

## PRODUCT SPECIFICATION

**PRODUCT NAME : ORTHOPAEDIC LATEX SURGICAL GLOVES STERILE POWDERFREE**

### Special Features

- Provides extra protection during complicated or rigorous orthopedic surgery, particularly against bone fragments and other surgical debris
- Unique brown colour minimizes eyestrain in the operation theatre, providing a good contrast to light-coloured organs and improving visibility
- Anatomical design to reduce fatigue during extended surgery

### Product Information

Material	: Natural Rubber Latex
Colour	: Brown
Design	: Hand Specific, Micro rough textured, Beaded / Bead-less Cuff
Powder Content	: 2mg / dm <sup>2</sup>
Extractable Protein Level	: < 50 micro gram/dm <sup>2</sup> .
Sterilization	: Ethylene Oxide / Gamma as per customer requirement
Labeling	: Shall comply with the corresponding labeling specification and customer requirement.
Shelf Life	: 3 years from the date of manufacture.
Storage condition	: Shall be stored in cool dry place and away from direct light.

### Packaging Details

Wrapper	1 pair
Pouch	1 pair
Inner Box	40 pairs
Master Carton	240 pairs (6 inner boxes)
20 feet container	1,34,400 pairs (560 Cartons)
40 feet HC container	3,26,000 pairs (1358 Cartons)

**Product Certificates** : CE  
ISO 9001 : 2008  
ISO 13485 : 2003

**Quality Standard** : ASTM D 3577, EN455

### Physical Dimensions

Length(mm) Min	Size	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
	Length	300 ±10 mm							
Width (mm)	Size	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
	Width ( +6)	70	76	83	89	95	102	108	114
Thickness(mm) Min	Cuff	0.20 Min							
	Palm	0.22 Min							
	Finger	0.28 Min							

### Physical Properties

Characteristics	Before Ageing	After Ageing (70± 2 °C for 166 ± 2 hrs)
Tensile Strength (Mpa) min.	24 mpa Min	18 mpa Min
Ultimate Elongation (%) min.	750% Min	560% Min
Stress at 500% Elongation (Mpa) Max.	5.5 mpa	NA
Force at break (N) Min.	12	9

### Inspection Level (Pre-Shipment)

Characteristics	Inspection Level	AQL
Freedom from Holes	G-1	1.5
Visual attributes – Major Defects	G-1	1.5
Visual attributes – Minor Defects	G-1	2.5
Physical Dimension	S-2/N=13	4.0
Physical Properties	S-2	4.0
Force at Break	N=3	N/A
Extractable Protein Content	N=3	N/A
Powder free residue	N=5	N/A
Sterility (for sterile product)	N=5	N/A

## Directions For Use:

**1.1 Preparation for use** : Ensure selection of gloves with correct size.

Below is the correct glove size width:

Size	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Width Range (mm) (+6)	70	76	83	89	95	102	108	114

### **1.2 How to use**

- Dry hands before donning the gloves.
- Take out the product after checking the package.
- 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.
- The gloves should be discarded with an appropriate waste disposal container after use according to local disposal regulations.

### **1.3 Cautions for Use**

- The product is for single use.
- Sterility guaranteed until package is opened or damaged.
- Isolated cases of allergic reactions to latex product or powder have been reported. If you experience a reaction to this product, discontinue use immediately and seek medical help.

### **1.4 Storage Condition**

- The atmosphere must always be conducive to the storage of the gloves.
- Gloves before opened for use shall be stored in dark, cool and dry place.
- Gloves need to avoid area with excessive heat. The storage areas need to be controlled below 40°C/ 104 °F.
- Gloves need to be stored at the areas with good air ventilation.
- Gloves need to be shielded from direct sunlight and fluorescent lighting.
- Gloves need to be stored far away from any energy radiating and heat generating equipment.

### **1.5 Expiration Date**

- The shelf life of the gloves is 3 years from the date of manufacture.