

Patient Safety Alert

Veterans Health Administration Warning System
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AL06-011

April 3, 2006

- Item:** **Transrectal ultrasound transducer assembly, Models 8808 and 8551, manufactured by B-K Medical Systems, Inc., Wilmington, MA.**
- Specific Incident:** During patient safety rounds in the Urology Clinic at the reporting facility, the lumen of a needle guide of a reprocessed (i.e., ready to be used for a procedure) reusable B-K Medical transrectal ultrasound transducer assembly was found to be soiled. Upon investigation, it was discovered that brushes were not being used to clean the lumen of the needle guide.
- General Information:** This Alert provides guidance on reprocessing reusable B-K Medical's Model 8808 and 8551 transrectal transducer assemblies. This guidance provides a condensed, uniform set of instructions for each device to assure proper reprocessing by facilities using these devices.
- Background:** Transrectal (also called endorectal or endocavity) transducer assemblies are devices used for ultrasonic viewing of the prostate, as well as for biopsy of the prostate under ultrasonic guidance. B-K Medical's Model 8808 transducer assembly is shown in Attachment #1, and the Model 8551 transducer assembly is shown in Attachment #2. These devices have a needle guide that directs biopsy needle insertion. The biopsy needle repeatedly traverses the guide, affording the opportunity for fecal and blood materials (i.e. bioburden) to accumulate. Bioburden can also accumulate in other parts of the transducer assembly.
- Brushes are required to clean the transducer assemblies to reduce bioburden and remove proteins. Transducer assembly kits have not always been supplied with brushes. Not using brushes for cleaning has resulted in improperly reprocessed transducer assemblies, which could lead to pathogen transmission between patients.
- Actions:** **If the B-K Medical transrectal ultrasound transducer assembly is used at your facility:**
1. By **close of business (COB) April 5, 2006**, Supply, Processing, and Distribution (SPD) and Infection Control shall review the facility's current and prior processes (since inception of these devices at the facility) for reprocessing B-K Medical's Model 8808 and 8551 transducer assemblies to ensure that these processes meet and have previously met the minimum criteria set forth in Attachments #3 (8808) and #4 (8551).
 2. By **COB April 12, 2006**, institute the following three procedures in accordance with Attachments #3 (8808) and #4 (8551):
 - a) A procedure to clean the B-K Medical transducer assemblies. This procedure must include the use of brushes, detergent, and enzymatic cleaner to clean all parts of the transducer assemblies, including internal channels of the parts.

b) A procedure for high-level disinfection or sterilization (using STERIS SYSTEM 1®) of the 8808 and 8551 transducers.

c) A procedure for steam sterilizing the following reusable parts:

- UA 1272 (dummy bracket for the 8808 transducer assembly),
- UA 1257 (biopsy channel bracket for the 8808 transducer assembly),
- UC 5298 (needle guide for the 8808 transducer assembly), and
- UC 5299 (needle guide for the 8551 transducer assembly).

NOTE: If necessary, purchase a sufficient supply of these parts such that turn-around times do not delay procedures. B-K Medical is working to supply these parts; however, it may be 30-60 days before the parts become available. Lack of availability of additional parts by April 12, 2006, does not negate the need for instituting steam sterilization of the parts.

3. By **COB April 12, 2006**, the facility will provide in-service training, in accordance with Attachments #3 (8808) and #4 (8551), for staff responsible for reprocessing the transducers and associated accessories.
4. By **COB April 12, 2006**, post/display specific step-by-step reprocessing instructions (Attachments #3 and #4, or equivalent) for the B-K transducer assemblies in applicable departments responsible for reprocessing the device (e.g., Urology clinic, SPD).

Addl. Information:

Guidance - regarding notification of any patients that may have been potentially exposed to pathogens as a result of inadequate reprocessing technique - will be provided in a separate communication.

For other information regarding the transducers and accessories, consult B-K Medical's General Transducer Information Guide and the Model 8808 and 8851 User Guides. If you have misplaced a manual or otherwise need a replacement manual, contact B-K Medical at spuzar@bkmedus.com, who can email you a PDF version of the manual at no charge.

Source:

A reporting VA Medical Center and B-K Medical.

Contact:

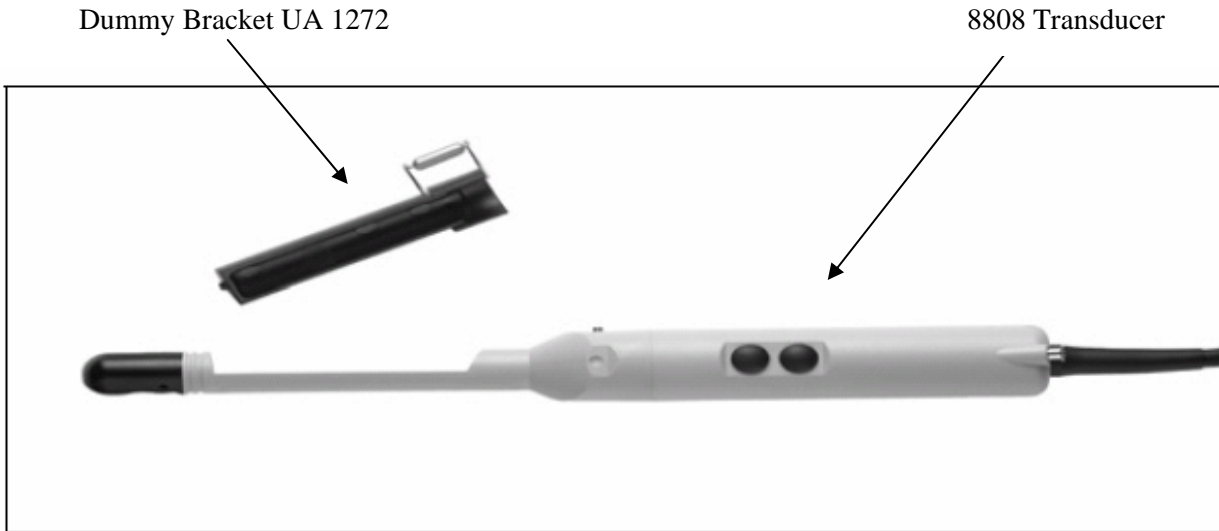
- Susan Seaney, Director of Clinical Applications, B-K Medical at (800) 876 7226 x133.
- Linda Danko, Clinical Program Coordinator, Infectious Diseases Program VACO at (513) 475 6374.
- Bob Osburn, SPD Executive Program Director VACO at (202) 273 6056.
- Lori King, VA National Center for Patient Safety (NCPS) at (734) 930 5890.

Attachments:

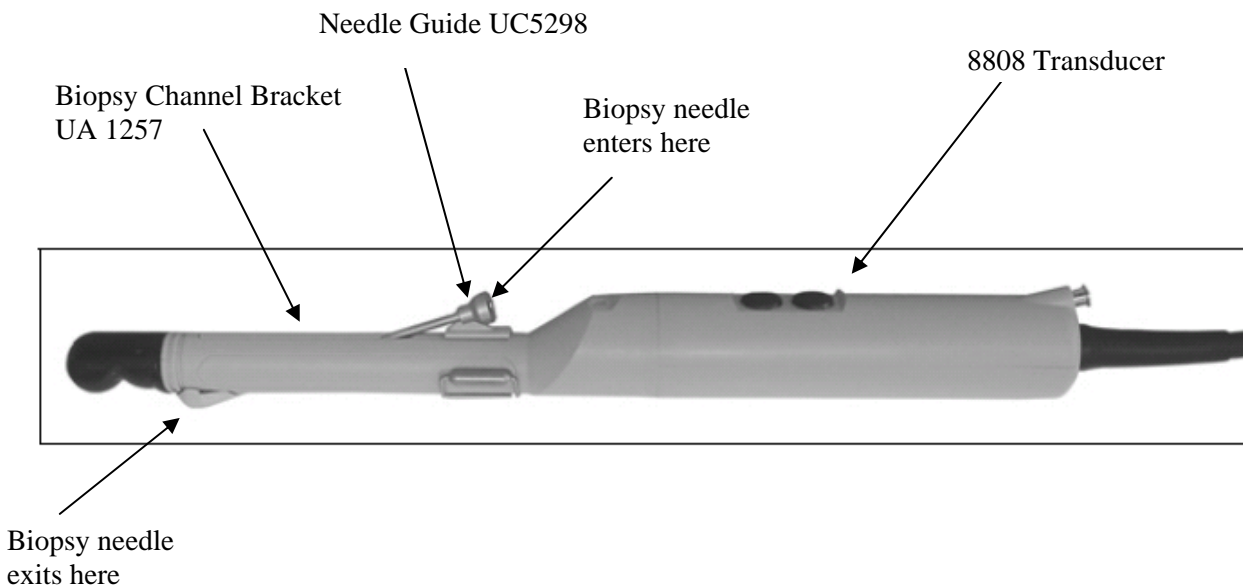
- Attachment #1: B-K Model 8808 Transducer Assemblies
- Attachment #2: B-K Model 8551 Transducer Assembly
- Attachment #3A: Reprocessing Instructions for the B-K Medical Model 8808 Transducer Assembly – Scan only/no biopsy performed
- Attachment #3B: Reprocessing Instructions for the B-K Medical Model 8808 Transducer Assembly – Biopsy performed
- Attachment #4: Reprocessing Instructions for the B-K Medical Model 8551 Transducer Assembly

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Attachment #1:
B-K Medical Model 8808 Transducer Assemblies

Model 8808 Transducer Assembly: Scan without biopsy

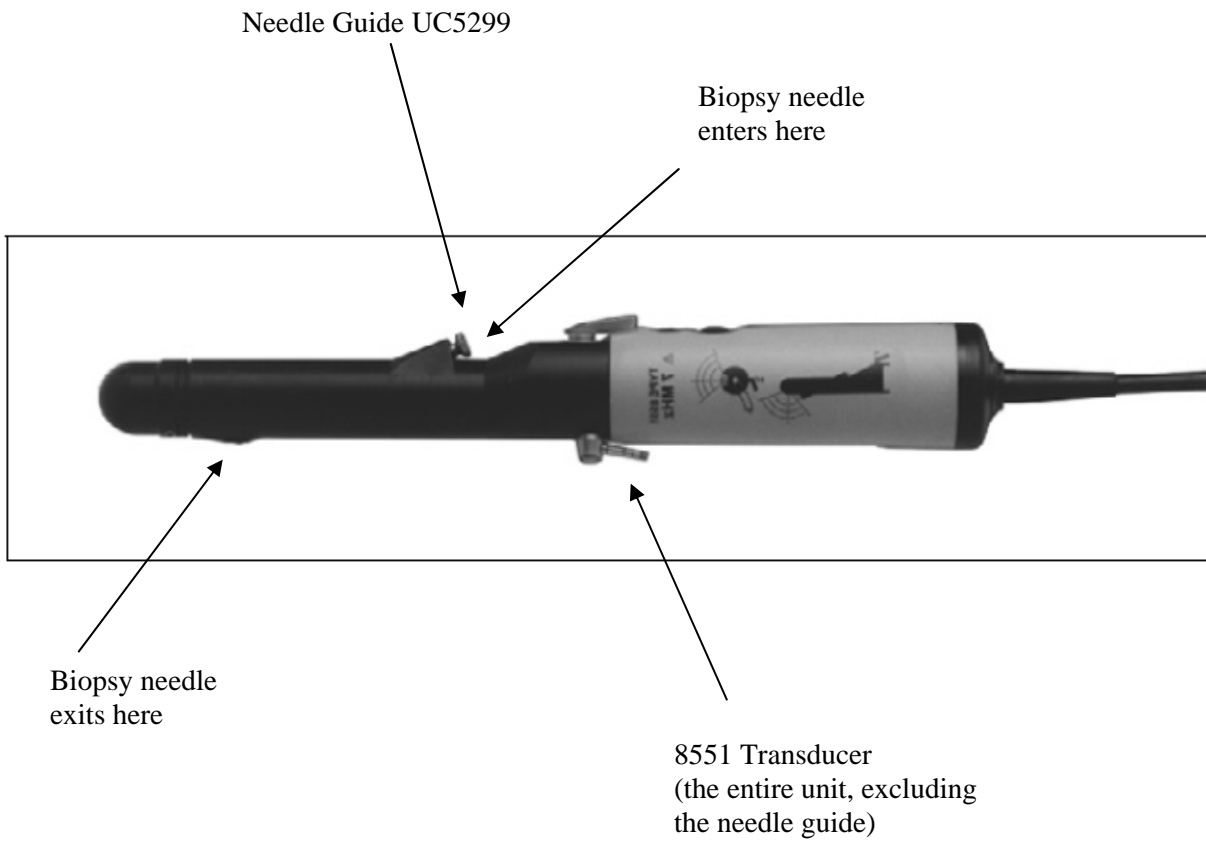


Model 8808 Transducer Assembly: Scan with biopsy



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Attachment #2:
B-K Medical Model 8551 Transducer Assembly

Model 8551 Transducer Assembly: Scan with or without biopsy



Attachment #3A:

**Reprocessing Instructions for the B-K Medical
Model 8808 Transducer Assembly – Scan only/no biopsy performed**



8808 Transducer
(used for scanning and biopsy)



Dummy Bracket (UA 1272)
(used for scanning only – no biopsy)

Following a scan with no biopsy performed:

In Urology:

Cleaning:

1. Remove any auxiliary precautionary items that have been applied (e.g., condoms/transducer covers, o-ring) and the dummy bracket from the 8808 transducer assembly.
2. Using tap water – no cooler than 50°F or warmer than 104°F - **immediately rinse** both the transducer and dummy bracket to remove any visible contamination (e.g., scanning gel, biological substances). **NOTE: Tap water temperatures cooler than 50°F or warmer than 104°F will result in serious damage to your transducer.**
3. Send the dummy bracket to SPD for reprocessing.
4. Use an EPA registered hospital grade detergent to meticulously wash the transducer.
5. Rinse the transducer with tap water (no cooler than 50°F or warmer than 104°F).
6. Scrub the transducer using a soft, bristled nail brush (like surgeons use) with an enzymatic cleaner (if following steps 8 and 9, use cleaner recommended by disinfectant supplier) to remove proteins. **The nail brush should not be used on the crystals at the end of the transducer as it can cause serious damage to your transducer. NOTE: This additional cleaning (step 6) is required and cannot be used in lieu of step 4.**
7. Rinse the transducer with tap water (no cooler than 50°F or warmer than 104°F).

Disinfection - If sterilizing the transducer with STERIS SYSTEM 1® go to step 10.

8. High-level disinfection of the 8808 transducer must be achieved using an FDA approved 2 - 3% glutaraldehyde product or an FDA approved ortho-phthalaldehyde product. Follow the disinfectant's instructions for use (e.g., soak time).
9. Rinse the disinfectant off of the transducer using tap water (no cooler than 50°F or warmer than 104°F).

Sterilization:

10. If high-level disinfection was not performed (steps 8 and 9), sterilize the 8808 transducer in the STERIS SYSTEM 1® using STERIS 20® and the appropriate quick-connects for the STERIS SYSTEM 1®. **NOTE: Transducers should not be sterilized without quick-connects. Transducers can withstand up to 300 cycles in the STERIS SYSTEM 1®.**

NOTE: Refer to the General Transducer Information Guide and the 8808 User Guide for additional information.

In SPD:

Cleaning:

1. Use an EPA registered hospital grade detergent to meticulously wash the dummy bracket.
2. Rinse the dummy bracket with tap water (no cooler than 50°F or warmer than 104°F).
3. Scrub the dummy bracket using a soft, bristled nail brush (like surgeons use) with an enzymatic cleaner to remove proteins. **NOTE: This additional cleaning (step 3) is required and cannot be used in lieu of step 1.**
4. Rinse the dummy bracket with tap water (no cooler than 50°F or warmer than 104°F).

Sterilization:

5. Sterilize the dummy bracket using steam sterilization. **NOTE: The dummy bracket can degrade over time from sterilization and should be replaced when it no longer fits snugly into the transducer. (This generally occurs after 50 or more sterilizations.)**

NOTE: Refer to the General Transducer Information Guide and the 8808 User Guide for additional information.

Attachment #3B:

**Reprocessing Instructions for the B-K Medical
Model 8808 Transducer Assembly – Biopsy performed**



8808 Transducer
(used for scanning and biopsy)



Biopsy Channel Bracket (UA 1257)
(used when biopsy needed)



Needle Guide (UC 5298)
(used when biopsy needed)

Following a scan with biopsy performed:

In Urology:

Cleaning:

1. Remove any auxiliary precautionary items that have been applied (e.g., condoms/transducer covers, o-ring), the biopsy channel bracket, and the needle guide from the 8808 transducer assembly.
2. Using tap water – no cooler than 50°F or warmer than 104°F - immediately rinse the transducer, biopsy channel bracket, and needle guide and flush the needle guide to remove any visible contamination (e.g., scanning gel, biological substances). **NOTE: Tap water temperatures cooler than 50°F or warmer than 104°F will result in serious damage to your transducer.**
3. Send the biopsy channel bracket and needle guide to SPD for reprocessing.
4. Use an EPA registered hospital grade detergent to meticulously wash the transducer.
5. Rinse the transducer with tap water (no cooler than 50°F or warmer than 104°F).
6. To remove proteins: **NOTE: This additional cleaning (step 6) is required and cannot be used in lieu of step 4.** Scrub the transducer using a soft, bristled nail brush (like surgeons use) with an enzymatic cleaner (if following steps 8 and 9, use cleaner recommended by disinfectant supplier). **The nail brush should not be used on the crystals at the end of the transducer as it can cause serious damage to your transducer.**
7. Rinse the transducer with tap water (no cooler than 50°F or warmer than 104°F).

Disinfection - If sterilizing the transducer with STERIS SYSTEM 1® go to step 10.

8. High-level disinfection of the 8808 transducer must be achieved using an FDA approved 2 - 3% glutaraldehyde product or an FDA approved ortho-phthalaldehyde product. Follow the disinfectant's instructions for use (e.g., soak time).
9. Rinse the disinfectant off of the transducer using tap water (no cooler than 50°F or warmer than 104°F).

Sterilization:

10. If high-level disinfection was not performed (steps 8 and 9), sterilize the 8808 transducer in the STERIS SYSTEM 1® using STERIS 20® and the appropriate quick-connects for the STERIS SYSTEM 1®. **NOTE: Transducers should not be sterilized without quick-connects. Transducers can withstand up to 300 cycles in the STERIS SYSTEM 1®.**

NOTE: Refer to the General Transducer Information Guide and the 8808 User Guide for additional information.

Reprocessing instructions continued on the following page.

Attachment #3B (continued):

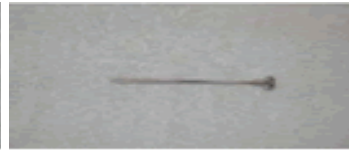
**Reprocessing Instructions for the B-K Medical
Model 8808 Transducer Assembly – Biopsy performed**



8808 Transducer
(used for scanning and biopsy)



Biopsy Channel Bracket (UA 1257)
(used when biopsy needed)



Needle Guide (UC 5298)
(used when biopsy needed)

In SPD:

Cleaning:

1. Use an EPA registered hospital grade detergent to meticulously wash the biopsy channel bracket and needle guide. Remove biological substances from the internal channels using a suitable brush (e.g., part number PC3 reusable brush, part number QZ0039 disposable brush, or equivalent) with the detergent, passing the brush through the biopsy channel bracket and needle guide – as shown below.



Biopsy Channel Bracket (UA 1257)
(photograph depicts the interior of the bracket)



Needle Guide (UC 5298)

2. Rinse the biopsy channel bracket and needle guide with tap water (no cooler than 50°F or warmer than 104°F), and flush the internal channels repeatedly with the tap water until the return water is clear.
3. To remove proteins: **NOTE: This additional cleaning (step 3) is required and cannot be used in lieu of step 1.**
 - a. Scrub the biopsy channel bracket and needle guide using a soft, bristled nail brush (like surgeons use) with an enzymatic cleaner.
 - b. Scrub the internal channels using a suitable brush (e.g., part number PC3 reusable brush, part number QZ0039 disposable brush, or equivalent) with the enzymatic cleaner, passing the brush through the biopsy channel bracket and needle guide – as shown above.
4. Rinse and flush the biopsy channel bracket and needle guide with tap water (no cooler than 50°F or warmer than 104°F).

Sterilization:

5. Sterilize the biopsy channel bracket and needle guide using steam sterilization. **NOTE: The biopsy channel bracket can degrade over time from sterilization and should be replaced when the needle guide will no longer fit snugly into it. This generally occurs after 50 or more sterilizations. The needle guide should not degrade from sterilization.**

NOTE: Refer to the General Transducer Information Guide and the 8808 User Guide for additional information.

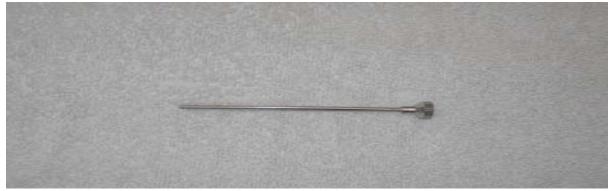
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Attachment #4:

**Reprocessing Instructions for the B-K Medical
Model 8551 Transducer Assembly**



8551 Transducer



Needle Guide (UC 5299)

Following a scan - with or without biopsy performed:

In Urology:

Cleaning:

1. Remove any auxiliary precautionary items that have been applied (e.g., condoms/transducer covers, o-ring) and the needle guide from the 8551 transducer assembly.
2. Using tap water – no cooler than 50°F or warmer than 104°F - immediately rinse the transducer and flush the needle guide to remove any visible contamination (e.g., scanning gel, biological substances). **NOTE: Tap water temperatures cooler than 50°F or warmer than 104°F will result in serious damage to your transducer.**
3. Send the needle guide to SPD for reprocessing.
4. Use an EPA registered hospital grade detergent to meticulously wash the transducer. Remove biological substances from the internal channel using a suitable brush (e.g., part number PC4 reusable brush, part number QZ0039 disposable brush, or equivalent) with the detergent, passing the brush through the built-in puncture canal of the 8551 transducer - as shown below.



5. Rinse the transducer with tap water (no cooler than 50°F or warmer than 104°F), and flush the built-in puncture canal of the transducer repeatedly with the tap water until the return water is clear.
6. To remove proteins: **NOTE: This additional cleaning (step 6) is required and cannot be used in lieu of step 4.**
 - a. Scrub the transducer using a soft, bristled nail brush (like surgeons use) with an enzymatic cleaner (if following steps 8 and 9, use cleaner recommended by disinfectant supplier). **The nail brush should not be used on the crystals at the end of the transducer as it can cause serious damage to your transducer.**
 - b. Scrub the internal channel using a suitable brush (e.g., part number PC4 reusable brush, part number QZ0039 disposable brush, or equivalent) with the enzymatic cleaner, passing the brush through the built-in puncture canal of the 8551 transducer - as shown above.
7. Rinse the transducer with tap water (no cooler than 50°F or warmer than 104°F).

Disinfection - If sterilizing the transducer with STERIS SYSTEM 1® go to step 10.

8. High-level disinfection of the 8551 transducer must be achieved using an FDA approved 2 - 3% glutaraldehyde product or an FDA approved ortho-phthalaldehyde product. Follow the disinfectant's instructions for use (e.g., soak time).
9. Rinse the disinfectant off of the transducer using tap water (no cooler than 50°F or warmer than 104°F).

Sterilization:

10. If high-level disinfection was not performed (steps 8 and 9), sterilize the 8551 transducer in the STERIS SYSTEM 1® using STERIS 20® and the appropriate quick-connects for the STERIS SYSTEM 1®. **NOTE: Transducers should not be sterilized without quick-connects. Transducers can withstand up to 300 cycles in the STERIS SYSTEM 1®.**

NOTE: Refer to the General Transducer Information Guide and the 8551 User Guide for additional information.

Reprocessing instructions continued on the following page.

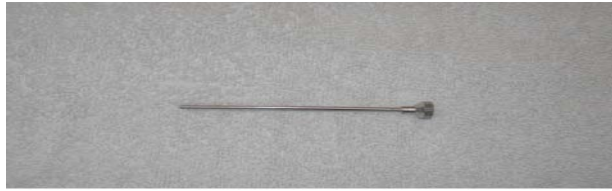
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Attachment #4 (continued):

**Reprocessing Instructions for the B-K Medical
Model 8551 Transducer Assembly**



8551 Transducer



Needle Guide (UC 5299)

In SPD:

Cleaning:

1. Use an EPA registered hospital grade detergent to meticulously wash the needle guide. Remove biological substances from the internal channel using a suitable brush (e.g., part number PC4 reusable brush, part number QZ0039 disposable brush, or equivalent) with the detergent, passing the brush through the needle guide - as shown below.



2. Rinse the needle guide with tap water (no cooler than 50°F or warmer than 104°F), and flush the internal channel of the needle guide repeatedly with the tap water until the return water is clear.
3. To remove proteins: **NOTE: This additional cleaning (step 3) is required and cannot be used in lieu of step 1.**
 - a. Scrub the needle guide using a soft, bristled nail brush (like surgeons use) with an enzymatic cleaner.
 - b. Scrub the internal channel using a suitable brush (e.g., part number PC4 reusable brush, part number QZ0039 disposable brush, or equivalent) with the enzymatic cleaner, passing the brush through the needle guide - as shown above.
4. Rinse and flush the needle guide with tap water (no cooler than 50°F or warmer than 104°F).

Sterilization:

5. Sterilize the needle guide using steam sterilization.

NOTE: Refer to the General Transducer Information Guide and the 8551 User Guide for additional information.