SURGICAL GOWNS

PPE Product Information for the COVID-19 Response

DESIGN REQUIREMENTS PER ASTM

- Surgical gowns shall be designed to comply with the barrier performance requirements of AAMI PB70. AAMI PB70 is a liquid barrier performance measure. Gowns are rated from Level 1 – 4 based on permeability. Levels 1 – 3 cannot be considered impermeable, but can provide increasing resistance to liquids. Level 4 is impermeable.
- Surgical gowns which are intended for reuse shall have affixed or attached a means for marking or recording the number of laundering and sterilization cycles to which the specific item has been subjected.
- The sizes of the critical zone(s) of a surgical gown shall be defined by anatomical reference in accordance with AAMI PB70.

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

Biocompatibility

- Materials used in the construction of surgical gowns shall be classified as external devices that contact breached or compromised surfaces for limited exposures and shall pass the
- The selected sterilization process for surgical gowns shall have a sterility assurance level of at least 10-6.

Flame Spread

- Materials used in the construction of surgical gowns shall meet the requirements for Class 1 "normal flammability" in accordance with 16 CFR Part 1610 before and after conditioning

Natural Rubber Latex

- Gowns that contain natural rubber latex should include the latex caution statement (per CFR 801.437), "THIS PRODUCT CONTAINS NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTION"

Product Labeling

Each surgical gown item shall be prominently labeled with the following information:

- Manufacturer name
- Product or style name
- The barrier performance level for the surgical gown
- Product lot or serial number - The product lot or serial number applies to either individually manufactured surgical gowns or to groups or lots of manufactured surgical gowns, and serves as a means for tracing the manufacture of products.
- Size

Sizing

- A description of the manufacturer's sizing system indicating the range of wearer dimensions for which the specific size is intended

Updated: May 11, 2020

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS CONT

Package Labeling

- Each package containing surgical gowns shall be prominently labeled with the same information as required in product labeling including the lot number, unless the same lot number is used for identifying all products in the package. The following additional information shall be provided on the packaging labeling:
- If the gown contains natural rubber latex, it must be labeled with a caution statement. If the gown and its components are composed of materials that are free from natural rubber latex, it is optional for this information to be on a label.
- When requested by the purchaser, the following technical information shall be provided:
  - Manufacturer address and phone number.
  - Detailed information on the performance of all areas of the critical zone(s). Suggested forms of this information are a graphical presentation of the product showing the level of barrier performance of each component, a narrative description of the level of barrier performance of each component or both.
  - The results of each test used for the performance properties of materials and seams for the surgical gown based on this specification.
- For multiple-use products, processing instructions, including a statement of the number of times that the product can be processed and continue to maintain its safety and performance characteristics.
- For multiple-use products, instructions on inspections that can be performed by processors to verify the continued safety and effectiveness of the product.
- A statement indicating the compliance of the surgical gown, including the number year/issue, and revision letter.

The following specifications are considered necessary, but there are no tests available for their validation:

- If present on surgical gowns, the neckline closure should close easily and properly, stay secure during wearing, and open easily for removal.
- All types of waist closures should remain securely closed during wearing. The tie card assembly should allow easy aseptic transfer, for closure and tying. Ties should allow for ease of gown removal.
- The gown should be folded and packaged so that the size and level of barrier performance is visible and can be picked up without contamination.
- The surgical gown should be constructed with appropriate amount of stitching and construction adhesive so that the gown can be opened up freely and easily donned.
- The surgical gown should have no visible tears, cuts, holes, excessive stains or excessive patches.
- The surgical gown should contain no visible foreign matter such as dirt, grease, extraneous fabric or thread on the surface of the gown or folded into the gown.

SURGICAL GOWN DOCUMENTATION REPORT

F2407 – 06 (2013)ε1

TABLE X1.1 Description, Application, and Limitations of Physical Properties Reported for Documentation Purposes

Performance Property	Description	Application and Limitations
Tensile strength[A,B] (ASTM D5034)	A 100mm [4.0-in.] wide specimen is mounted centrally in 50-mm [2.0-in.] clamps of a tensile testing machine and a force applied until the specimen breaks. Values for the breaking force and the elongation of the test specimen are obtained from machine scales, dials, autographic recording charts, or a computer interfaced with the testing machine.	Tensile strength is reported in pounds force (lbf) or Newtons (N). A higher reported tensile strength indicates a stronger material.
Tensile resistance[A,B] (ASTM D5587, Option 1 for woven fabrics, and ASTM D5733 for nonwoven fabrics)	An outline of an isosceles trapezoid is marked on a rectangular material specimen. The specimen is still at the base of the small side of the trapezoid to start the tear. The non-parallel sides of trapezoid marked on the specimen are clamped into parallel grips of a tensile testing machine. The separation of the jaws is continually increased to apply a force to propagate the tear along the specimen. At the same time, the force developed is recorded. The force to continue the tear is calcuated from autographic chart recorders or microprocessor data collection systems. Option 1 uses the average of the highest measured forces as the reported tear resistance. The procedure for testing nonwoven materials is identical except that the maximum recorded force is reported as the tear resistance.	Tear resistance is a measurement of the ease with which a fabric can be torn apart. Tear resistance is reported in pounds force (lbf) or Newtons (N). A higher reported tear resistance indicates a stronger material.
Seam strength (ASTM D1683 for woven and non-woven materials; ASTM D751 for sketch woven and knit materials)	For woven and nonwoven materials, the strength of seam is measured in the same way as material tensile strength. The applied force is longitudinal and perpendicular to the seam. A force is applied until seam failure occurs. An observation is made whether the break occurs at the seam or in the material adjacent to the seam. For stretch woven and knit materials, the burst strength is measured. A specimen, with the sewn seam bisecting it, is securely clamped without tension between grooved, circular plates of the ball burst attachment secured to the pulling (movable) jaw for the constant-rate-of traverse (CRT) testing machine. A force is exerted against the specimen by a polished, hardened steel ball that is attached to the pendulum-actuating (fixed) clamp of the machine, until rupture occurs.	Seam strength is reported in pounds force (ibf) or Newtons (N). A higher reported seam strength indicates stronger seams, that are less likely to seperate or break open when garments are strained through use.
Linting (ISO 9073 Part 10)	This test uses a device which subjects a rectangular material specimen to a combined twisting and compression action in a test chamber. During the flexing, air is withdrawn from the chamber and particulates in the air stream are counted and classified in a particle counter. Depending on the choice of counter, the size ranges can fall within the limits of 0.3 or 0.5 to 25 micron particle sizes.	The particles that are counted during the test may be airborne debris (dust) or fragments from fibers, binders or other process treatments. Higher particle counts indicate materials that lint more readily. Reproducibility is only moderate in absolute numbers but rankings are very reproducible, particularly when testing is conducted at the same laboratory for the materials that are being compared. Comparison between materials must be made for the same range of particle size.
Evaporative resistance (ASTM F1868, Part B)	The test involves a guarded hot plate that is heated to skin temperature, saturated with water, and covered with permeable material that allows vapor to pass through, simulating human sweating. The hot plate and specimen are placed in an atmospheric chamber, where the air temperature, relative humidity, and air velocity are tightly controlled. First, the resistance to evaporation of water vapor is measured for the bare plate. The evaporative resistance is measured by relating the power needed by the plate for maintaining a constant temperature to the difference in water vapor pressure in the atmospheric chamber and the pressure at the plate surface.	Evaporative resistance is intended to be a measurement of material comfort. Test results are reported in pascal meters squared per watt (Pa m^2/W). Lower values of evaporative resistance indicate materials that permit a higher amount of water vapor to go through (under test conditions). This test permits evaluation and discriminates performace among all fabrics, films, coating, and multilayerd material systems; however, some extremely lightweight, single layer materials does not maintain contact with the plate.
Water vapor transmission resistance rate (ASTM D6701)	A dry chamber, guard film, and a wet chamber make up a diffusion cell in which the materials is sealed. A first test is made of the water vapor transmission rate of the guard film and air gap between an evaporator assembly that generates 100% relative humidity. A sensor produces an electrical signal, the amplitude of which is proportional to water vapor concentration. The electrical signal is routed to a computer for processing. The computer calcuates the transmission rate of the air gap and guard film and stores the value for further use. The material is the sealed in the test cell and the apparatus started in the test mode. As before, the electrical signal representing the water vapor is sent to the computer which then calcuates the transmission rate of the combination of the air gap, the guard film, and the test barrier. The computer then uses this information to calcuate the water vapor transmission rate of the material being tested. The computer determines when the measured results indicate that the specimens have reached equilibrium values and when the testing is considered finished.	Water vapor transmission rate is intended to be a measurement of material comfort. Test results are reported in grams of water vapor per square metre of fabric per day (g/m^2/day). Higher water vapor transmission rates indicate materials that allow greater water vapor transfer through the materail (under test conditions). This test is generally applied to nonwoven fabrics and plastic barrier materials; however it does not discriminate performance of multilayer material systems.

[A]These properties are reported in the two directions based on the way the material is made one value represents the direction parallel to the roll (warp or machine direction); the other direction represents the direction perpendicular to the roll (fill or cross machine direction).
[B]Measurement of tensile and tear strength properties may not be indicative of snag or puncture resistance. There are no generally accepted test methods for snag or puncture resistance available at this time.