



Instructions for use – Please read carefully!



H.E.L.P. NaCl 0.9 %

[1] Product description

Sterile priming and rinsing solution for extracorporeal treatment systems. Only intended for extracorporeal use within the context of H.E.L.P. apheresis.

Steam sterilised and endotoxin-free.

Composition:

1000 ml contains:

Sodium chloride 9.0 g

Water for injection

Which corresponds to:

Na^+ 154 mmol/l

Cl^- 154 mmol/l

Theoretical osmolarity 308 mmol/l

[2] Intended use

The sterile H.E.L.P. NaCl 0.9 % solution is a priming and rinsing solution that is used for the extracorporeal circuit within the context of H.E.L.P. therapy with the Plasmat® Futura or Plasmat® Secura (summarized below as „Plasmat®“).

[3] Indications, contraindications, and side effects

Pay attention to the indications, contraindications and side effects described in the instructions for use of the H.E.L.P. Futura set and in the operating manual of the Plasmat®.

[4] Warnings and precautions

- Not intended for intravenous infusion!
- The H.E.L.P. NaCl 0.9 % solution must not be used after the expiry date stated on the container and outer packaging
- Only use if the solution is clear and colourless and if the container and connections are undamaged
- Only remove the outer packaging immediately before use.
- Store the solution out of children's reach
- Animal experiments have shown DEHP to be potentially toxic to reproduction. Given the current state of scientific knowledge, a risk (in case of long-term use) especially for premature male babies cannot be completely excluded. As a precaution, the application of medical products containing DEHP should be restricted to short-term use for pregnant women, breastfeeding mothers, infants and children
- FOR SINGLE USE ONLY! DO NOT REUSE!

Re-use of single-use devices creates a potential risk of the patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

- DO NOT add any additives
- Discard unused portion

[5] Instructions for use

Remove the outer packaging of the bag and connect it to the H.E.L.P. Futura Set or the tubing of the Plasmat® Secura in accordance with the operating manual of the Plasmat®.

In case of replacement of individual filters within the context of the H.E.L.P. therapy, use H.E.L.P. NaCl 0.9 % solution to flush the new filter(s). The filter replacement procedure is described in the operating manual of the Plasmat®.

[6] Method of administration and duration of the treatment

Comply with the specifications in the instructions for use of the H.E.L.P. Futura Treatment Set and in the operating manual of the Plasmat®.

DIN: 02373815



Do not use if packaging
is damaged



Store at

B | BRAUN

MANUFACTURER

B. Braun Avitum AG
34209 Melsungen, Germany

CANADIAN DISTRIBUTOR

Chief Medical Supplies Ltd.
411-19th Street S.E.
Calgary, Alberta T2E 6J7



Mode d'emploi – À lire attentivement



H.E.L.P. Nacl 0.9 %

[1] Description du produit

Solution stérile d'amorçage et de rinçage pour systèmes de traitement extracorporels. À usage extracorporel uniquement dans le contexte de l'aphérese H.E.L.P.

Stérilisé à la vapeur et sans endotoxines.

Composition:

1000 ml contiennent:	
Chlorure de sodium	9.0 g
Eau pour injection	

Qui correspondent à

Na ⁺	154 mmol/l
Cl ⁻	154 mmol/l
osmolarité théorique	308 mmol/l

[2] Utilisation prévue

La solution stérile H.E.L.P. Nacl 0.9 % est une solution d'amorçage et de rinçage utilisée pour le circuit extracorporel dans le contexte du traitement avec Plasmat® Futura ou Plasmat® Secura (ci-après « Plasmat® »)

[3] Indications, contre-indications et effets secondaires

Veuillez tenir en compte des indications, contre-indications et effets secondaires décrits dans le mode d'emploi du kit H.E.L.P. Futura et dans le manuel d'utilisateur de Plasmat®.

[4] Mise en garde et précautions

- Ne peut être administré par perfusion intraveineuse !
- La solution H.E.L.P. NaCl 0.9 % ne doit pas être utilisée au-delà de la date d'expiration stipulée sur le récipient et l'emballage
- Utiliser la solution seulement si elle est nette est transparente et si le récipient et les fermetures sont intacts
- Retirer l'emballage extérieur immédiatement avant utilisation
- Tout excès de solution doit être éliminé
- Conserver la solution hors de la portée des enfants
- Les études sur l'animal ont montré que le DEHP pouvait être toxique pour la reproduction. Étant donné l'état actuel de la science, il est impossible d'exclure définitivement un risque (en cas d'utilisation à long terme), en particulier pour les bébés prématurés de sexe masculin.

Par précaution, il est conseillé de ne pas administrer des médicaments contenant du DEHP sur de longues durées aux femmes enceintes ou allaitantes, aux nourrissons et aux enfants

- **À USAGE UNIQUE NE PAS REUTILISER!**
La réutilisation d'éléments à usage unique est dangereuse pour le patient ou l'utilisateur. L'élément peut être contaminé et/ou ne plus fonctionner correctement, ce qui peut entraîner chez le patient des blessures et des maladies potentiellement mortelles
- NE PAS ajouter d'additifs
- Jeter la portion inutilisée

[5] Mode d'emploi

Retirer l'emballage extérieur de la poche et la connecter au kit H.E.L.P. Futura ou à la tubulure de Plasmat® Secura, conformément au manuel d'utilisation de Plasmat®.

En cas de remplacement des filtres individuels dans le contexte du traitement H.E.L.P., utiliser la solution H.E.L.P. NaCl 0,9 % pour rincer le(s) nouveau(x) filtre(s). La procédure de remplacement de filtre est décrite dans le manuel d'utilisation de Plasmat®.

[6] Mode d'administration et durée du traitement

Il convient d'observer les spécifications du mode d'emploi du kit H.E.L.P. Futura et du manuel d'utilisation de Plasmat®.

DIN: 02373815



Ne pas utiliser si l'emballage est endommagé



Conserver à

B | BRAUN

FABRICANT

B. Braun Avitum AG
34209 Melsungen, Germany

DISTRIBUTEUR CANADIEN

Chief Medical Supplies Ltd.
411-19th Street S.E.
Calgary, Alberta T2E 6J7



Instructions for use – Please read carefully!



H.E.L.P. NaCl 0.9 %

[1] Product description

Sterile priming and rinsing solution for extracorporeal treatment systems. Only intended for extracorporeal use within the context of H.E.L.P. apheresis.

Steam sterilized and endotoxin-free.

Composition:

1000 mL contains:
Sodium chloride 9.0 g
Water for injection

Which corresponds to:

Na ⁺	154 mmol/L
Cl ⁻	154 mmol/L
Theoretical osmolarity	308 mmol/L

[2] Intended use

The sterile H.E.L.P. NaCl 0.9 % solution is a priming and rinsing solution that is used for the extracorporeal circuit within the context of H.E.L.P. therapy with the Plasmat® Futura.

[3] Indications, contraindications, and side effects

Pay attention to the indications, contraindications, and side effects described in the instructions for use of the H.E.L.P. Apheresis Set and in the operating manual of the Plasmat® Futura Apheresis System.

[4] Warnings and precautions

- Not intended for intravenous infusion!
- The H.E.L.P. NaCl 0.9 % solution must not be used after the expiry date stated on the container and outer packaging.
- Only use if the solution is clear and colorless and if the container and connections are undamaged.
- Only remove the outer packaging immediately before use.
- Any remaining solution must be discarded.
- Store the solution out of children's reach.

[5] Instructions for use

Remove the outer packaging of the bag and connect it to the H.E.L.P. Futura Set in accordance with the operating manual of the Plasmat® Futura Apheresis System.

In case of replacement of individual filters within the context of the H.E.L.P. therapy, use H.E.L.P. NaCl 0.9 %

solution to flush the new filter(s). The filter replacement procedure is described in the operating manual of the Plasmat® Futura Apheresis System.

[6] Method of administration and duration of treatment

Follow the specifications in the instructions for use of the H.E.L.P. Apheresis Set and in the operating manual of the Plasmat® Futura Apheresis System.

Rx only



Expiry date



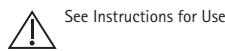
Batch number



Manufacture date



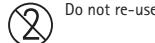
Article number



See Instructions for Use



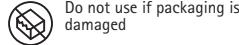
Steam sterilized



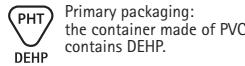
Do not re-use



Store at



Do not use if packaging is damaged

Primary packaging:
the container made of PVC
contains DEHP.

B | BRAUN

B. Braun Avitum AG
34209 Melsungen
Germany

US Distributor

B.Braun Medical Inc.
Bethlehem, PA 18018-3524
Made in Germany

