

On-Site Cleaning and Decontamination of iPRECIO Pump and Programmer

All new iPRECIO infusion pumps shipped to an investigator are sterile and ready for implantation. DSI has developed procedures for cleaning and sterilizing iPRECIO pumps when returning them to DSI for investigation.

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 pump. 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 iPRECIO pumps. When used properly, chemical sterilants will destroy all viable forms of microbial life. DSI tested and approved products are: Cidex® (Johnson & Johnson Company).

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.aspij.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 pump.

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. Saline and Tap Water

This can be used as a rinse for the sterilized pump in order to remove all traces of the infused chemical and the chemical sterilant before returning pump to DSI.

4. 70% Ethanol/IPA/IMS

This can be applied to a clean cloth or soft paper towel to decontaminate the programmer.

iPRECIO Pump

Immediately following removal from the animal, rinse the pump in tap water to remove gross contamination from blood and tissue. Empty any remaining fluid from the pump and fill and rinse the reservoir with saline three times. If possible allow the saline to rinse the catheter out. Remove all remaining fluid from the reservoir but do not leave it collapsed. Fill the reservoir with 450ul of air to ensure that the reservoir is not damaged. Place the pump in the detergent and soak for at least 4 hours to allow breakdown of the surface contaminants. Remove and examine the pump. If traces of blood or tissue remain, additional soaking in the detergent may be required. Rinse the pump thoroughly in tap water.

To sterilize using Cidex: Use in a well ventilated area. Pour an adequate amount (enough to cover and sterilize the pump) into a sterile container. Place the pump 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 pump in Cidex, thoroughly rinse the pump three times with saline or tap water. Air dry the pump and package it for safe shipping to DSI.

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

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

Some examples of chemicals that will cause damage to the iPRECIO pump 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.

iPRECIO Programmer

Clean the programmer with a clean cloth or soft paper towel saturated with 70% ethanol/IPA/IMS. Package the programmer for safe return to DSI.