

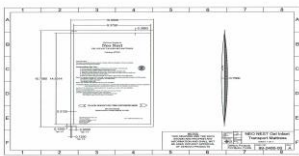

























Instructions for Use: Neo-Nest® Gel Infant Transport Mattress

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| Brand Name of Product: | Neo-Nest® Gel Infant Transport Mattress Manufactured by DeNovo® Products LLC |
| Generic Name of Product: | Neo-Nest® Gel Infant Transport Mattress (P/N 99-2400-00) |
| Product Code Number(s) | K112547 IMD "Class II" |
| Purpose of Product: | Neo-Nest® Gel Infant Transport Mattress are intended "For Use by hospital, Ambulatory Surgery Staff, Outpatient Clinics, for warming of infant, to protect infant in cold environments, for transporting infant to different areas or locations within the hospital or between medical facilities. |
| Range of Applications for Product: | N/A |
| Key specifications of product: | DeNovo® Neo-Nest® Gel Infant Transport Mattress 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 "3:02 to 3:12 (lb:oz)" of a branded solution (See Compound section of this document for branded solution details). |

| Shipping & Storage | |
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| Shipping Conditions & Requirements: | <ul style="list-style-type: none"> a) While DeNovo® products "(Neo-Nest® Gel Infant Transport Mattress) 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 or box. 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 Neo-Nest® Gel Infant Transport Mattress 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 Neo-Nest® Gel Infant Transport Mattress 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. In addition, the manufacturing date is on a label that is attached to the front (printed side) of the bag. |
| Compound | Sodium Acetate (food grade), Potable Water (H2O), IFC Kosher Certified Color and Hydroxy Ethyl Cellulose(HEC). |

| Instructions for Using Product | |
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| Description of Use (s) | DeNovo® Neo-Nest® Gel Infant Transport Mattress are intended to protect infant in cold environments, for transporting infant to different areas or locations within the hospital or between medical facilities. 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’s expiration date code specifications. 2. Ensure that pouch physical conditions (pouch seal), and contents looks fine. 3. Before activation, massage mattress pouch to bring solution close to manufacturer’s activation temperature recommendations 75-78 °F (23.8 -25.6 °C). |
| Diagrams (drawings, pictures) |    <p style="display: flex; justify-content: space-around; margin-top: 5px;"> FRONT BACK DRAWING P/N 99-2400-00 </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. 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 to unattended infants. b) Disposable product – Single Use Only – ***DO NOT REUSE*** |
| Interpretation of Results | N/A |
| Contraindications of Test Results | N/A |
| Documentation | DeNovo® Neo-Nest® Gel Infant Transport Mattress is registered under FDA 510(k) Premarket Submission Nos.: K112547 IMD “Class II”. The product is registered under FDA Class II medical device in compliance with (US) United State FDA requirements. Also conforms to the international product standards and norms: (EU) European Medical Device Directive MDD 93/42/EEC, and its amendment 2007/47/EC, also conforms to Canadian Medical Devices Conformity Assessment System (CMDCAS) for class 1 medical device. 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. |
| 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. <p style="margin-top: 20px;"> <ol style="list-style-type: none"> c) Monitor Infant Core temperature. d) Check infant skin for redness. </p> |
| <u>(continuation page)</u> | |

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| Special Warnings and Cautions: | <ul style="list-style-type: none"> e) Consult a physician when using this product on Premature Infants. f) Do not swallow g) All components in this product are non-toxic; however, if liquid solution come in contact with skin or eye, flush with water. h) While flexing metal disc do not over bend the metal more than 25-degree angle of its flatness. i) This is a non-sterile product. j) Do not steam sterilize these pouches, as they will melt. k) Some of the product components are sensitive to UV-light and may change color over time, if not stored properly. l) Pouches should be stored in closed cabinets or otherwise protected from a UV-light source. | | | | | | | | | | | | | | | | |
| Disposal | Please refer to the local/national regulations regarding waste disposal. | | | | | | | | | | | | | | | | |
| Explanation of Symbols | <table style="width: 100%; border: none;"> <tr> <td style="width: 30%;"></td> <td style="width: 30%;">Consult Instructions for use</td> <td style="width: 30%;"></td> <td style="width: 10%;">Single Use Only</td> </tr> <tr> <td></td> <td>Catalog Number</td> <td></td> <td>Not a Sterile Product</td> </tr> <tr> <td></td> <td>Expiration Date</td> <td></td> <td>Manufacture Date</td> </tr> <tr> <td></td> <td>Batch Code</td> <td></td> <td></td> </tr> </table> |  | Consult Instructions for use |  | Single Use Only |  | Catalog Number |  | Not a Sterile Product |  | Expiration Date |  | Manufacture Date |  | Batch Code | | |
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| Reprocessing Instruction | |
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| 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 |
| Sterilization: | N/A |
| Storage: | N/A |
| Additional Information: | The products is for single use only. ***DO NOT REUSE*** Disposable |
| Related DeNovo Products Product | DeNovo® Gel Infant Heel Warmers |
| 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 |