

Latex Surgical Gloves, Sterile Powder Free

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	SRGLUE	NULIFE
Elbow length Gynaecology gloves	ELGLUE	
Double pair gloves (High risk)	DPGLUE	
Under gloves	SUGLUE	
Microsurgery Gloves	MICLUE	
Orthopaedic gloves	ORTLUE	
Ultra gloves Beaded	ULTLUEBD	
Ultra Gloves Beadles	ULTLUEBL	

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:

8905159SRGLPFB9

DEVICE DESCRIPTION:

Latex Surgical Gloves – Sterile (Powder Free Gloves)

Latex Surgical gloves are Sterile anatomically shaped medical gloves with the thumb positioned

Rev. No.	A	Rev. Date	24-6-2022	Doc No:	MRK/IFU/SRG-PF/S	Page 1 of 6	Device Name	Latex Surgical Gloves, Sterile Powder Free
----------	----------	-----------	-----------	---------	------------------	-------------	-------------	--

Latex Surgical Gloves, Sterile Powder Free

towards the palmer surface of the index finger rather than lying flat. These gloves are Powder Free. The surgical gloves are intended for use in invasive surgeries.

Elbow length Gynaecology Procedure Latex Gloves- Sterile (Powder Free 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 powder-free. The Elbow length gynaecology gloves are intended for use various gynecological procedures.

Double Pair Gloves (High risk gloves) – Sterile (Powder Free 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 (Powder Free Gloves)

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

Microsurgery Gloves - Sterile (Powder Free 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 (Powder Free 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 (Powder Free 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 (Powder Free 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.

Rev. No.	A	Rev. Date	24-6-2022	Doc No:	MRK/IFU/SRG-PF/S	Page 2 of 6	Device Name	Latex Surgical Gloves, Sterile Powder Free
----------	----------	-----------	-----------	---------	------------------	-------------	-------------	--

Latex Surgical Gloves, Sterile Powder Free

DEVICE SHELF LIFE:

VARIANTS	SHELF LIFE
* Elbow length Gynaecology gloves	3 years from the date of manufacture printed on the Product Label
* Double pair gloves (High risk)	
* Under gloves	
Microsurgery Gloves	5 years from the date of manufacture printed on the Product Label
Orthopaedic gloves	
Ultra gloves Beaded	
Ultra Gloves Beadless	
Latex Surgical Gloves	

* Variants are chlorinated.

STORAGE INSTRUCTION:

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

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.

Latex Surgical Gloves, Sterile Powder Free

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. Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.
2. 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.
- 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

Rev. No.	A	Rev. Date	24-6-2022	Doc No:	MRK/IFU/SRG-PF/S	Page 4 of 6	Device Name	Latex Surgical Gloves, Sterile Powder Free
----------	----------	-----------	-----------	---------	------------------	-------------	-------------	--

Latex Surgical Gloves, Sterile Powder Free

- 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

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		Use by Date/ Expiry Date		Keep Dry

Latex Surgical Gloves, Sterile Powder Free

	representative European Union				
	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
	Single sterile barrier system with protective packaging inside		CE Mark Symbol		Storage Temperature
	No: of gloves in the package				

• 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.



MRK Healthcare Pvt. Ltd.

S. No. 153/P& 310, Panch Pippal,
Hansapur, Runi, Unjha-Patan Road, Patan – 384265, Gujarat, India.



Authorized EU REP

OBELIS S.A

Bd. Général Wahis, 53
1030 Brussels, Belgium