































Instructions for Use: DeNovo® Infant Heel Warmer

Brand Name of Product:	Infant Heel Warmer, Manufactured by DeNovo® Products LLC
Generic Name of Product:	Cloth Infant Heel Warmer (P/N 99-2201-00), Clear Infant Heel Warmer (P/N 99-1301-00), Teddy Infant Heel Warmer (P/N 99-1101-00), Aero-Med Cloth Infant Heel Warmer (P/N 99-2505-00), 355CW, 355NW, AM355NW, W001.
Product Code Number(s)	K103549MPO "Class 1"
Purpose of Product:	DeNovo® Infant Heel Warmer are intended "For Use by hospital, Ambulatory Surgery Staff, Outpatient Clinics, for warming of infant's heels prior to drawing blood for sampling or general analysis or therapeutic purposes".
Range of Applications for Product:	N/A
Key specifications of product:	DeNovo® Heel Warming Pouches are a see-through package constructed of 1oz /A/606a BONA/2 mill LLDPE, heat-sealed together forming a pouch. Inside the Pouch is a Stainless Steel .75 +/- .01 diameter disc and "0.08 to 1.8 oz" of a branded solution (See Compound section of this document for branded solution details)

Shipping & Storage	
Shipping Conditions & Requirements:	<ul style="list-style-type: none"> a) While DeNovo® products "(infant heel heaters) are in transit they must be kept on their original Pallet, wrapped with plastic shrink film. b) Do not double stack and keep in its closed cardboard boxes. c) Do not make any sudden movements, do not drop the pallet. d) Should be maintained in a clean, dry and well-ventilated areas at all times. e) Product must be protected from direct sunlight, UV light sources and excessive moisture. f) Shipment must be kept as close to room temperature as possible, avoid freezing temperature under 50°F and Hot Temperatures above 78°F.
Storage Conditions:	DeNovo® recommends that infant heel warmers are kept in the original, closed transport carton or inside a closed cabinet to its point of use. Product should be stored in a dry, clean and well-ventilated environment and protected from direct sunlight, UV light sources and excessive moisture. Product must be stored as close to what is known as "room temperature" (between 50°F and 78°F) as possible.
Packaging Conditions:	Packing conditions should be able to protect the Heel Warmer from UV rays to its point of use.
Shelf Life:	The shelf life is time related and not event related. It is recommended that the products are put to their end use within 2 years of manufacture. The recommended "Expiration" date, and the Lot number are printed on the product inner and outer carton Box. Also, the date of manufacture is printed on the sealed area of the left front (printed side) of the bag.
Compound	Sodium Acetate (food grade), Potable Water (H2O), IFC Kosher Certify Color

Instructions for Using the Product	
Description of Use (s): (Intended Use)	DeNovo® Infant heel warmers are intended to aid in the drawing of blood for sampling or general analysis. If indicated by a physician, this product can be used as a therapeutic component to provide warmth to the patient.
Preparation for Use:	<ol style="list-style-type: none"> 1. Confirm product date code is within Manufacturer expiration date code specifications. (Maximum Two (2) years from manufactured date) 2. Ensure that pouch physical conditions (pouch seal), and contents looks fine. 3. Before activation, massage pouch to bring solution close to manufacturer's activation temperature recommendations 75-78 °F (23.8 -25.6 °C).
Diagrams, Drawings, Pictures	 <p style="text-align: center;"> FRONT BACK P/N 99-2201-00 or P/N 99-2505-00 </p> <p style="text-align: center;"> FRONT BACK P/N 99-1301-00 </p> <p style="text-align: center;"> FRONT BACK P/N 99-1101-00 </p>
Steps for Use of Product:	<ol style="list-style-type: none"> 1. Inside the pouch locate a round metal disc and grasp with thumb and forefingers. Confirm that recommended activation set temperature (Start Temperature) is within +/- 75 °F (23.8 °C) +/- 1°F. 2. Flex the disc rapidly until pouch liquid transform to crystals and pouch begins to warm up. 3. Massage the bag for 30 seconds to increase the product temperature, distribute the heat evenly and soften the bag. Insure that the product does not feel too warm prior to application. 4. Apply the pouch Non-Printed side to the patient. 5. To secure the bag, peel the paper covering the adhesive part of the strap and adhere it to the opposite side of the bag. 6. Monitor the patient's skin occasionally to see if the skin is reddened. <p>Notes:</p> <ol style="list-style-type: none"> a) Do Not apply the adhesive part of the strap to infant skin. b) Do not apply to unattended infants. c) Disposable product – Single Use Only – ***DO NOT REUSE***
Interpretation of Results	N/A
Contraindications of Test Results	N/A
Documentation:	<p>DeNovo® Infant Heel Warmers is registered under FDA 510(k) Premarket Submission Nos.: K103549. The products are registered under FDA Class 1 medical device in compliance with (US) United State FDA requirements. Also conform to the international product standards and norms: (EU) European Medical Device Directive MDD 93/42/EEC, and its amendment 2007/47/EC, also conform to Canadian Medical Devices Conformity Assessment System (CMDCAS) for class 1 medical device.</p> <p>Denovo® products are designed, validated, and manufactured under CGMPs to comply with CFR title 21 part 820 to suit their intended purposes and are in process to be certified ISO 9001; ISO 13485; ISO 11607-1:2006, ISO 11607-2:2006, EN 868-5: 2009.</p>
Special Warnings and Cautions:	<ol style="list-style-type: none"> a) U.S Federal law restricts this device to sale by or on the order of a physician. b) Out dated product should not be used and must be discarded immediately. c) Monitor Infant Core temperature. d) Check infant skin for redness.

<p align="center"><u>(continuation page)</u></p> <p>Special Warnings and Cautions:</p>	<p>e) Consult a physician when using this product on Premature Infants.</p> <p>f) Do not swallow</p> <p>g) All components in this product are non-toxic; however, if liquid solution come in contact with skin or eye, flush with water.</p> <p>h) While flexing metal disc do not over bend the metal more than 25-degree angle of its flatness.</p> <p>i) This is a non-sterile product.</p> <p>j) Do not steam sterilize these pouches, as they will melt.</p> <p>k) Some of the product components are sensitive to UV-light and may change color over time, if not stored properly.</p> <p>l) Pouches should be stored in closed cabinets or otherwise protected from a UV-light source.</p>																				
<p>Disposal</p>	<p>- Please refer to the local and national regulations regarding waste disposal.</p>																				
<p>Explanation of Symbols</p>	<table border="0"> <tr> <td></td> <td>Consult Instructions for use</td> <td></td> <td>Single Use Only (Do Not Reuse)</td> </tr> <tr> <td></td> <td>Catalog Number</td> <td></td> <td>Non-Sterile</td> </tr> <tr> <td></td> <td>Use by</td> <td></td> <td>Manufacturer</td> </tr> <tr> <td></td> <td>Batch Code</td> <td></td> <td>Date of Manufacture</td> </tr> <tr> <td></td> <td>Storage Range Temperature</td> <td></td> <td></td> </tr> </table>		Consult Instructions for use		Single Use Only (Do Not Reuse)		Catalog Number		Non-Sterile		Use by		Manufacturer		Batch Code		Date of Manufacture		Storage Range Temperature		
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Reprocessing Instruction	
Point of use:	N/A
Preparation for decontamination:	N/A
Disassembly Instructions:	N/A
Cleaning – Manual:	N/A
Cleaning – Automated	N/A
Disinfection	N/A
Drying	N/A
Maintenance, inspection, and testing	N/A
Reassembly Instructions	N/A
Packaging	N/A
Storage	N/A
Sterilization:	N/A
Additional Information:	The products are for single use only. ***DO NOT REUSE*** Disposable
Related DeNovo® Products Product	DeNovo® Infant Transport Mattress (Neo-Nest®)
Other Product Support Documents	N/A
Customer Service contact:	DeNovo® Product LLC 17051 Alico Commerce Court # 3 Fort Myers, Florida 33967 1-888-696-4601 QA@denovoproducts.com