Medical Gowns

Coronavirus Disease (COVID-19) (/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)

- Surgical Mask and Gown Conservation Strategies - Letter to Healthcare Providers (/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-health-care-providers)
  - FAQs on Shortages of Surgical Masks and Gowns (/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns-during-covid-19-pandemic)
- CDC Prevention and Treatment (https://www.cdc.gov/coronavirus/2019-ncov/about/prevention-treatment.html)
  - Healthcare Supply of Personal Protective Equipment (https://www.cdc.gov/coronavirus/2019-ncov/hcp/healthcare-supply-ppe.html)

Recalled Cardinal Health Surgical Gowns and Procedure Packs

Medical device manufacturer Cardinal Health sent urgent medical device recall letters to its customers for some of its Level 3 surgical gowns and PreSource Procedure Packs that contain those gowns.

For the list of affected gowns (sizes, item codes, catalog numbers, and lot numbers or lot codes), please see the FDA's Medical Device Recalls database information on the recalled gowns (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=&productdescriptiontxt=&productcode=fya&IVDProducts=&rootCauseText=&recallstatus=&centerclassificationtypetext=&recallnumber=&postda and recalled packs (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=&productdescriptiontxt=&productcode=lro&IVDProducts=&rootCauseText=&recallstatus=&centerclassificationtypetext=&recallnumber=&postda

For more information, see the January 2020 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).

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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 transferring microorganisms that could harm vulnerable patients, such as those with weakened immune systems. Gowns are one part of an overall 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 that the gown provides 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)

Regardless of how the product is named (that is, isolation gown, procedure gown, or cover gown), when choosing gowns, look for product labeling that describes an intended use with the desired level of protection based on the above risk levels. Product names are not standardized.

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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 front of the body from top of shoulders to knees and the arms from the wrist 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.

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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.

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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.

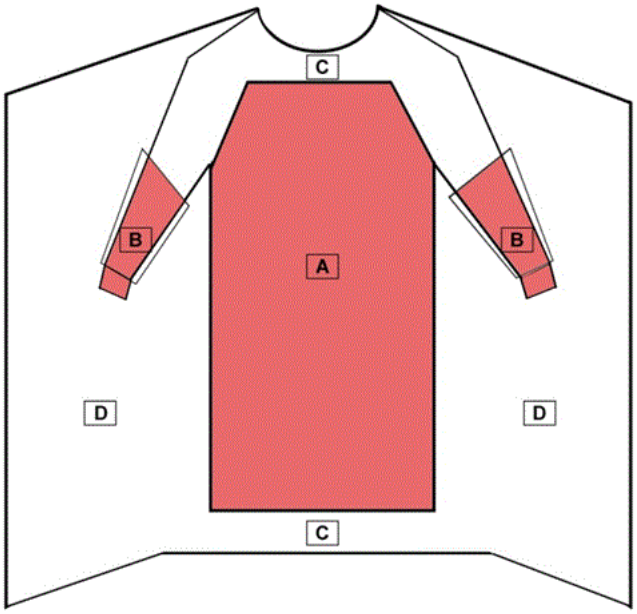

Figure 1 - Critical Zones for Surgical Gowns

- 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.

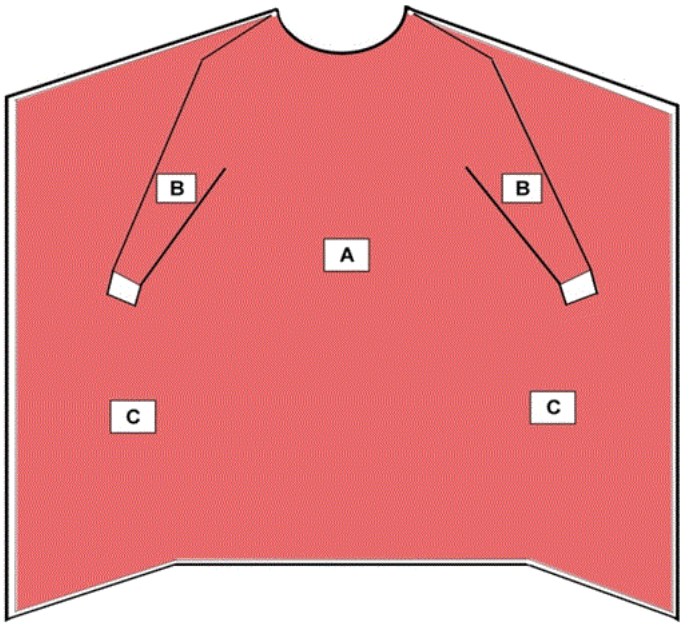

Figure 2 - Critical Zones for Surgical Isolation Gowns and Non-Surgical Gowns

- 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.

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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 tested using 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
			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.

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Sterility Information for Gowns

For a device sold sterile, the FDA recommends sponsors provide the following information as detailed in the final guidance entitled Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile (/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled). This information may include:

- Sterilization method that will be used.
- A description of the method that will be used to validate the sterilization cycle, but not the validation data itself (for established sterilization methods).
- Reference to a standard method (e.g., AAMI Radiation Standard) usually is sufficient for established sterilization methods with FDA-recognized standards.
- The sterility assurance level (SAL) for the device which the firm intends to meet. An SAL of 10^{-6} is required for surgical drapes and surgical gowns which are to be used during surgical procedures.
- A description of the packaging's ability to maintain the device's sterility.
- If sterilization involves ethylene oxide (EtO), the maximum levels of residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol which remain on the device. The levels should be consistent with the draft Federal Register Notice on EtO limits.
- In the case of radiation sterilization, the radiation dose.

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Biocompatibility Information for Gowns

Surgical gowns are devices that are considered a surface-contacting device with intact skin with a contact duration of ≤ 24 hours. The FDA recommends that cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), and irritation or intracutaneous reactivity (ISO 10993-10) is evaluated for a device. For more information about biocompatibility end point assessment, please refer to the final guidance document entitled, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

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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)

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Additional Information

- Guidance: Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings - Guidance for Industry and Food and Drug Administration Staff (/regulatory-information/search-fda-guidance-documents/premarket-notification-requirements-concerning-gowns-intended-use-health-care-settings)
- Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes (/regulatory-information/search-fda-guidance-documents/guidance-premarket-notification-510k-submissions-surgical-gowns-and-surgical-drapes)
- Guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and)

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