Instruction for Use

Natural Rubber Latex Surgical Gloves, Powdered

RFB LATEX LIMITED

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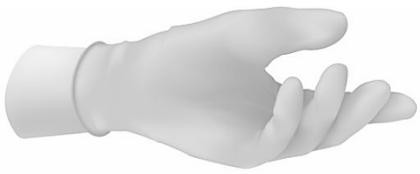


Product Name: Natural Rubber Latex Surgical Gloves, Powdered

Trade Name: RFB

Trade Mark:

Brand Name: SurgiSens

Intended Purpose: 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.

Product Description: Natural Rubber Latex Surgical Gloves, Powdered are intended to provide barrier protection for both the healthcare professional and patient during invasive surgical procedures. It is powdered with hypoallergenic Modified corn starch powder which acts as a lubricant to facilitate donning. The gloves are supplied as sterile and are sterilized by ETO sterilization process and have shelf life of 5 years. The gloves are anatomically shaped for precision touch, comfort and reduce hand fatigue.

Material of Construction: Natural Rubber Latex, and Modified corn starch powder.

Indication:

- Natural Rubber Latex Surgical Gloves, Powdered are intended to be used in an invasive surgical procedure involving single patient.

Contraindication:

- Latex gloves are made of natural rubber latex, which may cause allergic reactions including anaphylaxis response if the user or patient is allergic to latex.

Point of Contact

- Intact or injured skin and mucous, and body fluids

Intended User:

- Healthcare professionals.

Use Environment:

- Hospital & healthcare set up

Patient Population:

- It can be used in all patient population except in patients with known allergy to natural latex rubber.

Duration of Use:

- Gloves used for transient use only (less than 60 minutes).

Sterility State of the Device:

- Sterile- ETO sterilized.

Usage Frequency:

- Single Use.

Side-effects/Residual Risks:

- Itching;
- Temporary discomfort;
- Skin irritation;
- Skin inflammation;
- Latex Allergy.
- Granulomatous peritonitis
- Intraperitoneal Adhesion formation
- Infection potentiation
- starch-induced peritonitis
- Hypersensitivity
- Aeroallergen associated respiratory complications
- Dyspnea

Limitations:

- The gloves shall not be used for more than 60 minutes, in order to reduce the risk of strain/fatigue on hands and loss of barrier protection.

Instructions for Use:

Donning Procedure:

- Wash and dry or sanitize hands before donning the gloves;
- For maximum comfort choose the gloves size most appropriate to our hands. Donning the correct size will reduce the risk of strain/fatigue on hands during use;
- Remove the walleted gloves (inner wrapper) from the pouch (outer wrapper) by peel open from the corner for pouch (peel down to open pouch);
- Using the thumb and the first two fingers of the nondominant hand, pinch the cuff of the folded edge of the glove cuff for the dominant hand, touching only the inside surface of the glove;
- Slide dominant hand in to the gloves keeping hand point downwards and pull up to wrist;

- Using the glove hand insert the 4 fingers under the cuff of the other glove and pull the glove up to the arm;
- Adjust the gloves as necessary;
- In order to reduce risk of barrier failure and to ensure protection during examination which extends beyond 60 minutes, users are advised to change the gloves on hourly basis.

Removal Procedure:

- Take hold of the first glove at the wrist;
- Fold it over and peel it back, turning it inside out as it goes. Once the glove is off, hold it with your gloved hand;
- To remove the other glove, place your bare fingers inside the cuff without touching the glove exterior;
- Peel the glove off from the inside, turning it inside out as it goes. Use it to envelope the other glove;
- Discard the soiled gloves and change to new ones immediately: as soon as any puncture, tear or damage is noticed and after contact with contaminated or unsterile surface.

Precaution:

- Before usage, inspect the gloves for any defects or imperfections. If in doubt do not use the glove, get a new pair;
- The gloves should be worn on dry hands only;
- Remove any jewellery or sharp objects from hands & finger before wearing gloves;
- Healthcare professional should not have sharp fingernail;
- Sterility and performance are not guaranteed on devices that have passed their use by date or if the packaging or seals have been damaged. If label including use by date is illegible, do not use;
- If the individual is allergic to latex, gloves made from an alternative material must be used. If unsure, an alternative material should be used in case the individual is allergic. Testing for a reaction to determine if allergic or not should be undertaken before latex gloves can be safely worn;
- If the individual is allergic to powder, powder free gloves shall be used.
- Care must be taken when selecting the correct glove size to reduce the risk of strain/fatigue on hands during use;

- Promptly and safely dispose of any gloves that have touched a potentially contaminated surface in accordance with relevant local regulations pertaining to safe disposal of clinical waste.
- Do not use if the you have known side effects as mentioned in the side effect/residual risk section.

Warning:

- This product contains natural rubber latex which may cause allergic reaction, including anaphylactic responses;
- Do not use if the pouch is torn or compromised;
- Do not use if the glove is visibly torn or damage;
- Do not reuse, if reused- loss of sterility, high risk of cross-contamination, deterioration of gloves property;
- Do not re-sterilize the device by any method, RFB Latex Limited assumes no liability for devices that have been re-sterilized;
- Do not use the device after use by date;
- Do not use for more than 60 minutes to reduce the risk of strain/fatigue on hands and loss of barrier protection.
- This Product contains modified corn starch powder, which may cause allergic reactions. If you are allergic to it, kindly do not use this product.
- If you experience any side effects mentioned in the side effects or residual risk section, kindly consult your physician.

Storage condition:

- Store the gloves in their original packaging away from sunlight, and keep in dry place;
- Store ideally between 5°C to 35°C.

Benefits:

- Surgical Gloves helps to prevent contamination between patient and healthcare professional during invasive surgical procedures from potentially infectious materials and other contaminants.

Performance Characteristic of the device:

- Surgical gloves are available in multiple sizes. There is a size for everybody;
- Surgical gloves conform to size and shape of hand, translating to a comfortable fit for the wearer;

- Anatomically Shaped for comfort.
- Prevent contamination between patient and healthcare professional during invasive surgical procedures from potentially infectious materials and other contaminants.

Shelf Life:

- 5 years from the date of manufacture.

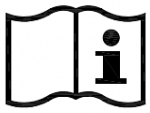
Disposal:

- Dispose of soiled surgical gloves in accordance with relevant local regulations pertaining to safe disposal of clinical waste.

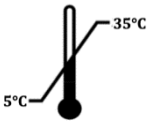
Notice to User:

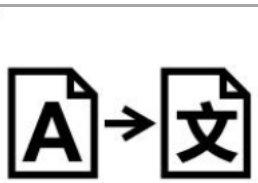
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Symbols Used on Packaging –

Symbol	Title of Symbol	Description
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.
	Do not re-use	Indicates a medical device that is intended for one use.
	Date of Manufacturer	Indicates the date when the medical device was manufactured.
	Country of Manufacture	Identify the country of manufacture of products Country code- India (IN)

Symbol	Title of Symbol	Description
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Do not use if Package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	Caution	This symbol is to denote that there are some warnings or precautions associated with device, which are not otherwise found on labels.
	Authorized Representative in European Community	**CMC Medical Devices & Drugs S.L.** **Address:** C/ Horacio Lengo No 18, CP 29006, Málaga, Spain **Contact Number:** +34951214054 **Email Address:** info@cmcmedicaldevices.com **Webpage:** http://www.cmcmedicaldevices.com/es/
	Manufacturer	RFB Latex Limited **Address:** 78-80, Noida Special Economic Zone, Noida – 201305, UP, India. **Contact Number:** +91 1204944150 **Email ID:** rfblatex@rfblatex.com **Website:** www.rfblatex.com
2862	CE Mark	A CE Mark is a symbol that must be affixed to many products before they can be sold on the European market.

Symbol	Title of Symbol	Description
	Keep Dry	Indicates a medical device that needs to be protected from moisture.
	Keep away from sun light	Indicates a medical device that needs protection from light sources.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	Use by date	Indicates the date after which the medical device is not to be used.
	Sterilized by ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilize.
	Contains or presence of latex rubber	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging
	Medical device	Indicates the item is a medical device

Symbol	Title of Symbol	Description
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information
	Blue Man Symbol	To signify that the instruction manual/booklet must be read
	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside
	Translation	To identify that the original *medical device* information has undergone a translation which supplements or replaces the original information

REVISION HISTORY

Revision No.	Revision Date	Description of change	Approval Authority
00	23-09-2022	Initial Issue	Managing Director
01	03-10-2024	Term “clinical Benefit” is changed to “Benefit”	Managing Director
02	10-12-2024	Updated side effects/Residual Risk, Warning and precautions related to modified corn starch powder	Managing Director
03	25-01-2025	Updated the EU Rep symbol as per ISO 15223-1:2021/AMD-1:2025	Managing Director