

Shandong Intco Medical Products Co., Ltd.

Instructions for use

File No: CE-03-02-01

Version: A/2

Page: 1 of 3

Instructions for use

【Product】 Sterile Latex Surgical Gloves

[Model] 6, 6.5, 7, 7.5, 8, 8.5

[Manufacturer and address] Shandong Intco Medical Products Co., Ltd.

Qiwang Road No.9888, Naoshan Industrial Park, Qingzhou, Shandong, China.

【Contact】TEL: +86-400-050-6868 Fax: 0536 - 6136999

【Product function】 Breaking force: ≥9N

【Intended use】 The Sterile Latex Surgical Gloves is used for protection during clinical surgical operation. It is used to protect patients and users and avoid cross infection.

【Intended Users】 Medical staff in clinical surgical operation.

【Instructions for use】 The Surgical glove is a disposable device that is intended to be worn the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminations.

Transportation and storage

Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition. Recommended to store in the temperature of 5-38°C and relative humidity 75%.

[Contraindications]

Do not use if you are sensitive or allergic to natural rubber latex.

[warnings and precautions]

- This product has a latex component, so it contains potential cytotoxicity, which is determined by the nature of latex, and will not cause harm to the human body.
- This product contains natural rubber. The user who are allergic to nature rubber

NTCO 英科医疗

Shandong Intco Medical Products Co., Ltd.

Instructions for use

File No: CE-03-02-01 Version: A/2

Page: 2 of 3

should avoid using it.

- This product should not be used for more than 24 hours.
- Please follow the [Instructions for use] use of gloves.
- After wearing The Sterile Latex Surgical Gloves, use sharp objects carefully to prevent sharp objects from puncturing the gloves. If the gloves are punctured, disinfect them immediately.
- Damaged gloves may cause cross infection. Check whether the gloves are intact before use. If the gloves are damaged or damaged during use, stop using them immediately and replace them with new gloves.
- Please choose the appropriate size of gloves for use, too large or too small gloves will affect the surgical process.
- The intended use population is Medical staff in clinical surgical operation. Not for other people.
- The Sterile Latex Surgical Gloves is for single use only and has to be disposed after use. Used device shall follow a handling and elimination process for bio-hazard products, in accordance with all local and national regulations.
- Reprocessing, resterilization and/or reuse of this product is prohibited.
- Do not use this device if the device is damaged or the unit packaging is damaged or opened;
- Before use, please read the instructions carefully and use in the correct way;
- The sterilization period of this product is three years, please use within the validity period;
- Avoid coming into contact with petroleum-based lubricants, such as Que oil,



Shandong Intco Medical Products Co., Ltd.

Instructions for use

File No: CE-03-02-01

Version: A/2 Page: 3 of 3

mineral oil and petroleum jelly, before or during the use of the product. If there is a possibility of contact, please pay attention to the glove damage and replace the glove in time.

- During the storage and transportation of this product, due to mutual extrusion, the inner surface may produce slight fit, which will not affect the use.
- See the label for batch number, expiry date and other information.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

【Valid】 3 year.



















Name: Shandong Intco Medical Products Co., Ltd.

Address: Qiwang Road No.9888, Naoshan Industrial Park, Qingzhou City, Shandong

Province, China..

Mail: xujuan@intco.com SRN: CN-MF-000002100

Name: Lotus NL B.V

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Mail: peter@lotusnl.com

Tel: +31644168999

SRN: NL-AR-000000121