SurgiTex™
SURGICAL TEXTILE SOLUTIONS

GOWN SELECTION GUIDELINES

Before choosing your surgical gowns, get to know these organizations and their guidelines.

STANDARD TEXTILE est. 1940

AORN

www.aorn.org

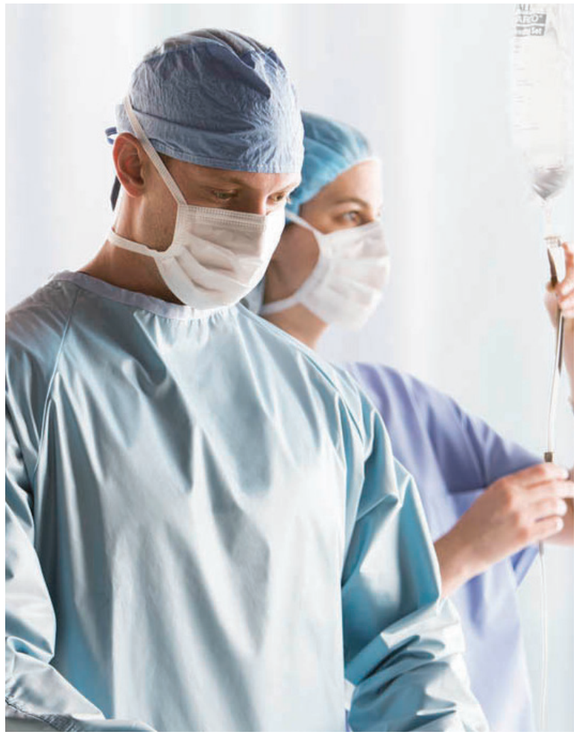
The Association of PeriOperative Registered Nurses (AORN) offers comprehensive guidance[1] that includes the types of gown protection needed for operative and other invasive procedures.

Seams and points of attachment minimize penetration of liquid and contaminants.

Must provide a barrier resistant to blood and fluid penetration that is based on the gown's intended use.

Appropriate gown size and sleeve length.

As lint-free as possible.



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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AAMI

www.aami.org

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 protection level do I need?

Level 4

Highest Fluid & Microbial Barrier

Protection against blood-borne pathogens in critical zones. Needed for long, fluid-intensive procedures and for operating on patients with potential blood-borne pathogen risk.

Level 3

Moderate Fluid Barrier Protection

Used for the widest range of surgical procedures, where moderate fluid protection is indicated.

Level 2

Minimal To Low Fluid Barrier Protection

For use only for low-fluid, minimally invasive surgical procedures, lumps and bumps, Cataracts.

Level 1

Minimal Fluid Barrier Protection

FDA

www.fda.gov

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

In December 2015, the FDA issued new, more stringent guidance[3] 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:

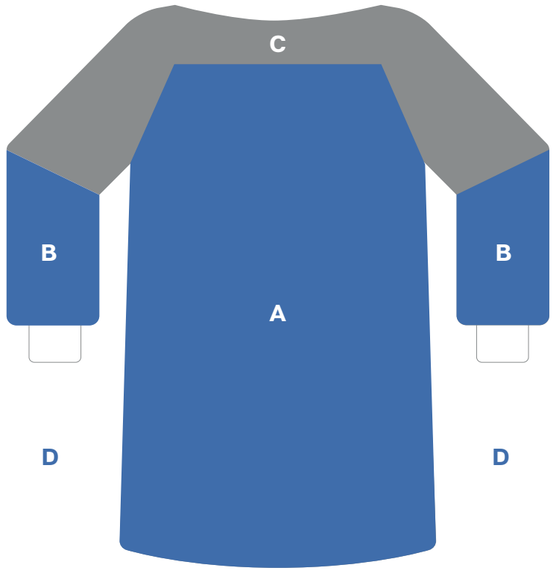
- The gown complies with the claimed liquid barrier protection (ANSI/AAMI PB70 or equivalent standard). Please refer to AAMI Standards column 2.

- Labeling clearly identifies the level of liquid barrier protection (per ANSI/AAMI PB70) as well as directions and indications for use.

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.

See below:



GOWN TESTING

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

This outline provides guidelines for barrier testing of Standard Textile's protective products including Personal Protective Equipment (PPE), surgical drapes, wrappers, and hamper bags.

Test Method

Hydrostatic pressure testing is the preferred method for testing protective textiles with liquid resistant claims.

This tests for fluid resistance by measuring the force required for water to penetrate a fabric. There are several commercially available units. The surface test area of these units should be a minimum of 12.5 square inches (4" circle) with a maximum pressurization rate of 15 psi/minute. Room temperature distilled water is the preferred test medium for hydrostatic testing.

A procedure for operation of hydrostatic units should be based on the equipment manufacturer recommendations.

Frequency of Testing

Each facility should establish a sampling and testing program to monitor the performance of protective items as they age.

Programs with a long-standing history and positive results, i.e., few performance complaints, could employ a random/weekly testing program. However, new programs, products or ones with negative trends may need to employ a statistically based batch or washer load testing program. The frequency of these programs should be based on historical hydrostatic results and results from the field.