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## SONATA IUUS PROBE REPROCESSING TRAY OM-1000-GS

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- (EN) IUUS PROBE REPROCESSING TRAY **INSTRUCTIONS FOR USE: English**
- (FR) PLATEAU DE RECONDITIONNEMENT DE SONDÉ IUUS **MODE D'EMPLOI: Français**
- (DE) WIEDERAUFBEREITUNGSSCHALE FÜR IUUS-SONDEN **GEBRAUCHSANWEISUNG: Deutsch**
- (IT) VASSOIO DI RICONDIZIONAMENTO PER LA IUUS PROBE **ISTRUZIONI PER L'USO: Italiano**
- (ES) BANDEJA DE REPROCESAMIENTO DE SONDÁ IUUS **INSTRUCCIONES DE USO: Español**
- (PT-BR) BANDEJA DE REPROCESSAMENTO DE SONDÁ IUUS **INSTRUÇÕES DE UTILIZAÇÃO: Português**
- (NL) IUUS PROBE-HERVERWERKINGSSCHAAL **GEbruIKSAANWIJZING: Nederlands**
- (SV) IUUS TRÅG FÖR OMBEARBETNING AV PROB **ANVÄNDARINSTRUKTIONER: Svenska**
- (DA) IUUS PROBE GENINDVINDINGSKASSETTE **BRUGSANVISNING: Dansk**
- (FI) IUUS-ANTURIN UUDELLEENKÄSITTELYTELINEEN **KÄYTTÖOHJEET: Suomi**
- (EL) ΔΙΣΚΟΣ ΕΠΑΝΕΠΕΞΕΡΓΑΣΙΑΣ ΑΝΙΧΝΕΥΤΗ IUUS **ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ: Ελληνικά**
- (PL) TACA DO STERYLIZACJI IUUS PROBE **INSTRUKCJA UŻYTKOWANIA: Polski**
- (TR) IUUS PROBE YENİDEN İŞLEM TEPSİSİ **KULLANMA TALİMATLARI: Türkçe**
- (RU) IUUS ДЛЯ ПОВТОРНОЙ ОБРАБОТКИ ЗОНДА **ИНСТРУКЦИИ ПО ЭКСПЛУАТАЦИИ: Русский**
- (CS) TÁC NA ZPRACOVÁNÍ SONDY IUUS **NÁVOD K POUŽITÍ: Čeština**
- (HU) IUUS PROBE REGENERÁLÓ TÁLCA **HASZNÁLATI ÚTMUTATÓ: Magyar**
- (SK) PODNOS NA OPĀTOVNÉ SPRACOVANIE SOND IUUS **POKYNY NA POUŽITIE: Slovenčina**
- (NO) REPROSESSERINGSBRETTE FOR IUUS-SONDE **BRUKSANVISNING: Norsk**
- (SL) PLADENJ ZA PONOVRNO OBDELAVO IUUS PROBE **NAVODILA ZA UPORABO: Slovensko**
- (BG) ТАБЛА ЗА ПРЕРАБОТКА IUUS PROBE **ИНСТРУКЦИИ ЗА УПОТРЕБА: български**
- (RO) TAVA DE REPROCESARE IUUS PROBE **INSTRUCȚIUNI DE UTILIZARE: Română**
- (ET) IUUS PROBE TAASTÖÖTLUSALUS **KASUTUSJUHEND: Eesti**
- (LV) IUUS ZONDES ATKĀRTOTAS APSTRĀDES PĀPLĀTE **LIETOŠANAS INSTRUKCIJA: Latviski**
- (HR) PLITICA ZA PONOVRNO PROCESIRANJE IUUS SONDI **UPUTE ZA UPORABU: Hrvatski**
- (SR) TACNA ZA PONOVRNU OBRADU SONDÉ IUUS PROBE **UPUTSTVA ZA UPOTREBU: Srpski**
- (LT) "IUUS PROBE" PAKARTOTINIO APDOROJIMO PADĒKLAS **NAUDOJIMO INSTRUKCIJA: Lietuvių k.**
- (ZH-CN) IUUS 探針再處理托盤 **使用說明書: 簡體中文**
- (ZH) IUUS 探針再處理託盤 **使用說明書: 繁體中文**
- (KO) IUUS PROBE 재처리 트레이 **용도 표기: 한국어**
- (JA) IUUSプローブ再処理トレイ **取扱説明書: 日本語**

For the full instructions for use visit:  
Pour le mode d'emploi complet, visitez le site :  
Die vollständige Gebrauchsanweisung finden Sie unter:  
Per le istruzioni per l'uso complete visitare:  
Para ver las instrucciones de uso completas, visite:  
Para as instruções completas de utilização visite:  
Ga voor de volledige gebruiksaanwijzing naar:  
För att få tillgång till hela bruksanvisningen, besök:  
Se hele bruksanvisningen her:  
Täydelliset käyttöohjeet ovat osoitteessa:  
Για πλήρεις οδηγίες χρήσης, επισκεφτείτε:  
Pełną instrukcję użytkowania można znaleźć na stronie:  
Kullanma talimatlarının tamamı için şu adresi ziyaret edin:  
Для получения полных инструкций по эксплуатации посетите:  
Pro úplný návod k použití navštivte:  
A teljes használati utasításért látogasson el ide:  
Úplné pokyny na použitie nájdete na:  
For en komplett bruksanvisning, gå til:  
Za celotna navodila obiščite:  
За пълните инструкции за употреба посетете:  
Pentru instrucțiunile de utilizare complete, accesați:  
Täieliku kasutusjuhendi leiate aadressilt:  
Lietošanas instrukcijas pilna versija ir pieejama šajā tīmekļa vietnē:  
Potpuno upute za upotrebu pronađite pod:  
Kompletna uputstva potražite na adresi:  
Išsamią naudojimo instrukciją rasite:  
有关完整的使用说明, 请访问:  
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<https://summitmedicalusa.com/ifu/documents/26523-private-label-ifu/>

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The instructions provided within have been validated by the device manufacturer as being capable of reprocessing reusable medical devices.

Individual sterilizers, instrument cleanliness, specific loading of instrument trays, types and geometry of instruments, sterilization containers, filters, and wrappings vary at each location.

## READ THIS SECTION BEFORE PLACING PRODUCT INTO SERVICE

### INTENDED USE/INDICATIONS FOR USE SUMMARY

The IUUS Probe Reprocessing Tray OM-1000-GS (Instrument Protection System) is intended to contain and protect the Sonata® Intrauterine Ultrasound (IUUS) Probe model IUSP-002 during transport, sterilization, and storage. The IUUS Probe Reprocessing Tray is used to organize and protect IUUS Probes that are sterilized by a healthcare provider. The IUUS Probe Reprocessing Tray is intended to allow sterilization of the enclosed IUUS Probe model IUSP-002 during these sterilization cycles:

- STERRAD® 100NX® Standard
- STERIS® AMSCO® V-PRO 1®, V-PRO 1 Plus, V-PRO maX and V-PRO maX 2

The IUUS Probe Reprocessing Tray is intended to be used in conjunction with a legally marketed wrap. The IUUS Probe Reprocessing Tray is not intended on its own to maintain sterility. A full list of device models is provided in Appendix A.

### DEVICE DESCRIPTION

IUUS Probe Reprocessing Trays manufactured by Summit Medical are used to enclose and hold the Sonata® IUUS Probe model IUSP-002 in an organized manner during the sterilization process and subsequent storage and transportation. The tray does not have direct patient contact. The tray by itself does not maintain sterility. The tray has a rectangular base with latchable cover. The tray has perforations to allow sterilant penetration. The tray contains silicone inserts in the base and/or cover to hold, organize, and protect the IUUS Probe within the tray during the sterilization process and subsequent storage and transportation.

### INTENDED USER

The IUUS Probe Reprocessing Tray is intended to be used by healthcare professionals in the operating room and sterile processing department for transportation, sterilization, and storage of the Sonata® IUUS Probe model IUSP-002.

### LIMITATION ON PROCESSING

1. The end of useful life on the IUUS Probe Reprocessing Tray is a minimum of 25 sterilization cycles. Inspect the tray before use for wear and damage caused by use. Discontinue use if visible signs of wear are present, including corrosion, mechanical failures, cracking, peeling, flaking, broken welds, damaged feet, damaged latches, damaged Hold-Its®/Hold-Downs®, discoloration, etc.
2. See **Table 2** for sterilization methods and configurations.
3. **DO NOT OVERLOAD** Systems or components.
4. **DO NOT OVERLOAD** individual Hold-Its® slots. Load only one instrument per Hold-Its® slot.
5. Inside of sterilizers, **DO NOT STACK** individually wrapped Systems or components. Separate wrapped Systems or components from each other or any other items on separate shelves of the sterilizer to allow for maximum sterilant flow.
6. The total weight of the system (e.g. tray, and instrument load) must not exceed 25 pounds (11.34 kg).
7. The Sonata® IUUS Probe should be prepared and sterilized according to the IUUS Probe manufacturer's instructions.
8. It is the responsibility of the processor to maintain specific validations for the terminal sterilization process being applied to the configurations of instruments being presented to the sterilization process.

## WARNINGS

- Do not use if package is damaged or unintentionally opened prior to use.

**Note: Clean and inspect trays according to the instructions provided prior to placing into service.**

## UNIVERSAL PRECAUTIONS

- Personnel should wear all personal protective clothing and equipment as required by their employer's/department's operating procedures for the contamination level they will be exposed to.
- Keep dissimilar metals separated during sterilization to prevent corrosion.

## POINT OF USE

Remove gross soil with disposable cloth/paper wipe. Contaminated components should be kept moist until qualified cleaning processes can be applied.

## CLEANING

Refer to the instrument manufacturer's instructions for use for specific instructions for cleaning the instruments in the trays.

Use one of the following validated cleaning options to clean the tray is recommended.

**DO NOT** use scouring pads or abrasive cleaners. **DO NOT** store tray in liquid.

**NOTE: These cleaning methods and cycles are validated for the tray ONLY. Refer to the Sonata® IUUS Probe Instructions for Use (REF-003, IUSP-002 Manual) for validated cleaning methods for the IUSP-002 IUUS Probe in the tray OM-1000-GS.**

### 1. Manual Gross Decontamination:

- Materials needed: Neutral pH (6.0 – 8.5) enzymatic detergent, soft bristle brush, and running water.
- Remove all visible soil and contaminants using a soft bristle brush. The entire tray should be immersed while cleaning, to aid in the removal of contaminants and to reduce splashing of detergent on personnel, for a minimum of 2 minutes.
- Rinse thoroughly for a minimum of 1 minute with clean water to remove all detergent. See rinsing instructions on the detergent label.

### 2. Ultrasonic Clean:

- Prepare enzyme wash in an ultrasonic cleaning unit.
- Place a single tray in the detergent and run for a minimum of ten minutes.
- Rinse for a minimum of 2 minutes with cold tap water.
- Visually inspect tray for contaminants. Repeat the cycle if necessary to remove visible contamination.

### 3. Automated Washer:

The Instrument Protection Systems have been validated for the automatic wash system cycle listed in **Table 1**. Qualification of specific parameters will need to be conducted by the processor.

**Table 1**

CYCLE	WATER TEMPERATURE	CLEANING PROCESS
Pre-Wash 1 & 2	Cold Tap Water	Re-Circulation Time: 2 Minutes
Enzyme Wash	Hot Tap Water	Soaking Time: 4 Minutes
Wash 1	Heated at 150°F (65.5°C)	Re-Circulation Time: 15 Minutes
Rinse 1 & 2	Hot Tap Water	Re-Circulation Time: 5 Minutes

**Note:** After completion of an automatic wash cycle, visually inspect the System (tray and accessories) for any remaining visible soil. All visible soil must be removed by hand cleaning, brushing, ultrasonic, or additional automatic cycles prior to sending to sterilization.

## DISINFECTION

Systems are intended to be terminally sterilized.

## MAINTENANCE, INSPECTION, AND TESTING

Systems may be reused until unacceptable deterioration such as corrosion, cracking, rust, peeling, flaking, discoloration, or mechanical failure occurs.

### Signs of Mechanical Failure Include:

- Broken or cracked corners or welds
- Broken or non-working latches
- Missing, torn, or cut silicone inserts
- Missing or damaged feet

## STERILIZATION

See **Table 2** for typical sterilization parameters that have been qualified for the sterilization of Sonata IUUS Probe Reprocessing Tray.

**NOTE: These sterilization methods and cycles are validated for the tray ONLY. Refer to the Sonata® IUUS Probe Instructions for Use (REF-003, IUSP-002 Manual) for validated sterilization methods for the IUSP-002 IUUS Probe in the tray OM-1000-GS.**

**Table 2.**

<b>STERILIZATION METHOD FOR TRAY</b>	<b>CYCLE (times)</b>
STERRAD 100S	<i>Standard</i>
STERRAD 100NX	<i>Standard</i>
STERRAD 100NX	<i>Express</i>
STERRAD 100NX	<i>Flex</i>
STERRAD NX	<i>Standard</i>
STERIS AMSCO V-PRO 1	<i>Standard</i>
STERIS AMSCO V-PRO 1 PLUS	<i>Lumen, Non-Lumen</i>
STERIS AMSCO V-PRO maX	<i>Lumen, Non-Lumen</i>
STERIS AMSCO V-PRO maX 2	<i>Lumen, Non-Lumen</i>

**Summit Medical has validated the following sterilization methods:**

- The STERRAD 100S Standard sterilization cycle in legally marketed wrap cleared by the FDA.
- The STERRAD 100NX Standard sterilization cycle in legally marketed wrap cleared by the FDA.
- The STERRAD 100NX Express sterilization cycle in legally marketed wrap cleared by the FDA.
- The STERRAD 100NX Flex sterilization cycle in legally marketed wrap cleared by the FDA.
- The STERRAD NX Standard sterilization cycle in legally marketed wrap cleared by the FDA.
- The STERIS AMSCO V-PRO, V-PRO 1 PLUS, V-PRO maX and V-PRO maX 2 sterilization cycles in legally marketed wrap cleared by the FDA.

Use an FDA cleared accessory to maintain sterility.

Please consult the sterilizer instruction manual to ensure intended loads are compatible with the intended sterilization cycle.

Ensure IUUS Probe Reprocessing Tray and enclosed instrument are completely dry before STERRAD or STERIS V-PRO sterilization.

## INDICATIONS FOR USE

### STERILIZATION OF IUUS PROBE IS ONLY VALIDATED FOR WRAP, STERRAD 100NX AND V-PRO CYCLES

#### STERRAD® 100S & STERRAD® 100NX® Standard Cycles, Wrap

InstruSafe® Instrument Protection System trays are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System trays are intended to allow sterilization of the enclosed medical devices during a Sterrad 100S Standard and Sterrad 100NX Standard sterilization cycles. The InstruSafe Instrument Protection System trays are intended to be used in conjunction with legally marketed wrap. The InstruSafe Instrument Protection System trays are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

*\*Validated by Summit Medical for use in STERRAD 100S Standard Cycle and STERRAD 100NX Standard Cycle ONLY.*

#### AMSCO® V-PRO® Low Temperature Sterilization Cycles, Wrap

InstruSafe® Instrument Protection System trays are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System trays are intended to allow sterilization of the enclosed medical devices during Amsco V-PRO Low Temperature Sterilization Cycles. The InstruSafe Instrument Protection System trays are intended to be used in conjunction with a legally marketed wrap. The InstruSafe Instrument Protection System trays are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

AMSCO V-PRO Low Temperature Sterilization Systems			
Sterilizer	Standard Cycle	Lumen Cycle	Non Lumen Cycle
V-PRO 1	X	N/A	N/A
V-PRO 1 PLUS	N/A	X	X
V-PRO maX	N/A	X	X
V-PRO maX 2	N/A	X	X

*\*Validated by Summit Medical for use in AMSCO V-PRO Low Temperature Sterilization Systems ONLY.*

## STORAGE

Store terminally sterile trays that are wrapped on storage shelf in a horizontal position. Consult wrap manufacturer for shelf life information.

## DISPOSAL

In the event the Instrument Protection Systems do not pass inspection prior to use or have otherwise been deemed no longer fit for purpose, the devices shall be disposed of in line with local protocol. The method of disposal shall depend on the potential risks of cross-contamination and infection when the need for disposal is identified.

## SERIOUS INCIDENT REPORTING

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the FDA/competent authority of the Member State in which the user and/or patient is established.

## WARRANTY

### LIMITED WARRANTY FOR SUMMIT MEDICAL INSTRUMENT PROTECTION SYSTEM.

THIS LIMITED WARRANTY AND THE REMEDY PROVIDED HEREIN ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES AND, UNLESS STATED HERE-IN, ANY STATEMENTS OR REPRESENTATIONS MADE BY ANY OTHER PERSON OR FIRM ARE VOID. THE DURATION OF ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE SHALL BE LIMITED TO THE DURATION OF THE EXPRESS LIMITED WARRANTY. NEITHER SUMMIT MEDICAL NOR ITS AFFILIATES SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL LOSSES OR DAMAGES, RESULTING FROM THE USE OR INABILITY TO USE THE SYSTEM, WHETHER RESULTING FROM BREACH OF WARRANTY OR ANY OTHER LEGAL THEORY.

This Limited Warranty gives you specific legal rights, and you may also have other rights which vary from State to State. Some States do not allow limitations on how long an implied warranty lasts, or do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusions may not apply to you.

**What Is Covered.** Summit Medical warrants the original purchaser that the system enclosed with this Limited Warranty conforms to the manufacturer's specifications and is free from defects in workmanship and material for a period of 12 months from the date of original purchase. If the original purchaser transfers the System to another party, this Limited Warranty will not be enforceable by the party to whom the product is transferred.

**What We Will Do To Correct Problems.** Should your System prove defective during this period, you must notify Summit Medical or an authorized distributor or dealer of Summit Medical. You must permit Summit Medical or its representatives to make such investigation, examination and tests as Summit Medical deems appropriate and, if requested to do so, you will return the product to the factory at the address set forth below. Summit Medical's sole obligation under this Limited Warranty is, at its option, to repair or replace the defective product or products, without charge for parts or labor. Postage, insurance or shipping costs incurred in presenting your System product for warranty service are your responsibility.

**What Is Not Covered.** This Limited Warranty is contingent upon proper use and maintenance of the product; it does not cover products that have been improperly shipped, or that have been misused, abused, neglected, or improperly maintained, cleaned or stored, or that have been serviced other than by Summit Medical or an authorized distributor or dealer of Summit Medical or that have been modified without the express approval of Summit Medical. Failure to follow the directions in the owner's manual may constitute improper use or maintenance of the product and causes this Limited Warranty not to apply. This Warranty does not extend to normal wear or to replacement items.

**If you have questions or claims related to this warranty, contact:**

Customer Service Department  
Summit Medical  
815 Vikings Parkway, Suite 100  
St. Paul, MN 55121 | USA

**[www.instrusafe.com](http://www.instrusafe.com)**

PHONE: 651-789-3939 | 888-229-2875

FAX: 651-789-3979 | 888-229-1941

EMAIL: [customerservice@innoviamedical.com](mailto:customerservice@innoviamedical.com)

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