

Instruction for Use

Sentinex Latex Surgical Gloves

Device Identification:

Name	Latex surgical gloves	
Types	Powder-free, smooth/textured, cuffed/uncuffed	
Sizes	5.5/6/6.5/7/7.5/8/8.5/9	
Product series	Product code	Product description
	400710 -400717	Sentinex [®] Latex Pro, size 5.5 through to 9, cream/transparent coloured
	400720 -400727	Sentinex [®] Latex Touch, size 5.5 through to 9, cream coloured
	400730 -400737	Sentinex [®] Latex Underglove, size 5.5 through to 9, green coloured
	400700 -400707	Sentinex [®] Latex Essential, size 5.5 through to 9, white coloured

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.

Caution

The product contains natural latex which may cause allergic reactions including anaphylactic reactions.

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.
- 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.

Donning instruction

- Perform hand hygiene in accordance with instructions of your organization.

- Examine the sterile glove packaging for integrity. Open the pouch to expose the inner wrapper.
- Place the inner wrapper on a clean, dry surface without touching the surface. Open and unfold the wrapper so the glove cuffs are nearest to the clinician.
- Using the thumb and index finger of one hand, carefully grasp the folded cuff edge of the glove.
- Slip the other hand into the glove in a single movement, keeping the folded glove at wrist level.
- Pick up the second glove by sliding the fingers of the gloved hand underneath the cuff at wrist level.
- In a single movement, slip the second glove onto the ungloved hand. If necessary, adjust the fingers and interdigital spaces until the gloves fit comfortably.
- Unfold the cuff of the first glove by gently slipping fingers inside the fold – avoid contact with ungloved surfaces.

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.

Warning

- 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.
- Glove does not claim protection against ionising radiation
- This product does not protect against mechanical risks.

Shelf Life: 3 years

Labelling:

1		Symbol for CE Mark. EU Regulation 2017/745.
2		Symbol for CE Mark. EU Regulation 2016/425.
3		Indicates the Authorized representative in the European Community.
4		DATE OF MANUFACTURE. This symbol shall be accompanied by a date to indicate the date of manufacture.
5		Do not re-use
6		Keep dry
7		Keep away from sunlight
8		Use-by date
9		Caution, See attached files for reference
10		Batch Code
11		Temperature limit
12		End of shelf life
13		Humidity limitation
14		Do not use if package is damaged
15		Consult instruction for use

16	 ISO 374-5:2016/Type B XYZ	Protection against chemicals
17	 EN ISO 374-5:2016 VIRUS	Protection against micro-organism hazards
18	 EN 421:2010 Radioactive contamination	The gloves were found to meet the criteria for protection against radioactive contamination specified by EN 421:2010

Distributor/Importer: Lohmann & Rauscher GmbH & Co. KG, Westerwaldstraße 4, 56579 Rengsdorf

Manufacturer: Guilin HBM Health Protections, Inc.

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Tel: 86-773-2550119

Email: export@hbmchina.com

EU Authorized Representative: Continental Medical B.V.

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

Remark:

1. The IFU can be found at www.hbmchina.com.

2. Notified Body responsible for CE certification and ongoing conformity:

SATRA Technology Europe Ltd.

Bracetown Business Park, Clonee, Dublin, D15 YN2P, Ireland (Notified Body: 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.