pouch<br>• IUUS Probe Backer Card<br>• IUUS Probe Backer Card Tube<br>• IUUS Probe Backer Card Strap<br>• Bubble Bag<br>• Box, Individual IUUS Probe Shipment<br>• IUUS Probe Shipper Kit Instructions |
| **Dimensions**<br>length x width x height | As packaged for sterilization: 24" x 9" x 2"<br>As packaged for shipment: 24" x 6" x 4" |
| **Transit** | Validated for common carrier - air (intercity) and motor freight (local) |
| **Storage Conditions** | Temperature: 15 - 29°C (59 - 85 °F)<br>Relative Humidity: 0-70% |
| **Shelf-Life** | Shelf life of SHPR-001, prior to use: Use-By date shown on SHPR-001 label.<br>Shelf life of sterile IUUS Probe when packaged in the SHPR-001 packaging system: 1 year from date of sterilization |
| **CAUTIONS AND LIMITATIONS** | |
| **CAUTIONS** | For use only with the Sonata® Intrauterine Ultrasound Probe. Adequacy of this packaging system has not been demonstrated for any other instrument.<br>Do NOT steam sterilize (autoclave)<br>Do NOT double pouch. Sterilization effectiveness has not been demonstrated in a double pouch configuration. |
| **Limitations on Reprocessing** | <u>Sonata IUUS Probe Sterile Shipper Kit:</u><br>Single-use only; ability to maintain a sterile barrier has not been demonstrated if re-used.<br>For use only with the Sonata IUUS Probe. Use for sterilization of any other instrument has not been validated.<br>Inspect the sterile barrier system for damage before sterilization.<br>*For instructions related to the Sonata® Intrauterine Ultrasound Probe, refer to the IUUS Probe Instructions for Use, REF-003.* |

| INSTRUCTIONS | |
|---|---|
| **Point of use** | *For instructions related to the Sonata® Intrauterine Ultrasound Probe, refer to the IUUS Probe Instructions for Use, REF-003.* |
| **Preparation for cleaning** | *For instructions related to the Sonata® Intrauterine Ultrasound Probe, refer to the IUUS Probe Instructions for Use, REF-003.* |
| **Cleaning** | *For instructions related to the Sonata® Intrauterine Ultrasound Probe, refer to the IUUS Probe Instructions for Use, REF-003.* |
| **Drying after cleaning** | *For instructions related to the Sonata® Intrauterine Ultrasound Probe, refer to the IUUS Probe Instructions for Use, REF-003.* |
| **Disinfection** | *For instructions related to the Sonata® Intrauterine Ultrasound Probe, refer to the IUUS Probe Instructions for Use, REF-003.* |
| **Inspection and functional testing** | *For instructions related to the Sonata® Intrauterine Ultrasound Probe, refer to the IUUS Probe Instructions for Use, REF-003.* |
| **Packaging for Sterilization** | See Appendix A |
| **Sealing** | Seal the pouch per validated sealing process.<br>Each user must determine the optimum sealing conditions, as they are highly dependent upon the equipment. A recommended starting point for determination of optimum pouch sealing conditions is 2 second dwell time at 30 psi. |
| **Labeling** | **Label Materials:**<br>Labeling systems used must be compatible with the specified sterilization parameters and storage conditions. Compatibility with the EO and STERRAD sterilization processes described herein has been demonstrated for Flexcon Thermfilm Select 21830.002 White Polyester (TT Imprintable) roll stock, 4" x 6.5" and Herma GmbH Artikelnummer 1000000007.<br><br>**Label Placement Instructions** on sterile barrier system:<br>The label must only be placed on the film side of the pouch, not the Tyvek side. It is recommended that the label is applied to the pouch prior to filling it with the probe because the label on the Sonata IUUS Probe itself is not visible beneath the flap of the backer card once inserted into the pouch. The label can be placed anywhere on the film side of the pouch. |

<table>
<tr><th colspan="2">INSTRUCTIONS</th></tr>
<tr><td>Sterilization Load:</td><td>Sterilization should be performed with the Sonata IUUS Probe packaged in the sterile barrier system as shown below. Load the pouches in a manner to prevent overlap.<br>  </td></tr>
<tr><td>Sterilization:</td><td>Hydrogen Peroxide Sterilization Methods
<table>
<tr><th>Validated System</th><th>Use Cycle</th></tr>
<tr><td>*STERRAD® 100NX™</td><td>Standard Cycle</td></tr>
<tr><td>STERIS V-PRO® maX</td><td>Lumen,<br>Non-Lumen<br>Flexible</td></tr>
<tr><td>STERIS V-PRO® maX 2</td><td>Lumen,<br>Non-Lumen<br>Flexible<br>Fast Non-Lumen</td></tr>
<tr><td>STERIS V-PRO® 60</td><td>Lumen,<br>Non-Lumen<br>Flexible</td></tr>
<tr><td>STERIS V-PRO® s2</td><td>Lumen,<br>Non-Lumen<br>Flexible<br>Fast Cycle</td></tr>
</table>
* Includes AllClear™ Technology<br><br>Ethylene Oxide<br>Validated EO Cycle Parameters:<br>Temperature: 55°C<br>RH: 40%-80%<br>Precondition time: 90 minutes<br>Gas Exposure: 4 hours<br>EO Concentration: 725 mg/L<br>Gas Type: 100% EO<br>Aeration Time: 18 hours<br>Aeration Temp: 55°C</td></tr>
<tr><td>Packaging Sterile Probe for Transit and Storage</td><td>Refer to Appendix B</td></tr>
</table>

<table>
<tr><th colspan="2">REFERENCES</th></tr>
<tr><td>Related Gynesonics Product</td><td>Sonata® Intrauterine Ultrasound Probe IUSP-002</td></tr>
</table>

<table>
<tr><td>Reference Document</td><td colspan="2">Intrauterine Ultrasound (IUUS) Probe Instructions For Use, REF-003</td></tr>
<tr><td>Manufacturer Contact</td><td colspan="2">Gynesonics, Inc.<br>200 Cardinal Way #250<br>Redwood City, CA 94063 USA<br>Telephone: +1 650-216-3860<br>www.gynesonics.com<br>EU: customersupport@gynesonics.com<br>US: UScustomerservice@gynesonics.com</td></tr>
<tr><td rowspan="2">Authorized Representative</td><td>EC REP<br>Obelis s.a<br>Bd. Général Wahis 53<br>1030 Brussels, BELGIUM<br>Tel: +(32) 2. 732.59.54<br>Fax: +(32) 2.732.60.03<br>E-Mail: mail@obelis.net</td><td>UKRP:<br>Obelis UK Ltd.<br>Sandford Gate<br>East Point Business Park<br>Oxford, OX4 6LB<br>United Kingdom<br>+44.1491.378012<br>info@obelis.co.uk</td></tr>
<tr><td colspan="2">Hologic Ireland Ltd.<br>Sir John Rogerson's Quay 70<br>D02 R296 Dublin, Ireland</td><td>Hologic Suisse SA<br>World Trade Center<br>Avenue de Gratta-Paille 2<br>1018 Lausanne, Switzerland</td></tr>
<tr><td>Importer</td><td colspan="2">Hologic Ltd.<br>Oaks Business Parks, Crewe Road<br>Wynthenshawe, Manchester, M23 9HZ<br>United Kingdom</td></tr>
</table>

The instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Originally approved and supplied in the English language

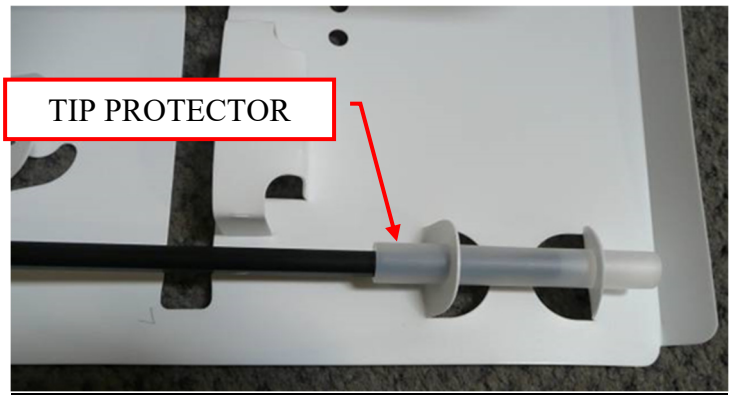


In the event of a serious incident related to use of the Sonata IUUS Probe Sterile Shipper Kit, notify Gynesonics. If located within the European Union, also notify the competent authority of the EU Member State in which the user and/or patient is established.

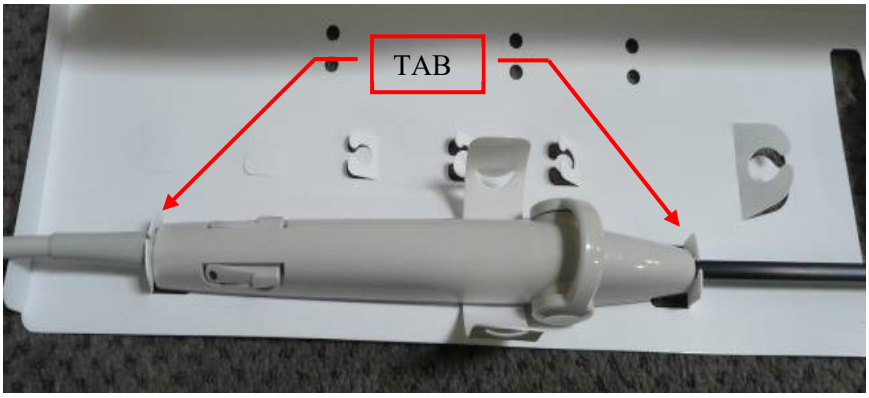
## APPENDIX A – PACKAGING FOR STERILIZATION

**Installing the Sonata® Intrauterine Ultrasound Probe on the backer card**

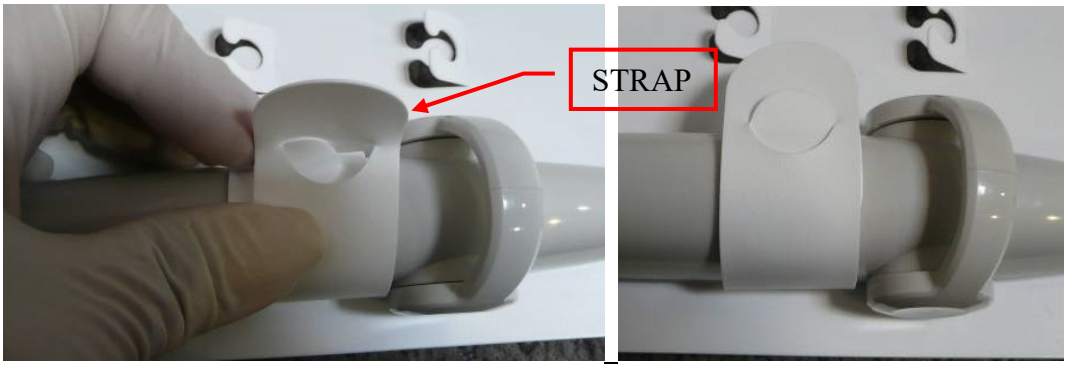
Insert the distal end of the IUUS probe into the tip protector tube on the backer card with the handle facing down.



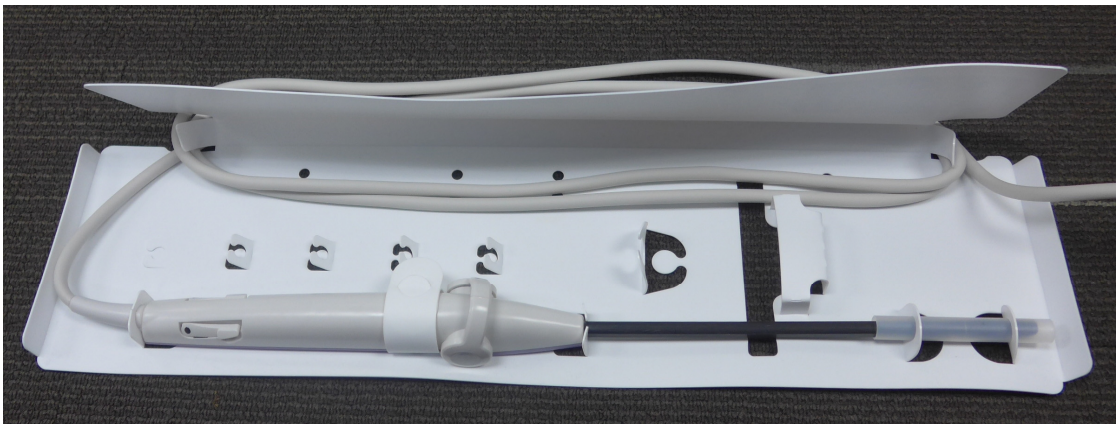

Lay the probe handle on the backer card. Lift the tabs on both ends of the handle for proper positioning.



Fold the strap over the probe handle to secure device. Fold short end of strap first, lifting the tab. Then fold over the longer end of strap by pushing the tab out and under the short end tab.



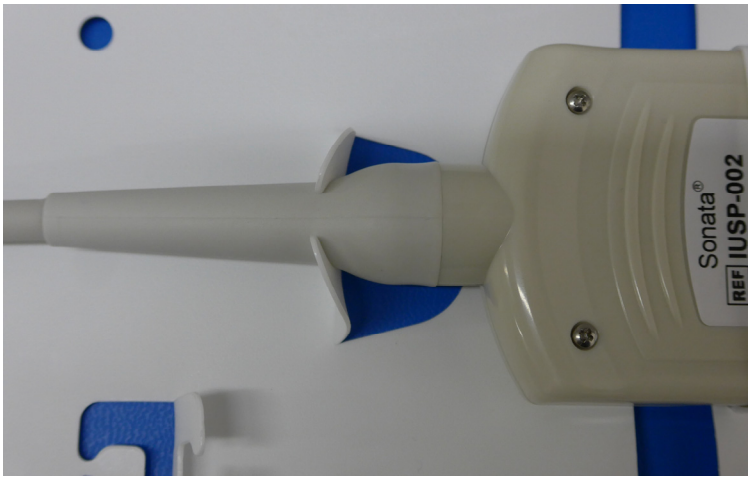

Loop the probe cable around the backer card flap about three times. Cable must be taut without deforming the backer card.



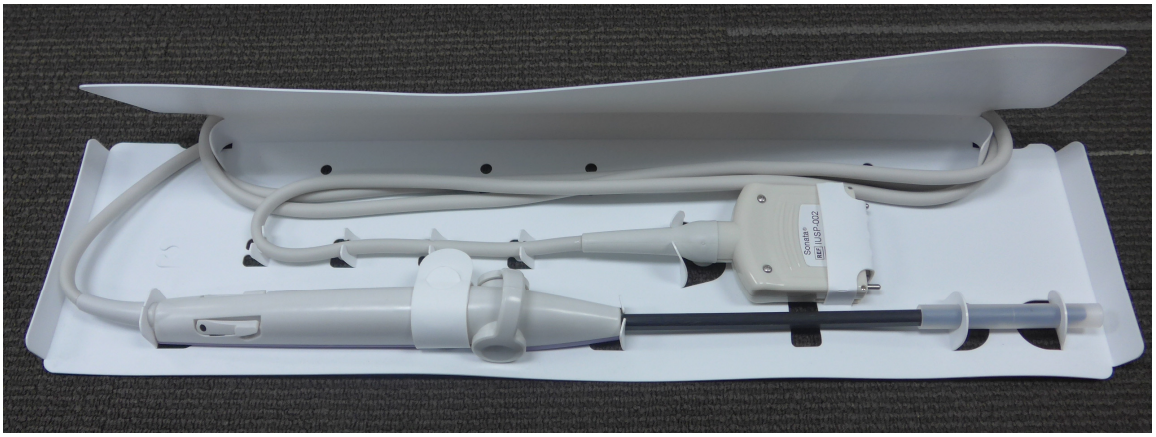
Carefully insert the electrical connector into its constraint on the backer card

The connector will fit snugly into the constraint. One way to seat the connector into the constraint is to first insert one of its corners and then slide the rest of the connector in, bringing the other corner in last.

Insert the strain relief into its holding tab to lock the connector in place.




Continue inserting the device cable into its tabs to secure it in place.



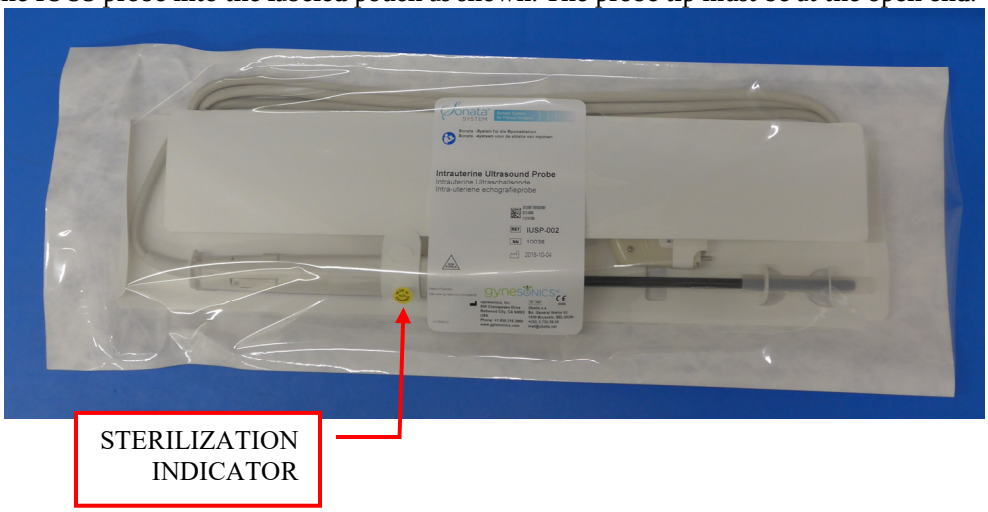
Fold the top half (flap) of the backer card over the device.

Obtain the empty Tyvek pouch and apply sterile product label on the film side of the pouch as shown below.

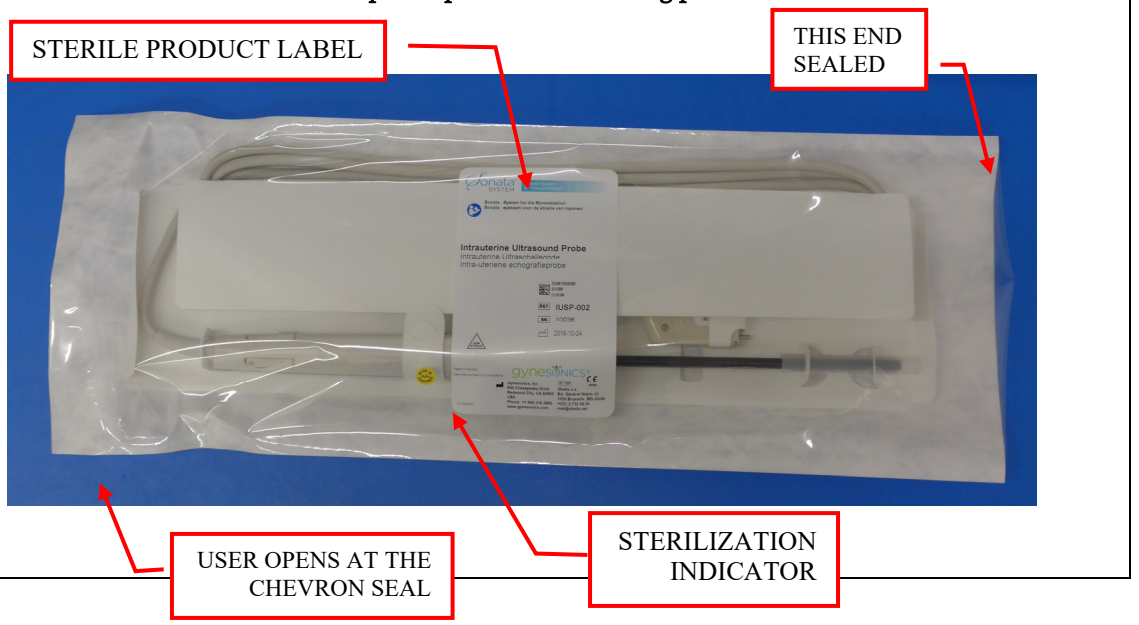

It is recommended to apply a commercially available sterilization exposure indicator (intended for use with specified EO cycle or with STERRAD®, as appropriate) to the clear side of the pouch. This indicator is not provided with the kit.

**Package backer card with IUUS probe into Tyvek pouch.**

Insert the IUUS probe into the labeled pouch as shown. The probe tip must be at the open end.



**Seal the pouch per validated sealing parameters.**



## APPENDIX B – PACKAGING FOR TRANSIT AND STORAGE

Insert the pouched device into the provided bubble bag. Do not seal bubble bag. Fold bubble bag as shown.

Place the wrapped device into the individual box.

Securely seal the box with tape.

Attach a shipping label to the outside of the sealed box.