On-Site Cleaning and Re-sterilization of DSI Transmitters Using Cidex/Glutaraldehyde

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

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

Available from most hospital supply companies, 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 transmitter. 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 cold or warm 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 Terg-A-Zyme (catalog #50-821-785, 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 cold or warm 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. (catalog #23-721050) 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 transmitters. When used properly, chemical sterilants will destroy all viable forms of

microbial life. DSI tested and approved products are: Cidex® (Johnson & Johnson Company) and Actril® (Minntech Corporation).

Cidex®Activated Dialdehyde Solution

Cidex is a Glutaraldehyde based chemical sterilant made by Johnson & Johnson Company. To make Cidex, pour the entire contents from the activator vial into the sterilizing and disinfecting solution. The solution will change to a green color after being mixed. Cidex has a shelf life of 14 days once the two containers are mixed together. After this time, the solution can no longer be used either as a sterilant or as a disinfectant. Cidex is available in both the U.S. and internationally. Please refer to the Johnson & Johnson website to find an authorized distributor (www.aspjj.com/us/products/cidex-activated/faqs).

There is also a 28-day formulation of Cidex available but it should not be used as it may damage the transmitter.

Glutaraldehyde

Glutaraldehyde may also be used to sterilize the transmitters. Glutaraldehyde must be diluted to 2% before use. Check your local chemical supply company for availability.

3. Sterile Saline*

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

Temperature Transmitters

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

To sterilize using Cidex: Use in a well ventilated area. Pour an adequate amount (enough to cover and sterilize the transmitter) into a sterile container. Place the transmitter into the sterile container and tightly cap both the bottle with the remaining solution and the sterile container. Allow the device to soak in Cidex for a minimum of 10 hours at approximately 25°C. After sterilizing the transmitter in Cidex, thoroughly rinse the transmitter three times with sterile saline and then soak the transmitter in sterile saline for a minimum of 10 hours. The transmitter 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 transmitter storage if you need to store the transmitters longer.

If using Glutaraldehyde, dilute to 2% and follow the procedure above for sterilizing.

Biopotential Transmitters

Immediately following removal from the animal, ensure that the suture ties are intact around each biopotential lead tip to prevent moisture entry. Rinse the transmitter 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 transmitter in the detergent and soak for at least 4 hours to allow breakdown of the surface contaminants. Remove and examine the

transmitter. If traces of blood or tissue remain, additional soaking in the detergent may be required. Rinse the transmitter thoroughly in tap water.

To sterilize using Cidex: Use in a well ventilated area. Pour an adequate amount (enough to cover and sterilize the transmitter) into a sterile container. Place the transmitter into the sterile container and tightly cap both the bottle with the remaining solution and the sterile container. Allow the device to soak in Cidex for a minimum of 10 hours at approximately 25°C. After sterilizing the transmitter in Cidex, thoroughly rinse the transmitter three times with sterile saline and then soak the transmitter in sterile saline for a minimum of 10 hours. The transmitter 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 transmitter storage if you need to store the transmitters longer.

If using Glutaraldehyde, dilute to 2% and follow the procedure above for sterilizing.

*Sterile water should be used for rinsing and soaking 4ET transmitters. Do not use sterile saline. Please see the 4ET User Manual for additional information about resterilizing and reusing this device

Pressure Transmitters

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

To sterilize using Cidex: Use in a well ventilated area. Pour an adequate amount (enough to cover and sterilize the transmitter) into a sterile container. Place the transmitter into the sterile container and tightly cap both the bottle with the remaining solution and the sterile container. Allow the device to soak in Cidex for a minimum of 10 hours at approximately 25°C. After sterilizing the transmitter in Cidex, thoroughly rinse the transmitter three times with sterile saline and then soak the transmitter in sterile saline for a minimum of 10 hours. The transmitter 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 transmitter storage if you need to store the transmitters longer.

If using Glutaraldehyde, dilute to 2% and follow the procedure above for sterilizing.

The catheter may need to be re-gelled prior to sterilizing and immediately prior to the time of surgery. Use aseptic conditions if re-gelling prior to surgery to prevent contamination. For more information see the technical notes on re-gelling pressure transmitters.

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 transmitters 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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