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INSTRUCTIONS FOR USE

PRODUCT: STERILE SINGLE USE LATEX SURGICAL GLOVES, PRE-POWDERED

BASIC UDI- 89043733LSG4H

TYPE OF GLOVES – TYPE-I

DEVICE CATALOGUE NO.:

S. No.	Device Name	Brand	Size	Catalogue Ref. Number
1	Sterile Single Use Latex Surgical Gloves, Pre-powdered	Medicmile	6.0	LSG0160
2	Sterile Single Use Latex Surgical Gloves, Pre-powdered	Medicmile	6.5	LSG0165
3	Sterile Single Use Latex Surgical Gloves, Pre-powdered	Medicmile	7.0	LSG0170
4	Sterile Single Use Latex Surgical Gloves, Pre-powdered	Medicmile	7.5	LSG0175
5	Sterile Single Use Latex Surgical Gloves, Pre-powdered	Medicmile	8.0	LSG0180
6	Sterile Single Use Latex Surgical Gloves, Pre-powdered	Medicmile	8.5	LSG0185

Intended Use:

The surgical gloves are intended to act as a protective barrier between the patient and health care worker during invasive surgeries and also to facilitate general hand hygiene.

Device Description:

Sterile, surgical gloves are single use disposable devices made of natural rubber latex that comes in creamy white colour. These gloves may or may not bear powder to facilitate donning. Hand Specific, Beaded Cuff, Micro rough textured. Surgical Gloves are designed to be perfectly anatomical for comfortable wrinkle-free fitting. The extremely soft rubber reduces finger fatigue and increases efficiency. Low powder content that minimizes skin irritation.

Caution:

Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions. Failure to do so may result in complications. To be used by an expert qualified medical professional. This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged. The device is for Single Use Only.

Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions.

Target Patient Population:

All age group Patients (including-Pre-term infants, Neonates, Children, Adolescents, Adults and Old Age).

Target User Groups:

Qualified medical professionals for performing surgical and other invasive procedures (Do not require high level of tactile sensibility) such as: Surgeons & Co-surgeons - General Surgery, Urology, Cardio, Vascular, Neuro, Oncology, Plastic, Paediatric, Endocrinology, Gastro, Anaesthesiologists, OT Staff, Nursing Staff, Technicians, Emergency medical technicians (EMTs), Paramedics, House Keeping staff from hospital & Caregivers, etc.

Target Environment:

The sterile single use latex surgical gloves are recommended to be used in sterile fields in the healthcare facilities such as operation room and other clinical settings that could introduce microbes into a patient.

These gloves can be used in healthcare facilities by the healthcare workers when they come in contact with a patient's bodily fluids, such as blood, vomit or urine, or any other possible contaminants, etc.

Device Packaging :

Sterile, One Pair of Paper Wrapped Gloves packed in tear-able paper pouch pack.

Size :

6.0, 6.5, 7.0, 7.5, 8.0, 8.5.

Material of Construction :

Natural Rubber Latex.

Device Shelf Life:

3 years from the date of manufacture printed on the Product Label.

Method of Sterilization :

ETO Sterilization Process.

Duration of Use :

Duration of Use is transient use (<60 min).

Application of the Body :

Surface contacting device & Contact with mucosal membranes.

Mode of action/Principle of operation:

The Sterile Single Use Latex Surgical Gloves creates a protective barrier between user hands and bodily fluids, bodily tissues, mucous membranes, broken skin, potentially infectious materials and other contaminants to prevent transmission of harmful diseases & viruses during invasive surgical procedures and hence protect both the patients and users from infection.

Medical Benefits:

- NRL gloves are competent barrier to protect against infections for both healthcare professionals and the patients.
- NRL gloves provide lower rates of perforation and lower viral leakage rates.
- NRL gloves are easy to put on comfortable to wear and provide adequate, durable protection.
- NRL gloves have good barrier integrity.
- NRL gloves have less after-use defects.
- NRL gloves have significant greater satisfaction with regard to factors such as quality, safety and durability.
- NRL gloves have high tear propagation strength.
- NRL gloves have high tensile strength.
- NRL gloves have good fit and comfort.

Care Instructions:

Storage:

It is recommended to store the gloves in dry place, in the temperature of 5-40°C and to protect them against direct sunlight and fluorescent light. If gloves are properly stored, as indicated above, they won't lose their performances and won't change the glove characteristics significantly. If gloves could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.

It is recommended to protect the gloves against humidity. Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone.

Cleaning: The gloves are not designed to be laundered.

Indications :

Wearing gloves helps protect both patients and health care workers from infection. When there is a likelihood of coming into direct contact with a patient or patient's blood or other potentially infectious materials (e.g. body fluid, moist body, substances and saliva [in dental procedures]). Defined pathogen barrier as protection from biological agents.

Contra-indications :

- Allergic to the patients or users those sensitive to natural rubber latex.
- Latex Gloves should not be used in protection from chemicals, radiations protection.
- These gloves are not to be used for Microsurgery procedures and chemotherapy procedures.

Potential Complications / Risks:

Dermatological response- Rash, Itch, Hives, Edema, Irritation, Erythema. Non-dermatological response – Dyspnea, Eye Irritation, Nasal Irritation, Wheezing. Diagnostic terms – Allergy (Type-I & IV), Anaphylaxis, Asthma, Contact dermatitis, Rhinitis, Irritant Dermatitis, Urticaria, Tissue Injury.

Powder-associated complications including inflammation, allergic reactions and increased risk of infection, contamination and irritation. Pinholes, Thin Spots, Tears, Ripped, Punctured, Exposure to body fluid, Swelling, Microbial penetration of Gloves, Gloves Perforation.

Warnings:

1) This device is intended for Single use only. Do Not re-sterilize and /or reuse of the device this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.
2) Re-use of single use device creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability.
3) Products containing natural rubber latex may cause allergic reactions. Some gloves might contain ingredients which are known to be a possible cause of allergies in sensitised persons, who may develop irritant and/or allergic contact reactions. If allergic reactions should occur, obtain medical advice immediately.
4) Gloves that are discoloured or stiff may also indicate excessive use or degradation from chemicals. Dispose of gloves when they show any sign of deterioration. Discard the device after single use.

Precautions :

1) Check the integrity of the individual sterilized pack of device, before use. Do not use if pack is damaged.
2) This product contains natural rubber latex.
3) Destroy / Dispose the device & its accessories after single use as bio-medical waste as per applicable laws.
4) Do not Re-sterilize. Do not Re-use. Discard after single use.
5) Before usage, inspect the gloves for any defects or imperfections such as holes, pinholes and tears. If the gloves are ripped or punctured during use, dispose of them immediately. If in doubt, do not use the gloves, get a new pair.
6) Contaminated gloves should be cleaned or washed before removal.
7) Ensure the body fluids, blood, chemicals and other infectious materials cannot enter via the cuff.
8) The gloves should not come in contact with a naked flame.
9) Gloves shall not be used for protection against ionising radiation or for use in containment enclosures.

Adverse Events :

Dermatological response- Rash, Itch, Hives, Edema, Irritation, Erythema. Non-dermatological response –Eye Irritation, Nasal Irritation, Wheezing. Diagnostic terms – Allergy (Type-I & IV), Anaphylaxis, Asthma, Contact dermatitis, Rhinitis, Irritant Dermatitis, Urticaria, Tissue Injury.
Powder-associated complications including inflammation, allergic reactions and increased risk of infection, contamination and irritation. Exposure to body fluid, Swelling, Microbial penetration of Gloves, Gloves Perforation.
Allergic manifestations due to natural rubber latex, Surgical Site Infections due to powder content.

Instructions / Measures to be taken in the event of device malfunction or any adverse event:

(1) To be used by a qualified medical professional. Use maximal sterile barrier precautions during use of the gloves.
(2) Wear sterile gloves ONLY for procedures where an aseptic technique is required.
(3) If hands come into contact with a patient's blood or body fluids due to a hole/puncture in gloves during surgery, remove the gloves immediately and wash your hands with soap. To continue the procedures please wear new pair of gloves on your hands.

Use Instructions :

(1) Wash up and scrub hands and preferably use pre sterile protective gloves.
(2) Tear open the tear-able pack and remove the device safely.
(3) Take out the inner wrap. Open the inner wrapper so that you can see both gloves.
(4) Before use, inspect gloves for physical damage such as tears or pinholes.
(5) Put the wrapped sterile gloves on your clean, dry work surface.
(6) ***Step 1. Put on the first glove***
(i) Take the hand you write with and grasp the glove for your other hand at the folded edge of the cuff.
(ii) Pick up the glove by the folded edge.
(iii) Put your hand inside the glove. Keep your hand flat and your thumb tucked in.
(iv) Pull the glove on.
(v) Be careful not to touch the outside of the glove. Touch only the part of the glove that will be next to your skin.
(vi) Leave the cuff on the glove folded.

Step 2. Put on the second glove

(i) Now, slip the fingers of your gloved hand into the folded cuff of the other glove.
(ii) Lift up the second glove.
(iii) Put the glove over your fingers. The hand that you are putting the glove on should stay flat. Keep the gloved thumb up and back to keep from touching your bare palm or wrist.
(iv) Pull the glove over your hand.
(v) Adjust each glove to get a snug fit.
(vi) Reach under the cuffed part to pull up or adjust.

Step 3. After the gloves are on

(i) Keep your hands in front of you and above your waist. Don't touch anything outside the sterile field.
(ii)If you break sterile procedure, remove the gloves, get a new package, and start again.
(7) Always wash hands with soap and water after removing gloves.

Disposal:

Used Gloves can be contaminated with contagious or other hazardous substances. They should be disposed as bio-medical waste as per local regulations.

Adverse Event Reporting:

In any device malfunction or in case of an adverse event that happened to the user or patient during surgical or examination procedure, please report this adverse event to the manufacturer (Swear Healthcare) or authorized representative and competent authority of the member state where user/ patient is established without any delay or within 24 hrs, as per applicable adverse event reporting regulations.

SYMBOLS USED IN MEDICAL DEVICE PACKAGING

	Manufacturer		Date of Manufacture		Keep away from Sunlight
	Use by Date/ Expiry Date		Keep Dry	LATEX	Contains presence of Natural Rubber Latex
LOT	Batch Code		Do not Re-use	IN	Country of Manufacture
STERILE EO	Sterilized using Ethylene Oxide		Do not use if package is damaged and consult instructions for use	STERILIZE	Do not resterilize
	Consult Instructions for Use	40 °C 5 °C	Storage Temperature		Caution
UDI	Unique Device Identifier	EC REP	Authorized Representative in the European Community/ Authorized representative European Union	MD	Medical Device
	Single sterile barrier system with protective packaging inside	A → 文	Translation	CE 2862	Intertek Medical Notified Body AB Torshamnsgatan 43, Box 1103 SE-164 22 Kista Sweden

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REVISION HISTORY

Revision No.	Revision Date	Description of change	Change Initiated by	Approval Authority
00	02.05.2023	Initial Issue	--	Managing Director / MR
01	21.08.2023	Updates as per TR comments: (1) Device Catalogue & Variants details updated. (2) Device Intended Use updated. (3) Device Shelf Life added. (4) Device Indications updated. (5) Device Potential Complications/Risks updated. (6) Device Disposal added. (7) Device Adverse Event Reporting added. (8) Manufacturer's Name & Address added.	Manager QA & RA	Managing Director / MR
02	01.10.2023	Updates as per TR comments: (1) Manufacturer's Regd. Office removed.	Manager QA & RA	Managing Director / MR
03	10.02.2025	EU MDR-Stage-2 Audit Finding IFU Doc. No. "SHC/IFU/LSG01/01" to "SHC/IFU/LSG01"	Manager QA & RA	Managing Director / MR