

Latex Surgical Gloves, Sterile Powdered

DEVICE 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 CATALOGUE NO.:

Variants	Sterile	Brand Name
Latex Surgical Gloves	SRGLPE	NULIFE
Elbow length Gynaecology gloves	ELGLPE	
Double pair gloves (High risk)	DPGLPE	
Under gloves	SUGLPE	
Microsurgery Gloves	MICLPE	
Orthopaedic gloves	ORTLPE	
Ultra gloves Beaded	ULTLPEBD	
Ultra Gloves Beadles	ULTLPEBL	

DEVICE SIZES:

Variants	Sizes
Latex Surgical Gloves	5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0
Elbow length Gynaecology gloves	6.5, 7.5, 8.5
Double pair gloves (High risk)	Inner:6.0,6.5,7.0,7.5,8.0,8.5, 9.0 Outer: 5.5,6.0,6.5,7.0,7.5,8.0,8.5
Under gloves	5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0
Microsurgery Gloves	5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0
Orthopaedic gloves	5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0
Ultra gloves Beaded	5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0
Ultra Gloves Beadless	5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0

BASIC UDI:

8905159SRGLPWCB

DEVICE DESCRIPTION:

Latex Surgical Gloves – Sterile (Powdered Gloves)

Latex Surgical gloves are Sterile anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat. These gloves are Pre-powdered. The surgical gloves are intended for use in invasive surgeries.

Latex Surgical Gloves, Sterile Powdered

Elbow length Gynaecology Procedure Latex Gloves- Sterile (Powdered Gloves)

Elbow Length gynaecology Gloves anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat. These gloves are pre-powdered. The Elbow length gynaecology gloves are intended for use various gynecological procedures.

Double Pair Gloves (High risk gloves) – Sterile (Powdered Gloves)

The double paired sterile gloves anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat. The double pair specialty gloves supplied in pair to protect healthcare from contiguous disease. The inner glove is supplied green color compare to outer glove which help user to notice if any perforation on the outer gloves.

Under Gloves – Sterile (Powdered Gloves)

Under gloves provide superior feel and natural sensitivity to the finger tips.

Microsurgery Gloves - Sterile (Powdered Gloves)

Microsurgery gloves provide superior feel and natural sensitivity to the fingertips during microsurgery. The microsurgery gloves are intended for micro surgery like ophthalmic surgeries.

Orthopaedic Gloves - Sterile (Powdered Gloves)

Orthopaedic gloves anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat. Its brown colour gloves. These gloves are intended for orthopaedic surgery.

Ultra Gloves Beaded - Sterile (Powdered Gloves)

Ultra Gloves anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat and Intended for surgery.

Ultra Gloves Beadless - Sterile (Powdered Gloves)

Ultra Gloves anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat and Intended for surgery.

INTENDED USER:

This is used by surgeons, operation theatre staff and healthcare professional

TARGET PATIENT POPULATION:

Used for all patient population except in patients with known allergy to natural latex rubber.

DEVICE SHELF LIFE:

5 years from the date of manufacture printed on the Product Label

STORAGE INSTRUCTION:

It is recommended to store the gloves in dry place, in the temperature of 5°C -40°C and to protect them against direct sunlight.

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Latex Surgical Gloves, Sterile Powdered

METHOD OF STERILIZATION:

Device is supplied after EO (Ethylene Oxide) Sterilization.

INDICATIONS:

Intended to be worn on the hands during medical surgical procedures to provide barrier against potentially infectious fluids and other contaminants.

WARNINGS AND PRECAUTIONS:

1. Do not use after the expiry date printed on the label.
2. Do not use if the Package is opened or damaged.
3. Do not Re-sterilize – The excess ETO residue which stays after re-sterilization may be toxic to the users and patients.
4. Do not Re Use - The reuse of the gloves may cause severe complications such as cross contamination, dermatitis, loss of physical properties, infection, allergic reaction and poor barrier protection.
5. Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.
6. Single Use Packaging label and Sales Packaging Label.
7. Device should not be stored in direct sunlight
8. Sterility guaranteed until package is opened or damaged.

CONTRA INDICATIONS:

1. Gloves contain Powder content, persons who are sensitive to powder may develop allergy towards the powder content
2. Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.
3. Gloves contain Natural Latex; persons who are sensitive to Latex should consult a physician before using

DIRECTION FOR USE:

- Select the appropriate size Gloves for the hand.
- Take out the Gloves from the pouch by peeling/tearing it off at the site of direction for open.
- Wear the gloves as left to the Left hand & Right to the Right Hand as denoted on the wallet.
- Must check the date of manufacturing and expiry date before use.
- Adjust the gloves as needed.

A) How to Donning Gloves:

- Rubbing the hand with alcohol or wash with water
- Dry hands before donning the gloves.
- Take out gloves from single unit packaging.
- Gloves need to be donned carefully; do not apply excessive force to pull the gloves when donning.
- Keep the fingernails short and change gloves frequently to avoid tearing issue.

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- For Double Pair Gloves, first wear the green colour inner glove & then wear the outer glove over it.

B) How to Remove Gloves:

- The gloves should be discarded with an appropriate waste disposal container after use according to local disposal regulations

DURATION OF USE:

Duration of Use is short term use (< 24 hours).

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 has significant greater satisfaction with regard to factors such as quality, safety and durability.
- NRL gloves have high tear propagation strength
- NRL gloves have low perforation rate
- NRL gloves have high tensile strength
- NRL gloves have good fit and comfort

SIDE EFFECTS:

Latex Allergy, Surgical site infection, Inflammation, Allergy, Pain, Rashes, Itching, Peeling of skin, Hypersensitivity type-I reaction, Skin redness, Ulcerated skin

RESIDUAL RISK:

- Anaphylaxis
- Blood-Borne Infection, Post-operative wound infection
- Respiratory tract & Pulmonary diseases
- Inflammation
- Toxic to environment
















DEVICE SINGLE UNIT PACKAGING (PRIMARY PACK) CONTAINS:

All Variants	1 Pair/02 Pcs
Double pair gloves (High risk)	Inner Gloves – 1 Pair /02 Pcs Outer Gloves – 1 Pair/02 Pcs



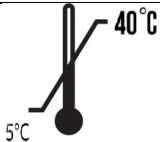

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DEVICE SALES PACKAGING (SECONDARY PACK) CONTAINS:

Variants	Each Pack Contains
Latex Surgical Gloves	50 Pairs
Elbow length Gynaecology gloves	25 Pairs
Double pair gloves (High risk)	20 Pairs
Under gloves	40 Pairs
Microsurgery Gloves	40 Pairs
Orthopaedic gloves	40 Pairs
Ultra gloves Beaded	40 Pairs
Ultra Gloves Beadles	40 Pairs

SYMBOLS USED IN DEVICE SINGLE UNIT PACKAGING AND SALES PACKAGING					
	Manufacturer		Date of Manufacture		Keep away from Sunlight
	Authorized Representative in the European Community/ Authorized representative European Union		Use by Date/ Expiry Date		Keep Dry
	Contains presence of Natural Rubber Latex		Batch Code		Do not Re-use
	Sterilized using Ethylene Oxide		Do not use if package is damaged and consult instructions for use		Caution
	Do not resterilize		Medical Device		Unique Device Identifier

Latex Surgical Gloves, Sterile Powdered

	<p>Single sterile barrier system with protective packaging inside</p>		<p>CE Mark Symbol</p>		<p>Storage Temperature</p>
	<p>No: of gloves in the package</p>				

• In case of any adverse event noted, contact manufacturer (MRK Healthcare Pvt Ltd) or authorized representative and competent authority of the member state where user/ patient is established without any delay or within 24 hrs



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Authorized EU REP

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