About

Clean & sterile sleeve/glove system, Nitrile sleeve attached to a size 8.5 hand specific Polychloroprene (BioClean BPZS) glove by a channel ring and O’ring. Sold by the pair, individually packaged.

Specifications

COMPATIBILITY:
ISO Class 4 & EU GMP Grade A

LENGTH:
Complete System: 32”/810mm

MATERIAL:
Nitrile sleeve/polychloroprene glove (BPZS)

PROTEIN LEVEL:
Nitrile contains no natural latex proteins

SURFACE:
Textured glove

SHAPE:
Hand specific glove

COLOUR:
White sleeve/natural glove

STERILIZATION:
Gamma Irradiated

Features

- Sleeve & glove tested against ASTM D6978-05 for handling chemo drugs
- Ultra-clean surface ensures product protection
- Sleeve 100% inspection & air leak tested (prior to being guillotined)
- Fits Port Size: 10-12” / 254-305mm

SLEEVE SUITABLE FOR AUTOCLAVING
SLEEVE CAN BE SANITIZED BY VHP OR IPA
Quality Standards

- Manufactured in a facility holding ISO 9001:2015 and PPER 2016/425 Module D
- Conforms to Category 3 - Complex Design Personal Protective Equipment PPE Regulation (EU)2016/425
- Processed in an NEBB certified ISO Class 4 environment
- Physical properties comply with European Medical Glove Standard EN455-2:2015
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- Sterilized in accordance with ISO 11137-1:2006
- Complies with the requirements of European Glove Standard EN 421 Protection against particulate radioactive contamination.

Sterilization

Method: Gamma irradiation
Minimum Dose: 25kGy
Sterility Assurance Level: $10^{-6}$

Shelf Life & Storage

Three (3) years from date of manufacture. Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.

Physical Properties

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>VALUE</th>
<th>TEST METHOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom From Holes</td>
<td>AQL 0.65 Performance Level 3 (Glove)</td>
<td>EN 374-2:2016</td>
</tr>
<tr>
<td>+/-10mm (mm/inches)</td>
<td>(System Length - Sleeve &amp; Glove)</td>
<td></td>
</tr>
<tr>
<td>Single Wall Thickness Minimum (mils/mm)</td>
<td>Cuff: 4.33/0.11</td>
<td>EN 455-2:2015</td>
</tr>
<tr>
<td></td>
<td>Palm: 5.91/0.15</td>
<td></td>
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<tr>
<td></td>
<td>Finger Tip: 7.09/0.18</td>
<td></td>
</tr>
<tr>
<td>Force At Break During Shelf Life</td>
<td>$\geq 9$ N (Glove)</td>
<td>EN 455-2:2015</td>
</tr>
</tbody>
</table>

PALM WIDTHS (mm) ± 5mm

<table>
<thead>
<tr>
<th>SIZE</th>
<th>mm</th>
</tr>
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<tbody>
<tr>
<td>8.5</td>
<td>108</td>
</tr>
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<table>
<thead>
<tr>
<th>Re-order code</th>
<th>Size</th>
<th>Packing</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSG10NIT85</td>
<td>8.5</td>
<td>One system - consisting of sleeve, size 8.5 glove (marked L) and channel ring/O-ring assembly packed in inner PE bag; One system - consisting of sleeve, size 8.5 glove (marked R) and channel ring/O-ring assembly packed in inner PE bag; two inner bags (two systems – one L &amp; one R) packed per outer PE bag; 10 outer bags (20 systems) per lined white Correx box.</td>
</tr>
</tbody>
</table>

For additional information visit us at [www.bioclean.com](http://www.bioclean.com), or contact us at:

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*Warning: No glove provides complete protection against all chemicals. Users must test the gloves against the particular chemicals and environment in which they will be used.*

**Please see product validation pack or contact Ansell customer service for specific data on use of gloves with cytotoxic drugs. Gloves used for protection against such drugs must be selected specifically for the type of chemicals used.*

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