

01 Product Description

Product Name : Powder Free Sterile Synthetic Polyisoprene Surgical Gloves
Material : Synthetic Rubber Latex
Colour : White
Shape : Anatomic
Cuff : Beaded
External Surface: Textured
Internal Surface : Polymer Coated
Size : 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 and 9.0
Sterilization : Ethylene Oxide (EO) / GAMMA (R)
Shelf Life : 3 years
Basic UDI-DI : 806363SIGFM3

02 Intended Use

This disposal medical device is made up of synthetic rubber latex which is anatomically shaped with thumb position towards the Palm side of the index finger which reduces the fatigue on the hands, intended to be worn on the hands usually in surgical settings to provide barrier against potentially infectious fluids and other contaminants.

03 Product Classification & Standard compliance

Medical Device Classification : Class IIa, Rule#06
Conformity assessment route : Annex II section 4 of council directive 93/42/EEC
Regulatory Authority : DNV Product Assurance As
Notified Body Number : 2460
Standard Compliance :
EN 455-1:2020, EN 455-2:2015, EN 455-3 : 2015, EN 455-4 : 2009, EN ISO 15223-1:2021, EN 1041:2013, EN 566-1:2001, EN ISO 11135: 2014/A1:2019, EN ISO 11137-1:2015/A2:2019, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, ISO 11607-1:2019, ISO 11607-2:2019, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-7:2008, EN ISO 10993-10:2021, EN ISO 10993-11:2017, EN ISO 10993-23 : 2021, ISO 10282 : 2014, ASTM D 3577 : 2019, ISO 13485:2016, ISO 14001:2015, ISO 9001 : 2015.

04 Storage Instruction

Gloves must be stored in cool dry environment which is dust free. Cartons and Boxes must be stored unopened until required. Recommended storage temperature is 5°C-35°C. Avoid exposure to direct light, heat and excessive humidity.

As ozone is deleterious, storage area should not contain any equipment capable of generating ozone such as ultraviolet light, fluorescent lights, mercury vapour lamps, photocopier, high voltage equipment, x-ray units, electric motors and electro surgical equipments.

05 Indication For Use

- ☞ Dry hands thoroughly before donning.
- ☞ Protective gloves should only be used for the intended application and in the correct size.
- ☞ These are sterile gloves for single use only.
- ☞ Users should take care when using the gloves. Using them solely according to their intended application.
- ☞ Before usage, inspect the gloves for any defect or imperfection.

06 Contraindication

- ☞ Gloves contain Synthetic Rubber Latex, persons who are sensitive to Synthetic Rubber Latex should consult a physician before using.

07 Precautions

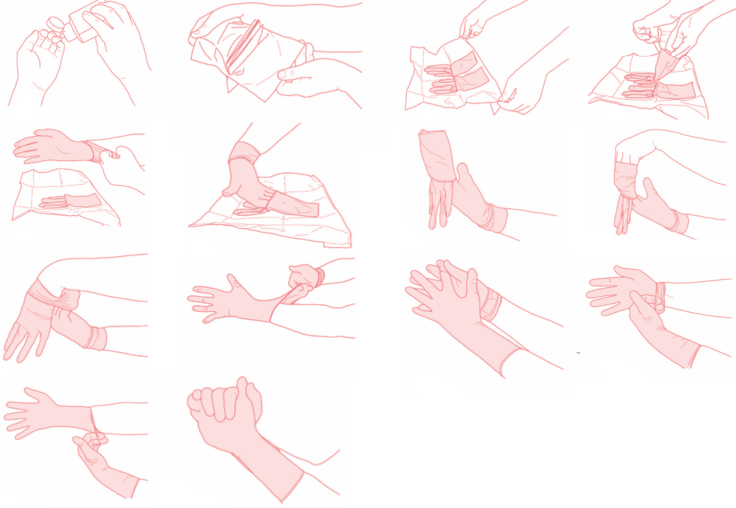
- ☞ Do not use package is damaged or wet.
- ☞ Risk of reuse: May cause infection, allergic reaction and poor barrier protection.
- ☞ Gloves shall not be worn where there is a risk of entanglement by moving parts of machines is needed.
- ☞ The results do not reflect the actual duration of protection in the workplace due to other factors influencing the performance, such as temperature, abrasion, degradation etc.

08 Warnings

- ☞ Device disposal should be done as per local regulatory norms.
- ☞ Do not re-sterilize.
- ☞ The product is not made with Natural Rubber Latex.
- ☞ The gloves not intend to prevent Electrical shock care should be taken to have proper earthing in Medical Device Electrical appliances user.
- ☞ Necessary caution to be practiced against probable Electrical Hazards.

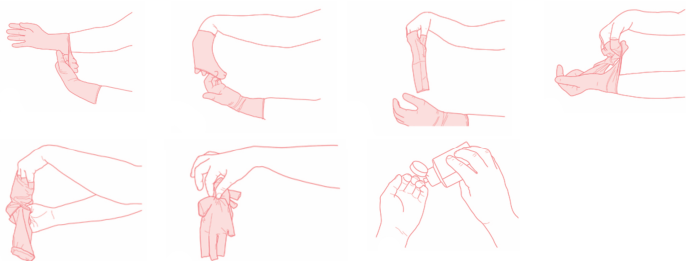
09 Directions for use

Glove Opening and Donning Procedure :



























- ☞ Remove the walled gloves (inner wrapper) from the Pouch (outer wrapper) by, Peel open from the corner for Paper Pouch (Peel down to open pouch).
- ☞ Open the walled glove to see “Left” and “Right” compartment.
- ☞ Pinch back upper and lower flaps of the inner wrapper.
- ☞ Using the middle flaps, open the wrapper touching only the 1 inch margin for safety.
- ☞ Be sure wrapper does not close over gloves after opening to avoid contamination.
- ☞ Using the thumb and the first two fingers of the non-dominant hand, pinch the cuff of the folded edge of the glove cuff for the dominant hand, touching only the inside surface of the glove.
- ☞ Slide dominant hand in to the gloves keeping hand point downwards and pull up to wrist.
- ☞ Using the glove hand insert the 4 fingers under the cuff of the other glove and pull the glove up to the arm.
- ☞ Adjust the gloves as necessary.

Glove Removal Procedure :



- ☞ Take hold of the first glove at the wrist.
- ☞ Fold it over and peel it back, turning it inside out as it goes. Once the glove is off, hold it with your gloved hand.
- ☞ To remove the other glove, place your bare fingers inside the cuff without touching the glove exterior. Peel the glove off from the inside, turning it inside out as it goes. Use it to envelope the other glove.

10 Explanation of Symbols

-  Manufacturer
-  Authorized representative in the European Community
AMSTERMED B.V.,
Saturnusstraat 46-62,
Unit 032, 2132 HB Hoofddorp,
The Netherlands
-  Date of Manufacture / Country of Manufacture
-  Use by date
-  Lot No
-  Reference Number / Catalogue Number
-  Serial Number
-  CE Logo
2460
-  Sterilization using Ethylene oxide
-  Sterilization using Irradiation
-  Single Sterile Barrier System
-  Do not re-sterilize
-  Do not use package is damaged or wet
-  Keep away from sunlight
-  Keep dry
-  Temperature limit
35°C
-  This way up or end up
-  Keep away from Ozone
3
-  Single Use
-  Instruction for Use
-  Caution
-  Latex Caution
-  Medical Device
-  Unique Device Identifier