

p.d. 4. Konservuojantis tirpalas kepenų
transplantacijai

PRESERVATION SOLUTION

StoreProtect

**Solution for perfusion and cold storage
of organs for transplantation ✓**

INSTRUCTIONS FOR USE

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 **carna**medica

PRESERVATION SOLUTION

Solution for perfusion and cold storage of organs for transplantation StoreProtect

DESCRIPTION ✓ Sudedamosios dalys:

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StoreProtect composition is:

Pentafraction (HES)	50 g/L
Lactobionic Acid (as Lactone)	35.83 g/L
Potassium Phosphate monobasic	3.40 g/L
Magnesium Sulfate heptahydrate	1.23 g/L
Raffinose pentahydrate	17.83 g/L
Adenosine	1.34 g/L
Allopurinol	0.136 g/L
Total Glutathione	0.922 g/L
Potassium Hydroxide	5.61 g/L
Sodium Hydroxide	qs pH: 7.4
Water for Injection	qs 1 liter

StoreProtect is a clear to light yellow, sterile, non-pyrogenic solution intended for hypothermic flushing and storage of organs (kidney, liver, pancreas). StoreProtect has an osmolality of approximately 320 mOsm/kg and a pH of approximately 7.4 at room temperature.

ACTIONS

StoreProtect solution, cooled at +2°C to +6°C, is used for flushing of the isolated organ immediately before removal from the donor and/or immediately after removal from the donor. The solution is then left in the organ vasculature during hypothermic storage and transportation. StoreProtect is not intended to be used with continuous machine perfusion. Administration of StoreProtect at the recommended temperature will effectively cool the organ and lower its metabolic requirements.

INTENDED USE ✓ p.d.4. StoreProtect skirtas plovimui ir hipotermijam laikymui

StoreProtect is intended for the flushing and the hypothermic storage of kidney, liver, pancreas or other organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into the recipient. inkstų, kepenų, kasos ar kt. organų, išėmimo iš donoro, paruošimo

CONTRAINDICATIONS ✓ saugojimui, transportavimui, ar transplantacijai į recipientą metu.

There are no known contraindications when used as directed.

WARNING

NOT INTENDED FOR DIRECT INJECTION OR INTRAVENOUS INFUSION.

PRECAUTIONS

The donor organ must be flushed free of the StoreProtect with physiological solution prior to the reperfusion to prevent occurrence (in the recipient) of potentially serious cardiovascular complications such as hyperkalemic cardiac arrest or bradyarrhythmia. This is necessary because of the high concentration of potassium in the solution. StoreProtect includes components (allopurinol and pentafraction (HES)) which individually have caused hypersensitivity reaction in patients.

ADVERSE REACTIONS

Vascular complications (thrombosis, fistulas, primary non-functions, graft rejections, dialysis needs, pancreatitis events after transplantation) have been reported while testing clinically solutions with the same composition as StoreProtect. However those post-transplantation reactions could not be attributed solely to solutions.

PREPARATION

Cool the solution to 2°C to 6°C. Remove overwrap prior to use. Check each bag for leaks by squeezing the container firmly. If a leak is found, discard solution bag. With the overwrap removed, perform a visual inspection of the solution for particulate matter. Do not use the solution if obvious particulate matter, precipitates, or contamination are evident in the solution. Use an administration set to flush the organ with StoreProtect solution. Prior to connection to the organ, the solution bag should be suspended from a sufficient height to allow for a steady stream of solution and to produce flow rates of at least 30 mL/min during flushing. Flushing should be continued until the organ is uniformly pale and the effluent is clear.

Suggested minimum volumes:

In situ aortic flush:	Ex vivo infusion:
Adults 2000 mL – 4000 mL Infants 50 mL/kg	<ul style="list-style-type: none"> Liver <ul style="list-style-type: none"> Adults 1200 mL Infants 50 mL/kg Kidney / Pancreas <ul style="list-style-type: none"> Adults 300-500 mL Infants 150-250 mL

Additional solution should be dispensed into the container holding the organ. The organ must be totally immersed. Seal the container aseptically. The organ storage container should be maintained within a well-insulated transport container. Ice should be used to surround the organ storage container, but should not be used within the container, where the ice could come into direct contact with the organ. Donor organs must be flushed free of StoreProtect prior to transplantation according to transplantation centers protocols. Those operations must be done by qualified operators.

PACKAGING AND STORAGE

Bag material: EVA (PVC free). 1000 mL StoreProtect solution in one liter bags carton of 10 or 2000 mL StoreProtect solution in carton of 5. Store StoreProtect at a temperature between +2°C and +25°C away from direct sunlight. Avoid excessive heat. Do not freeze the solution, and do not use if frozen.

ATTENTION

This medical device is to be used only by the qualified medical staff.

 Date of production	 Caution! See instruction for use	 2274	The product meets the requirements in the European Medical Devices Directive MDD. The manufacturer is certified by the Dokumenta elektroniniu parašu pasirašė EGLĖ TAURAITĖ The product is certified in accordance with the Data: 2019-04-17 15:39:41
 Expiration date	 Do not use if damaged		
 Series number	 Sterile (Aseptic filling)	 +25°C +2°C Restriction of acceptable storage temperatures	
 Catalog number	 Single use	 Manufacturer	

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