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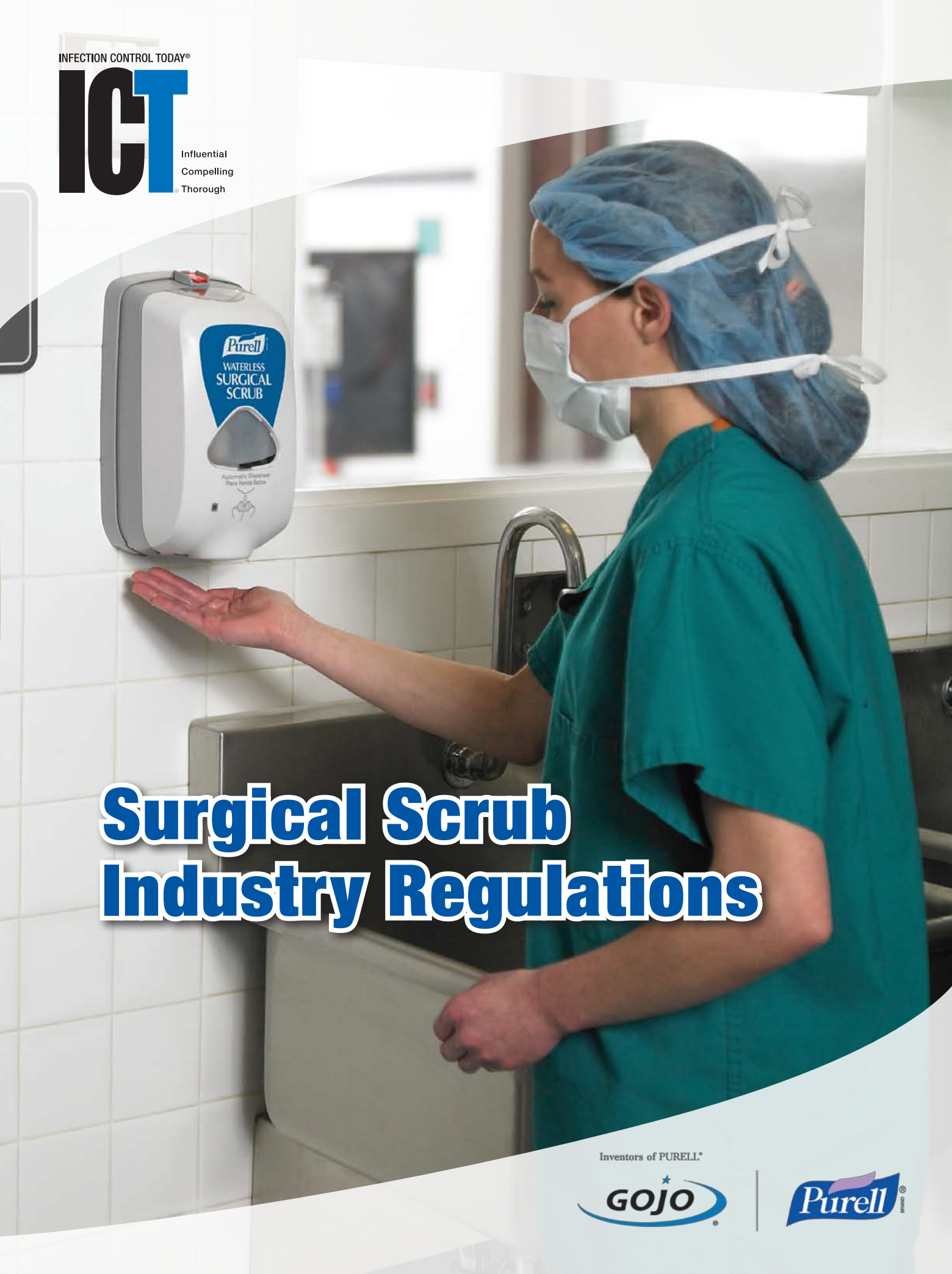

Surgical Scrub Industry Regulations

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Surgical Scrub **Industry Regulations**

By Jane Kirk, MSN, RN, CIC

Oftentimes infection preventionists, operating room nurses and purchasing agents are asked to select the operating room surgical scrub products. Learning the regulations and guidelines for surgical hand antisepsis as recommended by the Food and Drug Administration (FDA), Centers for Disease Control and prevention (CDC), Association of periOperative registered nurses (AORN) and Occupational Safety and Health Administration (OSHA) can be time-consuming and confusing. This can also be difficult to do because in many cases the regulatory organizations refer to each other's publications. In addition, some marketing materials might have condensed messages which could have references out of context. Without a thorough understanding of the regulations, this could lead one to draw an incorrect conclusion. Choosing the correct product impacts the patient, the OR team and the hospital as surgical wound infections can be caused by bacteria on the hands of the surgeon and their assistants.[1] Healthcare associated infections (HAI's) can result in untoward outcomes such as escalating cost of care, increased morbidity and mortality, longer length of stay, as well as the pain and suffering a patient may experience.[2]

The purpose of a surgical scrub is to remove resident and transient microorganisms from the hands and to inhibit the re-growth of resident flora for the duration of the procedure, despite the warm occluded environment under surgical gloves. This serves to protect the patient should a glove be compromised during the procedure.The objective of this eBook presentation is to provide reliable information summarizing the requirements and recommendations for a surgical scrub by the various regulatory and advising bodies.

FDA

Surgical scrubs are considered an over-the-counter antimicrobial drug product and therefore must be regulated by the FDA. In the U.S. the FDA is the primary governing source for surgical hand antisepsis. The FDA Topical Antimicrobial Drug Products for Human Use; Tentative Final Monograph (TFM) for Health Care Antiseptic Drug Products, published in 1994, defines a surgical hand scrub product as "an antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin; it is broad spectrum, fast acting and persistent."[3] In order for a manufacturer to legally market a surgical scrub product, the product must meet FDA regulations. Testing criteria requires that the surgical hand scrub must "reduce the number of bacteria 1-$\log_{10}$ on each hand within 1 minute and the bacterial cell count on each hand does not subsequently exceed baseline within six hours on the first day, and produces a 2–$\log_{10}$ reduction of the microbial flora on each hand within one minute of product use by the end of the second day of enumeration, and a 3–$\log_{10}$ reduction of the microbial flora on each hand within one minute of product use by the end of the fifth day when compared to the established baseline.[4]

The surgical hand scrub product must contain one of the following active ingredients to meet the TFM requirements. These active ingredients have been designated by the FDA as generally recognized as safe and effective (GRASE):

1. Alcohol 60 percent to 95 percent by volume

   Or

2. Povidine-Iodine 5 percent to 10 percent

There has been confusion around the suggestion that chlorhexidine gluconate (CHG) must be an ingredient in a waterless surgical scrub. CHG is not required in formulations for surgical scrub to meet the FDA requirements. Water-aided, traditional surgical scrubs often utilize CHG as the active ingredient, and some early alcohol- based surgical scrubs utilized CHG to as the secondary active ingredient to meet the antimicrobial efficacy requirements outlined in the TFM, but surgical scrubs with alcohol as the single active ingredient now exist that

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do not require a second active to meet the persistence requirement.

Some surgical scrubs do not utilize active ingredients that are outlined in the TFM, and must then follow a New Drug Application (NDA), often using one or more active ingredient such as CHG or dual active formulations.

AORN

AORN Recommended Practices are developed by perioperative nurse specialists and provide guidance for clinical practice in the OR setting to ensure quality of care and patient safety. The AORN Perioperative Standards and Recommended Practices for Hand Hygiene in the Operative Setting issued a revised Recommendation III in July 2009 to account for the multiple regulatory paths related to hand hygiene products. Recommendation III was revised to state, "A surgical hand scrub should be performed by healthcare personnel before donning sterile gloves for surgical or other invasive procedures. Use of either an antimicrobial surgical scrub intended for surgical hand antisepsis or an alcohol-based antiseptic surgical hand rub with documented persistence and cumulative activity that has met FDA regulatory requirements for surgical hand antisepsis is acceptable."[5] The term "FDA approved" was removed from the AORN Hand Hygiene Recommended Practice because confusion surfaced over TFM compliant surgical scrubs, which are allowed by FDA criteria.

AORN Recommendation IV states that "surgical hand hygiene products and hand lotions should be approved by the organization's infection prevention and control committee or designated authority with specialized knowledge of hand products"[6] The recommendation also states that "Antimicrobial surgical hand hygiene products should:

- Significantly reduce microorganisms on intact skin
- Contain emollients and humectants to prevent skin irritation
- Be broad spectrum
- Be fast-acting
- Have a persistent and cumulative effect[7]

CDC

According to the CDC, bacteria on the hands of surgeons can cause wound infections if introduced into the operative field during surgery. Rapid multiplication of bacteria occurs under surgical gloves if hands are washed with non-antimicrobial soap. Bacterial growth is slowed after perioperative scrubbing with an antiseptic agent. Reducing resident skin flora on the hands of the surgical team for the duration of a procedure reduces the risk of bacteria being released into the surgical field if gloves become punctured or torn during surgery.[8]

The CDC Hand Hygiene Guideline states that surgical hand scrubs should be evaluated for their ability to reduce the number of bacteria released from hands at different times including:

- Immediately after scrubbing
- After wearing surgical gloves for six hours (i.e., persistent activity)
- After multiple applications over five days (i.e., cumulative activity)

Immediate and persistent activity are considered the most important in determining the efficacy of the product.[9]

Product Selection

It is vital that infection prevention and control professionals as well as OR staff and other members of a product selection committee maintain knowledge of current recommendations and guidelines

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when selecting operating room hand hygiene products. Infection preventionists and other committee members need to review all the literature about products and ingredients and question test methods and product claims. A company that manufactures hand hygiene products should provide access to scientists who can provide evidence based studies to support the claims made about their product. Members of the product selection committee should review products claims, and validate that the claims are science based. They should feel comfortable calling the manufacturing company to discuss concerns with the scientists.

Staff should have the opportunity to trial the product for a recommended period of at least two to three weeks. Healthcare workers should be able to provide input on the choice of the product that will be used at their institution. Staff ownership of the choice in products has been rated as a very significant factor in improving hand hygiene compliance.[10] The Center for Disease Control 2002 Hand Hygiene Guideline advises that when evaluating hand-hygiene products for potential use in healthcare facilities, administrators or product-selection committees must consider factors that can affect the overall efficacy of such products, and the acceptance of hand hygiene products by personnel using the products.[11] Some factors that affect the staff's acceptance of the product include its fragrance, consistency, skin tolerance and ease of use.

OR Staff Skin Tolerance

Healthcare professionals have a higher prevalence of skin irritation than seen in the general population because of the necessity for frequent hand hygiene during patient care.[12] The tendency for some hand hygiene products to cause skin irritation and dryness has been a deterrent of product usage and acceptance by staff. Some antimicrobial compounds can be irritating or sensitizing. When reviewing OR staff feedback and concerns with skin irritation, it is important to evaluate not just the hands, but the forearms for signs of skin irritation.

Education for Usage of Surgical Scrubs

Various alcohol–based products require different amounts of product to meet the FDA's efficacy standards. The FDA requires that manufacturers should label the product with directions that "reflect the conditions used when the product was tested."[13] Staff must be educated regarding the directions for usage of the product in order to ensure that the product is used effectively and achieves the goal of surgical hand antisepsis. When using alcohol-based hand antiseptics, staff need to know the volume of product required and the length of time required for rubbing in the product, and how many applications of product are required to ensure hand antisepsis.

Knowledge and education about the requirements and recommendations for surgical hand hygiene products is essential to their efficacy, acceptance, usage, and ultimately surgical hand antisepsis and reduction of HAIs.

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*FDA Tentative Final Monograph (TFM) for Healthcare Antiseptic Drug Products.