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Instruction for Use

Sentinex Polyisoprene Essential Surgical Gloves

Intended Purpose

The surgical gloves are sterile and single use devices intended to be worn on he hands of operating room personnel to protect a surgical wound from contamination.

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.
- 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.

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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

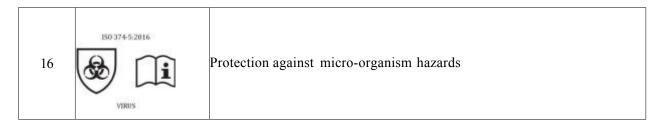
Shelf Life

3 years

Labelling:

Labelling		
1	(€ ₂₇₉₇	Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.
2	EC REP	Indicates the Authorized representative in the European Community.
3	w	DATE OF MANUFACTURE. This symbol shall be accompanied by a date to indicate the date of manufacture
4	(2)	Do not re-use
5	今	Keep dry
6	类	Keep away from sunlight
7	><	Use-by date
8	\triangle	Caution, See attached files for reference
9	LOT	Batch Code
10	X	Temperature limit
11	S yyyy/mm	End of shelf life
12	(26)	Humidity limitation
13		Do not use if package is damaged
14	Ţ <u>i</u>	Consult instruction for use
15	1S0 374-1:2016/Type 8	Protection against chemicals

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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.