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

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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).

- Single layer SMS
- Reinforced areas

Not made with natural rubber latex.

**SMS gown base fabric**
Blue SMS nonwoven fabric. Spunbond and meltblown composition is polypropylene.

**White cuff**
Polyester

**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.

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

**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.

**Breathable SFS**

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

**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.
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 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

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

Includes:
- Breathable SFS
- Poly Reinforced

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

AAMI Level 4 surgical gowns have the ability to resist high fluid exposure and blood-borne pathogens.

Indicates an integrated layer of film for added protection

Procedure suggestions per AAMI TIR11:2005 AAMI levels per ANSI/AAMI PB70:2012
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) International\(^3\) 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.

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

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### Non-reinforced scrub nurse* gowns

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### Fabric-reinforced surgical gowns

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### Fabric-reinforced scrub nurse* gowns

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## 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
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

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### SmartGown™ Breathable Scrub Nurse® Gowns

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*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.
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

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Poly-reinforced scrub nurse* gowns

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SmartSleeve™ Poly-Reinforced Breathable Sleeve Surgical Gowns

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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


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