

BIOCLEAN BARRIERPLUS™

Sterile Sleeve
S-BBNS0

About

BioClean BarrierPlus™ 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 available in lengths of up to 660mm (26"), and suitable for port sizes from 150mm (6.0") 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^{-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

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

PALM WIDTHS (mm) ± 5mm				
SIZE	6"	8"	10"	12"
mm	N/A	N/A	N/A	N/A
TEST METHOD	EN455-2:2009			

Resistance to Penetration

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

Protection Against Mechanical Risks

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"
8"
10"
12"

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.

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BioClean™ is a brand of Nitritex Ltd.

For more information, please visit www.bioclean.com

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