Medical Gowns

Quality Issues with Certain Cardinal Health Surgical Gowns and Packs

On January 11 and again on January 15, 2020, medical device manufacturer Cardinal Health alerted its customers to potential quality issues affecting some of its Level 3 surgical gowns and PreSource procedural packs that contain the gowns.

The FDA is working closely with Cardinal Health to understand and address the quality issues with these products, including the potential risks to users and patients, which specific product lots are impacted, and the potential impact on the supply chain.

For more information, see the statement from Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health, on quality issues with certain Cardinal Health surgical gowns and packs (/news-events/press-announcements/statement-quality-issues-certain-cardinal-health-surgical-gowns-and-packs).

On this page:

About medical gowns

Gowns are examples of personal protective equipment used in health care settings. They are used to protect the wearer from the spread of infection or illness if the wearer comes in contact with potentially infectious liquid and solid material. They may also be used to help prevent the gown wearer from contaminating vulnerable patients, such as those with weakened immune systems. Gowns are one part of an infection-control strategy.

A few of the many terms that have been used to refer to gowns intended for use in health care settings, include surgical gowns, isolation gowns, surgical isolation gowns, nonsurgical gowns, procedural gowns, and operating room gowns.

In 2004, the FDA recognized the consensus standard American National Standards Institute/Association of the Advancement of Medical Instrumentation (ANSI/AAMI) PB70:2003, "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities." New terminology in the standard describes the barrier protection levels of gowns and other protective apparel intended for use in health care facilities and specifies test methods and performance results necessary to verify and validate the newly defined levels of protection:

- Level 1: *Minimal risk*, to be used, for example, during basic care, standard isolation, cover gown for visitors, or in a standard medical unit
- Level 2: *Low risk*, to be used, for example, during blood draw, suturing, in the Intensive Care Unit (ICU), or a pathology lab
- Level 3: *Moderate risk*, to be used, for example, during arterial blood draw, inserting an Intravenous (IV) line, in the Emergency Room, or for trauma cases
- Level 4: *High risk*, to be used, for example, during long, fluid intense procedures, surgery, when pathogen resistance is needed or infectious diseases are suspected (non-airborne)

Top

Surgical Gowns

A surgical gown is regulated by the FDA as a Class II medical device that requires a 510(k) premarket notification. A surgical gown is a personal protective garment intended to be worn by health care personnel during surgical procedures to protect both the patient and health care personnel from the transfer of microorganisms, body fluids, and particulate matter. Because of the controlled nature of surgical procedures, critical zones of protection have been described by national standards. As referenced in Figure 1: the critical zones include the chest from scapula to knees and sleeves from cuff to above the elbow. Surgical gowns can be used for any risk level (Levels 1-4). All surgical gowns must be labeled as a surgical gown.

Top

Surgical Isolation Gowns

Surgical isolation gowns are used when there is a medium to high risk of contamination and a need for larger critical zones than traditional surgical gowns. Surgical isolation gowns, like surgical gowns, are regulated by the FDA as a Class II medical device that requires a 510(k) premarket notification. As referenced in Figure 2, all areas of the surgical isolation gown except bindings, cuffs, and hems are considered critical zones of protection and must meet the highest liquid barrier protection level for which the gown is rated. All seams must have the same liquid barrier protection as the rest of the gown. Additionally, the fabric of the surgical isolation gown should cover as much of the body as is appropriate for the intended use.

Product names may include but are not limited to isolation gown, procedure gown, or protective gown. Since names are not standardized, product labeling that describes its intended use for isolation precautions or liquid barrier protection in moderate or high risk situations fall into this category.

Top

Non-Surgical Gowns

Non-surgical gowns are Class I devices (exempt from premarket review) intended to protect the wearer from the transfer of microorganisms and body fluids in low or minimal risk patient isolation situations. Non-surgical gowns are not worn during surgical procedures, invasive procedures, or when there is a medium to high risk of contamination.

Like surgical isolation gowns, non-surgical gowns should also cover as much of the body as is appropriate to the task. As referenced in Figure 2, all areas of the non-surgical gown except bindings, cuffs, and hems are considered critical zones of protection and must meet the highest liquid barrier protection level for which the gown is rated. All seams must have the same liquid barrier protection as the rest of the gown.

Product names may include but are not limited to isolation gown, procedure gown, or cover gown. Since names are not standardized, when choosing these gowns look for product labeling that describes an intended use for protection in minimal or low risk situations.

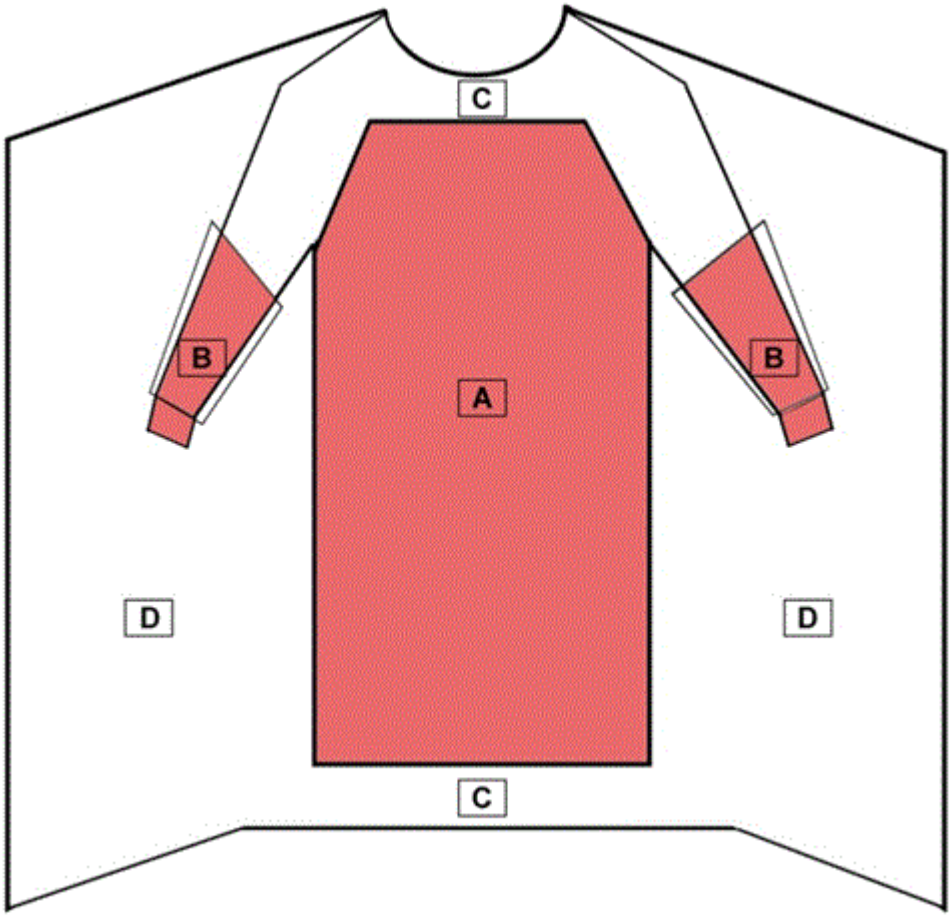

Figure 1 - Critical Zones for Surgical Gowns

- The entire front of the gown (areas A, B, and C) is required to have a barrier performance of at least level 1.
- The critical zone compromises at least areas A and B.
- The back of the surgical gown (area D) may be nonprotective.

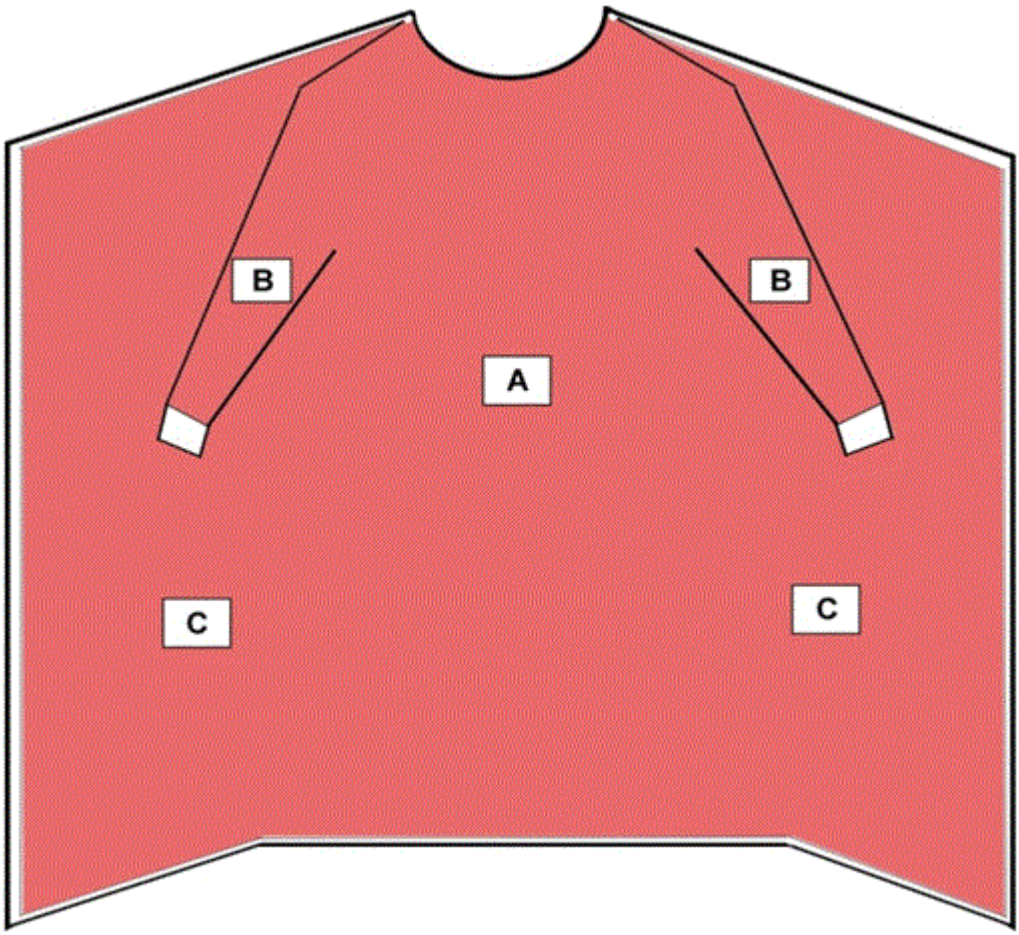

Figure 2 - Critical Zones for Surgical Isolation Gowns and Non-Surgical Gowns

- The entire gown (areas A, B, and C), including seams but excluding cuff, hems, and bindings, is required to have a barrier performance of at least Level 1.
- Surgical isolation gowns are used when there is a medium to high risk of contamination and need for larger critical zones than traditional surgical gowns.

Top

Standards for Gowns

Labeling that shows a product has been tested to and meets appropriate performance standards is one way for users and procurers to determine when to use a particular gown.

The performance of gowns is primarily tested using two consensus standards:

American Society for Testing and Materials (ASTM) F2407 is an umbrella document which describes testing for surgical gowns: tear resistance, seam strength, lint generation, evaporative resistance, and water vapor transmission.

Below is a summary of ASTM F2407 standard recognized by the FDA.

- Tensile Strength, ASTM D5034, ASTM D1682
- Tear resistance : ASTM D5587(woven), ASTM D5587 (nonwoven), ASTM D1424
- Seam Strength: ASTM D751 (stretch woven or knit)
- Lint Generation (ISO 9073 Part 10)
- Water vapor transmission (breathability) ASTM F1868 Part B, ASTM D6701 (nonwoven), ASTM D737-75

American National Standards Institute (ANSI) and the Association of the Advancement of Medical Instrumentation (AAMI): ANSI/AAMI PB70:2003 describes liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

Below is a table summarizing the ANSI/AAMI PB70 standard recognized by the FDA.

Type of PPE	Feature Tested	Standard Designation	Sub headings	Description	Applicability
Gowns	Liquid Barrier Performance	AAMI PB70:2012		Classifies a gown's ability to act as a barrier to penetration by liquids or liquid-borne pathogens based on four levels. The critical protective zones for surgical and non-surgical gowns are defined differently by the standard. While the critical zones designate different protective areas for the different gowns, the levels of protection are the same for both surgical and non-surgical gowns	Liquid barrier performance is not related to the strength of the material. This standard references several other standards
			Level 1	• Used for MINIMAL risk situations • Provides a slight barrier to small amounts of fluid penetration • Single test of water impacting the surface of the gown material is conducted to assess barrier protection performance.	basic care, standard hospital medical unit

Type of PPE	Feature Tested	Standard Designation	Sub headings	Description	Applicability

			Level 2	• Used in LOW risk situations
				• Provides a barrier to larger amounts of fluid penetration through splatter and some fluid exposure through soaking
				• Two tests are conducted to assess barrier protection performance:
				  ◦ Water impacting the surface of the gown material
				  ◦ Pressurizing the material
					Blood draw from a vein, Suturing, Intensive care unit, Pathology lab

			Level 3	• Used in MODERATE risk situations
				• Provides a barrier to larger amounts of fluid penetration through splatter and more fluid exposure through soaking than Level 2
				• Two tests are conducted to test barrier protection performance:
				  ◦ Water impacting the surface of the gown material
				  ◦ Pressurizing the material
					Arterial blood draw, Inserting an IV, Emergency Room, Trauma

			Level 4	• Used in HIGH risk situations • Prevents all fluid penetration for up to 1 hour • May prevent VIRUS penetration for up to 1 hour • In addition to the other tests conducted under levels 1-3, barrier level performance is tested with a simulated blood containing a virus. If no virus is found at the end of the test, the gown passes.	Pathogen resistance, Infectious diseases (non-airborne), Large amounts of fluid exposure over long periods

Conformance with recognized consensus standards is voluntary for a medical device manufacturer. A manufacturer may choose to conform to applicable recognized standards or may choose to address relevant issues in another manner.

Top

Choosing Which Gown to Use

- CDC Guidance for the Selection and use of PPE in Healthcare Settings (http://www.cdc.gov/HAI/pdfs/ppe/PPEslides6-29-04.pdf) (PDF file)

Top

Additional Information

- Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings - Guidance for Industry and Food and Drug Administration Staff (/media/92146/download) (PDF - 319KB)

Top