



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**¹ 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



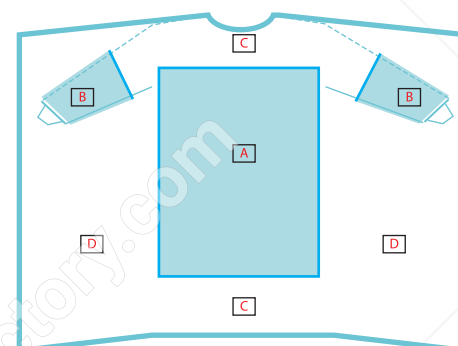
Bacteria-carrying lint can settle in surgical sites and wounds, increasing the risk of postoperative complications.

DETAILS AVAILABLE AT
www.aornstandards.org

AAMI

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

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.

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 guidance³ 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 or ask your Halyard Rep.

How Are Gowns Tested?

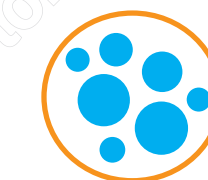
To make sure surgical gowns meet the standards set out by these organizations, they undergo a variety of standard tests, including:



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
[HTTPS://DRAMERICOFACTORY.COM/GUIDE-TO-GOWN-GUIDELINES/](https://dramericofactory.com/guide-to-gown-guidelines/)

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.