

### About

BioClean RABS & Isolator Sleeves are manufactured from accelerator-free nitrile with incredibly low levels of particles and excellent ESD properties. Designed for use in product contact areas, BarrierPlus Sleeves are fully validated for sterility with an SAL (Sterility Assurance Level) of  $10^{-6}$  and are suitable for port sizes from 150mm (6") to 300mm (12"). With a cuff ring diameter of 90mm (3.5") the sleeves will fit the majority of available cuff ring systems.

### Specifications

**COMPATIBILITY:**  
ISO Class 4 & EU GMP Grade A

**LENGTH:**  
660mm (26")

**MATERIAL:**  
Nitrile

**PROTEIN LEVEL:**  
Nitrile contains no natural latex proteins

**SURFACE:**  
Smooth

**SHAPE:**  
Sleeve. Cuff size: 90mm (3.5")

**COLOUR:**  
White

**STERILIZATION:**  
Gamma irradiation

### Features

- Tested against ASTM D6978-05 for handling chemo drugs
- Ultra-clean surface ensures product protection
- 100% inspection & air leak tested (prior to being guillotined)
- Suitable for use with a wide range of cuff systems
- Suitable for port sizes 150mm - 300mm (6" to 12")

COMPATIBLE WITH RANGE OF CUFF SYSTEMS

SUITABLE FOR AUTOCLAVING

CAN BE SANITIZED BY VHP OR IPA



## Quality Standards

- Manufactured in a facility holding ISO 9001: 2008 certifications
- Processed in an NEBB certified ISO Class 4 environment
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- Sterilized in accordance with ISO 11137-1:2006

## Sterilization

Method: Gamma irradiation  
 Minimum Dose: 25kGy  
 Sterility Assurance Level: 10<sup>-6</sup>

## 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

CHARACTERISTICS	VALUE	TEST METHOD
Freedom From Holes	0.65 AQL	EN 374-2:2003
Glove Length +/-10mm (mm/inches)	660/26	EN 420:2003
Single Wall Thickness Minimum (mils/mm)	Cuff: 0.00/N/A Palm: 0.00/N/A Finger Tip: 0.00/N/A	EN 455-2:2009
Force At Break During Shelf Life	≥ 6 N	EN 455-2:2009

PALM WIDTHS (mm) ± 5mm				
SIZE	6" port	8" port	10" port	12" port
mm	N/A	N/A	N/A	N/A
TEST METHOD			EN 420:2003	

## Resistance to Penetration

Characteristic	Water Leak Test	Air Leak Test
AQL	0.65	3
Performance Level	0.65	3

## Protection Against Mechanical Risks (EN388)

Risk	Performance Level	Risk	Performance
Abrasion Resistance	Level 3	Tear resistance	Level 0
Blade cut resistance	Level 1	Puncture resistance	Level 1

## TO ORDER

### Re-order code

S-BBNS0-60  
S-BBNS0-80  
S-BBNS0-10  
S-BBNS0-12

### Size

6" port  
8" port  
10" port  
12" port

### Packing

One piece per sealed inner PE bag; one inner bag per sealed second inner PE bag; one second inner bag per sealed outer PE bag; 20 outer bags per lined inner white Correx polyethylene box; two inner Correx polyethylene boxes per outer white Correx polyethylene box (40 pieces)

#### Please Note:

Resistance to penetration test and Protection Against Mechanical Risks were carried out prior to the end of the sleeve being guillotined.

For additional information visit us at [www.bioclean.com](http://www.bioclean.com), or call us at +44 1638 663338

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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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