

# SIMPLIFIED GUIDE to GOWN GUIDELINES

Guidelines can help in gown selection. But which guidelines? Before you choose your surgical gowns, know the organizations and what their guidelines cover.

## AORN

The Association of periOperative Registered Nurses (AORN) offers **comprehensive guidance**<sup>1</sup> that includes the **types of gown protection needed** for operative and other invasive procedures.



- Must provide a barrier resistant to blood and fluid penetration that is based on the gown's intended use
- Seams and points of attachment minimize penetration of liquid and contaminants
- Resistant to tears, punctures and abrasions
- Made of non-abrasive and non-toxic materials
- Appropriate gown size and sleeve length
- As lint-free as possible



Bacteria-carrying lint can settle in surgical sites and wounds, increasing the risk of postoperative complications.

DETAILS AVAILABLE AT  
[www.aornstandards.org](http://www.aornstandards.org)

## AAMI

ANSI/AAMI PB70:2012 provides standards for **liquid barrier performance**, with ratings for different levels of gown protection.<sup>2</sup>

AAMI addresses fluid protection in the **critical zone**, the gown area where an OR staff member is most likely to come in direct contact with potentially infectious material.



**WHAT IS THE CRITICAL ZONE?** In surgical gowns, it includes much of the sleeves and front (**areas A and B**). Both fabric and construction (sleeve seams and front tie attachment) are tested. The back of the gown (**area D**) may be non-protective.

**WHICH PROTECTION LEVEL?** It depends on the type of procedure.

**AAMI LEVEL 4 HIGHEST FLUID AND MICROBIAL BARRIER PROTECTION** against blood-borne pathogens in critical zones

Needed for long, fluid-intensive procedures. Also for operating on patients with potential blood-borne pathogen risk.

**AAMI LEVEL 3 MODERATE FLUID BARRIER PROTECTION** Used for the widest range of surgical procedures, where moderate fluid protection is indicated

**AAMI LEVEL 2 MINIMAL TO LOW FLUID BARRIER PROTECTION** For use only for low-fluid, minimally invasive surgical procedures, lumps and bumps

**AAMI LEVEL 1 MINIMAL FLUID BARRIER PROTECTION**

FOR DETAILED GUIDELINES, GO TO  
[www.aami.org](http://www.aami.org)

## FDA

Because surgical gowns are classified as Class 2 Medical Devices, they are regulated by the US Food and Drug Administration (FDA).

**CLASS 2 CLEARED MEDICAL DEVICES**

In December 2015, the FDA issued new, more stringent guidance<sup>3</sup> for pre-market verification of surgical gowns. Before performance claims are made on labeling and published materials, surgical gowns are thoroughly reviewed by the FDA to ensure that:

- The gown complies with the claimed liquid barrier protection (ANSI/AAMI PB70 or equivalent standard)
- Performance test data backs up that claim
- Drawings are clearly labeled with barrier protection level and dimensions/location of critical and non-critical zones
- Sample labeling clearly identifies the level of liquid barrier protection (per ANSI/AAMI PB70) as well as directions and indications for use



†FOR MORE INFORMATION, GO TO  
[www.FDA.gov](http://www.FDA.gov) or ask your Halyard Rep.

## How Are Gowns Tested?

To make sure surgical gowns meet the standards set out by these organizations, they undergo a variety of standard tests, including:

**FLUID AND BACTERIOPHAGE BARRIER (ASTM 1671)** Measures resistance of materials used in protective clothing to bloodborne pathogens using viral penetration at 2psi and ambient pressure

**HYDROSTATIC PRESSURE TEST (AATCC 127)** Tests for fluid resistance by measuring the force required for water to penetrate a fabric (including seams)

**GELBO LINT TEST** Determines the relative number of lint particles released from a fabric

**MARTINDALE ABRASION TEST (ASTM D4966)** A visual test of the abrasion resistance of fabric using a standard abrasive surface and a specified force to assess barrier/fabric integrity and lint production

**LASER AND IGNITION RESISTANCE (ISO 11810)** Used to assess the laser-induced flammability properties of gown fabrics, in the oxygen-rich environment of the OR. Includes front and back panels and sleeves.

**CPSC STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES** Measures a fabric's burn rate

TO LEARN MORE AND SEE SOME OF THESE TESTS IN ACTION, GO TO  
[WWW.HALYARDHEALTH.COM/SOLUTIONS/SURGICAL-SOLUTIONS/SURGICAL-GOWNS.ASPX](http://WWW.HALYARDHEALTH.COM/SOLUTIONS/SURGICAL-SOLUTIONS/SURGICAL-GOWNS.ASPX)

1 Burlingame et al, AORN Guidelines for Perioperative Practice 2016 Edition, Vol.1, Jan 2016. §3, II.a  
2 Association for the Advancement of Medical Instrumentation (AAMI), Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (ANSI/AAMI PB70:2012), May 2012, pp 6-7 (§4.2.1-4.2.3)  
3 U.S Food and Drug Administration (FDA), Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings, Guidance for Industry and Food and Drug Administration Staff, Doc. #1500025, pp 1-9.  
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