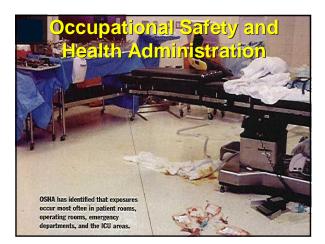
Creative Technologies Worldwide

Barrier Performance According to AAMI PB70

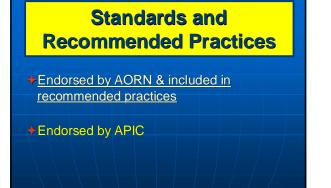
Medical Textiles Network and Biocomplexity Workshop University of California, Davis October 8, 2007

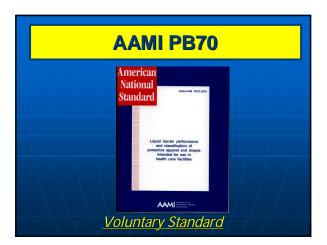
P. Brown, W. L. Gore & Associates, Inc.



FDA Medical Device Regulations

- AAMI PB70 is formally recognized by FDA
- AAMI PB70 is the basis for new barrier claims/labeling





Purpose

 Establish minimum performance requirements with a uniform classification system to help endusers select the most appropriate protective barrier products for the intended application

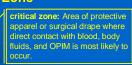
AAMI PB70

- ► Reusable & Disposable
- ▶ Drapes and Protective Apparel With Barrier Claims
- Minimum Barrier, Classification, & Labeling Requirements
- ▶ Four Barrier Performance Classifications
- Classification Based on Weakest Critical Zone Component
- Acceptable Quality Level = 4%
- ▶ End-of-life Is Predetermined for Reusable Products

AAMI PB70 Barrier Properties barrier properties: Ability of a protective <u>product</u> to resist the penetration of liquids and liquidborne microorganisms. For 2 Recretative references The bissues occurrents contents in the first sectors, contribut providers of an internal sectors of an internal sectors of a content sectors and an address of an address of an internal sectors and address of an address of an address of an address of address of a content sectors and address of a content sectors and address of a Constraints and a second purposes of this standard, levels Celebritors 3 associate public line (JAG), for a contrast series of line, the quality line that for the paperse of month indextool is the interface (Joint and Contraster). defined and classified according In terms of the second se to the barrier properties of the <u>critical zone</u>. (See Table 1.) Test Result AATCC 42:2000 AATCC 42:2000 ≤4.6 g ≤1.0 g Made and all help have in advances and made for human leng fields. Aurgour object when every contact with socio, body fives, and ≥ 1.0 g ≥ 20 cm ≤ 1.0 g ≥ 50 cm body faile aimain orthosi zane. An fail is most body to ca orthosi zone war AATCC 127:1998 AATCC 42:2000 . orant Element com The second distribution of MECHANIC Access that is a province of the tests and the test of the tests and the test of the tests of the test of tests of the test of tests of the test of tests of t AATCC 127:1998 ASTM F1671:2003 (surgical gowns and other protective apparel) ASTM F1670:2003 (surgical drapes and drape accessorie) epiperent). NOTO-Ten dealeró des sel aldens l'a propriate d'devolaritation persente leui polari aj gante fait mayte suad in the chanag, destriction, devolationater, et destabilitar et reducidences Pass

AAMI PB70 Critical Zone





critical zone component: Element, constituent, or item incorporated into the critical zone, including the materials, seams, and points of attachment.

AAMI PB70 Design Requirements



forging space, Source protective, spaces, kurging rights, private, the stress space has a strategies of an isolation pre-sentational of the stress stress stress stress stress stress stress and stress stress stress constructive. In controls, there are also all stress stress stress and stress stress stress stress stress stress stress and stress to be stress stre

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Level 3: When tested to solar solutions is according with APTOD 42 (report potential) and APTOD 47 (hydrodate pressure) and under the conditions specified in 52.5, all orbital prime components shall have a fibetim apply pairs from ones then 53 pairs a hydrodate maintenes of all last 50 cm, with an AQL of 4.5. The statistical institution of the single of the standbarry production individual information, as specified in 55.5. Lend 4 burglost genes and after protective append; When a singlest gene or ofter han of protective append; is burglost for equiptings in tradewidtage Photo's in according with ADMS (MP) and under the concerns therein the equipting of the state of the concerns of the state of the st

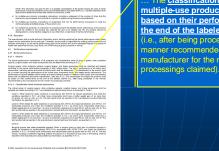
The <u>critical zone of a surgical</u> gown or other protective apparel (excluding isolation gowns) shall, at a minimum, comprise the front a minimum, comprise the front area of the gown from chest to knees and the sleeves from the cuff to above the elbow. The manufacturer shall define the exact dimensions of the critical

zone and shall, as specified in 4.1.3(a), provide detailed information on the barrier performance of each critical zone <u>component</u>. As specified in 4.1.3(b), the manufacturer also shall provide detailed information on the barrier performance of areas outside the critical zone.

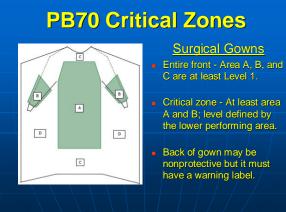
AAMI PB70 Classification and Labeling Surgical gowns, other protective Other-his elements on side is the of a pathod exemption of the setter's from the same of the setter of the se apparel, surgical drapes, and drape accessories shall be classified and labeled according to the barrier performance properties of their critical zones. The barrier performance of all critical zone components, including seams and The sound have shall prove substant identifies a value training the laster party means classification and an industrial set for an endown. Thereafter, for particular is required to be stading plateaux classification of postant and its involving to (a) for an endown. Thereafter, for product and (a) for a delayed and append a separate of hards many planets in classification (a) and (b) and (b) approximation of (b) and a delayed and append a separate of and many planets are stading and (b) and (b) and (b) approximation of the stading of the separate of hards many planets are stading and (b) approximation of the stading of the

points of attachments, shall be determined. The classification of the product shall be a number denoting the performance of the critical zone component having the lowest barrier performance.

AAMI PB70 Classification and Labeling of Multiple-use



The classification of multiple-use products shall be based on their performance at the end of the labeled use-life (i.e., after being processed in the manner recommended by the



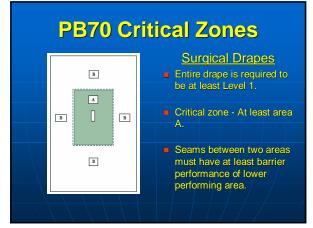
- C are at least Level 1.
- A and B; level defined by the lower performing area.

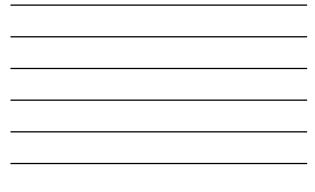
PB70 Critical Zones



Isolation Gowns

- Entire gown, including seams but excluding cuffs, hems, and bindings, is required to be at least Level 1.
- Critical Zone Entire gown.





AAMI PB70 Determining the End-of-Life

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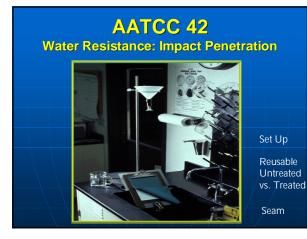
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4.1.3 Technical information (c) for multiple-use products, processing instructions, including a statement of the number of times that the product can be processed and continue to maintain its safety and performance characteristics (d) for multiple-use products, instructions on inspections that can be performed by processors to verify the continued safety and effectiveness of the product and

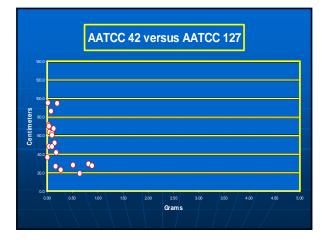
safety and effectiveness of the product and e) for multiple-use products, an instruction to processors that if the labeled barrier performance of the product cannot be verified or the product has reached the end of its labeled use life, the product should be downgraded to a nonprotective eaterony of use rather then a lower lovel category of use rather than a lower level of barrier performance.

Test Methods Test Methods AAMI PB70 Level 1, 2, 3 AATCC 42 **AATCC 127** Level 1, 2, 3 **ASTM F1670** Level 4 - Drapes **ASTM F1671** Level 4 - Apparel

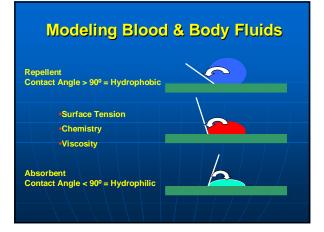












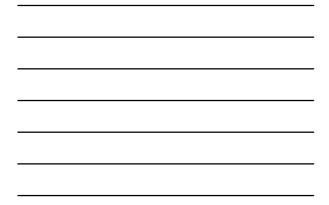








KSU Report						
Correlation Coefficients						
	ксс	AATCC	Mason	ASTM	ASTM	GORETM
KCC Test	Test NA	42	Jar	1 psi	2 psi	Elbow Lean
AATCC 42	.92*					
Mason Jar	.69	.75				
ASTM 1 psi	.38	.25	.54			
ASTM 2 psi	.60	.49	.37	.59		
AATCC 127	.92*	.75	.56	.63	.74	
GORETM	.61	.50	.38	.60	.98*	.75
Elbow Lean						
KSU IER Report #90-07A				* Signifi	cant @ 0.	01 Level



ASTM F1670 Resistance to Penetration by Synthetic Blood

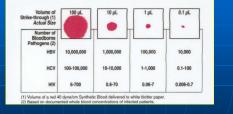


Disposable

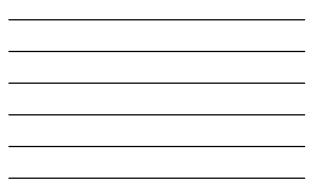
Disposable Procedure B

Reusable Procedure A With & Without Seam

Detecting Strike-through

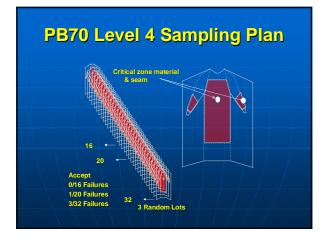


3.27 Strike-through: Passage of a liquid that could contain microorganisms through a barrier product (including it's seams and/or points of attachment).

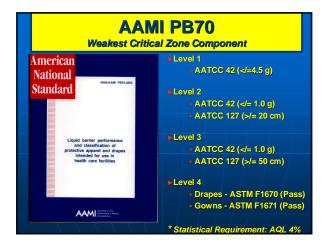










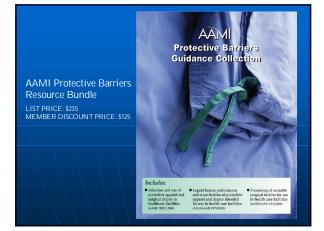




Advantages of AAMI PB70

- Requires Identical Labeling for Reusable and Disposable Products
- Addresses All Critical Zone Components
- Test Methods & Limits Provide More Discrimination in Barrier Performance
- ▶ Establishes Higher Statistical Confidence
- Helps Prevent Reuse Beyond Defined Life

	and	Drapes i	in Health	Use of Protective Apparel Care Facilities formance and anticipated exposure risks
ANSI/AAMI PB70 Barrier	Anticipated Risk of Exposure			Examples of Procedures with
Performance	Fluid Amount	Fluid Spray or Splash	Gown or Drape	Anticipated Exposure Risks
Level 1	Minimal	Minimal	Minimal	Simple/excisional biopsies Excision of "lumps and bumps" Ophthalmological procedures Simple eye, nose, & throat (ENT) procedures
Level 2	Low	Low	Low	Tonsille ctomies & adenoide ctomies Endoscopic gastrointestinal procedures Simple orthopedic procedures with tourniquets Open hernia repair Minimally invasive surgery
Level 3	Moderate	Moderate	Moderate	Mastectomies Anthroscopic orthopedic procedures Endoscopic urological procedures (e.g. transurethral prostate resections) Open gastrofurological procedures
Level 4	High	High	High	Any procedure with surgeon's hands & arms in a body cavity Orthopedic procedures without a tourniquet Cardiovascular / thoracic procedures Trauma procedures Caesarean sections



Impact/Long Term View

- + PB70 standard puts compliant reusable and disposable products on an even playing field
- Reusable manufacturers/processors must invest in PB70 compliant products, processes, & quality systems to succeed
- + PB70 will become the "standard of care" and impact the development of other national & international standards

Other Important Factors

Protection	Comfort			
 Good barrier 	Cool gowns			
 Good design 	 Warm drapes 			
 Strong / durable 	 Soft & light 			
General S&E	Cost			
 Biocompatible 	 Compliance 			
Sterile	 Acceptable quality 			
Flame resistant	 <u>Environmental impac</u> 			
Lint resistant	Minimize waste			

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