



Cardinal Health™ Surgical Gowns

The right protection for the best care

**You're dedicated to putting patients first.
That's why every day, healthcare providers
like you take on life-changing situations.**

Count on Cardinal Health to help ensure your safety every step of the way with the right surgical gown for every procedure — so you can give the best care.





Table of contents

Materials guide

per Association for the Advancement of Medical Instrumentation (AAMI) level

AAMI Level 3 **3**

AAMI Level 4 **4**

AAMI level guide

Overview **5**

AAMI Levels 3 and 4 **6**

AAMI testing: Level 3 **7**

AAMI testing: Level 4 **8**

Ordering information

AAMI Level 3 gowns **9**

AAMI Level 4 gowns **10**

Contact information **12**

More than a gown

When you choose Cardinal Health, you're getting more than physical products. We're dedicated to making sure you have what is needed to give you peace of mind.



Insights that give your staff every advantage



Our integrity is a part of every product we craft



A portfolio of products that accommodate every need

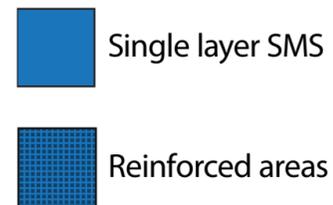


Materials guide

Know the difference. It's about your safety.

AAMI Level 3

AAMI Level 3 disposable surgical gowns are generally made of one type of material: spunbond-meltblown-spunbond (SMS).



Not made with natural rubber latex.

Biocompatibility

Cardinal Health™ Surgical Gowns are tested for and meet the toxicity requirements contained in the ISO 10993 standards for biological evaluation and biocompatibility testing of medical devices.

Flammability standard

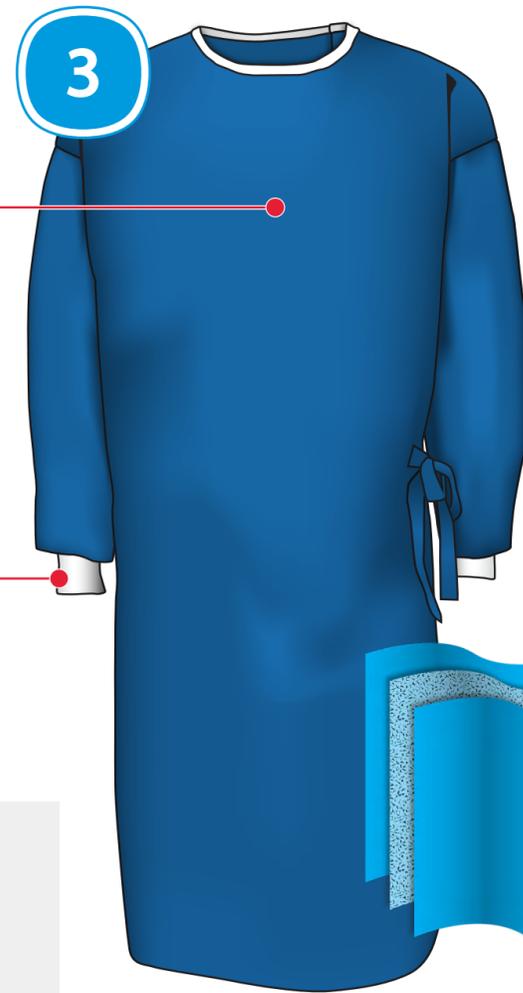
Cardinal Health™ Surgical Gown materials meet the "Standard for the Flammability of Clothing Textiles" for disposable surgical drapes and gowns required by the Consumer Product Safety Commission (16 CFR Part 1610, formerly CS 191-53). The base fabric comprising Cardinal Health™ Surgical Gowns meets Class 1: Normal Flammability, which is the rating required for consumer use. Cardinal Health promotes the safe use of our products and does not recommend placing any ignition or heat source in contact with our surgical gowns.

SMS gown base fabric

Blue SMS nonwoven fabric. Spunbond and meltblown composition is polypropylene.

White cuff

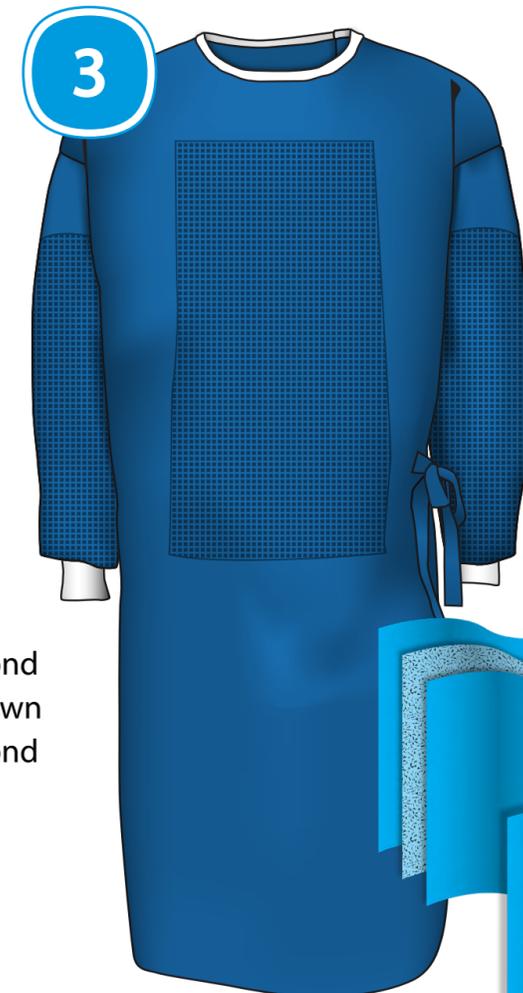
Polyester



Torturous path

Non-Reinforced SMS

The SMS can be used in a single layer like it is in Non-Reinforced.



Dual torturous path

Fabric Reinforced

SMS can also be used in double layer like it is in Fabric Reinforced. This product will typically have different performance in critical zones versus non-critical zones.



Materials guide (continued)

Know the difference. It's about your safety.

AAMI Level 4

AAMI Level 4 disposable surgical gowns all utilize a film layer today to create the AAMI Level 4 barrier.

 Single layer SMS

 Poly reinforced areas

 Single layer SFS

Not made with natural rubber latex.

Did you know?

Fabric reinforced surgical gowns are typically AAMI Level 3. All AAMI Level 4 surgical gowns contain a film barrier. A surgical gown can have different protection levels between critical zones and non-critical zones.

SFS gown base fabric

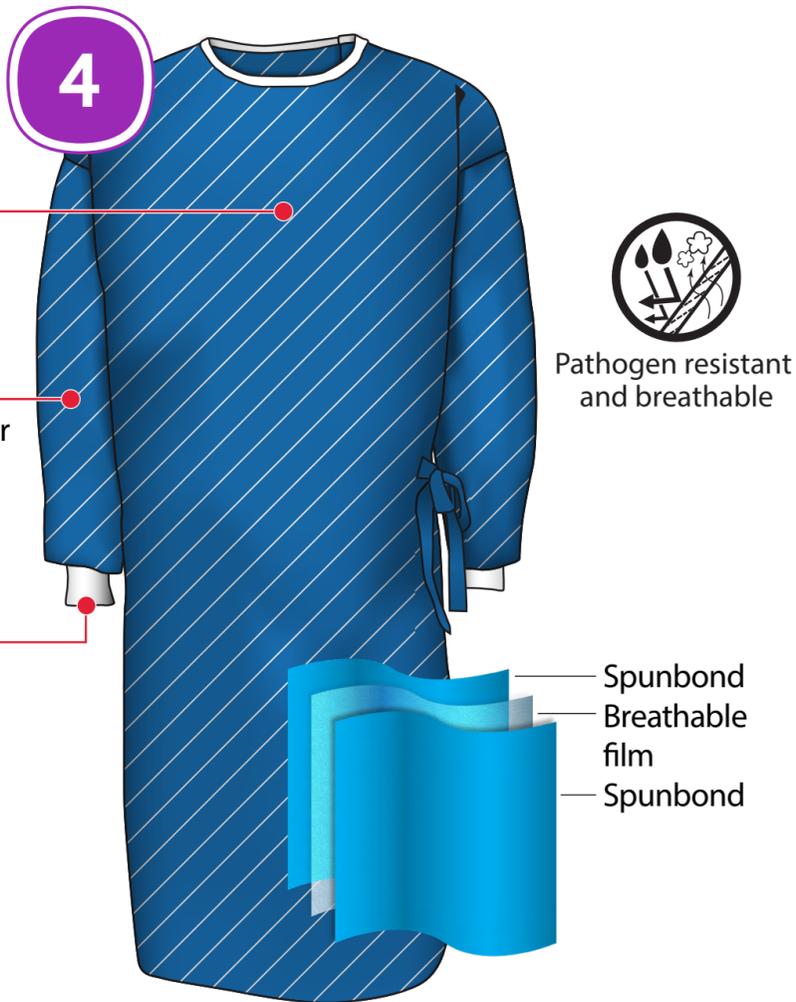
SFS: SMS/Polyester film/SMS

Sleeve

SFS spunbond-polyester film-spunbond. Spunbond composition is polypropylene.

White cuff

Polyester



Breathable SFS

The film can also be embedded in the material like it is in SFS material.

SMS gown base fabric

Blue SMS nonwoven fabric. Spunbond and meltblown composition is polypropylene.

Sleeve

SFS (spunbond-polyester film-spunbond). Spunbond composition is polypropylene.

Poly Reinforced chest reinforcement

Polyethylene film/SMS

White cuff

Polyester



Poly Reinforced

The film can be added as a second layer like it is in Poly Reinforced products. This product will typically have different protection levels in critical zones versus non-critical zones.





AAMI level guide

Knowing the difference makes all the difference

Not all surgical gowns are the same. Beyond fabric preference, sizing and sleeve type, there's one difference that all caregivers should know: AAMI levels.

Surgical gown manufacturers must meet a set of detailed standards set by AAMI. Based on objective tests, AAMI standards measure barrier effectiveness against penetration from blood, bodily fluids and other potentially infectious materials. Knowing the differences between these levels provides an easy way to evaluate the protection needed for a procedure and saves precious time and resources.

96% of OR staff stated they do not completely understand AAMI levels¹

63% of OR staff consider factors other than AAMI Level as the most influential factor in their gown selection¹

33% higher adoption of AAMI Level 4 surgical gowns within Joint Commission accredited hospitals for Gynecology and Cardiology²

Access a complete library of tools developed by Cardinal Health to help educate and reinforce AAMI level education across your OR staff. In addition, our clinical experts can work with your OR staff to select surgical gowns based on AAMI level ratings.



AAMI level guide (continued)

Least protective → Most protective



Minimal



Low



Moderate



High

AAMI established standard ANSI/AAMI PB70:2012 for protective apparel, including surgical gowns, outlining the testing requirements for the four different AAMI levels. The FDA recognizes this standard for all surgical gown manufacturers.

Dress for success

In the clinical setting, success equals safety. At their respective AAMI levels, surgical gowns protect your team from fluid exposure and blood-borne pathogens. Your safety comes first, and donning the right surgical gown at the right AAMI level is a critical first step.

When selecting a gown, consider:

- 1 How much exposure is expected?
- 2 How long will the exposure last?
- 3 What is my role in the procedure?

AAMI levels determined by ANSI/AAMI PB70:2012 — Suggested guidelines are not a substitute for clinician professional judgment and experience.

AAMI Level 3

These surgical gowns have the ability to resist **moderate** fluid exposure

Includes:

- Non-Reinforced
- Fabric Reinforced



AAMI Level 4

These surgical gowns have the ability to resist **high** fluid exposure and blood-borne pathogens

Includes:

- Breathable SFS
- Poly Reinforced

 Indicates an integrated layer of film for added protection

AAMI Level 3 procedures

- Mastectomies
- Arthroscopic orthopedic procedures
- Endoscopic urological procedures such as transurethral prostate resections (TURP)

Cardinal Health™ Non-Reinforced Surgical Gowns

- Features the AAMI Level 3 SMS material you know and trust

AAMI Level 4 procedures

- Any procedure in which the surgeon's hands and arms are in the body cavity
- Orthopedic procedures during which tourniquets are not used
- Open cardiovascular or thoracic procedures
- Trauma procedures
- Cesarean sections

SmartGown™ Surgical Gowns

- Features all-around AAMI Level 4 protection with a unique RESPONSIVEMEMBRANE™ technology to transport moisture from the skin to the surface of the fabric, keeping you cool, dry and comfortable

Procedure suggestions per AAMI TIR11:2005 AAMI levels per ANSI/AAMI PB70:2012



AAMI level guide (continued)

AAMI testing: Level 3

Protective apparel, including surgical gowns, is governed by a set of standards and test methods that all manufacturers must meet.

AAMI has identified American Association of Textile Chemists and Colorists (AATCC) 42 and AATCC 127 as the key test requirements that a surgical gown must pass in order to be labeled AAMI Level 3.

American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) PB70:2012 is the standard that establishes a classification system (Levels 1-4) for protective apparel, including surgical gowns, used in healthcare facilities based on liquid barrier performance using standardized test methods. The U.S. Food and Drug Administration (FDA) has adopted ANSI/AAMI PB70:2012 as the standard by which all surgical gown manufacturers must abide.

AATCC 42 is called the Water Resistance: Impact Penetration Test. It indicates how fabric will resist strikethrough when fluids splash or spray onto the fabric.

AATCC 127 is called the Water Resistance: Hydrostatic Pressure Test. It indicates how fabric will resist strikethrough when water pressure is applied to the surface of the fabric.



Critical zones that must pass

Front chest

Sleeve seam

Sleeve

Front belt*
attachment point

*The front belt attachment must pass if it is in the front chest critical zone.



Testing the gown

AAMI standards call for a surgical gown to meet the requirements mentioned above for AATCC 42 and AATCC 127 in the critical zones in order to be labeled an AAMI Level 3 surgical gown.

What areas are included in the critical zones?

There are typically four different areas that must pass within the critical zones, including two in the front chest and two on the sleeves. If a product passes AATCC 42 and AATCC 127 in all applicable areas, then it qualifies as an AAMI Level 3 surgical gown.



AAMI level guide (continued)

AAMI testing: Level 4

AAMI has identified American Society for Testing and Materials (ASTM) International³ F1671 as the key test requirement that a surgical gown must pass in order to be labeled AAMI Level 4.

ASTM International F1671 is called the Resistance of Materials Used in Protective Clothing to Penetration by Blood Borne Pathogens Test. This is a pass/fail test that an AAMI Level 4 surgical gown must pass. The test method has been specifically designed for modeling penetration of HBV, HCV and HIV. Because these organisms are difficult to use, the test uses a bacteriophage, Phi-X174. Phi-X174 is one of the smallest known viruses, and it is similar in size and shape to HCV, the smallest bloodborne viral pathogen.⁴

A surgical gown's material is subjected to a nutrient broth containing Phi-X174 for a specified time and pressure sequence:

1. Five min. at atmospheric pressure
2. One min. at two PSI (pounds per square inch)
3. 54 min. at atmospheric pressure

The test is terminated if visible liquid penetration occurs before the end of 60 minutes. If no visible liquid penetration is seen, then a sensitive microbial assay is performed to determine pass or fail. Any evidence of viral penetration for a test specimen constitutes a failure.

If a production lot of surgical gowns passes this test in all four surgical gown critical zones, it qualifies as an AAMI Level 4 surgical gown.



Critical zones that must pass

Front chest

Sleeve seam

Sleeve

**Front belt*
attachment point**

*The front belt attachment must pass if it is in the front chest critical zone.



Testing the gown

AAMI standards require a surgical gown to pass ASTM International F1671 in the critical zones in order to be labeled an AAMI level 4 surgical gown.

What areas are included in the critical zone?

There are typically four different areas that must pass within the critical zones, including two in the front chest and two on the sleeves. If a product passes ASTM International F1671 in all applicable areas, then it qualifies as an AAMI level 4 surgical gown.



Ordering information

AAMI Level 3 surgical gowns

Cardinal Health™ Surgical Gowns feature the AAMI Level 3 SMS material you know and trust. Plus, their royal blue color allows you to quickly differentiate between our AAMI Level 3 Non-Reinforced Surgical Gown and AAMI Level 4 SmartGown™ Surgical Gown.

Non-reinforced surgical gowns

Sterile	BNS	Description	Qty. Cs
9505		Small/medium	20
9515	9515NB	Large	20
9545	9545NC	X-large	20
9545ELA		X-large, X-long	20
9575	9575NB	XX-large	18
9575EL	9575ELNA	XX-large, X-long	16
9585	9585N	XXX-large	18
95995	95995N	XXX-large, X-long	18
9599		XXXX-large	18

Non-reinforced scrub nurse* gowns

	90270NB	Large	n/a
	90370NB	X-large	n/a

Fabric-reinforced surgical gowns

9511	9511NB	Large	20
9541	9541NA	X-large	18
9571	9571NA	XX-large	18

Fabric-reinforced scrub nurse* gowns

Sterile	BNS	Description	Qty. Cs
	90970NA	Large	n/a
	91070NB	X-large	n/a

RoyalSilk® Non-Reinforced Surgical Gowns

9518	9518NC	Large	20
9548	9548NC	X-large	20
9578	9578NB	XX-large	18
95998	95998N	XXX-large, X-long	20

RoyalSilk® Non-Reinforced Scrub Nurse* Gowns

	90280NC	Large	n/a
	90380NC	X-large	n/a

Did you know?

Cardinal Health has established a standard color-coding system for quick AAMI level identification on labels, transfer tabs and stickers:

Blue for AAMI Level 3

Purple for AAMI Level 4



9511

9515



Ordering information (continued)

AAMI Level 4 surgical gowns

Cardinal Health™ SmartGown™ Surgical Gowns feature complete AAMI Level 4 protection with a unique RESPONSIVEMEMBRANE™ technology to transport moisture from the skin to the surface of the fabric to help keep clinicians cool, dry and comfortable.

SmartGown™ Breathable Surgical Gowns

Sterile	BNS	Description	Qty. Cs
89005	89005N	Small/medium	20
89015	89015NA	Large	20
89045	89045NA	X-large	18
89075	89075NA	XX-large	14
89085	89085N	XXX-large	12
89095		XXXX-large	12

SmartGown™ Breathable Surgical Gowns with raglan sleeves

39015	39015NA	Large	20
39019	39019N	Large, X-long	14
39045	39045NA	X-large	18
39049	39049NA	X-large, X-long	14
39075	39075NB	XX-large	14
39079	39079NB	XX-large, X-long	14
39099	39099NA	XXX-large, X-long	14
32474	32474NA	X-large, X-long, A-line	16

SmartGown™ Breathable Scrub Nurse* Gowns

	324740NA	X-large, X-long, A-line	n/a
	890015NA	Large	n/a
	890045NA	X-large	n/a



*Scrub nurse gowns are bulk non-sterile (BNS) gowns intended for procedure kits. The gown and hand towel are wrapped in SMS material for placement in the kit. AAMI levels determined per ANSI/AAMI PB70:2012



Ordering information (continued)

AAMI Level 4 surgical gowns

Find the right balance of value, protection and comfort for your AAMI Level 4 surgical gowns with SmartSleeve™ Surgical Gowns from Cardinal Health. SmartSleeve™ Surgical Gowns offer zoned AAMI Level 4 protection along with a breathable sleeve material and breathable back for added comfort.



Poly-reinforced surgical gowns

Sterile	BNS	Description	Qty. Cs
9010	9010NB	Large	20
9040	9040NB	X-large	20
9070	9070NA	XX-large	18

Poly-reinforced scrub nurse* gowns

	90680NB	Large	n/a
	90780NB	X-large	n/a

SmartSleeve™ Poly-Reinforced Breathable Sleeve Surgical Gowns

9011	9011NB	Large	20
9011EL	9011ELNA	Large, X-long	20
9041	9041NA	X-large	20
9041EL	9041ELNA	X-large, X-long	20
9071	9071NA	XX-large	20
9071EL	9071ELNA	XX-large, X-long	20
9560	9560N	XXX-large, X-long	20

SmartSleeve™ Poly-Reinforced Breathable Sleeve Scrub Nurse* Gowns

	90020NA	Large	n/a
	90030NA	X-large	n/a

*Scrub nurse gowns are bulk non-sterile (BNS) gowns intended for procedure kits. The gown and hand towel are wrapped in SMS material for placement in the kit. AAMI levels determined per ANSI/AAMI PB70:2012





Beside you at every step so
you can provide the best care

For more information or to order, please contact your Cardinal Health sales representative, call **877.CARDINAL** or visit **cardinalhealth.com/surgicalgowns**

Reference: **1.** Key Group, AAMI Knowledge Research, June 2017. **2.** July 2017 annualized Cardinal Health™ Presource™ kits that contain surgical gowns and Joint Commission accreditation status per American Hospital Association data released October 2016. **3.** ASTM International, formerly known as American Society for Testing and Materials, is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services. <https://www.astm.org/> **4.** Association for the Advancement of Medical Instrumentation. Technical information report: selection and use of protective apparel and surgical drapes in health care facilities. https://www.aami.org/docs/default-source/products_store/standards/tir11_1510.pdf?sfvrsn=eb81931b_2. Published October 17, 2005. Accessed September 9, 2020.

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