

Instruction for Use

Sentinex Polyisoprene Surgical Gloves

Intended Purpose

The surgical gloves are single use devices in sterile condition, intended to be worn on the hands of operating room personnel, to protect the patient and the surgeon against contamination and also to provide a barrier for the wearer against potentially infectious material or different chemicals used within the healthcare sector. The gloves are appropriate for use during invasive and non-invasive medical procedures requiring sterility and are designed for use in the environments within hospitals and other healthcare facilities.

Innocuousness of gloves

Protective gloves shall not adversely affect the health or hygiene of the user. The materials should not, in the foreseeable conditions of normal use, release substances generally known to be toxic, carcinogenic, mutagenic, allergenic, toxic to reproduction, corrosive, sensitizing or irritating.

Instructions For Use

- Please read this instruction manual carefully before use.
- Before wearing the gloves, remove hand accessories such as rings and trim your nails smoothly.
- Before use, please clean, disinfect and dry your hands according to the regulations of the intended use environment.
- Inspect the gloves for any defect or imperfections
- The user should choose the appropriate size according to the hand shape, and make sure that the package is not damaged. After the product is within the validity period, open the package from the opening, take out the gloves, and wear them on the left and right hands. At the same time, check whether the appearance of the gloves is complete (such as visible holes, cracks, abnormal color, etc.). If any abnormality is found, the gloves should be discarded and replaced with new ones.
- EN ISO 374-4:2019 Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.
- This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.
- The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture.
- It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation

Precautions

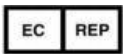
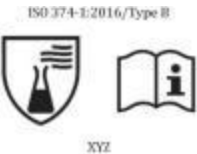
- This product should be kept in a ventilated area, protected against direct sunlight and accidental damage. Store in dry and well-ventilated places, free from corrosive gases, away from sources of Ozone, Keep away from direct sunlight and fluorescent light sources.
- Do not use if the sterile package is damaged or unintentionally opened before use. This product is disposable and for single use only. Reuse of this product may increase the risk of contamination.
- This product is not suitable to contact oil, acid, alkali, copper, manganese and other substances harmful to rubber, beware of sharp object to slash this product, affecting the use.
- Punctures or tears may occur. Inspect each glove frequently after donning and discontinue use immediately if damaged. As for EN ISO 374-5:2016, the penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.
- When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.
- Please dispose of the used gloves as medical waste according to the official and local standards for waste disposal

Doffing instruction

- Pinch one glove at the wrist level and gently peel off the hand allowing the glove to turn inside out.
- Remove the other glove by turning its outer edge on the fingers of the partially ungloved hand.
- Remove the glove by turning inside out entirely to ensure that the skin of the clinician is always and exclusively in contact with the inner surface of the glove.

Shelf Life: 3 years

Labelling:

1		Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.
2		Indicates the Authorized representative in the European Community.
3		DATE OF MANUFACTURE. This symbol shall be accompanied by a date to indicate the date of manufacture
4		Do not re-use
5		Keep dry
6		Keep away from sunlight
7		Use-by date
8		Caution, See attached files for reference
9		Batch Code
10		Temperature limit
11		End of shelf life
12		Humidity limitation
13		Do not use if package is damaged
14		Consult instruction for use
15		Protection against chemicals

16		Protection against micro-organism hazards
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Distributor/Importer: Lohmann & Rauscher GmbH & Co. KG, Westerwaldstraße 4, 56579 Rengsdorf, Deutschland

Manufacturer: Guilin HBM Health Protections, Inc.

Address: No.1-2, Shuijing East Road, Economic and Technological Development Area, Guilin, China

Tel: 86-773-2550119

Email: export@hbmchina.com

EC Authorized Representative: Continental Medical B.V.

Add: Strevelsweg 700 303 Unit E7288 3083AS Rotterdam, Netherlands

Remark:

1.NOTIFIED BODY (PPE): SATRA Technology Europe Limited, NUMBER: 2777

2.The user instruction refer to the fact that the product is certified to Modul B and D of the PPE Regulation 2016/425.