Instruction for use

TiPROTEC®

General info:

This instruction for use applies to TiPROTEC® Vascular Protection Solution, manufactured by:

DR. FRANZ KÖHLER CHEMIE GMBH
Werner-von-Siemens-Str. 14-28
64625 Bensheim, Germany
Tel.: +49 6251 1083-0, Fax: +49 6251 1083-146
E-Mail: www.koehler-chemie.de

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Every user is required to read this instruction for use and follow them thoroughly. User must inform the patient about any known side effect, precautions and warning contained in this instruction for use as well as appropriate post-operative care. Keep the Instructions accessible to all users at all times.

Non-compliance with this instruction for use can lead to patient hazard situations or unknown side effects.

Product description:

TiPROTEC® is a special vascular preservation solution for the cold storage of blood vessels for surgical vascular grafts and consists of three components:

- TiPROTEC® basic solution packaged in bag
- TiPROTEC® glucose solution in ampoule
- TiPROTEC® lyophilisate of iron chelators in vial

The ready-for-use solution is formed by dissolving the TiPROTEC® lyophilisate with the glucose solution and adding the TiPROTEC® glucose-lyophilisate solution to the TiPROTEC® basic solution.

Dispensing forms:

TiPROTEC® basic solution is available in 100 ml bags. The 100 ml bags come with ampoules containing 3.7 ml glucose solution and vial of 7 mg lyophilisate.

Packaging sizes:

- Packages with 1 bag of 100 ml TiPROTEC® basic solution,1 ampoule of 3.7 ml glcose solution and 1 vial of 7 mg lyophilisate for the creation of a ready-for-use TiPROTEC® solution
- Packages with 5 bag of 100 ml TiPROTEC® basic solution,5 ampoule of 3.7 ml glucose solution and 5 vial of 7 mg lyophilisate for the creation of a ready-for-use TiPROTEC® solution

Indication for use:

TiPROTEC® solution is a solution for flushing, for cold storage and for the transport of blood vessels for surgical interventions.

Intended user:

TiPROTEC® must be used in medical facilities by trained and skilled medical personnel only.

Contraindications:

TiPROTEC® is not indicated for intravenous infusion.

Method of application:

⚠ TiPROTEC® should only be used if the solution is clear and the containers are undamaged. The addition of the glucose solution from the enclosed ampoules to the lyophilisate in the vial as well as of the glucose-lyophilisate solution to the TiPROTEC® basic solution must be prepared under aseptic conditions. The glucose solution and the lyophilisate should be added immediately before using the finished TiPROTEC® solution. The entire contents of the glucose solution and of the lyophilisate vial is to be added aseptically to the 100 ml infusion bag of TiPROTEC® basic solution. This is done by means of a syringe via the injection port on the bag. After the addition of the glucose-lyophilisate solution to the 100 ml bag, mix well by repeatedly shaking the bag. After the glucose-lyophilisate solution has been added or the infusion bag or the ampoule or the vial have been opened, the finished TiPROTEC® solution is to be used within 6 hours. Any remaining solution should be discarded. The TiPROTEC® solution should be kept at a temperature of 2-6°C when being used. Depending on its size, the lumen of the removed blood vessel is to be flushed immediately after removal with 20 - 200 ml of the ready-to-use TiPROTEC® solution using the corresponding cannula. It is important to ensure that the blood vessel is not affected more than necessary (in particular not on the luminal side!). Afterwards, the blood vessel is completely immersed in TiPROTEC® and stored in a sterile container/bag (without compressing the vessel) at 2-6°C until surgical use. The maximum time for the blood vessel storage are 10 days. Immediately before implantation, the vessel is removed from the solution and depending on its size, it is rinsed with 20-200 ml of physiological saline solution using the corresponding cannula. The blood vessels taken from the TiPROTEC® solution must be verified for integrity and functionality before use.

TiPROTEC® composition

The ready-for-use solution contains 103.7 ml after the addition of glucose solution (Comp. 2) and lyophilisate (Comp. 3) to TiPROTEC® basic solution (Comp. 1):

Quantity [g]	Ingredient	Concentration [mmol/L]	
0.085	Sodium chloride	14	
0.566	Potassium chloride	73	
0.169	Magnesium chloride • 6 H_2O	8	
0.015	Disodium hydrogen phosphate	1	
0.001	Calcium chloride • 2 H_2O	0.05	
0.671	N-acetyl histidine • H_2O	30	**Component 1**
0.043	Tryptophan	2	
0.030	α-Ketuglutaric acid	2	
0.069	Asparagine acid	5	
0.078	Glycine	10	
0.046	Alanine	5	
0.712	Sucrose	20	
0.198	Glucose monohydrate	10	**Component 2**
0.0066	Deferoxamine mesylate	0.1	**Component 3**
0.0004	3,4-Dimethoxy-N-methylbenzohydroxamic acid	0.02	

Other ingredients: Water for injection purposes
Osmolality: 307 [mosmol/L]

Warnings, precautions and side-effects:

TiPROTEC® is only intended for external use. There are no known side effects due to the transfer of limited quantities of the solution into the recipient 's body within the context of vascular grafts/vascular surgery.

⚠ The entry of over 50 ml of solution into the circulatory system is to be avoided. Upon the entry of larger quantities (> 200 ml) of solution into the circulatory system, hypotension may result due to the deferoxamine mesylate contained in the solution.

⚠ Be aware of the high potassium content of the solution, when TiPROTEC® is used proximity to the heart.

⚠ Use clear solutions only

STERILE TiPROTEC® basic solution and TiPROTEC® glucose solution are delivered in sterile state. These components are steam sterilized. Sterilization has been validated.

STERILE A TiPROTEC® lyophilisate is delivered in sterile state. This component is sterile filtered. Sterilization has been validated.

TiPROTEC® delivered in sterile state and shall be not sterilized again

TiPROTEC® is single use and shall be not re-used.

TiPROTEC® should not be used after the stated expiration date printed out on packaging.

TiPROTEC® shall not be used if sterile packaging has been damaged. Sterility cannot be ensured anymore.

Disposal of the solution:

The used solution is to be disposed of properly by the tissue center. Not used remainders of the TiPROTEC® solution are to be diluted with water (1: 1) and discharged to the waste water.

Storing and transporting conditions:

TiPROTEC® shall be stored in a controlled temperature environment between +2 and +8 °C.

TiPROTEC® shall be stored in an environment protected by sunlight.

TiPROTEC® shall be stored in a dry environment.

Solution shelf-life:

TiPROTEC® shelf life has been validated up to 18 months.

Symbols used for TiPROTEC® IFU and labels:

Symbol	Description
	Symbol for “Manufacturer”
REF	Symbol for “Catalog number”
LOT	Symbol for “Batch number”
	Symbol for Consult instruction for use”
	Symbol for “Attention, caution, watch out”
STERILE	Symbol for “Steam sterilization or dry heat”
STERILE A	Symbol for “Sterile by using aseptic processing techniques”
	Symbol for “Do not reuse”
	Symbol for “Do not sterilize it again”
	Symbol for “Useable up to”
	Symbol for “Do not use if package is damaged”
	Symbol for “Temperature limits”
	Symbol for “Keep away from sunlight”
	Symbol for “Store in a dry place”
CE 0297	Symbol for “CE marking of conformity with Notified Body number”

CE 0297 CE marking with DQS ID number (0297)

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