

EasiSlush®

Sodium Chloride Solution for Slush Preparation

For Use in Organ Recovery and Organ Storage/Transport

(0.9% Sodium Chloride Irrigation, USP)

Directions for Preparation and Use

Description:

EasiSlush® is a clear, colorless, 0.9% Sodium Chloride solution for preparation of slushed solution to provide hypothermia during the recovery, storage, and transport of donor organs for transplantation. The solution is sterile, non-pyrogenic, isotonic and is contained in a sterile, flexible, non-PVC bag. Composition, osmolarity, pH, and ionic concentration are shown in the table below.

	Size (L)	Composition (g/L)	Osmolarity (mOsmol/L)	pH	Ionic Concentration (mEq/L)	
		Sodium Chloride, USP (NaCl)	(calc)		Sodium	Chloride
0.9% Sodium Chloride Irrigation USP	1.25	9	308	5.2 (4.5 to 7.0)	154	154

Indications and Use:

EasiSlush® slushed solution is intended for topical cooling of in-situ, abdominal donor organs during intraoperative recovery from the donor. It is also intended to maintain organ hypothermia during storage and transport to the transplant recipient.

EasiSlush® slushed solution is used to establish, and maintain hypothermia of donor organs during recovery, storage, and transport.

Organ Recovery

Prior to organ recovery, EasiSlush® slushed solution is delivered to the open peritoneal cavity of the donor to assist in creating hypothermia by topically cooling external surfaces of organs for recovery.

During organ recovery, if ice crystals are no longer visible, the temperature of the saline solution will begin to rise and additional EasiSlush slushed solution may be delivered per established transplant team procedures. (Temperature rise may be assessed with temperature probes, being careful that the probe is measuring the solution and is not in contact with the organ).

Organ Storage/Transport

For organ storage/transport, EasiSlush® slushed solution may be used to topically cool external surfaces of a sterile, sealed, primary organ bag containing chilled preservation solution and the organ. In this application, EasiSlush® may be added to a secondary bag or to a tertiary hard container to surround the primary organ bag. Once bagged, the organ can be placed in a bed of non-sterile ice in an insulated transport container, which is then closed. Actual use should follow standard practices of the OPO or hospital for transporting and storing specific types of donor organs using sterile, slush solutions.

Contraindications:

EasiSlush® solution is contraindicated for:

- flushing of organs or for perfusing organs during pump preservation.
- direct contact with organs during storage and transport.

Warnings:

NOT FOR INJECTION

NOT FOR USE TO INDUCE REGIONAL HYPOTHERMIA IN LIVING PATIENTS

Precautions:

Do not administer unless seals of sterile-barrier, inner pouch are intact.

Use only after controlled freezing and as a slushed solution (presence of both liquid and ice crystals).

Avoid prolonged direct contact between ice crystals and body tissues.

Do not use if discolored or if obvious particulate matter, precipitates, or contamination are evident in the solution.

Single use only. Discard unused portion.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

How Supplied:

EasiSlush® is supplied in bags containing 1,250 mL of 0.9% Sodium Chloride Irrigation, USP. Each product box includes eight (8) EasiSlush® bags.

It is recommended that this product be stored unfrozen at 2°C–25°C (36°F–77°F). Avoid excessive heat. Brief exposure, up to 40°C, does not adversely affect this product. EasiSlush® may also be kept frozen at temperatures between -30°C to -4°C (-22°F to 25°F) for up to 3 months.

Each EasiSlush® bag is supplied within a double barrier of 2 pouches:

1. A sterile-barrier, inner pouch maintains sterility of the EasiSlush® bag. The sterile-barrier pouch consists of a clear front and a Tyvek® back. Pouch design includes a peelable seal with a chevron to facilitate opening.
2. A clear, outer pouch maintains cleanliness of the sterile-barrier pouch. The outer pouch includes a notch to facilitate opening.

Directions for Use of Bridge to Life EasiSlush®

System Guidelines for Preparation of Slush:

The following instructions are intended only as guidelines for the preparation of slush using the Bridge to Life EasiSlush® product. The specific procedure necessary to achieve the desired slush consistency will depend on the type of freezer used, location of the product in the freezer, and the utilization of freezer capacity.

A. Slush preparation with controlled freezing:

1. Place product in freezer maintained at a temperature between -4°C and -15°C for 2 to 6 hours. Note: A pre-cooled product will require less time to freeze. The package should be laid flat on the freezer shelf to minimize the possibility of bent/folded or poorly shaped bags after freezing.
2. During the freezing process, remove the product from freezer periodically and carefully massage to break up any large frozen chunks of solution
3. Return product to freezer and repeat procedure until the desired degree of freezing is obtained.

B. Slush preparation with frozen EasiSlush®:

1. EasiSlush® may be frozen in advance and stored in a fully frozen condition prior to use.
2. Frozen product must be rewarmed until free liquid can be seen on the surface of the frozen solution. Free liquid indicates that product is at the melting temperature and that the preparation steps below will result in a slushed solution (presence of both liquid and ice crystals).
3. With free liquid visible, slush can be created by placing it on a smooth, flat surface and striking the flat surfaces of the outer pouch, with a mallet (or similar instrument), to break-up the solid mass of frozen solution until a desired size and distribution of ice crystals is obtained. Care must also be taken to avoid the use of small and/or sharp instruments that may perforate, or otherwise damage, the sterile-barrier pouch and the solution bag.
4. After slush preparation and prior to use, inspect the sterile-barrier pouch and solution bag for perforations or other indications of damage. Discard any product with visible signs of damage to the solution bag or sterile-barrier pouch as sterility may be compromised.

C. Repeat freezing:

1. Product which has been previously frozen and thawed may be frozen again up to 2 additional times to prepare slush using either the controlled freezing, or the pre-freezing method.
2. Prior to refreezing, check that all seals of the sterile-barrier pouch are intact. If any broken seals or holes are detected, discard product as sterility may be compromised.
3. EasiSlush® should not be refrozen or used if it has been removed from either the outer pouch or the inner Tyvek®, sterile barrier pouch.

To Open and Dispense EasiSlush®: Use Aseptic Technique

A. Prepare EasiSlush® outside the sterile field:

1. Confirm that content of the EasiSlush® bag is flexible. If not, allow it to sit at room temperature to regain flexibility.
2. Open the outer pouch by tearing at the notches. Remove the inner, Tyvek®, sterile- barrier pouch. (Figure 1)

3. Check that all seals of the sterile-barrier pouch are intact. If any broken seals or holes are detected, discard product as sterility may be compromised.
4. Exercising caution to avoid touch contamination, peel open the sterile-barrier pouch to expose the sterile, EasiSlush® bag and prepare it to be introduced to the sterile, surgical field. (Figure 2)

B. Transfer the EasiSlush® bag to the sterile, surgical field:

1. Exercising caution to avoid touch contamination, a designated person in the sterile field should remove the EasiSlush® bag bringing it into the sterile, surgical field.
2. For direct peritoneal and other applications, with the EasiSlush® bag in a horizontal position, cut the bag down the center using a sterile scalpel. Folding and opening the bag like a book, squeeze out slush from the back of the bag and deliver it to the desired location(s). (Figure 3)

Guidelines for Use of EasiSlush® Slushed Solution

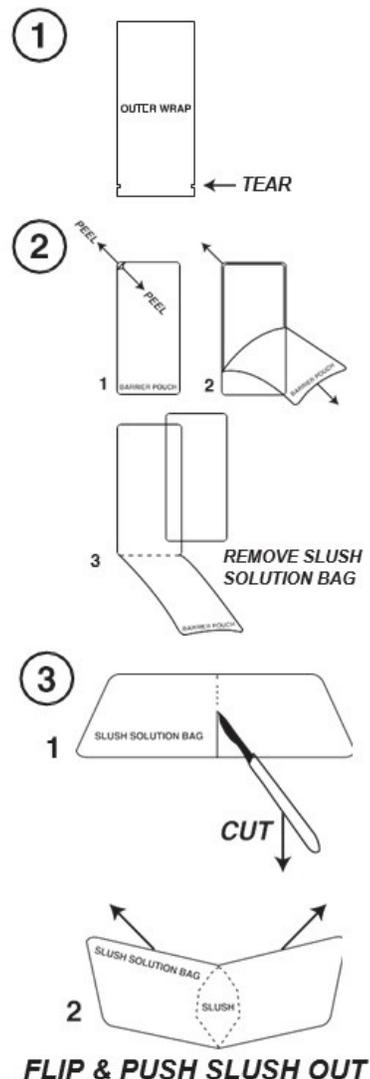
A. For use in cooling and creating hypothermia of in-situ, abdominal, donor organs:

- Slushed solution should be used in accordance with the preferences and practices of the hospital, the OPO (Organ Procurement Organization) protocol, and the organ procurement team.
- The volume of slushed solution required for direct application into the peritoneum will vary with the donor size, the organs targeted for retrieval, and the expected duration of the cooling effect desired, according to physician's instructions
- If ice crystals in EasiSlush® are no longer visible, the temperature of the saline solution will begin to rise and additional EasiSlush® slushed solution may be delivered per established transplant team procedures.

B. For use in storing and transporting donor organs:

- Partially fill an insulated organ transport cooler with non-sterile, crushed ice.
- Prepare the organ per institution protocol. Aseptically place the organ in an organ retrieval bag or other sterile container with enough cold preservation solution to assure that the organ will remain completely covered during storage and transport. Seal the bag/container and place it in a second organ retrieval bag. Seal the second bag/container so that the organ is now 'double bagged'.
- Separately, dispense EasiSlush® slushed solution into an organ retrieval bag (or sterile container) large enough to hold both the 'double bagged' organ and EasiSlush®. One bag of EasiSlush® (1.25L) is normally sufficient for a smaller organ (e.g., kidney; two bags may be needed for a larger organ, e.g., liver).
- Place the 'double-bagged' organ into the bag/container containing the EasiSlush® and seal it. The organ is now 'triple-bagged'.
- Place the triple-bagged organ on the bed of crushed ice, assuring that it is not in contact with an inside wall of the transport container.
- Add additional crushed ice to cover the triple-bagged organ.
- Close/seal the insulated organ transport container.

In laboratory tests using this method, hypothermic organ temperatures were demonstrated to be maintained for at least 36 hours.



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Patent Pending