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Technical Information Report

AAMI TIR11:1994

Selection of surgical gowns and drapes in health care facilities

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TIR11 Selection of Surgical Gowns and Drapes

Selection of Surgical Gowns and Drapes in Health Care Facilities

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NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

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FOREWORD

This technical information report (TIR) was developed by the AAMI Protective Barriers Task Force and approved for publication by the AAMI Standards Board. The TIR is intended to provide technical information that will assist health care personnel in the selection of surgical gowns and drapes, covering such subjects as types of protective materials used in the construction of surgical gowns and drapes, the

safety and performance characteristics of protective materials, prepurchase evaluation of surgical gown and drape products, care of surgical gowns and drapes, and pertinent medical literature.

The safety and performance of a surgical gown or drape depend not only on the materials from which it is fabricated but also on product design. There is considerable variation in design among commercially available surgical gowns and drapes. The particular gown or drape design chosen should be commensurate with the protective materials used in construction, the intended application, and the manner in which the product will be integrated with other protective products (e.g., boots, face shields) into a complete protective system. This TIR addresses the characteristics of protective materials in some detail, touches on the importance of design, and discusses various issues applicable to a surgical gown or drape product as a whole. Currently, however, there are no standard laboratory test methods that evaluate the impact of product design, so it is recommended that health care personnel screen products based on material test data (see Chapter 4 of the TIR) and then evaluate the safety and performance of selected surgical gown and drape products in actual use (see Chapter 5).

Like any other AAMI technical information report, this TIR is not a performance standard. It is not intended to establish minimum safety and performance criteria, and none of its provisions should be so interpreted. This TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving technology and because it does not treat all issues associated with surgical gowns and drapes in depth, readers are encouraged to consider information from other sources and, in particular, to keep abreast of the relevant medical literature.

Suggestions for the improvement of this TIR are invited. Comments and/or recommended revisions should be sent to: Technical Programs, AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

SELECTION OF SURGICAL GOWNS AND DRAPES IN HEALTH CARE FACILITIES

1 Introduction

Traditionally, surgical gowns and surgical drapes have been intended to help prevent wound infections by providing a barrier between nonsterile and sterile areas. In recent years, with the advent of the acquired immune deficiency syndrome (AIDS) and the increasing number of hepatitis B and hepatitis C infections among health care personnel, the protection of the surgical team has become an important concern.

Surgical gowns and drapes are fabricated from either multiple-use materials or single-use materials. These two basic types of products each have advantages and disadvantages. In addition, within each of the two broad categories, there is considerable variation in design and performance characteristics, which stems from trade-offs in economy, comfort, and the degree of protection required for particular surgical procedures. Consequently, health care personnel are faced with an extremely complex decision-making process when choosing the types or performance levels of products that will best serve their needs.

This technical information report (TIR) is intended to assist health care personnel in the selection of surgical gowns and drapes that are listed by and have received marketing clearance from the Food and Drug Administration (FDA). These products are classified as Class II medical devices and, under the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990, are subject to the FDA's premarket notification (510[k]) and medical device reporting (MDR) regulations. (For new or changed products introduced to the market since May 28, 1976, manufacturers are required to submit a premarket notification to FDA. Products found to be substantially equivalent to existing products are "cleared" by FDA for marketing; this clearance for marketing does not constitute FDA approval of the product's safety and effectiveness.) In addition, good manufacturing practices (GMPs) must be employed in the manufacture and commercial reprocessing of these devices, and they must be labeled in accordance with FDA requirements.

This report is also meant to serve as a resource that health care professionals can use when directing

questions to manufacturers about the performance characteristics of specific products.

The scope of this report includes:

- definitions of terms;
- types of protective materials;
- safety and performance characteristics ;
- selection and user evaluation;
- care of surgical gowns and drapes;
- an annex providing a brief review of relevant literature;
- an annex listing standard test methods used to evaluate safety and
- performance characteristics.

This TIR may not cover all the requirements that a health care facility may deem necessary to select a product, nor does it address criteria for evaluating experimental products.

2 Definitions of terms

barrier properties: ability of a material to resist the penetration of liquids and/or microorganisms.

NOTE—There are four general categories of barrier properties:

- **liquid-resistant material:** material that inhibits the penetration of liquids.
- **liquid barrier material:** material that prevents the visible penetration of liquids.
- **microbial barrier material:** material that prevents the penetration of microorganisms.
- **liquid-proof material:** material that prevents the penetration of liquids and microorganisms.

fenestration: opening provided in surgical drapes to allow access to the surgical site.*

fluid: "liquid or gas; ...composed of molecules which freely change their relative positions without separation of the mass."**

incise drape: adherent plastic film affixed to the patient's skin or over the primary drape during the draping procedure. This film usually extends beyond the fenestrated area of the drape, including the incision site; the incision is made by cutting through the film adhering to the patient's skin.*

liquid: "substance that flows readily in its natural state; ...neither solid nor gaseous."**

microbial model: microorganism which simulates human pathogenic microorganisms in size, shape, and concentration and which can be employed in testing the microbial barrier properties of protective materials.

nonwoven fabric: as defined by the Association of the Nonwoven Fabrics Industry (INDA), a sheet, web, or batt of natural and/or manmade fibers or filaments, excluding paper, that have not been converted into yarns and that are bonded to each other by any of several means.***

ply: single sheet or layer of fabric. Two-ply fabric, for example, is composed of two superimposed layers of fabric.****

reinforced area: region of some surgical drapes or gowns in which the base fabric has been supplemented with one or more plies of material for the purpose of strengthening the fabric, rendering it more resistant to liquids, and/or increasing its absorbency.

strike-through: penetration of a liquid or microorganism through a fabric.****

surface tension: measure of the degree to which a liquid can wet a material. The lower the surface tension, the more easily the liquid wets a material.

woven/knitted fabric: as defined by the American Reusable Textile Association (ARTA), a fabric

constructed from yarns made of natural and/or synthetic fibers or filaments that are woven or knitted together to form a web in a repeated interlocking pattern.

3 Types of surgical protective materials

A great many materials and manufacturing technologies have evolved in the attempt to meet the conflicting criteria for a safe, effective, and comfortable surgical protective barrier. Each type of material offers advantages and disadvantages in its safety and performance characteristics, and each may be more suitable for some uses than others. This chapter provides a general description of the major types of protective materials available at the time this TIR was drafted.

Multiple-use materials

"Multiple-use materials" for surgical drapes and gowns is a general classification encompassing a wide range of fabrics and technologies. The common element to all is their ability to be reprocessed and used repeatedly.

Traditional materials

The use of surgical fabrics began with what was readily available. Thus, hospital sheeting (cotton muslin) was the primary fabric used beginning in the late 19th century. Little changed in the use of these fabrics until the early 1970s when tightly woven fabrics with water-repellent chemical finishes were adopted for surgical use. The following three fabrics were the most commonly used during this era.

All-cotton muslin (140-thread-count muslin): A loosely woven fabric which is soft, absorbent, drapeable, and extremely porous. Since it is readily permeable, this material does not possess any liquid-resistance capability. In addition, it tends to abrade easily and generate lint.

Blended sheeting (180-thread-count percale): A polyester and cotton blended sheeting that has permanent press characteristics, but otherwise exhibits the same performance characteristics as muslin.

"T280 barrier" (280-thread-count, 270-thread-count, 272-thread-count, 175-thread-count): A tightly woven cotton or polyester and cotton blended fabric. This was the first reusable fabric with a water-repellent chemical finish. The fabric was liquid-resistant when new, but resistance to liquid penetration diminished quickly with repeated washing, drying, sterilization, and use cycles.

Advanced materials

In the 1980s, a new generation of surgical textiles with consistent, multiple-use protective qualities was developed. Although reusable, more consistent barrier properties, reduced flammability, low lint generation, and extended durability distinguished this group from its traditional reusable fabric predecessors. The following two classifications of products encompass all the known varieties available today:

Polyester sheeting: A tightly woven fabric made of continuous-filament synthetic yarn which is chemically finished and may be calendered to enhance liquid penetration resistance. The yarns in these fabrics may also be made from very fine filaments, sometimes called microfibers.

Composite materials: Combinations of woven or knitted fabrics that are "engineered" to obtain enhanced performance characteristics by laminating or coating them with various types of films that provide increased protection against strike-through (see the section, "Reinforcement of Multiple-Use and Single-Use Products").

Single-use materials

Single-use surgical gowns and drapes are commonly constructed of nonwoven materials, alone or in combination with materials which offer increased protection from liquid penetration, such as plastic films.

Nonwoven materials for surgical applications were developed and introduced in the 1960s in an attempt to

overcome the deficiencies in liquid penetration resistance of 140-thread-count cotton muslin. Nonwoven materials are engineered fabrics, which rely on fiber bonding technologies (thermal, chemical, or physical) to provide integrity and strength rather than on the interlocking geometries associated with woven and knitted materials. The basic raw materials comprising nonwovens are various forms of natural (e.g., wood pulp, cotton) and synthetic fibers (e.g., polyester, polyolefin). Fabrics can be engineered to achieve desired properties by the use of particular fiber types, bonding processes, and fabric finishes. The three most commonly used nonwoven fabrics for surgical gowns and drapes are as follows:

Spunlace: A material often consisting of a blend of wood pulp and polyester fibers. The fibers are subjected to high-velocity water jets which entangle the fibers to achieve mechanical bonding. For surgical drapes and gowns, a chemical treatment may also be used to improve liquid penetration resistance.

Spunbond/meltblown/spunbond: A fabric consisting of three thermally or adhesively bonded layers. Typically, for medical applications, this material is made of polypropylene. Treatments are often applied to provide improved liquid penetration resistance. Spunbonded materials are made up of continuous filaments which are formed by in-line melt spinning. Meltblown materials are similar in that they are formed from a polymer by in-line melt spinning, but the fibers are finer and may not be continuous.

Wet laid: A nonwoven fabric consisting of wood pulp or a blend of polyester and wood pulp fibers. The fibers are suspended in water to obtain a uniform dispersion and are then separated from the slurry by draining the water through a fine mesh screen. For medical-grade fabrics, a chemical binder is often used to bond the fibers together. A chemical treatment can be used to improve liquid penetration resistance.

Reinforcement of multiple-use and single-use products

Both multiple-use and single-use products are often reinforced to enhance or improve their properties and performance. For some surgical gowns and drapes, the barrier properties of one ply of a material may not be adequate for the particular application; in these cases, additional materials are often added (overall or zoned) in the form of additional layers of material, coatings, reinforcements, or laminates. Also, reinforcement may be added to improve absorbency, nonslippage, or other desirable characteristics. The following materials are being used in surgical gowns and drapes; they are selected based on the application's requirements.

Reinforcement fabrics: A second layer of fabric is sometimes used to reinforce base materials, providing such properties as improved resistance to liquid penetration, better absorbency, skid resistance, and additional strength. These fabrics are breathable and do not generally make the base material liquid-proof.

Breathable films: In microporous films, the pores are small enough to allow moisture vapor to pass through while still providing various degrees of liquid and microbial resistance, depending upon the technology; microporous films can prevent the passage of liquids and microorganisms. Nonporous breathable films are solid (monolithic), and they, too, can prevent the passage of liquids and microorganisms. Bicomponent films are laminates consisting of a combination of a microporous film and a breathable polymer; bicomponent films can also prevent the passage of liquids and microorganisms. The affinity of both nonporous and bicomponent films for water allows moisture to pass on a molecular level, and they are therefore considered to be breathable. (Moisture vapor is adsorbed onto the surface; the molecules diffuse through the membrane and are then desorbed into the atmosphere.)

Nonbreathable films: These films or coatings do not allow air or moisture vapor to pass through them and are therefore considered nonbreathable. They can prevent the passage of liquids and microorganisms.

Foams: Open-cell and closed-cell foams are used to provide reinforcement, a nonskid area, or absorbency and may possess either liquid-resistant or liquid-proof characteristics. They are primarily used in surgical drape applications.

For all of the above materials, quality (e.g., number of pinholes) and manufacturing technology influence the degree of liquid and microbial resistance.

4 Safety and performance characteristics

The primary performance characteristic of a surgical gown or drape is its effectiveness in providing the appropriate level of protection against the penetration of liquids and microorganisms. Other important safety and performance properties include abrasion resistance, strength, softness, drapeability, breathability, stain resistance, flammability, propensity for linting, toxicity, and sterility. Producing a product that is superior in all these performance attributes is a great challenge to manufacturers. Users often accept certain trade-offs and recognize that no one material is likely to possess all the properties that they need or desire. In addition, it is important to recognize that test methods have limitations and may not necessarily be representative of usual conditions of use; however, this does not preclude using the test results for comparison purposes.

This chapter discusses the safety and performance characteristics of protective materials, along with some of the test methodologies commonly used to evaluate them. The tests are discussed here in general terms; references to specific standard test methods are provided in annex B.

Barrier effectiveness

Resistance to liquid and microbial penetration

Surgical gown and drape materials must form an effective barrier against the transmission of microorganisms, both for the protection of the surgical patient against postoperative wound infection and for the protection of the surgical team against the transmission of bloodborne pathogens or other microorganisms. There are two general categories of protective materials, those that rely on repellent finishes and/or construction and those that rely on reinforcement by films. Even within the same product, one area or "zone" may be more resistant to liquid penetration than another; for example, the area around the fenestration of surgical drapes is typically reinforced in some way to provide more resistance to liquid penetration than other portions of the drape.

It has been clearly documented in the literature that when liquid penetrates a material, microorganisms are carried with it, and that microorganisms can penetrate a "reinforced" material without liquid being visible. Traditionally, the user community has associated lack of visible strike-through with lack of microbial transfer; it has been conclusively demonstrated that this is not necessarily the case.

Liquids are generally accepted as the most important vector of microbiological transport in surgery. Other possible vectors of microbiological transport in surgery include air, aerosols, laser plume, lint, and skin cells. Dry penetration of microorganisms that is promoted by mechanical action may also be possible through porous materials. An effective microbial barrier must resist both "wet" and "dry" penetration of microorganisms.

There are two fundamentally different types of liquid exposures which occur in surgery. These exposures may be described as either spraying and splashing or soaking with pressing and leaning. There may be single or multiple insults in both cases and various combinations of each type of challenge. Understanding these differences will help in determining the most appropriate type of challenge test to use in order to more accurately predict product performance and to help select the appropriate product for the application.

Four of the most commonly used industry test methods are:

Water resistance (hydrostatic pressure). This type of test determines the ability of a material to resist water penetration under constant contact with increasing pressure. Typically, the test sample is clamped in place horizontally, and the hydrostatic pressure is steadily increased by raising the height of the water column from zero to a predetermined level (1.0 pounds per square inch [psi] = 27.687 inches water = 70.325 centimeters of water = 6.894 kilopascals). The test is terminated when visible penetration of water droplets occurs. The higher the hydrostatic pressure, the more resistant the material to penetration by water.

Water resistance (impact penetration). This type of test determines the ability of a material to resist water

penetration under single spray contact. The test sample is oriented at a 45° angle and clamped in place over a piece of preweighed blotter paper. A measured amount of water is released from a funnel with a spray head located a specified distance above the test sample. The test is terminated when the funnel is empty. After the water spray is concluded, the test sample is removed and the blotter is weighed again. The lower the weight gain in the blotter, the more resistant the material to penetration by water.

Saline repellency (mason jar test). This type of test determines the ability of a material to resist saline penetration under constant pressure. In one such test method, 0.9% saline is added to a vented mason jar to achieve a specified pressure on the test sample. The test sample is clamped onto the top of the mason jar, which is inverted and placed on a glass plate. The test is terminated when visible penetration of saline is observed or at some predetermined time interval. The longer the time (in minutes) before the saline penetrates the material, the better the performance.

Alcohol repellency. This type of test determines the ability of a material to resist the spontaneous wetting and penetration of droplets of various alcohol and water solutions. In one such test method, 11 different test solutions, ranging from 0% to 100% isopropyl alcohol, are used. The sample is placed on a glass plate and, starting with the 0% alcohol solution, one small drop is put on the surface of the sample in three different locations. The test is terminated when visible penetration of one of the test solutions occurs within 5 minutes. Resistance to the penetration of test solutions with higher alcohol content is better.

Liquid challenge testing has been used over the years to characterize the barrier properties of protective materials. However, there are limitations in the industry liquid challenge test methods that have been developed as a means to predict liquidborne microbial barrier properties. Some of the more significant limitations are as follows:

1) Detecting liquid penetration by means of the naked eye or by weight gain in a paper blotter is significantly less sensitive than a microbiological assay and should not be used to infer absolute liquidborne microbial barrier properties. A significant number of microorganisms can be carried in a very minute volume of liquid, which may not be visible to the naked eye or measurable by weight gain in a blotter (see figure 1). For example, the number of infectious units of hepatitis B virus in a 0.1-microliter droplet is 10,000; this is one of the reasons why hepatitis B is so highly infectious and easily transmitted. It can be seen in figure 1 that a very small amount of infectious body liquid is capable of carrying a significant number of bloodborne pathogens. The number of a particular type of microorganism necessary to cause infection may not be known and may vary widely among microorganisms. For example, that number is estimated to be 10^7 for staphylococci (Krizek and Robson, 1975), while a single hepatitis B virus may be infectious (Shikata et al., 1977). Although the dosage required for infection may be unknown, gross and obvious transmission of infectious liquid cannot be the criterion for barrier quality.

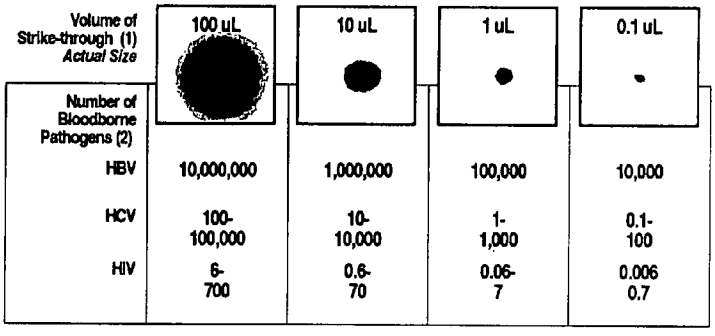

Figure 1—Bloodborne pathogen strike-through conversion chart. This chart converts the amount of strike-through to the amount of potential bloodborne pathogen contamination. The four spots at the top of the chart were formed from premeasured droplets of synthetic blood and are marked in microliters ranging

from 100 microliters to 0.1 microliters. Listed on the left are the three primary bloodborne pathogens: hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV). The approximate number of infectious units that could be present in each spot is shown for each type of virus. (Data derived from: Bradley [1984], Ho et al. [1989], Shikata et al. [1977])

2) Liquids commonly used in liquid challenge tests, such as water and saline, have different physical properties than blood and body liquids and do not wet or penetrate through protective materials as easily as blood and body liquids. Even using the whole blood of humans or animals may not be predictive of the wetting and penetration characteristics of the entire range of potentially infectious human body liquids. (The surface tension range of human blood and body liquids, excluding saliva, is 42 to 60 dynes per centimeter. Water and saline, which are poor body liquid models but are often used in testing materials, have surface tensions of 72 and 74 dynes per centimeter, respectively.) A more appropriate body liquid model would have a surface tension approximating the lower end of the blood and body liquid range and would be more predictive of the penetration characteristics of body liquids and other liquids with higher surface tensions.

3) Most test devices have limitations on the amount of pressure that can be applied to the liquid during the challenge procedure and may not be indicative of the pressures that can be exerted on liquids in contact with protective materials during use in surgery. (The pressures exerted on surgical gowns and drapes during pressing and leaning activities in surgery can range from less than 1.0 psi to more than 60.0 psi [Altman et al., 1991]. Smith and Nichols [1991] estimated representative abdominal pressures during surgical procedures to be between 0.25 and 2.0 psi.) There may well be a difference between the pressure applied to protective materials and the pressure actually applied to liquids during pressing and leaning. The pressures exerted on liquids have not yet been accurately quantified in surgical use.

4) Most liquid challenge test methods have specific time and pressure protocols and are conducted for shorter periods of time than the anticipated time of liquid challenge in surgery. The time of the liquid challenge test should be meaningful and representative of the end use application for the surgical gown or drape. It is generally agreed that shorter times may be necessary with higher liquid challenge pressures to achieve definitive test results.

5) The condition of the surgical gown or drape at the time of the liquid challenge test is very important. Liquid challenge testing prior to degradation by physical, chemical, and thermal stresses which could negatively affect the protective qualities of the material may lead to a false prediction of actual in-use performance. (The ultimate purpose for protective materials is to form an effective barrier to liquids and microorganisms throughout their entire use in surgery. The impact of other physical, chemical, and thermal stresses imposed during use in surgery and during reprocessing of multiple-use materials should be assessed. Physical stresses could include such things as stretching and relaxation, mechanical flexing, and abrasion. Chemical stresses could include such things as exposure to other clinical liquids, skin disinfectants and lubricants, irrigation fluids, perspiration, and body oils. Thermal stresses could include such things as direct contact with hot instruments and contact with high-energy devices such as electrocautery knives and lasers.)

Liquid challenge tests can be useful prescreening tools in determining which protective materials warrant further investigation with microbiological challenge tests, but should not be used alone to demonstrate a material's microbial barrier properties.

Recently, two test methods have been developed and approved as Emergency Standard Test Methods by the American Society for Testing and Materials (ASTM). This effort was undertaken by ASTM in response to questions regarding the performance of personal protective clothing posed in the Announced Notice of Public Rulemaking by the Occupational Safety and Health Administration (OSHA) concerning occupational exposure to bloodborne pathogens.* The objective was to develop a laboratory test method which took into consideration all of the important variables relevant to bloodborne pathogen exposure (surface tension of

challenging liquids, pressure, time, microbial model), and which provided a higher level of assurance in the barrier qualities of protective clothing for health care workers. These tests are intended to assess the liquid and viral resistance of protective materials for those body liquid exposures involving soaking with pressing and leaning. These tests may not be necessary or appropriate for applications involving only modest degrees of body liquid exposure.

NOTE—The two ASTM Emergency Standard Test Methods described here were developed and published by ASTM to meet a demand for more rapid issuance. The Executive Committee of ASTM Committee F23 on Protective Clothing recommended this publication, and the ASTM Committee on Standards concurred in the recommendation. These emergency standards differ from full consensus standards in that they were only balloted through the Subcommittee level as per the *Regulations Governing ASTM Technical Committees*. These documents were published by ASTM through August 1994. At the time of the publication of this AAMI TIR, ASTM had begun development of full consensus Standard Test Methods for evaluating the resistance of protective clothing material to synthetic blood and to bloodborne pathogens. As with any standard, the test methods described below may be revised to some extent as a result of the consensus process.

The following ASTM Emergency Standard Test Methods use specific time and pressure protocols and body liquid and microbial models in an attempt to overcome some of the weaknesses, outlined previously in this section, of industry liquid challenge test methods:

Emergency Standard Test Method for Resistance of Protective Clothing Materials to Synthetic Blood (ASTM ES21-92). This test determines the ability of a material to resist the penetration of synthetic blood under constant contact. The test sample is mounted onto a cell separating the synthetic blood challenge liquid and a viewing port. The time and pressure protocol specifies atmospheric pressure for 5 minutes, 2.0 psi for 1 minute, and atmospheric pressure for 54 minutes. The test is terminated if visible liquid penetration occurs before or at 60 minutes. This is a pass/fail screening test. Fabrics that pass this test should also be tested using ASTM ES22-92.

Emergency Standard Test Method for Resistance of Protective Clothing Materials to Penetration by Bloodborne Pathogens Using Viral Penetration as a Test System (ASTM ES22-92). This test determines the ability of a material to resist the penetration of a microorganism under constant contact. This test method has been specifically designed for modeling viral penetration of the hepatitis B, hepatitis C, and human immunodeficiency viruses. Since these organisms are difficult to use, the test utilizes a bacteriophage, Phi-X174. Phi-X174 is one of the smallest known viruses at 0.027 microns in diameter, and it is similar in size and shape to the hepatitis C virus, the smallest bloodborne pathogen (figure 2). The test sample is mounted onto a cell separating the microbial challenge and a viewing port. The time and pressure protocol specifies atmospheric pressure for 5 minutes, 2.0 psi for 1 minute, and atmospheric pressure for 54 minutes. The test is terminated if visible liquid penetration occurs before or at 60 minutes. A very sensitive microbial assay is performed to determine the passing or failing result, even in the absence of visible liquid penetration. Fabrics which pass this test are considered to be highly protective against liquid and microbial penetration.

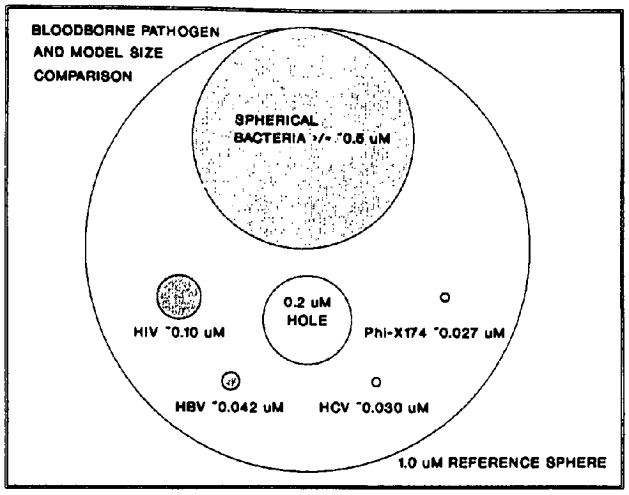

Figure 2—Bloodborne pathogen size comparison chart.

In the past, providing a barrier to the smaller size range of spherical bacteria (≥ 0.5 microns [µ]) was considered adequate when testing microporous materials with through holes of 0.2 µ. Today, however, there is a heightened awareness regarding the transmission of infectious microorganisms such as HIV, HBV, and HCV. Conducting a challenge with HIV (approximately 0.10 µ in diameter) may not predict the barrier properties of a material against HBV (approximately 0.042 µ) and HCV (approximately 0.030 µ), as they are much smaller and may pass through. Therefore, it is important to evaluate barrier properties using a model of the smallest microorganism. The model used in ASTM E22-92 is the Phi-X174 bacteriophage (approximately 0.027 µ in diameter).

Resistance to penetration by airborne, aerosol-borne, or dry particles

Test methods have been developed to evaluate the resistance of air-permeable or porous materials to airborne, aerosol-borne, or dry-particle microbial penetration. These methods typically involve pressure and are applied to materials intended for use in face masks and sterile packaging wraps. Therefore, they may not be representative of the types of challenges that confront surgical gown and drape products. Such test methods include the following:

Bacterial penetration (aerosol filtration). For this test, liquid containing the bacterial challenge is aerosolized and then sprayed onto or drawn through the test material. The reverse side of the material is then cultured and the number of colony-forming units (cfu's) counted. The most commonly used microorganisms for this test are *Staphylococcus aureus* and *Pseudomonas aeruginosa.*

Bacterial penetration (dry particle method). This test method is used to determine the resistance of materials to airborne microorganisms that may be carried by skin cells or lint. Talc particles are inoculated with *Bacillus subtilis* spores and then pumped through or sprayed against the test material. The reverse side of the material is then cultured and the number of cfu's counted.

Abrasion resistance

Surgical protective materials should not abrade significantly during normal use, under wet or dry conditions. Abrasion may weaken the material, adversely affecting barrier properties and causing it to tear or generate more lint. Of primary concern is the abrasion of one material against itself or against another material, as would occur if the arm rubs against the chest area of a gown or the stomach area of a gown rubs against a drape on the surgical table. Among the commonly used test methods are the following:

Rotary platform method. Under controlled conditions of pressure and abrasive action, a specimen is abraded through rotary rubbing action, using a rotary platform, double-head tester. The test specimen, mounted on a platform, turns on a vertical axis against the sliding rotation of two abrading wheels. One

abrading wheel rubs the specimen outward toward the periphery and the other inward toward the center. The resulting abrasion marks form a pattern of crossed arcs over an area of approximately 30 square centimeters. Resistance to abrasion is evaluated by various means.

Martindale abrasion. Abrasion resistance is assessed by means of a Martindale abrasion tester. This test requires that the test sample be subjected to rubbing motion in the form of a geometric figure; that is, a straight line which becomes a gradually widening ellipse until it forms another straight line in the opposite direction and traces the same figure again under known conditions of pressure and abrasive action.

Strength

Barrier materials should be strong enough to withstand the stresses encountered during typical use. Tears or perforations compromise the sterile field and can allow penetration of liquid. A material can be tested for both breaking strength and tear strength. Several test methods are used to determine each of these properties:

Breaking strength

Breaking strength is defined as the force required to rupture or break a material under specified conditions. Among the test methods commonly used to determine breaking strength are the following:

Grab tensile strength. This test measures a material's resistance to breaking under an increasing pulling force, without an initial tear in the material. A 4" wide by 6" long sample is typically used. The greater the force required to cause breaking, the better the performance.

Strip tensile strength. This test also measures a material's resistance to breaking under an increasing pulling force, without an initial tear in the material. A 1" wide by 6" long sample is typically used. The greater the force required to cause breaking, the better the performance.

Burst strength. This test measures a material's resistance to rupture under increasing pressure. The higher the pressure needed to cause a rupture, the better the performance.

Tear strength

Tear strength is defined as the force required to propagate a tear in a material under specified conditions. An initial tear is intentionally made in the test sample. Tests of tear strength determine the force needed to continue this initial tear. The three test methods most commonly used to measure tear strength are as follows:

Elmendorf tear strength. This test measures a material's resistance to tearing under a controlled force when there is an initial tear in the material. The greater the force required, the better the performance.

Trapezoidal tear strength. This test measures a material's resistance to tearing under an increasing force, the force being applied perpendicularly to the direction of the tear. The greater the force required, the better the performance.

Tongue tear strength. This test measures a material's resistance to tearing under an increasing force, the force being applied in the same direction as, or parallel to, the initial tear. The greater the force required, the better the performance.

Drapeability

Drapeability refers to the tendency of a material to conform to a given shape or object. Surgical drapes and related draping products should be flexible so that they will cover the patient closely and smoothly, allow placement and manipulation of instruments, and appropriately drape out other related equipment, such as ringstands, back tables, and mayo stands. Drapeability can be evaluated by tests that measure the softness of a material:

Handle-o-meter. This test measures the force required to push a specimen of defined size through a slot of

specified width, which is recorded as the softness. Testing is conducted in both principal directions of the sample. The lower the reading, the more drapeable the test sample.

Cantilever stiffness. This test measures the stiffness of fabric samples by sliding the samples over the edge of a horizontal surface. 1" wide by 6" long samples are typically used. The length of the fabric that has been pushed over the edge when the specimen bends to a certain point is determined. The shorter the length, the less stiffness.

These tests do not necessarily correlate with the actual perception of a fabric's softness and drapeability; however, no consensus method is currently available.

Comfort

The overall comfort of surgical gowns can be influenced by a number of factors, such as design, fit, breathability, weight, hand (softness), surface slickness, electrostatic properties, color, light reflectance (glare), odor, and skin sensitivity. Other important variables that can influence comfort include other clothing layers, health and physical condition, work load, mental stress, and environmental conditions (temperature, relative humidity, and air changes) in the operating room. Comfort is very subjective and may be influenced by one or a combination of the aforementioned factors, which would be very difficult to predict through experimental testing. The best assessment of overall comfort can be made by wear testing the product during use in surgery (after determining that the product's protective properties are appropriate for the application).

Thermal comfort exists when a balance occurs between the heat the human body loses and the heat the body generates. Traditionally, the term "breathability" has been used to describe the ability of porous protective materials to allow both air and moisture vapor penetration as a predictive assessment of the potential comfort of gowns constructed from the materials. However, since some of the film reinforcements used in gowns are not permeable to air, moisture vapor transmission is recognized as a measurement that allows a direct comparison of all materials, air-permeable and air-impermeable, as to the potential for surgical gown materials to prevent discomfort due to heat stress. As noted above, many factors affect comfort; air permeability and moisture vapor transmission rate lend themselves to objective measurement in materials although not in entire gowns.

Gowns are typically constructed from several materials, which vary in air permeability and moisture vapor transmission characteristics. Gowns or portions of gowns that permit evaporation and transfer of perspiration vapor from the surface of the skin through to the environment are more likely to allow the human body to maintain a thermoregulatory balance. Typically, a broader comfort range—or tolerance for higher temperatures, relative humidities, and work loads—is exhibited by those gowns which are constructed entirely or partially from materials that have higher air permeability or moisture vapor transmission rates. Gowns that do not permit sufficient evaporation or transport of perspiration vapor are more likely to interrupt the equilibrium and result in discomfort.

Health care workers have the option of selecting various levels of protection according to the intended use. Historically, liquid-resistant materials have had higher moisture vapor transmission rates than liquid-proof materials, which were impermeable to moisture vapor transmission. Today, however, choosing a liquid-proof level of protection can be a comfortable option with the advent of liquid-proof and breathable laminates and composites. Comfort can also be achieved with liquid-proof and impermeable materials by means of special design characteristics.

Among the tests used to assess air permeability and moisture vapor transmission properties are the following:

Air permeability. One method used to assess air permeability determines the ability of a material to allow air penetration under specific conditions with a differential pressure. The results are expressed in volume of

air/area/time. The higher the number, the more air-permeable the material. Materials demonstrating air flows of less than 1 cubic foot/square foot/minute require testing by other methods.

Moisture vapor transmission. The moisture vapor transmission rate of a material can be determined under specific conditions of temperature, relative humidity, and air flow in a test chamber. The test materials are sealed over the mouth of a cup containing water of a known weight. The cup is placed in the air flow chamber, either upright or inverted, and the weight loss of the water in the cup is determined over time. The results are reported as grams of moisture/area/time. The higher the number, the more permeable the material to moisture vapor.

Stain resistance (soil release)

The issue of aesthetic acceptability is important in the selection of multiple-use products. Any item presented to the operating room should be free from discolorations and residues that may warrant rejection from both an aesthetic and a septic standpoint. (Certain types of residues may protect microorganisms and prevent adequate sterilization.) The launderability of a material can be evaluated in the laboratory under conditions that are meant to simulate actual use; however, since the treatment of materials varies from institution to institution, these results may not be representative of all uses. The time between using multiple-use products in surgery and placing them into the laundering process can also vary. In addition, the laundering process will vary in the type of equipment used, the type and amount of chemicals used, the temperature of the water, the hardness of the water, and the actual wash formula itself. Part of the evaluation of multiple-use materials will necessarily involve the ability of the laundry to process the gowns and drapes in a way that will prevent problems with discolorations and residues. At the same time, the laundry's effect on the safety and performance characteristics of the products should be evaluated.

Electrostatic properties

In the context of surgical gowns and drapes, the primary electrical safety consideration is the ability of the material to accept or dissipate electrical charge. It should be noted, though, that many other factors affect electrostatic discharge, such as the relative humidity in the environment, the time of wear, motion during wear, and the combination of products used.

The National Fire Protection Association's *Standard for Health Care Facilities* (NFPA 99) is a comprehensive document covering many aspects of electrical, explosion, and fire safety in health care facilities (NFPA, 1993). Material requirements as well as recommended work practices are discussed. Section 12-4.1.3.8(f)(3) specifies electrical safety requirements for materials, and two test methods are recommended for satisfying the requirements. A material must meet at least one of these tests to be acceptable for use in those areas where flammable anesthetic gases may be encountered:

Electrostatic decay. In this test method, a sample of test material is equilibrated to specific temperature and humidity conditions. The sample is then suspended between two electrodes and charged with 5,000 volts (V) of static electricity. The discharge to 500 V (10% charge) is timed. A decay time of 0.5 seconds or less is required by NFPA 99.

Surface resistivity. In this test method, a sample of material is equilibrated to specific temperature and humidity conditions and then tested for electrical resistance using an electrical resistance meter. A resistivity of less than or equal to 1×10^{11} ohms per square is required by NFPA 99.

The requirements of NFPA 99 can alternatively be met by a label warning against using the product where flammable gases might be encountered. It is important to note that there is currently no standard test protocol for evaluating multicomponent products. In cases where multicomponent materials are used in gown and drape products, the individual materials can be evaluated separately by the test methods described above. However, the results for individual layers may not be predictive of the performance of multicomponent systems.

Materials may also be evaluated for electrostatic clinging. One test method for this property is as follows:

Electrostatic clinging of fabrics: Fabric-to-metal test. This test method evaluates the relative clinging tendency of certain fabrics due to electrical charge generation. In this test, specific rubbing fabrics are used to induce an electrostatic charge on the test specimen. After the specimen is placed on a metal plate, the time is measured for the charge to decay to a level where the electrical attractive forces between the specimen and the metal plate are overbalanced by gravitational forces and the specimen pulls away from the plate.

Flammability

By law (16 CFR 1610), all materials used in clothing must meet the Consumer Product Safety Commission's *Standard for the Flammability of Clothing Textiles* (CPSC, 1954). (In the past, an NFPA test method [NFPA 702-1980] was used to assess flame spread rate in textiles. Although this document was removed from NFPA's list of "active" standards in 1987, the test is still referenced.)

There are many potential ignition sources in the modern operating room, including surgical lasers, electrosurgical units, endoscopic fiberoptics, and other high-energy electromedical devices. All materials will burn if a high-intensity heat source (such as a laser or electrosurgical instrument) is applied to them, especially in the presence of elevated oxygen levels; however, the resistance to burning can differ among materials under various conditions. Appropriate work practices in the handling and use of high-energy sources is a key factor in reducing the incidence of fires in the surgical setting.

Lint generation

Most materials (woven, nonwoven, and knitted) will generate and release lint particles to some degree when abraded. In addition, it is well documented that some materials have a tendency to generate more lint particles than others. It is also generally accepted that the more lint that is generated in the operating room, the greater the possibility of a postoperative wound infection caused by either microorganism transfer or by a foreign body reaction. Nonviable particles (lint) as small as 2 to 4 µ in size have been reported to be the pathway for the introduction of viable organisms into the wound site (Scheinberg et al., 1983). It has also been demonstrated that lint particles generated from the surgical gowns and drapes themselves can cause foreign body reactions (Tinker et al., 1974; Tinker et al., 1977; Dragan, 1979; Janoff et al., 1984). Finally, the generation of lint can cause a buildup of particles in the ductwork of air handling systems and on the tops of cabinets and shelves, potentially impairing the operating efficiency of the air circulation system and increasing the maintenance and housekeeping required in operating rooms. Therefore, in order to minimize the possibility of postoperative complications caused by lint, surgical gowns and drapes should be as lint-free as possible (AORN, 1993b).

There are a number of test methods for assessing the propensity of a material to lint:

Flexing in air. A sample of material is flexed inside a clean test chamber; air is withdrawn from the chamber, and particulates are counted by means of an optical particle counter.

Shaking in water. This test involves placing a sample of material in a container of ultrapure water. The container is shaken to release the particles, the water is withdrawn, and the particles are counted in a liquid-borne optical particle counter.

"Helmke drum test." Test materials are placed in a rotating drum and tumbled to release particulate matter; an automatic particle counter samples the air within the drum to determine the particle density. Based on the results, the material tested is classified as Category I (lowest particle density), Category II, or Category III.

Twisting in air. This test measures the relative levels of particles released from a material when it is subjected to a continuous twisting movement.

In addition, Buras and Harris (1983) published a method that measures a material's propensity to generate lint by subjecting it to an abrasion test and then determining the weight of the loose particles.

Shrinkage

One available test procedure monitors the dimensional change of a material when it is subjected to laundering procedures commonly used in institutional and commercial washing situations. The original dimensions of the sample are recorded and then retaken after the client's prescribed washing, drying, and sterilization procedures are performed. The final answer is provided as a percentage indicating the amount of change in each direction. A gain in measurement is expressed by a plus (+) sign. Change in all locations is reported to the nearest 0.1%.

Toxicity

The materials from which surgical drapes and gowns are fabricated should be free of toxic ingredients that could irritate tissue or otherwise adversely affect the patient or user. Permanently bonded chemicals or other additives are sometimes used to enhance barrier properties or stain resistance; some of these substances may leach out, others may be nonleaching. Generally speaking, there has been little evidence of adverse reactions to surgical gowns or drapes currently on the market, although infrequent incidents of dermatitis have been observed as well as a very small number of allergic reactions.

The *Tripartite Biocompatibility Guidance for Medical Devices* was written as an international guideline for biocompatibility testing. Test methods are listed according to the type of contact that a device has with a patient and the duration of the contact. Surgical gowns would be classified as external devices that may contact intact surfaces for short-term exposures (defined as 5 minutes to 29 days); for this type of device, the listed testing includes irritation tests, sensitization assays, and cytotoxicity tests. Surgical drapes would be classified as external devices that may contact breached or compromised surfaces for short-term exposures; for this type of device, the listed testing includes the preceding tests as well as acute systemic toxicity, hemocompatibility/hemolysis, and subchronic toxicity assessments. It should be noted that the Tripartite document states that the guidelines should not be taken "to imply that all the tests listed under each category will be necessary or relevant in all cases." It should also be noted that even exhaustive biocompatibility testing may not preclude the possibility of individual allergic reactions to materials.

Sterility assurance

Typical methods of sterilization include radiation, chemical gas (ethylene oxide), and steam. Assurance of the sterility of surgical gown and drape products is a critical issue and should not be assumed or taken for granted. Other possible patient and worker safety issues, such as residual sterilants and other chemical byproducts of sterilization processes, should be evaluated. Residuals and other byproducts of sterilization may or may not be immediately obvious; however, any evidence of unusual odors and/or dermal reactions should be investigated.

Prepackaged, sterilized multiple-use and single-use products are considered sterile unless the integrity of the package is compromised. Those products which are to be sterilized by the hospital should be accompanied by the appropriate documentation and guidelines provided by the manufacturer to ensure that the on-site sterilization process will be effective. Surgical gown and drape products must allow for the effective permeation and removal of sterilants. Other important variables include recommended folding techniques and pack configurations, limitations on pack components and densities, and limitations on sterilizer chamber load configurations. Guidelines for inhospital sterility assurance are provided in AORN (1993c), AAMI (1992), and AAMI (1994).

Longevity

With each operation, under normal conditions of use and for the duration of time in which they are used,

surgical gown and drape products should prevent the penetration of blood, body fluids, and other potentially infectious materials. Garments should be removed immediately, or as soon as is feasible, if visible penetration of blood or other potentially infectious materials is noted. Conditions of use and time in use for various tasks and procedures can vary significantly and may dictate the use of products providing different levels of protection. Careful consideration should be given to attributes which can affect functionality during use, such as strength (break, puncture, and tear resistance), abrasion resistance (to the loss in barrier properties), flex durability, contamination resistance, and flammability. The impact of sterilization and storage time on product degradation should be assessed for both single-use and multiple-use products, and the impact of proper cleaning and disinfection procedures should be assessed for multiple-use products. Health care facilities are required to implement a system of repair or replacement of all personal protective equipment to maintain barrier effectiveness. Systems for monitoring, inspecting, testing, and repairing or replacing to ensure the proper maintenance and continued integrity of protective products are critical and must be thoroughly addressed by the manufacturer and/or supplier. It is the responsibility of the health care facility to implement the appropriate systems for the products that they process. Health care facilities should also ensure that external processors, such as central laundries, repackaging operations, and sterile pack lease/rental operations, are meeting these requirements.

5 Selection and user evaluation of surgical gowns and drapes

The selection of the surgical gowns and drapes that will best meet the needs of a particular health care facility involves a complex decision-making process. There are many factors that must be considered, such as protective properties, comfort, strength, and quality of materials. In today's health care environment, there is also the need for cost containment. This chapter provides guidelines on the selection and inhospital evaluation of surgical barrier products, including a framework and scale of value by which a hospital evaluator can objectively and/or quantitatively measure the performance of a product most appropriate for a particular use.

Information from manufacturers and/or suppliers

Hospital personnel performing the evaluation may wish to request test data and other pertinent information from manufacturers pertaining to the performance characteristics described in previous chapters. In addition, for multiple-use products, the health care facility should request information on reprocessing and care (see Chapter 6).

Health care personnel may wish to pose the following questions to manufacturers when selecting a surgical gown or drape product:

What are the regulatory requirements for the product? If applicable, has a 510(k) premarket notification for the product been submitted to FDA, and has the product been cleared for marketing?*

Is the manufacturing facility registered with FDA? Is the product listed with FDA?

Are good manufacturing practices used in the manufacture of the product?

Are there clinical reports, scientific papers, or research data available to substantiate the efficacy of the product? Are the data presented representative of the current product? Are the laboratory tests used consistent with those referenced in this TIR?

Are there references who can be contacted concerning their experience with the product?

Are there any precautions that should be taken to ensure that the product performs as intended?

What are the recommended disposal guidelines for the product? If it is to be incinerated, what are the potential byproducts?

If the product is intended for multiple uses, what are the recommended processing guidelines? What could

be the result of not following the recommended guidelines?

If the product is intended for multiple uses, what are the manufacturer's recommendations for assessing its performance (e.g., resistance to liquid penetration) after reprocessing in order to help prevent failure under usual conditions of use?

If the product is intended to be sterilized by the health care facility, are data available to validate that the product can be effectively sterilized? Will the sterilization process used in this health care facility effectively sterilize the product? How can the effectiveness of the sterilization process be demonstrated? Is the product permeable to steam and/or ethylene oxide? Does it allow elution of EO to take place within the time frames and aeration cycles available in hospital equipment? What are the recommended sterilization guidelines? Are there any limitations on folding configurations, pack size or density, load mix, or chamber loading capacity?

If the product is intended for multiple uses, is there a limit on the number of reuses? What is the longevity of the product?

Product evaluation

In addition to the review of test data supplied by manufacturers, product evaluations may also be necessary, particularly when comparative test data are not conclusive as to the most appropriate product for a particular use. There are certain performance qualities and aesthetic and comfort considerations for which no or few test standards are available. Also, the design and construction of a surgical gown or drape are important factors in its effectiveness and are best evaluated under actual conditions of use (Quebbeman et al., 1992; AORN, 1993b). Approval trials should include as many conditions of use as possible in order to properly evaluate acceptability for clinical evaluation (e.g., wearing a surgical gown to determine the comfort level). Caution should be exercised in the use of non-objective field tests that do not duplicate clinical applications. Also, to avoid risks to personnel and patients, it is most important for health care personnel to understand the performance characteristics of the product in relation to the projected use before embarking on in-use testing.

Cost comparisons

Costs are generally comparable only on functional equivalences; in other words, cost assessments are only valid if all the costs of all products necessary to accomplish a particular objective are compared. Evaluations should be made among products that are functionally equivalent, not different. It is also important to include nonclinical costs in comparing products used in the operating room (e.g., staff time and acquisition, storage, inventory, reprocessing, and disposal costs).

Staff input

Rarely can department managers make product choices for successful large-scale conversions without staff involvement and input, which should include actual in-use trials. This is true not only because of the variety of clinical input needed but also because of the psychological impact of active participation. General guidelines for staff participation and other aspects of product evaluation are provided in AORN (1993a).

Performance priorities in relation to product function

The selection of the surgical gowns and drapes to be used by a health care facility is a complex and cumbersome task. Product selection should be guided by the product's anticipated use, the performance attributes of the products in relation to the anticipated use, the cost of the product, and the quality systems built into the manufacture and supply of the product. It is important to note that there may be a need for more than one type of product in the surgical setting and that it may be appropriate to evaluate each need separately (e.g., ophthalmic surgery has different needs than orthopedic surgery). The "Product Evaluation Table" (see table 1) is an example of one method of assessing performance priorities in relation to product

function. The following procedure is used to complete the table:

1) Select the test methods to be used in evaluating the various properties from the methods described in this TIR or from methods with which you have had previous experience, and list them in the appropriate section of the table.

2) Assign a priority to each performance attribute as it relates to the needs of your health care facility. Use the following scale to assign priorities:

1 — Not important/expected
2 — Desired
3 — Important
4 — Extremely important

INSTITUTION:_____ DATE:_____

CLASSIFICATION/ANTICIPATED USE:_____

PERFORMANCE ATTRIBUTE	PRODUCT 1 NAME: DESCRIPTION:			PRODUCT 2 NAME: DESCRIPTION:			PRODUCT 3 NAME: DESCRIPTION:		
	PRIORITY	RATING	EXTENSION	PRIORITY	RATING	EXTENSION	PRIORITY	RATING	EXTENSION
LIQUID BARRIER EFFECTIVENESS									
MICROBIAL BARRIER EFFECTIVENESS									
ABRASION RESISTANCE									
STRENGTH									
COMFORT									
FLAMMABILITY									
LINTING PROPENSITY									
OTHER									
	TOTAL SCORE			TOTAL SCORE			TOTAL SCORE		

Table 1—Product evaluation table

Once a priority has been assigned to a particular performance attribute, it should be used for all products being evaluated for that level of performance.

3) Assign a performance rating to each of the products when tested using the methods chosen. The performance rating assigned should be based on testing performed by the health care facility or on documentation provided by the manufacturer. The following scale should be used to assign performance ratings:

1 — Poor (falls well below requirements)

2 — Below average
3 — Average (meets requirements)
4 — Above average
5 — Exceptional (exceeds requirements)

It may be appropriate to use the above rating when comparing the actual test results for all of the products being evaluated. It is important to note, however, that if the rating system is used in this fashion, all products must be evaluated by the same test methods.

4) Multiply the priority by the performance rating; enter the result in the "extension" column.

5) Add up the values in the "extension" column to calculate the total score for each product being evaluated. It is important that all products have a score for each of the properties being evaluated.

The resultant total scores can then be used to rank the overall physical performance of the various products evaluated in relation to the needs of the particular health care facility. This score, when used in conjunction with the costing and quality assurance attributes of the individual products, can help simplify the task of selecting the protective materials to be used by the health care facility.

Periodic reassessment

In light of the continuing evolution of available products and changing practices in surgery, it is advisable to reassess products at least every 2 years.

6 Care of surgical gowns and drapes

The safety and performance characteristics of all surgical gown and drape products, both multiple-use and single-use, are of the utmost importance, since the quality and performance of these products can directly affect both patient care and employee safety. Health care facilities should take whatever precautions are necessary with their various suppliers to assure that they are continuing to provide the highest quality products that are economically feasible.

Surgical gowns and drapes are used as a barrier to liquids and, therefore, to microorganisms. In consideration of their fabric nature, the frequency of challenge to their integrity must be minimized. Any drape or gown on the market today can be punctured, cut, or torn, compromising the intended barrier quality; for this reason, the use of such instruments as perforating towel clamps is no longer considered aseptically acceptable and should be discontinued. Surgical drapes, other than those which are intended to be cut, should not be cut. Cutting these drapes, which generates lint, is contrary to the principles of aseptic technique and may require the repair or retirement of multiple-use products. Proper handling of all products is critical to their cost-effectiveness and protective properties.

Handling of contaminated gowns and drapes

Surgical gowns and drapes that have been contaminated with potentially infectious material should be handled with caution. Personal protective equipment should be used for handling infectious medical waste and when collecting and transporting contaminated products from the surgery area to the reprocessing area or to the holding area for external pick-up. In accordance with the OSHA standard on occupational exposure to bloodborne pathogens (29 CFR 1910.1030), the user should also review the personnel protection "exposure control plan" before handling any potentially infectious materials.

Single-use products

Users of surgical gowns and drapes should review the policies and procedures that govern the removal of soiled or waste items generated during a surgical procedure. The health care institution should have a facility-wide waste management program that defines when surgical gowns and drapes should be considered as potentially infectious medical waste and describes transport and disposal procedures to follow.

Single-use drapes and gowns that have been used during a surgical procedure and that have been determined to be contaminated as infectious medical waste under the facilities' waste disposal policies should be placed in the proper infectious waste container for disposal. Those items that have not been contaminated as infectious medical waste should be placed in the general waste container.

Contaminated single-use drapes and gowns should be treated and disposed of in the same manner as other items considered as potentially infectious medical waste by the health care institution. Recommended treatment methods include, but are not limited to, incineration, steam sterilization, and chemical disinfection. The user should check local and state regulations for the approved methods for treatment and disposal of infectious waste in that area. Some users may have the option to contract with an approved commercial infectious waste disposal firm for the treatment and disposal of this waste.

Multiple-use products

There are many multiple-use product options available to health care facilities. These options range from purchasing and reprocessing products on-site to the lease/rental of sterile products. Health care facilities must take appropriate steps to ensure that adequate quality assurance programs are in place to maintain the safety and performance of the gowns and drapes they use.

Tracking the number of uses

Manufacturers of multiple-use gowns and drapes that specify the number of times their products can be reprocessed by the health care facility and reused while still maintaining acceptable safety and performance characteristics should provide the appropriate data to substantiate their claims. The health care facility should establish a method of tracking the number of times that each gown or drape can be used before it is no longer appropriate for continued use. Many products are provided with a grid, bar code, or other device that can record each time the product is inspected before reuse.

Laundering

There are a variety of multiple-use protective materials available today. Consequently, laundry techniques are specifically designed for the particular type of material or combination of materials. The manufacturer should be consulted for appropriate guidelines.

Laundry workers should be advised of the risk of exposure to bloodborne pathogens from contaminated gowns and drapes. An "exposure control plan" should be established, and personnel should wear the proper protective equipment when transporting and sorting contaminated items and when loading them into the washing machines in the laundry. Infection control procedures and work practices should be developed to minimize the risk of contaminating clean laundry products.

Multiple-use laundry bags used for collecting and transporting contaminated, multiple-use surgical gowns and drapes should also be considered contaminated and processed appropriately. In accordance with OSHA regulations, all bags used for contaminated linens should be appropriately labeled to alert workers to the hazards associated with the full and empty soiled linen bags. Nondispersable, single-use laundry bags should be handled and disposed of as infectious medical waste.

Inspection, testing, folding, and assembly

Before selecting any product as a surgical barrier, the user must establish quality standards for its performance. In addition to the important performance characteristics of protective quality and comfort, aesthetics are to be considered. The user's standards should address product integrity, prior to reuse, through visual inspection, performance testing, incidence and severity of staining, incidence and quality of patching, and frequency and type of other repair or replacement. (See the section, "Longevity," in chapter 4, "Safety and Performance Characteristics.") Cost-effectiveness should be evaluated using these criteria.

The method of folding should represent the reverse sequence of the easiest method of aseptic presentation and use, and it should be documented for consistency. Similarly, the assembly sequence for the positioning of products within a pack should be the reverse of the actual use of the products. It should also be documented for consistency.

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Annex A

Historical background

This annex is intended only as a brief historical review of significant studies pertaining to the protective properties of surgical gowns and drapes. Some of the papers cited have generated controversy, and the data have been interpreted in various ways. Readers are encouraged to review the original articles and reach their own conclusions. It is recognized that this historical review is not all-inclusive. At the time the TIR was drafted, additional articles had been published that were not cited.

The age of aseptic surgery emanated from the works of Semmelweis, Pasteur, Lister, and Koch. In the late 1800s, it was determined that "the surgeon's hands must be scrubbed, his instruments must be boiled, and the wound drapes must be rendered germ-free." "The disease-stained old frock coat must give way to the freshly laundered, sterile gown" (Nuland, 1988). One or more layers of sterile cotton sheeting were typically used to drape the surgical wound and gown the surgical team.

In February 1952, Beck and Collette published their classic paper challenging the barrier effectiveness of cotton cloth when it becomes wet. They demonstrated that various agents—water, plasma, and salt solutions—transported bacteria from the nonsterile to the sterile surface. The paper recommended that cotton cloth be replaced with an impermeable, waterproof material for draping instrument tables, that gowns be changed when they became wet, and that a method be pursued to render cotton cloth either waterproof or bacteria-proof. Karlson et al. (1959) confirmed the studies of Beck and Collette.

In 1963, Beck experimented with plastic drapes, but abandoned this option because plastic prevents the normal homeostatic mechanisms of sweat evaporation. Then he tested a new fabric that was described as a scrim-reinforced tissue with a water-repellent treatment. This fabric was characterized as impervious to bacterial passage, wet or dry, and disposable.

In August 1963, Beck and Carlson defined an aseptic barrier as a "material placed between an aseptic area, such as an operative incision, and areas which harbor microorganisms with the purpose of preventing the spread of bacteria into the sterile zone." This definition established the principle of wicking action, which diffuses liquid media over a wide area. Beck and Carlson also suggested that a surgical organization set up a special committee to formulate specifications and standardized tests for barrier materials.

Sweeney (1964) conducted a comparative study in obstetrical patients. Clinic patients with an anticipated higher infection rate due to less favorable living conditions, nutrition, and hygiene factors were draped with the new fabric; private patients were draped with conventional cloth drapes. The anticipated higher infection rate in clinic patients did not occur, demonstrating a "superior aseptic barrier to bacterial migration in obstetrical patients."

In 1967, it was demonstrated that direct bacterial transfer across the surgical gown and scrub attire may be reduced by wearing surgical attire constructed of tightly woven cotton cloth (Bernard et al., 1967). Charnley and Eftekhar (1969) demonstrated bacterial penetration of gowns made of finely woven material, balloon cloth, even in the presence of sterile air in the operating room. Beck and Mandeville (1969) described a modification to the "hydrostatic head test" (ASTM and British Standard 2823) developed for testing waterproofing of barrier materials.

Dineen (1969) compared permeability, shedding, and clinical observations with readily permeable muslin and liquid-resistant disposable materials. His results demonstrated that the disposable materials prevented both wet and dry bacterial penetration. Dineen also identified the impact of weakened host defenses on the ability of a variable-size inoculum to cause postoperative infection.

The 1970s brought a proliferation of interest in and publications on protective materials. Dineen's efforts continued, and his comparative study of airbome bacteria in operating rooms using disposable surgical drapes and gowns versus operating rooms using cotton or traditional, loosely woven muslin cloth drapes and gowns revealed a 90% reduction in airborne organisms in operating rooms using disposable drapes (Dineen, 1973).

Laufman et al. (1975) "described a test that correlated the stress of stretching surgical gown and drape material with moist bacterial strike-through." In this "unopposed weight-support test," a 2-kilogram (kg) (4.4-pound [lb]) weight was suspended in a hammock of test material to evaluate unopposed pressure or friction points on surgical gowns. The authors concluded that

> not all woven and nonwoven surgical gown and drape materials are impermeable to moist contamination for equal periods of time. Under the conditions of our tests, Quarpel-treated Pima tight-woven cotton was impermeable to moist bacterial strike-through equally well after up to 75 washing and sterilizing cyclings. Ordinary linen and untreated Pima cloth, on the other hand, permitted bacterial penetration almost immediately. Among the nonwoven gown and drape materials, spread tow plastic film composite remained impermeable to moist bacterial penetration throughout all tests .... Four other nonwoven gown and drape materials were considered satisfactory, but not as consistently impermeable as the spread tow plastic film composite. These were scrim-reinforced tissue, scrim-reinforced embossed tissue, spunbonded polyethylene nonwoven fabric, and spunlace nonwoven fabric. Two gown and drape materials were found to be poor bacterial barriers, allowing wet bacterial penetration within 5 minutes in most test runs. These were wet-laid nonwoven fabric and fiber-reinforced tissue.

It was also stated that stockinette gown cuffs permitted an immediate passage of wet contamination. Moylan et al. (1975) "conducted a clinical evaluation of bacterial penetration through operating room gowns during 100 general surgical operations using traditional, loosely-woven cloth and a disposable gown. . . . In the last 15 cases, an impermeable plastic patch was sealed to the abdominal area of the gown prior to ethylene oxide sterilization." The study results indicated that bacterial penetration was a function of time in both products. "The overall post-operative rate of external gown bacterial contamination was 89% with traditional, loosely-woven cloth and 46% for spunbonded olefin." No bacteria were cultured from under the impermeable patch on the spunbonded olefin, while the average rate of contamination under the patch on the traditional, loosely woven cloth gown was 90%. "The wound infection rate was 5%. In these cases the same coagulase-positive staphylococcus cultured from the wound was cultured from the scrub suit preoperatively and the external gown surface post-operatively." These results demonstrated that bacteria penetrated the gown made of the traditional, loosely woven cloth in the dry state.

In 1975, "the Board of Regents of the American College of Surgeons endorsed a suggestion made by the Subcommittee on Aseptic Barriers of the Committee on Operating Room Environment, indicating that the Fellowship of the College accepted the principle that materials used as barriers in operating rooms for gowns, drapes, pack[s], instrument covers, etc. should be impervious to the penetration of bacteria under the

usual conditions of use" (Bernard and Beck, 1975). In the same year, the Association of Operating Room Nurses became the first organization to publish standards of practice requiring an effective barrier between sterile and nonsterile areas (AORN, 1975). (The latest edition of these recommended practices was published in AORN [1993].) In 1978, the Association for the Advancement of Medical Instrumentation (AAMI) established a committee to develop a "Guideline for Selection and Processing of Aseptic Barrier Material." However, this effort was abandoned several years later when it proved impossible for the committee to reach consensus on standard test methods.

Belkin (1978) acknowledged "that all cotton, loosely woven, type 140 muslin is quite readily permeable to both liquids and bacteria." He identified the barrier qualities of 272-threads-per-square-inch, Quarpel-treated pima cotton.

In 1979, Laufman et al. used a modified water-resistance hydrostatic-pressure test to evaluate protective materials and reported findings similar to those of their 1975 study. Using scanning electron microscopy, Laufman et al. (1980) reconfirmed the barrier effectiveness of tightly woven, waterproofed linen and "demonstrated that nonwovens were dependably impermeable to moist, bacterial strike-through only if reinforced with plastic material."

Seaman (1980) reviewed the available tests which measured liquid barrier or repellency properties and selected two for consideration: the hydrostatic head test (AATCC Test Method 127-1974) and the vented mason jar test (INDA IST 80.9-70T). Utilizing these tests on six materials, four nonwoven types and two woven types, Seaman concluded that only the 140-thread-count muslin exhibited extensive strike-through and bacterial growth.

Schwartz and Saunders (1980) conducted tests similar to Moylan's 1975 protocol and demonstrated that spunbonded olefin, spunlaced wood pulp polyester, and treated 270-plus pima cotton were effective barriers under both laboratory and in-use conditions. Penetration was dependent on the surface tension of the liquid as defined in their surface penetration test.

Moylan and Kennedy (1980) reported on the first prospective clinical study to determine the effect of surgical gown and draping material on the incidence of surgical wound infections. During alternating 6-week periods of the 18-month study, two draping materials, spunbonded olefin and traditional, loosely woven cotton, were used in two hospitals by the same surgeons and residents. Moylan and Kennedy reported a significant reduction in postoperative wound infection rate when a disposable, spunbonded olefin gown and drape system was used.

In 1981, Ha'eri and Wiley used human albumin microspheres labeled with ^{99M}Tc to trace wound contamination postoperatively in orthopedic procedures. These researchers concluded that "conventional woven fabrics" were totally ineffective barriers and that nonwoven fabric were effective barriers. In the same year, Baldwin et al. (1981) reported the results of a clinical study demonstrating a significant reduction in postoperative wound infections when a wood pulp polyester disposable was used as compared to 140-thread-count muslin.

Laufman (1982) recommended that all 140-thread-count cotton and unreinforced nonwoven materials sold for surgical use should be imprinted: "WARNING: This material is not impermeable to bacterial strike-through, especially when wet." He also recommended the use of a grid to annotate the number of use cycles for Quarpel-treated materials. Olderman (1984) recommended the use of two tests, the fixed liquid pressure test and the dynamic impact test, to assess liquid penetration and surface wettability of a barrier material.

Moylan et al. (1987) assessed the wound infection rates in 2,181 clean and clean-contaminated general surgical procedures, comparing a spun-laced disposable to 280-thread-count cotton. He concluded that there was a significant reduction in surgical wound infections with the disposable barrier system. While this study and the earlier reports cited indicated a strong correlation between type of barrier material and incidence of

surgical wound infections, other studies during the same period did not demonstrate such a relationship (e.g., Garibaldi et al. [1986], Bernard [1982], Olson and Lee [1980], Cruse and Foord [1980]).

With the end of the decade and the rise in the prevalence of human immunodeficiency virus (HIV/AIDS), the focus began to shift from "aseptic barriers" for the protection of patients to "protective barriers" for the protection of surgical staff as well as patients.

In October 1990, Shadduck et al. reported the use of hydrostatic pressure generators to test the ability of 17 commercially available surgical gowns to resist strike-through of HIV virus. Four gowns demonstrated penetration of HIV-1 in the absence of visible liquid soak-through, nine gowns allowed visible penetration, and four gowns were impermeable to HIV-1 at all exposures tested.

Reeves (1990) referenced a test that was designed to measure the level of resistance to blood strike-through in protective clothing, specifically the blood repellency under conditions of uniformly applied pressure.

Smith and Nichols (1991), utilizing an apparatus designed to simulate the pressures experienced at the operating room table, demonstrated that all gowns tested, both reusable and disposable, allowed strike-through in varying amounts. The greatest pressure seen during any maneuver was 1.84 pounds per square inch (psi) while reaching. Only gowns reinforced with impervious plastic offered complete protection.

Altman et al. (1991) determined that the peak contact pressures exerted on the abdominal and forearm regions in surgical gowns during use in surgery during pressing and leaning exceeded 60 psi. These findings led the authors to question the validity of existing industry standard test methods.

In June 1991, Brown proposed a simple simulated in-use liquid challenge test, known as the "elbow lean." This test, used in combination with a simulated body liquid, was described as being useful for quickly demonstrating which products might be capable of preventing strike-through during pressing and leaning. This "elbow lean" method served as the rationale for the modification of the American Society for Testing and Materials (ASTM) test procedure F903, *Standard Test Method for the Resistance of Protective Clothing Materials to Penetration by Liquids,* which resulted in a new test method being proposed to ASTM by Brown (1992). Brown also strongly recommended the use of a microbial challenge as the definitive measurement of barrier performance.

From 1990 to 1992, Schoenberger, Song, and McCullough at Kansas State University conducted two studies which analyzed and compared the protection and comfort properties of several types of surgical gowns, both single-use and processed multiple-use (Schoenberger and McCullough, 1990; Song and McCullough, 1992). Based on these studies, recommendations were made concerning the protective qualities and comfort of gowns. A comprehensive comparison of test methods for assessing liquid barrier and thermal comfort properties was also made, resulting in recommendations for the use of the new ASTM ES21-92 synthetic blood penetration method (ASTM, 1992a).

In December 1991, the Occupational Safety and Health Administration promulgated a final regulation on occupational exposure to bloodborne pathogens (OSHA, 1991) (29 CFR 1910.1030). This regulation requires that health care workers be provided with "appropriate personal protective equipment" that "does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used."

Quebbeman et al. (1992) reported on a study conducted "to evaluate the barrier function of several surgical types of gowns during use in surgical procedures and identify the frequency of failure of the gowns and some causes for this failure." They found "significant differences between gowns based on the material used and the design of the gowns," and concluded that "gowns of different designs and degrees of protection should be chosen based on the body area likely to be exposed to blood and the amount of predicted blood

contamination."

Also in 1992, ASTM published two "emergency standards:" *Emergency Standard Test Method for Resistance of Protective Clothing Materials to Synthetic Blood,* designated ASTM ES21-92; and *Emergency Standard Test Method for Resistance of Protective Clothing Materials to Penetration by Bloodborne Pathogens Using Viral Penetration as a Test System,* designated ASTM ES22-92. These standards (ASTM, 1992a, 1992b) are discussed in chapter 4 of the main text.

Using various test methods for barrier properties, McCullough (1993) evaluated 13 different types of reusable and disposable surgical gown materials. In regard to the application of the ASTM emergency standards, she noted the following:

> [The ASTM] methods identify the most protective materials that are available for use in the operating room. However, gowns that fail these ASTM tests may still be used in a large number of surgical situations. Hospital personnel should assess the risk (degree of anticipated exposure to blood) to each person and for each type of procedure in the operating room. A decision can be made on the basis of this risk assessment concerning the level of protection needed; that is, whether a liquid-proof gown should be worn (high-risk situation) or a liquid-resistant gown is appropriate. Hospitals should have both types of gowns available for their employees.

McCullough also described some of the limitations of the ASTM tests and noted that work is underway to develop additional standard test methods "that would apply direct mechanical pressure at different levels on synthetic blood and the materials; distinguish different levels of protection among barrier materials; be small, inexpensive, and portable for use in the field (e.g., by laundry and hospital personnel); and be nondestructive to the barrier product."

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Annex B Test methods

This annex lists test methods that are available for use in assessing various safety and performance characteristics of barrier materials.

Table B.1—Summary table of standard test methods used to evaluate safety and performance characteristics

	ASTM	AATCC	IST	Other
Liquid penetration				
Water resistance (Low-range FTMS 191A, hydrostatic pressure)			127-1989	80.4-92 Method 5514
Water resistance (High-range hydrostatic pressure)	D751-89			FTMS 191A, Method 5512
Water resistance (Impact penetration)		42-1989	80.3-92	FTMS 191A, Method 5522
Saline repellency (Mason jar)			80.5-92	
Alcohol repellency			80.6-92	
Synthetic blood resistance	ES21-92			
Microbial penetration				
Viral penetration (Direct liquid contact)	ES22-92			
Bacterial penetration (Aerosol filtration)				MIL-M-36954B 1/6/74
Abrasion resistance				
Rotary platform, Double head method	D3884-92		20.4-92	FTMS 191A, Method 5305
Inflated diaphragm	D3886-92		20.1-92	FTMS 191A, Method 5302
Martindale	D4966-89		20.5-92	
Strength				
Breaking				
Grab tensile	D5034-90			FTMS 191A, Method 5100.1
Strip tensile	D5035-90			FTMS 191A, Method 5102
Tearing				
Elmendorf	D1424-83		100.1-92	FTMS 191A, Method 5132
Trapezoidal	D1117-90		100.2-92	
Tongue	D2261-83			FTMS 191A, Method 5134
Bursting (Mullen diaphragm)	D3786-8		30.1-92	
Drapeability				
Handle-o-meter			90.3-92	
Cantilever stiffness			90.1-92	FTMS 191A, Method 5206
Comfort				
Moisture vapor transmission				
Upright cup (Water)	E96-90B		70.2-92	

Upright cup (Desiccant)			70.2-92	
Inverted cup	E96-90BW			
Air permeability				
Frazier	D737-90		70.1-92	FTMS 191A, Method 5450
Gurley				FTMS 191A, Method 5452
Electrostatic properties				
Electrostatic decay			40.2-92	FTMS 191A, Method 5931
Surface resistivity	D4238-90	76-1989	40.1-92	FTMS 191A, Method 5930
Electrostatic clinging of fabrics		115-1986		
Flammability				
45°				CPSC CS-191-53
45°				NFPA 702-1980*
Lint generation				
Flexing in air			160.1-92	
Shaking in water			160.2-92	
Tumbling in air (Helmke drum)				IES-RP-CC-003-87
Twisting in air				BS 6909:1988
Shrinkage due to commercial laundering		96-1988		
Toxicity				Tripartite Biocompati-bility Guidance

* This test method was removed from NFPA's list of active standards in 1987.

KEY TO ACRONYMS: ASTM (American Society for Testing and Materials); AATCC (American Association of Textile Chemists and Colorists); BS (British Standard); IES (Institute for Environmental Science); IST (Association of the Nonwoven Fabrics Industry Standard Test); CPSC (Consumer Product Safety Commission); FTMS (Federal Test Method Standard); MIL (Military Specification).