Boston Scientific

Advancing science for life™

We've got you covered

EndoArmor™+ Surgical Gown

AAMI Level 3

Boston Scientific

EndoArmor+ Surgical Gowns meet the respective Level 3 requirements of **ANSI/AAMI PB70:2012** liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.[1]

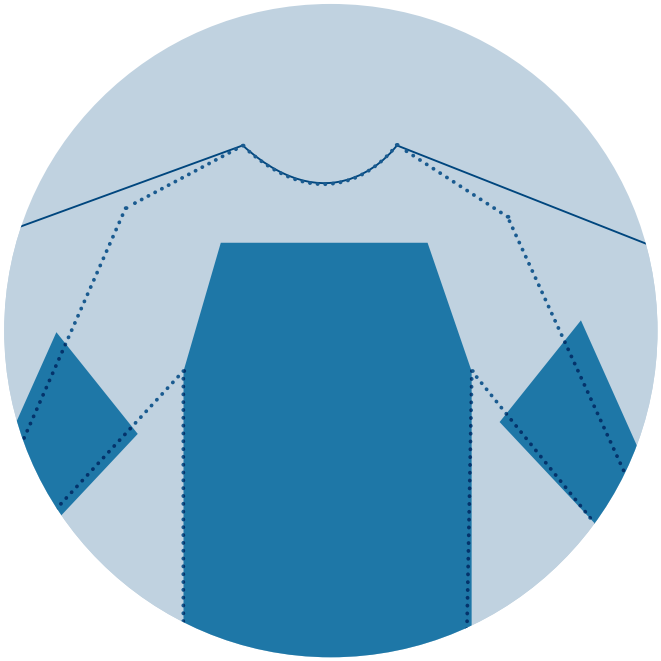
Gown 101:
Choosing Your Gown

It is suggested to wear a gown that is appropriate to the task to protect skin and prevent soiling of clothing during procedures and activities that could cause contact with blood, body fluids, secretions, or excretions. Selecting the appropriate gown may be key for the protection of the HCP and the wearer.

Selection tips:

- Use a risk assessment-based approach to identify the appropriate gown for the task
- Read the gown label – intended use, and level of protection (Level 1-4) are critical
- Follow any OSHA or state-mandated recommendations
- Refer to applicable guidelines

Material presented is for informational purposes only. The information is not intended to replace medical advice offered by physicians or the policies and procedures of your facility. Boston Scientific makes every effort to provide information that is accurate and timely, but and makes no guarantee in this regard. With regard to any information presented, Boston Scientific does not make any warranty, express or implied and specifically disclaims any legal liability or responsibility for the accuracy, completeness, or usefulness of any information presented

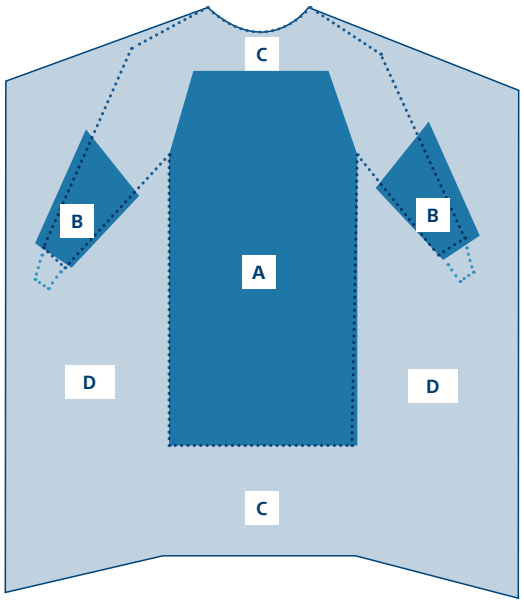


Gown 101: Construction

ANSI/AAMI PB70 defines the critical zone of a gown as the area where direct contact with blood, body fluids, and other potentially infectious material is most likely to occur.[1]

A gown's defined critical zone will vary depending on the intended use of the gown. Not only do gowns have different performance requirements based on risk level (AAMI Levels 1-4), but those performance requirements must be demonstrated at different locations on the gown, depending on the gown's intended use.[2]

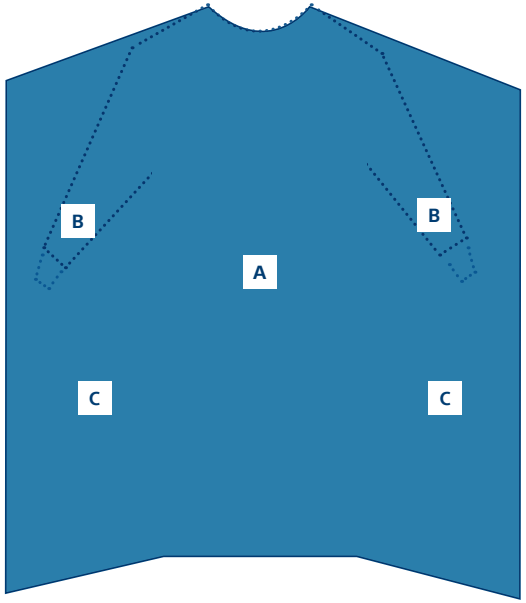
= critical zone



Surgical Gown[3]

- Can be provided Sterile or Non-Sterile
- Can be AAMI Level 1-4
- Entire front of the gown (Areas A, B,C) is required to have a barrier performance of at least Level 1.
- The critical zone comprises at least areas A & B. The classification of the surgical gown is based on the lower performing component of the two.
- The back of the surgical gown may be non protective.
- Seams between protective and non protective areas have no barrier requirements
- Seams between two protective areas are required to have at least the barrier performance of the lower-performing area

= critical zone



Isolation Gown[3]

- Can be provided Sterile or Non-Sterile
- Can be AAMI Level 1-4
- The entire isolation gown (areas A, B, & C), including seams but excluding cuffs, hems, and bindings, is required to have a barrier performance of at least Level 1.

Gown 101: Materials

Per AAMI TIR11-2005 Selection and use of protective apparel and surgical drapes in health care facilities. Single-use protective apparel and surgical drapes are commonly constructed of nonwoven materials (although other types of materials may be used), alone or in combination with materials that offer increased protection from liquid penetration, such as plastic films.

The most commonly used nonwoven fabrics for protective apparel and surgical drapes are:

- **Spunlace**
- **Spunbond Meltblown Spunbond (SMS)**
- **Composite**
- **Polyethylene Coated Polypropylene**
- **Wet-laid**

Material Definitions

Spunlace — A material often consisting of a blend of wood pulp and polyester fibers. High-velocity water jets are used to entangle the fibers to achieve mechanical bonding. For protective apparel and surgical drapes, a chemical treatment may be used to improve liquid penetration resistance.[4]

Spunbond Meltblown Spunbond (SMS) — A multi-layer fabric consisting of an inner layer of meltblown polypropylene between the outer layers of spunbond polypropylene that are thermally or adhesively bonded. Spunbonded materials are made up of continuous filaments formed by in-line melt spinning. Meltblown materials are similar in that they are formed from a polymer by means of in-line melt spinning, but the fibers are finer and might not be continuous.[4]

Composite — A combination of nonwoven fabrics, films, or both created through lamination or coating processes. The resulting material has enhanced performance because it has attributes of each component.[4]

Polyethylene Coated Polypropylene — A multi-layer fabric comprised of nonwoven spunbond polypropylene fabric layer coated with a breathable film. Allows for breathability during long wear.[4]

Wet-laid — A nonwoven fabric consisting of wood pulp or a blend of polyester and wood pulp fibers. The fibers are suspended in water to obtain a uniform dispersion and are then separated from the slurry by draining the water through a fine mesh screen. For medical-grade fabrics, a chemical binder is often used to bond the fibers together. A chemical treatment can be used to improve liquid penetration resistance.[4]

Gown 101: Classification

The US FDA recognizes the consensus standard ANSI/AAMI PB70:2012 and utilizes the standard's terminology to describe and assess the barrier protection levels of gowns intended for use in health care facilities.[1]

The development of ANSI/AAMI PB70, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, was to better quantify barrier performance claims through a classification system of levels of barrier performance of surgical gowns, other protective apparel, surgical drapes, and drape accessories.[1]

This classification system is based on standardized test methods and is intended to enable users to better choose the appropriate level of protection for a given clinical use.[4]

Boston Scientific

AAMI PB70 Performance Requirements & Level Guide[1,3,5,6,7]

AAMI Level	Risk Level	Description	Required Testing & Laboratory Performance	Use Examples
Level 1	Minimal	Slight barrier to small amounts of fluid penetration	Spray Impact: ≤ 4.5g	• Basic care
Level 2	Low	Barrier to larger amounts of fluid penetration • splatter, some soaking	Spray Impact: ≤ 1.0g Hydrostatic Pressure: ≤ 20cm	• Venous blood draw • Suturing • ICU • Path Lab
Level 3	**Moderate**	**Barrier to larger amounts of fluid penetration** **• splatter, more soaking than level 2**	**Spray Impact: ≤ 1.0g** **Hydrostatic Pressure: ≤ 50cm**	**• Aterial blood draw** **• Inserting IV** **• ER/Trauma**
Level 4	High	No fluid or virus penetration up to 1hr	No fluid or virus penetration up to 1hr, with pressure	• Contact precautions • Pathogen resistance

Boston Scientific

EndoArmor+ Surgical Gowns

are single-use personal protective equipment intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter.

- Gowns meet the respective Level 3 requirements of ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.[1]
- They may be worn by the wearers throughout medical facilities where AAMI Level 3 surgical gowns are appropriate, per facility, policy, protocols, that may include the endoscopy suite, endoscope reprocessing room, urology department, emergency rooms, labor and delivery, clinical labs, and biopsies department.

EndoArmor+: Sizing

The EndoArmor+ Surgical Gown is single-use, one-size fits most personal protective equipment supplied with sterilization instructions and validated sterilization parameters to enable the end-user to sterilize the gown prior to being used in sterile surgical procedures. Design features of the EndoArmor+ Surgical Gown allow the gown fit to be adjusted for most users:

- **Knit cuffs** at the end of the sleeves allow the gown to conform to the user's wrist designed for appropriate sleeve length.
- **Hook and loop closure** at the neckline allows the user to adjust neck size.
- **Waist tie** allows users to close the gown body by tying around waist.

EndoArmor+ Dimensions	
Length from Neckline to Hem	125cm
Circumference	140cm
Width	70cm

EndoArmor+: Construction

The EndoArmor+ Surgical Gown is constructed from a polyethylene film laminated with nonwoven spunbond polypropylene that provides AAMI Level 3 liquid barrier performance in the critical zones[2] (*please refer to EndoArmor+ Surgical Gown technical document*).

The EndoArmor+ Surgical Gown back was designed to allow for airflow and breathability to support user comfort. The back of the gown is constructed from spunbond polypropylene and is non-protective.

Boston Scientific

Ordering Information:

Item #	Description	Unit
M00501972	EndoArmor™+ Surgical Gown, AAMI Level 3	Box 100

Sources

1. ANSI/AAMI PB70:2012. Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

2. 926630593 – AAMI PPE Gown Critical Areas Testing Spec Source

3. U.S. Food & Drug Administration. Medical Gowns. Webpage. Accessed Dec 2020. https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns

4. AAMI TIR11-2005

5. ASTM F1671/F1671M-13. Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

6. AATCC Test Method 42-2013. Water Resistance: Impact Penetration Test.

7. AATCC Test Method 127-2014. Water Resistance: Hydrostatic Pressure Test.

All photographs owned by Boston Scientific.

All trademarks are the property of their respective owners.

Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

ENDO-938305-AC

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.BostonScientific.com

2022 Copyright © Boston Scientific Corporation or its affiliates.
All rights reserved