

It's time for superior protection

AAMI Level 4

Flyte and SurgiCool Togas

As you and your facility take a hard look at the costs and causes of hospital-acquired infections, there's never been a better time to insist upon an effective layer of protection for your patients and caregivers alike.

Stryker's Flyte and SurgiCool Personal Protection Togas are classified as AAMI Level 4, the highest rating possible. SurgiCool Togas have AAMI Level 4 protection in critical zones, while Flyte Togas offer additional protection with AAMI Level 4 fabric as the base material in the hood.

Levels of classification for surgical gowns under AAMI PB70:2012:

Level 4 – Gowns

Surgical gowns and protective apparel with critical zones that demonstrate the ability to resist liquid and viral penetration in a laboratory test. ASTM F1671 (Standard test method for resistance of materials used in protective clothing to prevent penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system).

The critical zones on the Flyte and SurgiCool Togas pass the ASTM F1671 for viral penetration test, meeting the requirements of a Level 4 barrier in the AAMI standard.

Level 3 – Gowns and drapes

Describes surgical gowns, other protective apparel, surgical drapes and drape accessories that demonstrate the ability to resist liquid penetration in two laboratory tests. AATCC 42 Water resistance: Impact penetration test and AATCC 127 Water resistance: Hydrostatic pressure test. For Level 3 classification, the test criterion for AATCC 127 performance is set at a higher value than for Level 2.

Level 2 – Gowns and drapes

Describes surgical gowns, other protective apparel, surgical drapes and drape accessories that demonstrate the ability to resist liquid penetration in two laboratory tests, AATCC 42 Water resistance: Impact penetration test and AATCC 127 Water resistance: Hydrostatic pressure test.

Level 1 – Gowns and drapes

Describes surgical gowns, other protective apparel, surgical drapes and drape accessories that demonstrate the ability to resist liquid penetration in a laboratory test, AATCC 42 Water resistance: Impact penetration test.

AAMI Level 4 – Flyte and SurgiCool Togas

What is AAMI?

The Association for the Advancement of Medical Instrumentation (AAMI), a nonprofit organization founded in 1967, is a unique alliance of nearly 6,000 members from around the world united by the common goal of increasing the understanding and beneficial use of medical instrumentation. AAMI is the primary resource for the industry, the professions and government for national and international standards.


What is AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities?

This standard was developed by the AAMI Protective Barriers Committee. It establishes a system of classification for protective apparel such as the Flyte and SurgiCool Togas, based on their liquid barrier performance. The Centers for Disease Control and Prevention’s Guideline for the Prevention of Surgical Site Infection also sets forth the recommendation that drapes and gowns be impermeable to liquids and viruses.

Under AAMI PB70:2012, a surgical garment may be categorized as Level 1, Level 2, Level 3 or Level 4.*

Why AAMI Level 4?

Expected use conditions and recommendations for each AAMI level. Sourced from AAMI: Selection and Use of Protective Apparel and Surgical Drapes in Health Care Facilities (AAMI TIR11:2005).

AAMI level	Risk of exposure			Examples of procedures with associated risk
	Fluid amount	Fluid spray	Pressure on gown	
Level 1	Minimal	Minimal	Minimal	Simple ENT, ophthalmological and biopsy procedures.
Level 2	Low	Low	Low	Minimally invasive surgery, endoscopic procedures, radiology or catheter lab procedures.
Level 3	Moderate	Moderate	Moderate	Endoscopic urological, mastectomies, arthroscopic orthopaedic and open gastrointestinal and genito-urinary procedures.
Level 4  Flyte and SurgiCool Togas	High	High	High	<ul style="list-style-type: none"> Any procedure in which the surgeon’s hands/ arms are within the body cavity Orthopaedic procedures without a tourniquet Open cardiovascular or thoracic procedures Trauma procedures Caesarean sections

- AAMI has adopted the ASTM F1671 evaluative test method for viral penetration to establish minimum barrier performance requirements for procedures that involve large blood volume, contact with the patient and blood, and possible exposure to blood-borne viruses that can pose significant risk to life and health.
- The pressure levels involved in testing for viral penetration for level 4 are more than twice the levels required for hydrostatic pressure in level 3.

*For a complete copy of AAMI PB70:2012, visit their website at www.aami.org.