Technical Note

On-Site Cleaning and Re-sterilization of DSI Transmitters Using Actril/Spor-Klenz

All new and exchanged devices shipped to an investigator are sterile and ready for implantation. In studies where devices are implanted for short periods; significant battery life may remain at the end of the study allowing reuse of the device. DSI has developed procedures for cleaning and sterilizing devices on-site, and for regelling pressure catheters. These procedures will increase the number of times an investigator can use each device before returning it to DSI via the Device Exchange program, helping to reduce overall costs per study.

DSI only recommends cold sterilization between uses and does not recommend ETO machines. The implants will have changed compared to the unused product in that there would likely be more retained moisture and in particular disruption of gel (e.g. water, blood, or air mixing in the gel). This change in gel property may cause an increased risk for gel extrusion in pressure catheters. Secondly, there are numerous variables and specific parameter settings per ETO machine, and the customized settings used at DSI are proprietary. Lastly, even with our current process, there are some unused devices that do have gel or fill blowouts and must go back to be re-filled and gelled. **Note: If a device is re-sterilized with an ETO machine, it will be at the customer's risk and "off label".**

All products returned to DSI must be cleaned and decontaminated. Shipments that have not been cleaned and decontaminated will be charged a handling fee per item. These products are subject to transportation regulations as published by the US DOT or ICAO, or your carrier. If the products are fully decontaminated, they may be exempt from part or all of the requirements (including packaging, marking, labeling and documentation).

Supplies Needed

1. **Enzymatic Detergent**
   Enzymatic detergents are available from most hospital supply companies, and they are generally labeled for use on fabrics or surgical equipment/instruments. The purpose of the detergent is to remove blood, serum proteins, and tissue debris from the surface of the device. DSI-tested and approved products are Terg-A-Zyme® (Alconox, Inc.) and Haemo-Sol® N.S. (Haemo-Sol, Inc.).

   Terg-A-Zyme
   Terg-A-Zyme is an enzyme-active powdered detergent made by Alconox, Inc. To make a 1% solution, mix 10 grams of powder with 1 Liter of water. Allow the device to soak for a minimum

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of 4 hours and a maximum of 72 hours in the solution. Rinse thoroughly, preferably with running water. Fisher Scientific is a vendor that supplies Terg-A-Zyme (www.fishersci.com) but please refer to the Alconox website for other domestic and international vendors (www.alconox.com).

Haemo-Sol N.S.

Haemo-Sol N.S. is a non-sudsing, proteolytic powdered detergent made by Haemo-Sol, Inc. To make 1 Liter of the solution, mix 5 grams of powder with 1 Liter of water. Allow device to soak for a minimum of 4 hours and a maximum of 72 hours in the solution. Rinse thoroughly, preferably with running water. Fisher Scientific is a vendor that supplies Haemo-Sol N.S., but please refer to the Haemo-Sol website for other domestic and international vendors (www.haemo-sol.com). It is important to note that there are multiple types of Haemo-Sol available, but DSI only recommends using the N.S. (non-sudsing) type.

2. **Chemical Sterilant**

Available from most hospital supply companies, chemical sterilants are considered cold sterilants and should be used for the sterilization of heat sensitive medical equipment such as DSI devices. When used properly, chemical sterilants will destroy all viable forms of microbial life. DSI-tested and approved products are Actril® (Medivators, Inc.) and Spor-Klenz® (Steris).

Actril

Actril is a chemical sterilant made up of a mixture of peracetic acid, hydrogen peroxide, and acetic acid and is made by Medivators, Inc. Actril has a shelf life of 1 year from the date it is first opened. Actril is available directly from Medivators, Inc. (https://www.medivators.com/).

Actril is available in the U.S. and internationally. Please refer to Medivators, Inc. website for a list of domestic and international distributors.

Spor-Klenz

Spor-Klenz is a chemical sterilant composed of the same mixture (peracetic acid, hydrogen peroxide, and acetic acid) as Actril, but produced by Steris (https://shop.steris.com/en/us).

Spor-Klenz is available in the U.S. and internationally.

******Note on Cidex******

Cidex is classified as a high-level disinfectant, not a sterilant. DSI has assessed material compatibility but makes no express guarantee of **sterilization** post-exposure to Cidex.

3. **Sterile Saline**

This can be used as a rinse for the sterilized device to remove all traces of the chemical sterilant before implantation. Use it to temporarily store (< 48 hours) the device aseptically until surgical implantation. See the technical note on device storage if you need to store the devices longer.

	**Important**: Sterile water should be used for rinsing and soaking 4ET devices. Do not use sterile saline. Please see the 4ET User Manual for additional information about re-sterilizing and reusing this device.

Implant Procedures

Temperature Implants

Immediately following removal from the animal, rinse the device in tap water to remove gross contamination from blood and tissue. Place the device in the detergent and soak for at least 4 hours to allow breakdown of the surface contaminants. Remove and examine the device. If traces of blood or tissue remain, additional soaking in the detergent may be required. Rinse the device thoroughly in tap water.

To sterilize using Actril/Spor-Klenz: Use in a well-ventilated area. Pour an adequate amount (enough to cover the device completely) into a sterile container. Place the device into the sterile container and tightly cap both the bottle with the remaining solution and the sterile container. Allow the device to soak in Actril/Spor-Klenz for a minimum of 5.5 hours at approximately 25°C. The sterilant will remain a clear liquid. After sterilizing the device in Actril/Spor-Klenz, thoroughly rinse the device three times with sterile saline and then soak the device in sterile saline for a minimum of 5.5 hours. The device can be left in the sterile saline until ready for implantation within 48 hours. If the device will not be used within 48 hours, air dry and store in a safe dry place. See the technical note on device storage if you need to store the devices longer.

Biopotential Implants

Immediately following removal from the animal, ensure that the suture ties are intact around each biopotential lead tip to prevent moisture entry. Rinse the device in tap water to remove gross contamination from blood and tissue. Take care to clean the suture rib/tab and remove any foreign material that may be present. Then place the device in the detergent and soak for at least 4 hours to allow breakdown of the surface contaminants. Remove and examine the device. If traces of blood or tissue remain, additional soaking in the detergent may be required. Rinse the device thoroughly in tap water.

To sterilize using Actril/Spor-Klenz: Use in a well-ventilated area. Pour an adequate amount (enough to cover and sterilize the device) into a sterile container. Place the device into the sterile container and tightly cap both the bottle with the remaining solution and the sterile container. Allow the device to soak in Actril/Spor-Klenz for a minimum of 5.5 hours at approximately 25°C. The sterilant will remain a clear liquid. After sterilizing the device in Actril/Spor-Klenz, thoroughly rinse the device three times with sterile saline and then soak the device in sterile saline for a minimum of 5.5 hours. The device can be left in the sterile saline until ready for implantation within 48 hours. Otherwise, air dry and store in a safe dry place. See the technical note on device storage if you need to store the devices longer.

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Pressure Implants

Immediately following removal from the animal, rinse the device in tap water to remove gross contamination from blood and tissue. Carefully remove any residual tissue adhesive and suture material from the surface of the catheter. If there is blood in the tip of the catheter, remove as much as possible by directing a stream of saline at the tip to flush it out. Take care to clean the suture rib/tab and remove any foreign material that may be present. Place the device in the detergent and soak for at least 4 hours to allow breakdown of the surface contaminants. Remove and examine the device. If traces of blood or tissue remain, additional soaking in the detergent may be required. Rinse the device thoroughly in tap water.

To sterilize using Actril/Spor-Klenz: Use in a well-ventilated area. Pour an adequate amount (enough to completely cover the device) into a sterile container. Place the device into the sterile container and tightly cap both the bottle with the remaining solution and the sterile container. Allow the device to soak in Actril/Spor-Klenz for a minimum of 5.5 hours at approximately 25°C. The sterilant will remain a clear liquid. After sterilizing the device in Actril/Spor-Klenz, thoroughly rinse the device three times with sterile saline and then soak the device in sterile saline for a minimum of 5.5 hours. The device can be left in the sterile saline until ready for implantation within 48 hours. Please note, storage in saline for this length of time will make the catheter material quite soft, which may make catheter insertion more challenging in certain procedures. For cannulation in the heart, it is strongly recommended to decant the saline and store the sterile device dry in its sterile container to be rehydrated immediately prior to surgery. If the device will not be used within 48 hours, air dry and store in a safe dry place. See the technical note on device storage if you need to store the devices longer.

The PhysioTel Digital implant should be removed from Actril/Spor-Klenz within 24 hours. Discoloration of the titanium housing will occur; however, the housing will not be damaged.

The catheter may need to be regelled prior to sterilizing or immediately prior to the time of surgery. Use aseptic conditions if regelling prior to surgery to prevent contamination. For more information, see the technical notes on regelling pressure devices.

Customers are liable for product repair if products other than the specified detergents and sterilants are used.

Some examples of chemicals that **will cause damage** to DSI devices include, but are not limited to alcohols, phenols, iodophors, and hypochlorite. Please check with DSI Technical Services before using any product other than the approved products listed.

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