



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.