HEAD OFFICE

Malaysian Rubber Council
Unit No. 36-02, Level 36, Q Sentral
2A Jalan Stesen Sentral 2, KL Sentral
50470 Kuala Lumpur, Malaysia

Tel : +60 3 2782 2100
Fax : +60 3 2782 2199
Email : mpd@myrubbercouncil.com

CHINA OFFICE

Shanghai

Unit 1708, Hong Kong Plaza
283 Huaihai Road Central, Huangpu District
Shanghai 200021, P.R. China

Tel : +86 21 3376 7001
Fax : +86 21 3376 7002
Email : shanghai@myrubbercouncil.cn

Guangzhou

Room 505, Block A, China Shine Plaza
No. 9 Linhe Xi Road, Tianhe
Guangzhou 510610, P.R. China

Tel : +86 20 2205 7707
Fax : +86 20 2205 7706
Email : guangzhou@myrubbercouncil.cn

USA OFFICE

3516, International Court
NW, Washington DC
20008 USA

Tel : +1 202 572 9771 / 9721
Fax : +1 202 572 9787
Email : usa@myrubbercouncil.com

EUROPE OFFICE

Gebouw 200, 10th Floor
Weena 290
3012 NJ Rotterdam
The Netherlands

Tel : +31 (0)10 282 1200
Fax : +31 (0)10 282 1222
Email : europe@myrubbercouncil.com

INDIA OFFICE

907, Tulsiani Chambers
Nariman Point
Mumbai-400021
Maharashtra, India

Tel : +91 22 6221 6725
Fax : +91 22 6223 2359
Email : mumbai@myrubbercouncil.com

www.myrubbercouncil.com

MRC
MALAYSIAN RUBBER COUNCIL

Know Your Medical Gloves

Contents

Know Your Medical Gloves

Rubber Medical Gloves

Medical gloves are a form of personal protective equipment that prevent contamination of healthcare workers' hands and help reduce transmission of pathogens when they are used appropriately along with proper hand hygiene practices.

All medical gloves are disposable, single-use items to prevent cross-contamination. The two main types of disposable medical gloves are examination gloves and surgical gloves and they are available in various types of materials including natural rubber latex, nitrile, polychloroprene and synthetic polyisoprene.

Medical gloves protect both healthcare providers and patients from the spread of infection or disease during medical procedures and examinations. The Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA) all stress the importance of appropriate glove selection. In 2020 alone, an estimated 348 billion pieces of rubber gloves were consumed globally with most of them for medical purposes.

Functions and Limitations of Medical Gloves

A protective barrier for healthcare workers when handling potentially infectious materials or during patient care.

Reduce the risks of hand floral migration from healthcare workers to patients which may cause infections, such as surgical site infections, and vice versa.

Reduce the risks of transmitting pathogens from one patient to another patient or from a contaminated surface to a patient by changing the gloves worn between contacts, followed by hand hygiene procedures.

- Depending on the barrier effectiveness of the gloves used, gloves do not provide complete protection from cross-contamination or needle stick injuries.
- Small defects in gloves or inappropriate glove removal may transmit pathogens. The defects may be developed during the glove manufacturing process, storage, or prolonged use, or inappropriate handling by users, such as donning gloves while wearing rings with sharp edges.
- Depending on the conditions of use, surgical gloves should be changed at least once every 90 minutes while examination gloves once every 15 minutes due to the risk of perforation.
- Hand hygiene is a must before wearing and after removal of glove to ensure no contamination.

Disposable Medical Gloves

Medical gloves are single-use items for safety reasons and the reprocessing of used disposable medical gloves for reuse is not recommended for the following reasons:

- Soiled used medical gloves are usually highly contaminated. Reprocessing of these gloves may not be able to completely decontaminate them, basically due to the glove design.
- Used gloves may contain prions that can cause transmissible spongiform encepha lopathies (TSE) which is known to be resistant to many methods of decontamination and sterilisation.
- Used gloves also contain different levels of soiled biological and chemical materials which can make cleaning and sterilisation of the reprocessed gloves difficult. Sterility can only be assured when the bioburden is below 1000cfu/unit product.
- In addition, certain chemicals may be released during reprocessing, which can cause adverse irreversible chemical reactions to the gloves such as dissociation of crosslinks.
- As such, reprocessing can cause deterioration in the properties of gloves, such as tensile and tear strength, resulting in reduced durability of the final products.
- Reprocessed gloves may also contain endotoxins from the dead bacteria found in the soiled gloves.

Currently, there is no validated method available for addressing the above risks. Until such a method is developed/established, healthcare workers are advised against the use of reprocessed medical gloves.

BARRIER PROPERTIES
Superior than those of gloves of other materials.

TEAR RESISTANCE
Better than nitrile and synthetic polyisoprene gloves, among others.

TACTILE SENSITIVITY
Surpasses all other gloves available in the market place.

GOOD ELASTICITY
Provides good fit and comfort, as well as reduces hand fatigue. The cuff grips well to the surgical gown.

ALCOHOL RESISTANCE
Better than nitrile gloves.

Benefits of Using NR Gloves

PRODUCT OF ESTABLISHED TECHNOLOGY
Easy to make and low defect rate due to the long history of manufacturing, less waste is generated during manufacturing.

ENVIRONMENTALLY FRIENDLY
Low carbon footprint products, biodegradable because NR gloves are made from plant-based materials.

GOOD DURABILITY
High tensile and tear resistance properties.

LOWER COST
Lower costs than most synthetic gloves except for PVC gloves which are not durable.

ABILITY TO RESEAL SMALL PERFORATIONS WHEN PUNCTURED BY SHARP OBJECTS
Provides additional barrier protection against transmission of infectious pathogens. This unique property is not found in most if not all non-NR gloves.

GOOD RESISTANCE
Resistant against polar liquids and chemicals.

GOOD BARRIER PROPERTIES
Suitable for use as medical gloves.

CONTAIN NO PROTEINS
Suitable for use by healthcare workers who are allergic to NR proteins.

CONFORM CLOSELY TO THE HAND CONFIGURATION
Due to the stress relaxation properties of rubber and body heat after wearing.

OIL RESISTANCE
Better resistance against oils, toluene, petrol than NR or synthetic polyisoprene.

PUNCTURE RESISTANCE AGAINST ROUNDED PROBE
Better than NR gloves. Both nitrile and NR gloves have a similar puncture resistance against needles.

Benefits of Using Nitrile Gloves

ACCELERATOR-FREE NITRILE GLOVES
Easier to make than accelerator-free NR gloves and are therefore readily available in the market.

ANTISTATIC PROPERTIES
Suitable for clean room applications such as handling semi-conductor products.

THIN-FILM NITRILE GLOVES
Consumes less rubber material per glove than NR, with improved tactile sensitivity than regular nitrile gloves.

OZONE RESISTANCE
Better than NR gloves, ozone cracking rarely occurs in nitrile gloves during storage.

Benefits of Using Polychloroprene Gloves

GOOD BARRIER PROPERTIES
Suitable for use as medical gloves.

CONTAIN NO PROTEINS
Suitable for use by healthcare workers who are allergic to NR proteins.

GOOD SOLVENT RESISTANCE
Solvent resistance against polar and non-polar solvents.

GOOD AGEING RESISTANCE
Ageing resistance against heat, ozone and light.

GOOD ELASTICITY
The cuff can grip well to the surgical gown.

Benefits of Using Synthetic Polyisoprene (PI) Gloves

GOOD BARRIER PROPERTIES
Suitable for use as medical gloves.

CONTAIN NO PROTEINS
Suitable for use by healthcare workers who are allergic to NR proteins.

ALCOHOL RESISTANCE
Better than nitrile gloves.

GOOD ELASTICITY
The cuff can grip well to the surgical gown and the fit and feel are similar to NR gloves.

Surgical Gloves:
Double Gloving & Breach Detection

Medical gloves are normally tested fresh under unused conditions.

Under actual use conditions, their properties may deteriorate significantly due to repeated stretching, abrasion, handling of sharp objects and exposure to different types of liquids and chemicals.

The perforation rate of medical gloves during use depends on the duration of use.

The failure rate of surgical gloves due to perforation during use can be as high as 70%.

Surgical glove perforation is one of the reasons that causes surgical site infections to patients.

Risks of contracting diseases due to injury during surgery: HIV up to 0.4%; Hepatitis B up to 30%; and Hepatitis C up to 10%.

A study indicated that the perforation rate of surgical gloves can be reduced from as high as 47.8% for single gloving to as low as 0.4% for double gloving, i.e. the rate where both outer and inner gloves were perforated.

The invasive nature of surgery with its increased exposure to blood could lead to a high risk of transfer of pathogens. Therefore, double gloving is often practised in surgical operations to enhance the needed safety.

Furthermore, in double gloving, wearing a darker colour under glove and a lighter colour outer glove will allow the user to visually detect glove breach via the strong colour contrast of the wet look mark due to liquid ingress.

Acceptable Quality Level (AQL) for Medical Gloves

AQL is an internationally accepted quality standard for measuring the percentage of pinhole defects in disposable gloves (for both sterile and non-sterile), which gives an indication of the glove's barrier performance.

This is an important requirement that must be met by all glove manufacturers/exporters.

- A statistical method of evaluating the quality of medical gloves based on the ISO 2859 standard.
- The number of samples drawn from a lot for testing depending on the lot size and inspection level.
- Larger lot size and higher inspection level require a larger sample size to be drawn for testing.
- The properties tested for AQL include water tightness, dimensions and physical properties such as tensile strength and elongation at break.
- The acceptance criterion depends on the AQL number.
- A high AQL number implies high tolerance for defects and therefore poorer quality and vice versa.
- Process average is the percentage of defective gloves found in samples drawn from a lot. Example: Four defects in 315 samples yield a process average of 1.2%.
- The lower the process average, the better the quality of production lots or batches.
- ASTM (American), EN (European) and ISO (International) standards specify the AQL values for several properties of medical gloves as shown in Tables 1 and 2. Customers may set a lower AQL value if higher quality medical gloves are required.

Table 1: Standards and AQL values for water-tightness of medical gloves

Standards	Examination Gloves		Surgical Gloves	
	AQL for water-tightness	Inspection Level	AQL for water-tightness	Inspection Level
ASTM	2.5	G1	1.5	G1
EN	1.5	G1	0.65	G1
ISO	2.5	G1	1.5	G1

Table 2: Standards and AQL values for dimension and tensile properties of medical gloves

Standards	Examination Gloves		Surgical Gloves	
	AQL for Physical Dimension & Tensile Properties	Inspection Level	AQL for Physical Dimension & Tensile Properties	Inspection Level
ASTM	4.0	S2	4.0	S2
EN	N/A	N/A	N/A	N/A
ISO	4.0	S2	4.0	S2

USFDA Labelling Requirements for Medical Gloves

All medical gloves intended for the US market are required to have the following information on the packaging:

- Name and place of business.
- Country of origin.
- Identity of products – Must be specific & common Language, labelling must be in English with several exceptions.
- Net quantity of contents statement – e.g. "100 gloves, by weight."
- Adequate directions for Use – e.g. "single use only."
- Lot number – not compulsory but may be included.
- Bar coding – FDA encourages the use of bar coding.
- Gloves that contain natural rubber must have a caution statement. For example:

  "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."
- Water extractable proteins claim must not be lower than 50µg/dm^2, based on both unaged and aged test results.
- Powder free claim must not have more than 2 mg of residual or trace powder and debris per glove.
- Expiration date: Expiration date labelling is voluntary. Claims must meet the properties at the end of shelf life. These properties include barrier property; physical properties; sterility and package integrity tests; and tests to support labelling claims.

MDR Labelling Requirements for Medical Gloves

All medical gloves intended for the European market are required to have the following information in the packaging:

- Name or registered trade name and address of the manufacturer.
- For imported devices, the label, or the outer packaging, or instructions for use, shall also contain the name and address of the authorised representative.
- The details strictly necessary to identify device and contents of the packaging especially for users.
- Gloves that contain natural rubber must have a prominent indication on the primary packaging that the gloves contain natural rubber and a warning that the gloves may elicit anaphylactic responses in individuals who are allergic to latex.
- A prominent indication of whether the glove is powdered or powder-free. The control limit of powder-free gloves as established by ISO is 2µg/glove.
- For sterile gloves, the indication of its sterile state and the sterilization method shall be informed. Sterilized powdered gloves must include a warning about the need to minimize tissue exposure to powder residual.
- Indication of any special storage and/or handling condition that applies.
- For sterile gloves, the word 'STERILE' shall be used.
- For traceability, Unique Device Identifier (UDI), batch code, 'LOT NUMBER', or the serial number shall be used.
- The date by which the device shall be used, in safety, expressed as the year and month.
- Manufacturing date shall be the packaging date.
- Indication that the device is for single use. A manufacturer's indication of single use must be consistent across the European Community.

Labelling Requirements of International ISO 11193 Standard for Examination Gloves

All examination gloves intended for the countries that adopt the ISO 11193 standard are required to have the following information in the packaging:

- The name or trademark of the manufacturer or supplier.
- The glove material used.
- The words "TEXTURED" or "SMOOTH", "PRE-POWDERED" or "POWDER FREE" or words to that effect for the appropriate glove finish.
- For powdered gloves, a caution statement shall be included. For example:

  "CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimise the risk of adverse tissue reactions."
- The manufacturer's identifying lot number; glove size.
- The words "FOR SINGLE USE" or similar words with the same effect.
- The words "NON-STERILE" shall be used for non-sterile examination gloves ("STERILE" for sterile examination gloves);
- The words "STERILE UNLESS THIS PACKAGE IS OPENED OR DAMAGED"
- The words "EXAMINATION GLOVE" (or "EXAMINATION GLOVES") or "EXAM GLOVE" (or "EXAM GLOVES");
- The words "DATE OF MANUFACTURE" or similar words with the same effect, and the year in four digits and month of manufacture;
- The words "PRODUCT IS MADE FROM NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS" or similar words with the same effect for natural rubber gloves.

Labelling Requirements of International ISO 10282 Standard for Surgical Gloves

All surgical gloves intended for countries that adopt the ISO 10282 standard are required to have the following information on the packaging:

- Inner wrap shall have information on
  - i) Glove size,
  - ii) Left and Right for left hand glove and right hand glove, respectively.
- Outer web shall have:
  - i) Name or trademark of the manufacturer or supplier.
  - ii) Glove material used.
  - iii) The words "Straight Fingers" or "Curved Fingers" or similar words with the same effect for the glove
  - iv) The words "TEXTURED" or "SMOOTH", "PRE-POWDERED" or "POWDER-FREE" or words to that effect for the appropriate glove finish.
  - v) Glove size.
  - vi) The manufacturer's identifying number for traceability such as lot number.
  - vii) "Date of Manufacture" or words to that effect and the year in 4 digit & month.
  - viii) The words "Sterile unless this package is opened or damaged."
  - ix) The words "For Single Use."
  - x) The words "Surgical Gloves."
  - xi) The words "Product is made from natural rubber latex which can cause allergic reactions" or similar words with the same effect for natural rubber glove.
- Multi-unit packaging shall also include "xx pairs of surgical gloves" and instruction for storage, in addition to the above.

Good Manufacturing Practices (GMP)

All medical glove manufacturers, including re-packers of bulk packed medical gloves must practise the GMP principles. These include:

- Manufacturing facilities must be clean and hygienic.
- Have procedures to prevent cross-contamination and protect product integrity.
- Manufacturing processes and operating procedures must be clearly documented.
- Critical processes and changes must be validated.
- The manufacturing process can only be handled by trained personnel and training records must be maintained.
- Potential cross-contamination must be declared.
- Manufacturing records must be systematically maintained and traceable.
- Product distribution must not impact the product quality.
- Procedure for recalling from market.
- Procedure of handling complaints, including corrective actions and preventive actions.

MALAYSIA'S STRENGTHS

Malaysia is the
WORLD'S LARGEST PRODUCER AND EXPORTER
of rubber gloves with
65% global market share

The export value of rubber products was RM5.44 billion in 2001 of which rubber gloves constituted 58%. In 2020, the
EXPORT VALUE
RM40.96 BILLION
with 86% from **rubber gloves**

The glove manufacturers in Malaysia have tremendously improved
PRODUCTION EFFICIENCY
via automation and innovation over
THE LAST **30 YEARS**

PRODUCTION SPEED
increased from just 3000 gloves per hour in 1988 to the current speed of 45,000 gloves per hour

REDUCTION IN NUMBER OF WORKERS
for the production of **one million pieces** of gloves was reduced from 9.7 in 2009 to 1.7 in 2021 (est.)

PRODUCT QUALITY
has also improved tremendously from **1.5 to AQL 0.65 or even 0.1 for certain types of surgical gloves.**

The manufacturers have also started to embrace
INDUSTRY 4.0
such as integration of robotics, real time data collection via remote-controlled sensors, digitisation, analyses, and integration of different production facilities via internet for easy management, cost reduction, quality control and maintenance.

WELL-ESTABLISHED ECO-SYSTEMS
such as machine fabricators, chemical suppliers, synthetic latex manufacturers, and support from the **Malaysian Rubber Council** which actively promotes and enhances the competitive advantage of the **rubber glove industry.**

Other Considerations

- Medical gloves are classified as medical devices and are highly regulated products as they may be in contact with highly infectious pathogens such as Ebola, Hepatitis B and human immunodeficiency virus (HIV).
- Good barrier properties are of paramount importance to prevent the transmission of pathogens from patients to healthcare workers and vice versa.
- Improper use of medical gloves may lead to the spread of infectious diseases. This includes using inferior quality medical gloves, reprocessing and reusing medical gloves, removing and disposing used medical gloves improperly.
- Labelling of medical gloves is also important to ensure traceability and prevent adulteration.
- Labelling claims must be scientifically substantiated.
- All medical glove manufacturers and distributors must be registered and regularly audited to ensure that only good quality medical gloves are allowed to be commercially distributed.
- Re-packers of bulk packed medical gloves must ensure traceability of the re-packed products and no adulteration. They must also adhere to the good manufacturing practice principles.
- Medical gloves made of different materials have different performance properties.
- Users should use the most appropriate gloves and duration for their work to reap the optimum benefits of the products.