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Surgical gowns
Best practices in use and purchasing

New standards, research and innovations are reshaping how hospitals purchase surgical gowns. New pathogens and drug-resistant organisms, combined with an emphasis on reducing healthcare-associated infections (HAI), influence the need for hospitals to reevaluate gown purchasing decisions to optimize patient and staff safety, as well as cost effectiveness.

This white paper describes best practices for choosing surgical gowns. It summarizes standards and guidelines used by federal agencies and professional groups to govern the manufacture and use of gowns. The article helps purchasing managers and end-users ensure safety and cost effectiveness by following the most current research.

Surgical apparel: Getting the safety level right.

Surgical gowns and other apparel (masks, footwear, gloves) serve two purposes: 1. protecting patients from microorganisms carried by the surgical team or patients themselves, and 2. protecting healthcare providers from contact with infectious microorganisms harbored by the patient. Pathogens transmitted through blood, bodily fluids and skin cells can cause dangerous infections including Human Immunodeficiency Virus (HIV), Hepatitis B and C Viruses (HBV and HCV) and the Ebola Virus.[1] Surgical site infections (SSI) are the most common type of healthcare-associated infection[2] and cost $11,000 to $35,000 per incident, costing the industry as a whole $3 billion to $10 billion annually.[3]

For workers' safety and to prevent SSIs, hospitals purchase a variety of surgical gowns for use during procedures. The proper gown varies based on:

- What type of procedure will be performed?
- How long will the procedure last?
- How much fluid will be present?
- What will be the clinician's role in the procedure?

The U.S. Food and Drug Administration regulates surgical gowns as Class II medical devices and has recognized a consensus manufacturing standard since 2004.[4] The Association for the Advancement of Medical Instrumentation (AAMI) and the American National Standards Institute (ANSI) set these standards, most recently in a 2012 update to ANSI/AAMI PB70.[5]

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Testing the gown

AAMI standards require a surgical gown to pass ASTM F1671 in the critical zones in order to be labeled an AAMI level 4 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 ASTM F1671 in all applicable areas, then it qualifies as an AAMI level 4 surgical gown.

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

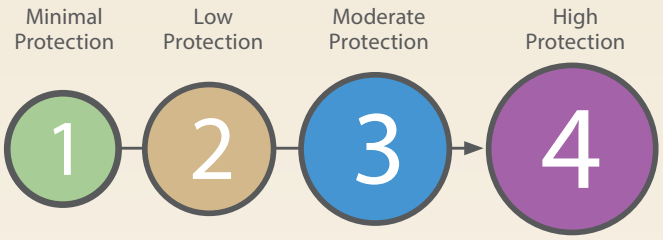
AAMI levels determined per ANSI/AAMI PB70:2012

Surgical apparel: Getting the safety level right *continued*

The AAMI standards establish a classification system that measures protective apparel based on its liquid barrier performance.[6] AAMI uses a range of factors to establish barrier effectiveness, including a material's resistance to water, and blood penetration and efficacy in critical zones (including a gown's front chest, sleeves and sleeve seams).

AAMI ranks barrier protection on a scale of Level 1 (least protective) to Level 4 (most protective), providing an easy-to-understand starting point for evaluating the protection needed for a procedure. For example, a colectomy will likely require AAMI level 4 protection because of the length of the procedure and fluid exposure involved.[7] By contrast, a laparoscopic procedure, performed through a small incision, will require less protection, perhaps AAMI level 3.[8]

AAMI levels and surgical gowns



Relationships between barrier performance and anticipated risks of exposure*

ANSI/AAMI PB70 barrier	Risk of exposure: Fluid amount, fluid spray or splash and pressure on gown	Examples of procedures with anticipated exposure risks
Level 1	Minimal	• Simple excision biopsies • Excision of "lumps and bumps" • Ophthalmological procedures • Simple ear, nose and throat (ENT) procedures
Level 2	Low	• Tonsillectomies and adenoidectomies • Endoscopic gastrointestinal procedures • Open hernia repair • Minimally invasive surgery (MIS) • Interventional radiology or catheter laboratory procedures
Level 3	Moderate	• Mastectomies • Arthroscopic orthopedic procedures • Endoscopic urological procedures (such as transurethral prostate resections [TURP])
Level 4	High	• Any procedure in which the surgeon's hands and arms are in a body cavity • Orthopedic procedures during which tourniquets are not used • Open cardiovascular or thoracic procedures • Trauma procedures • Cesarean sections

*Note: Risks assess fluid amount, fluid spray or splash and pressure on gown. Examples listed are not all-inclusive for every situation, nor is the table a substitute for professional judgment and experience.

AAMI levels determined per ANSI/AAMI PB70:2012

Chart reference: Association for the Advancement of Medical Instrumentation (AAMI): Selection and use of protective apparel and surgical drapes in health care facilities, AAMI Technical Information Report (TIR), No. 11:2005, Arlington, VA, 2005, Author.

Understanding and ensuring safety

AAMI is the standard in surgical gown manufacturing. It is based on objective tests that measure barrier effectiveness against penetration from blood, bodily fluids and other potentially infectious materials. Each gown should have a label attached identifying its AAMI level. Labels on packaging, while an important part of inventory management, are seldom seen by end users.

The FDA discourages the use of words such as "impervious" or "impermeable" because these terms are vague, easily misinterpreted and potentially misleading.[9] Yet, even today, labeling issues continue to complicate surgical gown purchasing decisions. For example, a gown marketed as a "Breathable Film Surgical Gown" containing material meeting a particular material standard may fail to qualify as an AAMI level 4 gown because protection is poor in crucial areas.

In addition to AAMI's safety levels, purchasing managers must consider other selection criteria contained in AAMI Technical Information Report 11 (TIR11).[10] TIR11 considers comfort, drapeability, flammability, lint generation, resistance to tears and other factors. For example, all surgical gowns, no matter what the material, are flammable under the right circumstances, especially in the oxygen-enriched environment of a hospital operating room.[11] Also, some end-users consider AAMI level 4 gowns less comfortable than less protective surgical garments, although innovations in microfibers have reduced comfort concerns in the most protective gowns.

In sum, material managers must educate themselves on which gowns should be used in different circumstances. "All surgical gowns are not created equal; this is an important consideration when trying to decide what level of gown is needed for a surgical or invasive procedure. The AAMI standard addresses the barrier effectiveness of surgical gowns, but OR directors, infection preventionists, safety officers, material managers, and other product committee members should consider many other attributes related to the safety and efficacy of surgical gowns, as well as other protective apparel, when choosing these products."[12]

Cost-effective purchasing

In addition to clinical safety, purchasing managers must consider the costs of buying and maintaining an inventory of surgical clothing. Hospitals may struggle to effectively manage gown purchases and inventory because of a lack of product knowledge and a poor understanding of how barrier protection needs vary.[13] Both under- and over-protection can be a problem. Each facility's overall product mix will depend on the procedures performed. Regardless of the scope and volume of procedures, using fewer products in smarter ways generally results in simpler, more cost-effective buying decisions.[14] Purchasing from a supplier with a full product line makes this strategy easier to execute.

Best practice summary

Materials managers should consider the following strategies to optimize surgical gown purchases:

1. Involve clinical staff in the evaluation process; ask that SSIs and costs be considered, as well as personal preference and comfort.
2. Use the AAMI standard as the starting point for determining the product mix needed in a facility; avoid both under- and over-protection.
3. Streamline product and vendor selection to improve gown choices for end-users while maximizing cost effectiveness and safety for the facility as a whole.

AAMI levels determined per ANSI/AAMI PB70:2012

About Cardinal Health

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1 Considerations for Selecting Protective Clothing used in Healthcare for Protection against Microorganisms in Blood and Body Fluids http://www.cdc.gov/niosh/npptl/topics/protectiveclothing/

2 Surgical Site Infection (SSI) Event. https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf

3 The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. Centers for Disease Control. http://www.cdc.gov/HAI/pdfs/hai/Scott_CostPaper.pdf

4 Medical Gowns, Food and Drug Administration. https://www.fda.gov/medicaldevices/productsandmedicalprocedures/generalhospitaldevicesandsupplies/personalprotectiveequipment/ucm452775.htm

5 PB70: Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities http://www.aami.org/productspublications/ProductDetail.aspx?ItemNumber=1570

6 Considerations for Selecting Protective Clothing used in Healthcare for Protection against Microorganisms in Blood and Body Fluids, Centers for Disease Control. http://www.cdc.gov/niosh/npptl/topics/protectiveclothing/

7 AAMI Levels and Surgical Gowns: Know If You're Protected, p. 19. http://www.pfiedler.com/ce/1191/files/assets/common/downloads/AAMI levels and surgical gowns; know if you.pdf

8 AAMI Levels and Surgical Gowns: Know If You're Protected. P. 19. Ibid.

9 Medical Gowns, Food and Drug Administration. https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM452804.pdf

10 Considerations for Selecting Protective Clothing used in Healthcare for Protection against Microorganisms in Blood and Body Fluids http://www.cdc.gov/niosh/npptl/topics/protectiveclothing/

11 AAMI Levels and Surgical Gowns: Know If You're Protected. P. 20. Ibid.

12 AAMI Levels and Surgical Gowns: Know If You're Protected. P. 18. Ibid.

13 Understanding Barrier-Level Protection of Medical Gowns. http://www.infectioncontroltoday.com/articles/2008/11/understanding-barrier-level-protection-of-medical.aspx?pg=4#content

14 AAMI Levels and Surgical Gowns: Know If You're Protected. P. 22. Ibid.

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