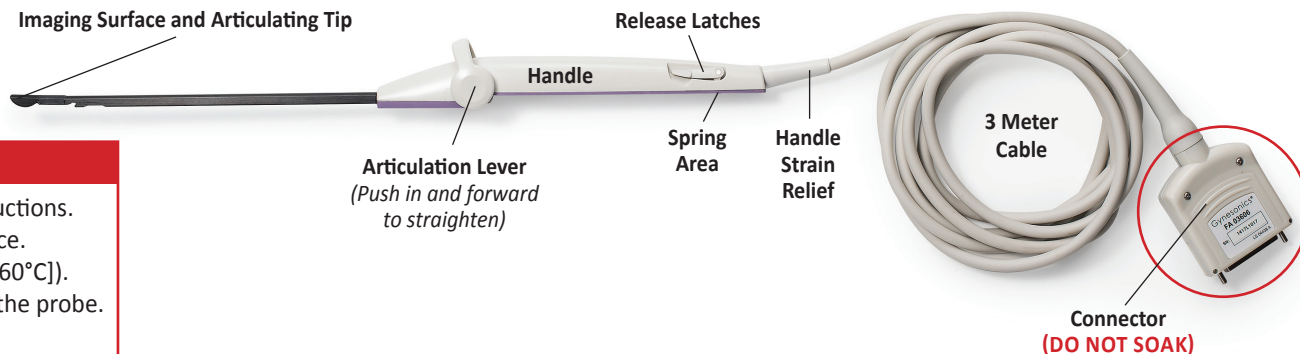


Sonata[®] SYSTEM IUUS Probe (IUSP-002)

Reprocessing Reference Guide



IMPORTANT INFORMATION

- Refer to Sonata Probe Instructions for Use REF-003 for full instructions.
- Probe has been exposed to blood, handle as contaminated device.
- Imaging Surface fragile & temperature sensitive (limit to 140°F [60°C]).
- DO NOT STEAM STERILIZE (AUTOCLAVE)!** Doing so will destroy the probe.
- Articulating Tip fragile
- Connector **not** waterproof

1 INSPECT

1 Inspect Tip, Handle, Cable and Connector



- Tip – straight, no surface damage



- Handle – no cracks or separation of parts
- Cable and Strain Relief – no cracks or cuts
- Connector – no cracks

DO NOT reprocess or use if there is any damage to the IUUS Probe.

2 CLEANING OPTION 1: MANUAL CLEANING

MATERIALS:

Medical Grade Low Alcohol Surface Disinfectant Wipes (e.g., Metrex™ CaviWipes™)

DRYING OPTIONS:

- Clean, Soft, Lint-free Cloth
- Drying Cabinet
- Air Dry

1 Immerse and soak in enzymatic solution, clean all areas

- Mix enough warm water with solution to immerse in tray and brush the device: approximately 1 gallon or 3.8L.
- Immerse in tray for 12 minutes with connector outside.
- With fresh solution, brush device, especially in areas with corners, gaps, and mechanisms.
- Remove all visible contamination. Re-soak if necessary and repeat until clean.

MATERIALS:

- Enzymatic Detergent (Use Manufacturer instructions)
- Warm water (95°F to 104°F) (35°C to 40°C)
- Clean tray, approximately 48 x 25 x 6 cm (19 x 10 x 2.5 in)
- Timer



2 Rinse to remove enzymatic solution

- Thoroughly rinse enzymatic detergent with water.
- Rinse for at least 2 minutes, or for as long as needed.
- 95°F to 104°F [35°C to 40°C] (use of purified, distilled or demineralized water is recommended).



3 Wipe 2 times from Connector to end of Handle

- Wipe from Connector to end of handle, wetting surfaces.
 - Repeat with a new wipe, wetting surfaces for period per manufacturer.
 - Inspect for visible soil; repeat if needed.
- Wipe Connector, Connector Strain Relief, Cable, and Handle Strain Relief.

Note: If disinfection is required per local or institutional policies prior to sterilization, probe is compatible with ASP® Cidex® OPA Ortho-Phthalaldehyde Solution. Immerse the Handle and Cable in ASP Cidex with connector outside, as in step 1. Immerse for 12 minutes at room temperature (minimum of 68°F [20°C]).



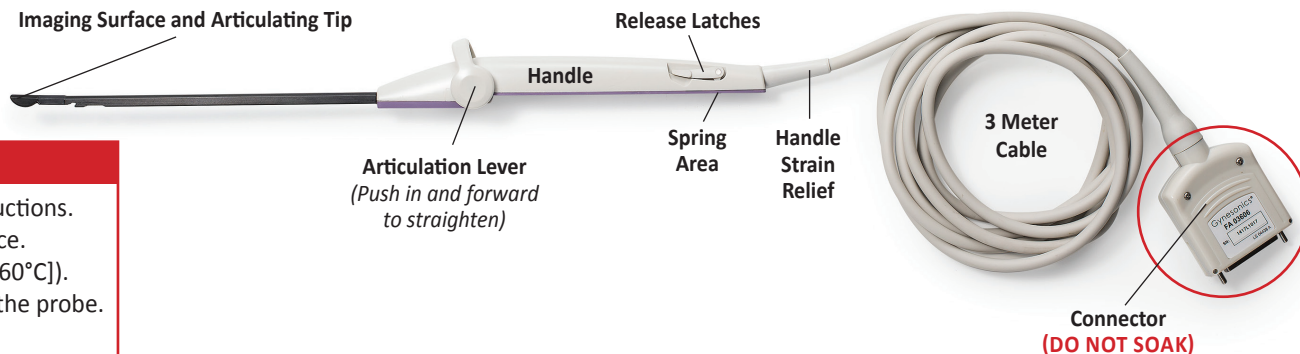
4 Dry completely

- Completely dry with a clean, soft, lint-free cloth.
- If using a drying cabinet, DO NOT exceed 140°F (60°C).
- Fully dry mechanisms, gaps, and corners.
- Wipe residual chemicals from Connector.



Sonata[®] SYSTEM IUUS Probe (IUSP-002)

Reprocessing Reference Guide



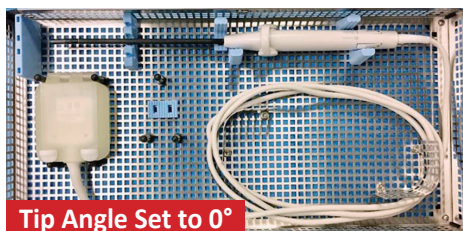
IMPORTANT INFORMATION

- Refer to Sonata Probe Instructions for Use REF-003 for full instructions.
- Probe has been exposed to blood, handle as contaminated device.
- Imaging Surface fragile & temperature sensitive (limit to 140°F [60°C]).
- DO NOT STEAM STERILIZE (AUTOCLAVE)!** Doing so will destroy the probe.
- Articulating Tip fragile
- Connector **not** waterproof

2 CLEANING OPTION 2: AUTOMATED CLEANING AND DISINFECTION

VALIDATED MATERIALS:

- Cleaning detergent: pH neutral to mildly alkaline (pH 7-11) enzymatic detergent
- Disinfectant: neoDisher Septo DN (Dr. Weigert GmbH & Co.) or neo Disher SEPT PAC (Dr. Weigert GmbH & Co.)
- Automated Washer: Getinge model S-8668
- Other equivalent programmable washer-disinfectors may also be used; the washer should be ISO 15883-1 compliant



- Ensure the Sonata IUUS Probe Connector Protector (ACCY-018) is on the IUUS Probe Connector
- Place the IUUS Probe within the Reprocessing Tray, articulation angle at 0 and transducer facing down
- Place the tray in the automated washer-disher and set the following parameters:

STEP	MINIMUM TIME SETTING	MINIMUM TEMPERATURE SETTING	CHEMICAL
Pre-cleaning rinse	5 minutes	~20°C	Tap water or deionized water
Cleaning	10 minutes	Mediclean Forte: 45°C	Mediclean Forte: 0.5% (5mL per liter)
Rinse	5 minutes	35°C +/- 5°C	Tap water
Disinfection	5 minutes	Septo DN: 55°C; DO NOT exceed 60°C SEPT PAC: 35°C	1.0% (10mL per liter)
Rinse	5 minutes	35°C +/- 5°C	Deionized or tap water (deionized water reduces water stains)
Air Dry	5 minutes	60°C	N/A

- If needed, use a lint-free cloth of additional manual cleaning

3 STERILIZATION

VALIDATED SYSTEM	USE CYCLE
+Sterrad 100NX [®]	Standard Cycle
Steris V-Pro [®] maX, Steris V-Pro [®] maX2, 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
+Sterrad [®] NX™	Standard Cycle

Devices sterilized using **OPTION 1** should **NOT** have the IUUS Probe Connector Protector attached. Doing so could destroy the probe.

VALIDATED SYSTEM
STERIS SYSTEM 1E [®]
STERIS SYSTEM 1 [®] Express

Devices sterilized using **OPTION 2** should not be stored and should be used immediately to minimize microbial proliferation.



OPTION 1: H₂O₂

STERRAD 100NX OR STERIS V-PRO:

Ensure the Connector Protector is **NOT** on the IUUS Probe Connector

- Insert in sterilization tray with the Tip set to 0° (see photo above)
- Enclose and fully wrap tray with sterilization wrap
- Sterilize per validated use cycles listed

STERRAD NX:

Wrap the IUUS Probe with sterilization wrap per your facility procedure and sterilize per validated use cycle listed

+ Includes AllClear™ Technology



OPTION 2: LIQUID CHEMICAL

- Cover the IUUS Probe Connector using the Connector Protector (ACCY-018)
- Place the IUUS Probe into the STERIS SYSTEM tray and add chemical indicator
- Load single-use S40 Concentrate cup and start the cycle

Please refer to the manufacturer's instructions for STERIS SYSTEM 1E or 1 Express Liquid Chemical Sterilant Processing Systems.