# ATTENTION PHARMACISTS and PHYSICIANS

- Enclosed is a treatment dose of BabyBIG® per your order; this treatment is intended for administration to the patient for whom it was ordered as indicated on the Invoice and Purchase Agreement (IPA) and whose MRN is associated with this order. It may not be used for other purposes. If your treatment plan for the patient has changed, please notify the IBTPP immediately at 510-231-7600 (24/7).

- **BabyBIG® may not be returned for a refund**. Once the treatment dose is received, the full dose should be given to the patient for whom it was ordered without delay. The fee for BabyBIG® is per treatment (not per vial) and no portion may be returned for a refund.

- Promptly forward a copy of the completed IPA to the Accounts Payable Department of your institution so that they may arrange for fee payment. The fee is due within five (5) business days after ordering BabyBIG®.

## Patient care:

- Ensure that the stool or enema specimen is promptly collected and sent to the appropriate public health laboratory for establishing the diagnosis of infant botulism. Refer to your state public health department for specimen collection and submission instructions and guidelines. Fecal specimens for infant botulism diagnostic testing can be collected before or after antitoxin administration. BabyBIG® does not neutralize botulinum toxin present in the lumen of the intestine, nor does it kill or prevent the growth of *Clostridium botulinum* or inhibit the formation of botulinum toxin in the infant's large intestine.
    - For California hospitals, please refer to our website www.infantbotulism.org under the "For Lab Scientists" link for specimen collection and submission instructions.
    - **Please note that the shipping costs for the diagnostic stool or enema specimen submission are the responsibility of your institution as specified in the IPA for BabyBIG®.**

BabyBIG® vials: If there is a suspect vial or remaining vial that was not reconstituted for administration, please:
1) immediately call the Program's 24/7 number 510-231-7600 and
2) ensure that the vial is held in a restricted-access, temperature-controlled, monitored refrigerator at 2-8°C.

Please save the insulated box that BabyBIG® was shipped in for one week, so that suspect or unreconstituted vials (if any) may be returned. As of November 2022, we are no longer requesting the return of partial vials. **Please do not return reconstituted residual medication to IBTPP.** Residual medication should be disposed of according to your hospital protocol.

## BabyBIG general information:

- To learn more about the efficacy and history of BabyBIG®, please visit www.infantbotulism.org

# BabyBIG® PREPARATION / ADMINISTRATION

- Enclosed is a single treatment dose of BabyBIG®; this treatment is intended for administration to the patient for whom it was ordered and may not be used for other purposes. If your treatment plan for the patient has changed, please notify us immediately at 510-231-7600 (24/7).

- **BabyBIG® may not be returned for a refund**. Once the treatment dose is received, the full dose should be given to the patient for whom it was ordered without delay. The fee for BabyBIG® is per treatment (not per vial) and no portion may be returned for a refund.

## BabyBIG Preparation:

- Upon receipt of the BabyBIG® medicine, all vials should be stored in a restricted-access, temperature-controlled, and monitored refrigerator at 2-8°C.

- Once intravenous access has been established and the patient is ready to receive the medicine, the **pharmacist** should be notified to reconstitute the vials of lyophilized BabyBIG®. Please follow Sections 2.1 and 2.3 of the Package Insert regarding preparation and administration. **Infusion must begin within two (2) hours of reconstitution.** BabyBIG should not be stored in the reconstituted state. See www.infantbotulism.org for more information.

- After reconstitution, the **pharmacist** will draw up in a **20 mL syringe** (see page 1 of Hemo-Nate® Syringe Filter Instructions For Use brochure) the reconstituted product to total the full treatment volume and send the medicine to the floor/PICU along with the package-enclosed minimum volume tubing, 18-micron filter, BabyBIG® package insert, and Hemo-Nate® Syringe Filter Instructions For Use brochure.

## BabyBIG Administration:

- Prior to administering the medicine, the **personnel responsible for administration** will obtain the necessary tubing, 18-micron filter, and Hemo-Nate® Syringe Filter Instructions For Use brochure which are included in the shipment. Review the Hemo-Nate® Syringe Filter Instruction For Use brochure for the proper method of infusion administration and prime the filter with saline solution. When attaching the tubing, filter and syringe, ensure the luer-lock connections are secure. Avoid overtightening the connections, which can result in cracking the filter hub. To avoid excessive pressure on the filter-tubing luer-lock connection during priming, please utilize a 20 mL syringe and slowly apply gentle pressure to administer the priming solution. The Hemo-Nate® Syringe Filter Instructions For Use brochure and the FDA-approved BabyBIG® package insert contain information on the proper syringe size and infusion administration instructions, respectively. If an incorrect syringe size is used, leakage from the filter may result.

- Administer the reconstituted BabyBIG® antitoxin according to the dose (50 mg/kg) and flow rates specified in the FDA-approved package insert.

**********
**USE 20 mL SYRINGE**
**********

Last updated: April 2023

**Disposal:** Dispose with other medical waste per facility protocol for products contaminated with bodily fluids and tissue.

EU Notice: Any serious incident (as defined in EU MDR Ch. I, Article 2 (65)) that occurs in relation to this device should be reported to the manufacturer and the competent authority of the Member State where the incident occurs.

References:


1. M.E. EYSTER, et al, TRANSFUSION, Sept-Oct 1978 Vol 18, No. 5
2. M.J. INWOOD, et al, TRANSFUSION, Nov-Dec 1978 Vol 18, No. 6
3. G.A. ROCK, et al, CANADIAN MEDICAL ASSOC JOUR., Feb. 15, 1983 Vol. 128



Procedure acknowledgment to Orthopedic Hospital, Hemophilia Rehab. Center, Los Angeles, CA.


| | | | |
|---|---|---|---|
| MD | Medical Device | | Do not use if package is damaged |
| Rx ONLY | Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner | LATEX | Product is not manufactured with natural rubber latex |
| 2 | Single Use/ Do Not Reuse | STERILE EO | Sterilized using ethylene oxide |
| 2 STERILIZE | Do not Resterilize | | Non-pyrogenic |
| | Manufacturer | EC REP | Authorized representative in the European Community |


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***United States***

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EC REP

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CE 1639

Gesco®




P/N 58088 REV 090920


UTAH MEDICAL PRODUCTS INC.

# Hemo-Nate® Syringe Filter

For use with:

- **Whole Blood and Packed Cells**
- **AHF Concentrates Cryoprecipitates**

## Instructions For Use

**Product Description:** The Hemo-Nate® filter is a small volume, disposable syringe filter having stainless steel filter media, bi-directional supported and bubble point tested for absolute retention and removal of harmful micro-debris (particulates) of 18 microns and larger that are present in AHF concentrates and cryoprecipitates.[1, 2, 3]

**Indications For Use:** For the filtration of stored blood, blood components and other fluids indicated for filtration. Infusion rates set by each individual hospital and /or physician's usual clinical procedures.

**Storage:** The device should be kept in its original pouch to avoid the possibility of damage and subsequent compromise of sterility of the components

**Important: Follow these instructions for aseptic technique.**

**Contraindications:** None Known (see precautions).

Clinicians must be familiar with and trained in the use of blood filtration methods according to established institutional protocol, including proper aseptic technique.

**Precautions:**

- Reuse of this sterile device poses a significant risk of cross contamination and sepsis and/or dependence on an unvalidated process. This device is not structurally designed or validated for reuse.
- Follow Universal Precautions.
- Peer group studies* have indicated no damage to cellular components in blood volumes up to 50 cc (whole blood).
- **Excessive force may damage blood cells. If resistance is encountered, change filter and proceed. For infusion, use 20 cc syringe or larger.**
- Use of packed cells may limit volumes to about 20 cc.
- Age of blood and/or debris concentration per unit volume may have an effect of the capacity of the filter.

* Warren, et al, PERINATOLOGY-NEONATOLOGY Vol 4, No 5. P. 41 Sept/Oct 1980

## For use with **Whole Blood and Packed Cells**

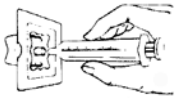
### Instructions For Use (Aseptic Technique)

**Note:** With filter media bi-directionally supported, filtration can be effected in either direction - depending upon what is being filtered. It is recommended that fluids with cellular components be aspirated through the **Hemo-Nate** filter prior to infusion.

**NOTE:** Due to the wide variations in viscosity of Cryoprecipitates, it is recommended that the **Hemo-Nate** be used in conjunction with a standard I.V. pump for administration rather than gravity flow. The use of a pump will also reduce infusion time and afford a much more accurate delivery.

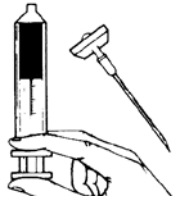


Spike container with Hemo-Tap blood bag spike.



Place Hemo-Nate filter on syringe and 18 Ga. needle on male luer adaptor of filter.

Enter Hemo-Tap injection site and remove the desired amount of fluid.



Withdraw from injection site, remove filter and needle and administer per standard clinical procedure.

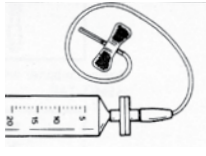
## For use with **AHF Concentrates/Cryoprecipitates**

### Instructions For Use

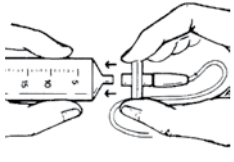
**FOR AHF CONCENTRATES:** Reconstitute the factor, fill the syringe or syringes and proceed as follows:

**FOR CRYOPRECIPITATES:** Employing the usual method of delivery, attach **Hemo-Nate** to distal end of administration set, proximal to patient, as a final filter. Attachment can be made either by a Luer-Slip or Luer-Lock.

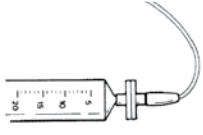
Attach Hemo-Nate filter to syringe filled with concentrate.



Attach minicath to end of syringe. Infuse concentrate.



Disconnect empty syringe from filter - press tubing against filter with thumb



Attach next syringe of concentrate and continue infusing.

UTAH MEDICAL PRODUCTS INC.

# Filtre Seringue Hemo-Nate®

Pour une utilisation avec:

- **Du sang total et des culots globulaires**
- **Des cyoprécipités et des concentrés d'AHF**

## Mode d'emploi

que l'écoulement par gravité. L'utilisation d'une pompe réduit également le temps de perfusion et permet une administration plus précise.

**Gestion des déchets :** Éliminer le produit utilisé avec les autres déchets médicaux selon le protocole de l'établissement concernant les produits contaminés par des fluides et des tissus corporels.

CONSIGNE EUROPÉENE: Tout incident grave (tel que défini au Ch. I, article 2 (65) du Règlement de l'UE relatif aux dispositifs médicaux) qui se produit en relation avec ce dispositif doit être signalé au fabricant et à l'autorité compétente de l'État membre où l'incident se produit.


Références:
1. M.E. EYSTER, et al, TRANSFUSION, Sept-Oct. 1978 Vol 18, No. 5
2. M.J. INWOOD, et al, TRANSFUSION, Nov-Dec 1978 Vol 18, No. 6
3. G.A. ROCK, et al, CANADIAN MEDICAL ASSOC JOUR., 15 fév. 1983 Vol. 128



Reconnaissance de la procédure de l'Orthopedic Hospital, Hemophilia Rehab. Center, Los Angeles, Californie.


| | | | |
|---|---|---|---|
| MD | Dispositif médical | | Ne pas utiliser si l'emballage est endommagé |
| Rx ONLY | Aux États-Unis, la loi fédérale n'autorise la vente de ce dispositif que sur ordonnance ou par un médecin ou tout autre professionnel de la santé agréé | LATEX | Le produit ne contient pas de latex de caoutchouc naturel comme matériau de fabrication |
| 2 | Ne pas réutiliser | STERILE EO | Stérilisé à l'aide d'oxyde d'éthylène |
| 2 STERILIZE | Ne pas restériliser | | Non pyrogène |
| | Fabricant | EC REP | Représentant autorisé dans la Communauté européenne |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CE 1639

Gesco®




P/N 58088 REV 090920

**Description du produit :** Le filtre Hemo-Nate® est un filtre seringue de petit volume à usage unique, ayant un élément filtrant en acier inoxydable, un support bidirectionnel et un point de bulle testé pour la rétention absolue et l'élimination des micro-débris nocifs (particules) de 18 microns et supérieurs qui sont présents dans les concentrés d'AHF et les cryoprécipités.[1, 2, 3]

**Mode d'emploi :** Destiné à la filtration de sang conservé, des composants sanguins et d'autres fluides indiqués pour la filtration. La vitesse de perfusion est établie selon les méthodes cliniques habituelles de l'hôpital et/ou du médecin.

**Conservation :** Le dispositif devrait être conservé dans son emballage d'origine afin d'éviter tout dommage et risque subséquent pouvant porter atteinte à la stérilité des composants.

**Important : Suivre ces instructions pour une technique aseptique.**

**Contre-indications :** Aucune connue (voir précautions).

Les médecins doivent avoir connaissance et être formés dans l'utilisation des techniques de filtration de sang conformément au protocole établi de l'établissement, y compris la technique aseptique appropriée.

**Précautions:**

- La réutilisation de ce dispositif stérile présente un risque important de contamination croisée et de septicémie et/ou de dépendance à l'égard d'un processus non validé. Ce dispositif n'est pas structurellement conçu ni validé pour être réutilisé.
- Appliquer les précautions universelles.
- Les études de groups de paires* n'ont indiquées aucun dommage aux composants cellulaires dans les volumes de sang jusqu'à 50 cc (sang total).
- **Une force excessive pourrait endommager les cellules sanguines. Si une résistance apparaît, changer le filtre et continuer. Pour la perfusion, utiliser une seringue de 20 cc ou plus.**
- L'utilisation de culots globulaires peut limiter les volumes à environ 20cc.
- L'âge du sang et /ou la concentration des déchets par unité de volume peut / peuvent impacter l'efficacité du filtre.

* Warren, et al, PERINATOLOGY-NEONATOLOGY Vol 4, No 5. P. 41 Sept/Oct 1980

## Pour une utilisation avec **du sang total et des culots globulaires**

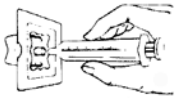
### Mode d'emploi (Technique Aseptique)

**Note :** Lorsque l'élément filtrant dispose d'un support bidirectionnel, la filtration peut être effectuée dans les deux sens, en fonction de ce qui est filtré. Il est recommandé d'aspirer les liquides contenant des composants cellulaires à travers le filtre **Hemo-Nate** avant la perfusion.

**NOTE :** En raison de grandes variations de la viscosité des cryoprécipités, il est recommandé d'utiliser l'Hemo-Nate avec une pompe à perfusion standard plutôt

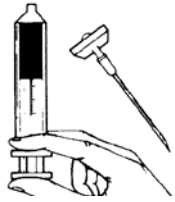


Perforer le récipient avec le perforateur de poche de sang Hemo-Tap.



Placer le filtre Hemo-Nate sur la seringue, et l'aiguille 18 Ga. sur l'adaptateur luer mâle du filtre.

Insérer l'Hemo-Tap dans le site d'injection et prélever la quantité de fluide souhaitée.



Retirer du site d'injection, enlever le filtre et l'aiguille, et administrer suivant la procédure clinique standard.

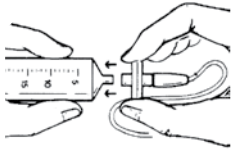
## Pour une utilisation avec **les concentrés d'AHF /Cryoprécipités**

### Mode d'emploi

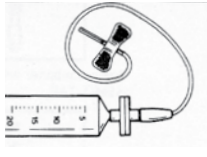
**POUR LES CONCENTRÉS AHF :** Reconstituer le facteur, remplir la seringue ou les seringues et procéder comme suit :

**POUR LES CRYOPRÉCIPTÉS :** En adoptant la méthode habituelle, fixer l'**Hemo-Nate**, comme filtre final, sur l'extrémité distale du set de perfusion, près du patient. La connexion peut être effectuée par Luer-Slip ou Luer-Lock.

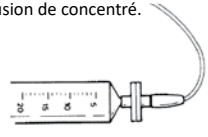
Fixer le filtre Hemo-Nate sur la seringue remplie de concentré.



Séparer la seringue vide du filtre – comprimer la tubulure contre le filtre avec le pouce.



Fixer le petit cathéter au bout de la seringue. Administrer la perfusion de concentré.



Fixer la seringue de concentré suivante et continuer la perfusion.