




## USER INFORMATION (SURGICAL POLYISOPRENE)


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| <b>a. Intended Use</b>                      | <p>These gloves are intended to be used during surgical procedures, short term, and single use only. This surgical glove acts as protective barrier when worn on the hand of surgeon and/or healthcare personnel to prevent contamination between healthcare personnel and the patient’s body, fluids, waste or environment against dangerous chemicals and micro-organisms.</p>  |
| <b>b. Precaution for Use</b>                | <p>Inspect the glove prior to use. Ensure the glove does not have any flaws and was not damaged when donning. It is important to select the appropriate glove size to prevent discomfort.</p>   |
| <b>c. Ingredients/Hazardous ingredients</b> | <p>This product contains synthetic Polyisoprene. Some gloves may contain ingredients that are known to be a possible cause of allergies to sensitive individuals, including irritations and/or allergic reactions. If this occurs, seek appropriate medical advice immediately.</p>   |
| <b>d. Storage:</b>                          | <ul style="list-style-type: none"> <li>The product is to be kept away from direct sunlight and fluorescent light and is to be stored in an environment with a temperature of 10°C - 40°C.</li> <li>The storage place shall not contain any equipment that generates ozone.</li> <li>The product shall not be stored in direct contact with metals.</li> <li>Avoid contact with oil-based antiseptic phenols or their derivatives, greases, petroleum jelly, petroleum spirit, paraffin, or other related compounds.</li> <li>Sterility is assured provided that the pouch-seal is intact and not torn.</li> <li>The expiry date indicated on the package or labelling based on product shelf life is valid for properly stored products.</li> </ul> |
| <b>e. Wearing Instructions:</b>             | <p><b><u>Assisted donning:</u></b><br/> Wash hands thoroughly using antiseptic soap and dry according to best-practice procedures. Hands remain inside the sterile gown sleeves and should not touch the gown cuff while donning is assisted by a scrub nurse. The gloved scrub nurse grasps the glove at cuff of the glove holding it at waist level the glove is stretched open with thumbs extended beneath the glove cuff with the palm of the glove facing the surgeon. With the cuff covering their hand the surgeon inserts their hand into the glove as the scrub nurse pulls the glove upwards, so the cuff of the glove fully covers the cuff of the gown. Never touch the outside of the glove with a bare hand</p>                      |

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|   | <p><b><u>Unassisted donning:</u></b><br/>Wash hands thoroughly using antiseptic soap and dry according to best-practice procedures. Peel opens the sterile outer wrap and open the inner wrap to display gloves with hands remaining inside sterile gown sleeves. Pick up one sterile glove with the rolled cuff. Insert fingers into glove pulling upwards so the cuff fully covers the cuff of the gown. Slide the fingers of your gloved hand under the rolled cuff of the other sterile glove. Insert your ungloved hand into the glove. Never touch the outside of the glove with a bare hand.</p> <p><b><u>Doffing:</u></b><br/>To remove the glove, use the gloved hand to grasp the outside edge of the glove near your wrist and pull glove away from your hand turning it inside out as you remove. Roll the removed glove into the palm of your hand that is still gloved. Next, slide fingers of ungloved hand under the wrist of the remaining glove making sure you do not touch the outside of the glove. Peel off the second glove. Never touch the outside of the glove with a bare hand. Discard gloves into proper trash receptacle. Wash hands thoroughly using antiseptic soap then dry according to best-practice procedures.</p> <p>Avoid letting the gloves snap, as this may cause contaminants to splash into your eyes or mouth or onto your skin or other people in the area.</p> <ul style="list-style-type: none"> <li>• Remove used gloves before touching anything: Countertops, faucets, pens, and pencils are frequently contaminated because healthcare workers touch them while wearing used gloves.</li> <li>• Remove both gloves being careful to touch only the inside surfaces of the gloves with your bare hands.</li> <li>• As the surgical gloves are recommended for single use only, dispose of them properly. Wash your hands immediately after gloves are removed since gloves may contain tiny holes or tears that leave you at risk of exposure to contaminated blood and other fluids.</li> </ul> |
| <p><b>f. Disposal</b></p>                       | <p>Dispose of the device in accordance with the local laws and regulations applicable in the country.</p>   |
| <p><b>g. Composition</b></p>                    | <p>Gloves are manufactured from synthetic Polyisoprene (latex-free). The surface material may assist the user in donning the gloves.</p>  |
| <p><b>h. Limitations/Cautions/Warnings:</b></p> | <ul style="list-style-type: none"> <li>• This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.</li> <li>• The chemical resistance data have been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. Results can be different if the chemical is used in a mixture.</li> </ul>  |

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|   | <ul style="list-style-type: none"> <li>• It is recommended to check that the gloves are suitable for the intended use. The conditions at the workplace may differ from the conditions depending on temperature, abrasion, and degradation.</li> <li>• Before usage, inspect gloves for any defects or imperfections.</li> <li>• Protective gloves may provide less resistance to dangerous chemicals due to changes in physical properties. Movements, snagging, rubbing, degradation caused by chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.</li> <li>• Penetration resistance data have been assessed under laboratory conditions and relates only to the tested specimen.</li> <li>• For single use only.</li> <li>• This glove does not protect against mechanical risks.</li> <li>• This glove is not intended for use in the direct or primary x-ray beam.</li> <li>• This product is to be stored in cartons during transportation.</li> <li>• Sterile, as long as the peel pouch is sealed and undamaged surgically only.</li> <li>• The glove is a device subject to wear, so frequent replacement is recommended particularly where imperfections are observed.</li> <li>• Wear gloves with dry, clean hands.</li> <li>• In rare cases, transient skin reactions and hypersensitivity reactions may occur. In case of reaction, discontinue use.</li> <li>• If more information is required, please contact your local distributor in the first instance. More information can be obtained from <a href="http://www.wrpworld.com">www.wrpworld.com</a>.</li> </ul> |
| <p><b>i. Conformity and Performance</b></p> | <p>Personal Protective Equipment of Complex Design Category III, in compliance with European Regulation (EU) 2016/425, Regulation 2016/425 on personal protective equipment, as amended to apply in GB, tested to EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 Type B, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016 &amp; ISO 16604:2004, CE2797; CE Class IIa Sterile Medical Device, in compliance with MDR (EU) 2017/745, tested to EN 455-1:2020, EN 455-2:2015, EN 455-3:2023, EN 455-4:2009, and ASTM D3577.</p>  |
| <p><b>j. Caution</b></p>                    | <div style="border: 1px solid black; padding: 5px;"> <div style="background-color: #0056b3; color: white; padding: 2px;"> <b>Caution</b></div> <p style="font-size: small;">This product to be stored in carton during transportation. This product does not contains natural rubber latex.</p> <div style="text-align: right;"></div> </div>   |

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| <b>k. Legal Manufacturer and Representative</b> |  <b>WRP Asia Pacific Sdn Bhd</b> 1 4 7 8 1 7 V<br>Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi<br>43900 Sepang, Selangor Darul Ehsan, Malaysia<br>Phone: +60 3 8706 1486<br>Email: inquiry@wrpworld.com | <b>EC REP</b> & Importer in the EU<br>Remesco Handelsges.m.b.H.<br>Muthgasse 36/19, A-1190 Vienna, Austria<br>Phone: +43 1 328 50 88<br>Email: office@remesco.com |
|   | <b>UK REP</b><br>Obelis UK Ltd<br>Sandford Gate, Oxford OX4 6LB, UK<br>Phone: +32 (0) 2 732 5954<br>Email: mail@obelis.net   | <b>CH REP</b><br>Obelis Swiss G.m.b.H.<br>Ruessenstrasse 12, 6340 Baar / ZG, CH<br>Phone: +41 41 544 15 26<br>Email: info@obelis.ch                               |

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| <b>Tested in accordance with ISO 374-5:2016</b><br><br><b>VIRUS</b> | <b>Tested Against Viruses</b><br>The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen. |
|  | Protection against bacteria and fungi - Pass   |
|  | Protection against viruses - Pass  |

| ISO 374-1:2016/<br>Type B<br><br>KPT | Tested in accordance with EN ISO 374-1: 2016+A1: 2018 Type B | EN 16523-1:2015 + A1:2018 Permeation Level | EN ISO 374-4:2019 Degradation |
|---|--|--|-------------------------------|
|   | 40% Sodium Hydroxide (K)                                     | 6  | -20.2%                        |
|   | 30% Hydrogen Peroxide (P)                                    | 4  | 24.1%                         |
|   | 37% Formaldehyde (T)   | 5  | 1.2%                          |

EN ISO 374-4:2019 Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

**EN ISO 374-1:2016+A1:2018 Type B Permeation levels based on breakthrough times as follows:**









| Performance Level               |     |     |     |      |      |      |
|---------------------------------|-----|-----|-----|------|------|------|
| 0                               | 1   | 2   | 3   | 4    | 5    | 6    |
| Minimum breakthrough Time (min) |     |     |     |      |      |      |
| >0                              | >10 | >30 | >60 | >120 | >240 | >480 |

| Tested in accordance with EN ISO 374-2:2019 |            |      |
|---|------------|------|
| 7.2   | Air Leak   | N/A  |
| 7.3   | Water Leak | PASS |

| Performance Level | AQL   | Inspection Level |
|-------------------|-------|------------------|
| <b>LEVEL 3</b>    | <0.65 | G1               |
| <b>LEVEL 2</b>    | <1.5  | G1               |
| <b>LEVEL 1</b>    | <4.0  | S4               |

+++ Inspection Level AQL <0.65  
 Declaration of conformity is available at our website [www.wrpworld.com](http://www.wrpworld.com)

| Symbol Used on the Packaging |  |  |  |
|------------------------------|--|--|--|
|                              | Medical Device   |  | Sterilized by irradiation  |
|                              | Medical Device Regulation (EU) 2017/745  |  | Single sterile barrier system with protective packaging inside                           |
|                              | Personal Protective Equipment of Complex Design Category III, in compliance with European Regulation (EU) 2016/425 |  | Designed to protect against chemical risks according to EN ISO 374-1/Type B              |
|                              | CE marking   |  | Designed to protect against microorganism risks according to EN ISO 374-5                |
|                              | UKCA marking   |  | Medical products handle with care  |
|                              | Single-use only  |  | Store this way up  |
|                              | Keep dry   |  | Allergen type IV   |
|                              | Keep away from sunlight  |  | Latex Free   |
|                              | Temperature limits 10° – 40°C  |  | UA Conformity mark with identification number of the national conformity assessment body |
|                              | Recycle  |  | 1 pair of gloves per pouch   |
|                              | Triman   |  | 50 pairs of gloves per dispenser   |

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|---|---|--|--------------------------|
|  | Authorized representative in the European Community |  | Lot number               |
|  | Authorized representative in Switzerland            |   | Date of Manufacture      |
|  | Authorized representative in UK                     |   | Expiration date          |
|  | Manufacturer  |  | Unique device identifier |