

# PURELL® Surgical Scrub

## The quickest way into the O.R.



**Brushless. Waterless. Ground-breaking.  
All from the brand you trust.**

TECHNICAL BULLETIN

# Still using **old** scrub methods?..



Photo courtesy of the Royal College of Nursing, UK



**Or** new alcohol-based methods that still don't meet the demands of your specialized environment.

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Hard scrubbing may take its toll on your own health – damaging skin by making it rough and open to possible infection.



**PURELL®**, the #1 brand in America now offers a breakthrough in surgical scrubs, that is highly effective, yet mild and non-sticky. With only 4 mLs of product required, PURELL saves time, money and gets you into the O.R. quicker.

For over 60 years GOJO has developed highly effective skin care regimens. Today, our Research and Development scientists have combined the latest in antimicrobial and skin care technology with our understanding of the healthcare environment to offer a surgical scrub hand antiseptic with the following performance characteristics:

- ✓ **Meets or exceeds surgical scrub requirements** — FDA, CDC and AORN.
- ✓ **Antimicrobial action** — broad spectrum, fast acting agent which significantly reduces microorganisms on intact skin.
- ✓ **Persistent antimicrobial activity** — decreases rebound of microbial growth after surgical hand antiseptics for up to six hours.
- ✓ **Maintain healthy skin** — mild, non-irritating and non-sensitizing.
- ✓ **Non-sticky** — quick easy application, silky-smooth, dries quickly and allows easy gloving.
- ✓ **Compatible** — does not impact the integrity of surgical gloves and is compatible with CHG.

## Proven Antimicrobial Efficacy

The purpose of surgical scrubs is to significantly reduce the resident microorganisms and eliminate transient microorganisms from the hands of the surgical team and to slow microbial repopulation thus reducing the potential for transfer of microorganisms into the surgical wound. **PURELL Surgical Scrub does just that.**

PURELL Surgical Scrub has been thoroughly tested for both in vitro and in vivo antimicrobial efficacy in accordance with the FDA Tentative Final Monograph (TFM) guidelines for the evaluation of surgical scrub antiseptics [FR 59: 116, 17 June 94, pp. 31448-31450]. PURELL Surgical Scrub provides rapid antimicrobial kill of a broad spectrum of microorganisms.

### Conclusion:

PURELL® Surgical Scrub demonstrated very rapid and effective reduction of Gram-negative and Gram-positive microorganisms. Therefore, PURELL Surgical Scrub exhibits broad-spectrum antimicrobial efficacy.

### In Vitro Time Kill Studies

Fifteen (15) second Time-Kill evaluations were performed utilizing fifty (50) challenge bacterial strains. The challenge inoculum was introduced to the test product at time zero; a portion of the sample was removed and placed in neutralizing media at the appropriate time (15 seconds). Standard plate counting techniques were used to enumerate viable challenge microorganisms

(Table 1).

Table 1

Challenge Microbe	ATCC No.	Exposure (Seconds)	Percent Reduction
Acinetobacter baumannii	19606	15	99.9999%
Bacillus megaterium (vegetative cells)	14581	15	99.9999%
Bacteroides fragilis	29762	15	99.9999%
Burkholderia cepacia	25416	15	99.9999%
Campylobacter jejuni	29428	15	99.9999%
Citrobacter freundii	8090	15	99.9999%
Clostridium difficile (vegetative cells)	9689	15	99.9994%
Clostridium perfringens (vegetative cells)	13124	15	99.9997%
Corynebacterium diphtheriae	11913	15	99.9996%
Enterobacter aerogenes	13048	15	99.9999%
Enterococcus faecalis (MDR, VRE)	51575	15	99.9999%
Enterococcus faecalis	29212	15	99.9999%
Enterococcus faecium (MDR, VRE)	51559	15	99.9999%
Escherichia coli	11229	15	99.9998%
Escherichia coli	25922	15	99.9998%
Escherichia coli (O157:H7)	43888	15	99.9998%
Haemophilus influenzae MDR	33930	15	99.9999%
Klebsiella pneumoniae			
Subsp. ozaenae	11296	15	99.9999%
Klebsiella pneumoniae			
Subsp. pneumoniae	13883	15	99.9999%
Lactobacillus plantarum	14917	15	99.9999%
Listeria monocytogenes	7644	15	99.9999%
Listeria monocytogenes	15313	15	99.9999%
Micrococcus luteus	7468	15	99.9999%
Proteus mirabilis	7002	15	99.9999%
Proteus vulgaris	13315	15	99.9999%
Pseudomonas aeruginosa	15442	15	99.9999%
Pseudomonas aeruginosa	27853	15	99.9999%

Challenge Microbe	ATCC No.	Exposure (Seconds)	Percent Reduction
Salmonella choleraesuis Serotype Choleraesuis	10708	15	99.9999%
Salmonella choleraesuis Serotype Enteritidis	13076	15	99.9999%
Salmonella choleraesuis Serotype Typhimurium	14028	15	99.9999%
Serratia marcescens	14756	15	99.9999%
Shigella dysenteriae	13313	15	99.9999%
Shigella sonnei	11060	15	99.9999%
Staphylococcus aureus	6538	15	99.9999%
Staphylococcus aureus	29213	15	99.9999%
Staphylococcus aureus (MRSA)	33591	15	99.9999%
Staphylococcus aureus (MRSA;PVL+)	120805Nr Sa384*	15	99.9999%
Staphylococcus epidermidis	12228	15	99.9999%
Staphylococcus haemolyticus	43253	15	99.9999%
Staphylococcus hominis	27845	15	99.9999%
Staphylococcus saprophyticus	49453	15	99.9999%
Streptococcus pneumoniae	33400	15	99.9999%
Streptococcus pyogenes	19615	15	99.9999%

Yeasts and Fungi	ATCC No.	Exposure (Seconds)	Percent Reduction
Aspergillus flavus	9643	15	99.9540%
Aspergillus niger	9642	15	95.5385%
Candida albicans	14053	15	99.9999%
Candida tropicalis	13803	15	99.9999%
Epidermophyton floccosum	52066	15	99.9052%
Penicillium citrinum	9849	15	99.9054%
Trichophyton mentagrophytes	9533	15	99.9029%

\* Clinical isolate  
Abbreviations: MDR, Multiple drug resistant; VRE, Vancomycin resistant Enterococci; MRSA, Methicillin resistant *Staphylococcus aureus*; PVL, Pantone-Valentine Leukocidin

## In Vivo Surgical Scrub Study

Testing according to the FDA, Tentative Final Monograph (TFM) for Health Care Antiseptic Drug Products requires both immediate kill and a “persistent” effect. Subjects use the product a total of eleven times over a 5 day period and reduction of the resident hand microflora is measured. The TFM minimum performance requirements for surgical scrub hand antiseptics are a 1 log (90%) reduction immediately after the first wash on Day 1, a 2 log (99%) reduction immediately after the first wash on Day 2, and a 3 log (99.9%) reduction immediately after the first wash on Day 5. Furthermore, the bacteria counts shall not exceed baseline within 6 hours (under glove occlusion) on day 1. (Table 2)

Table 2

Day	Sample	PURELL® Surgical Scrub			4% CHG Reference Product	FDA Acceptance Criteria
		Three Applications of 2 mL	Two Applications of 2 mL	Two 3 minute scrubs with 5 mL product and brush		
Day 1	Immediate	3.08	2.31	1.35	1	
	3 Hour	2.53	2.58	1.19	N/A	
	6 Hour	2.30	2.19	0.49	>0	
Day 2	Immediate	3.39	2.93	2.34	2	
	3 Hour	3.09	3.00	1.70	N/A	
	6 Hour	2.51	2.47	1.33	N/A	
Day 5	Immediate	3.02	3.15	3.77	3	
	3 Hour	2.99	3.14	2.93	N/A	
	6 Hour	2.64	2.88	2.75	N/A	

<sup>1</sup> N/A: Not applicable

<sup>2</sup> FDA acceptance criteria = bacterial cell count does not exceed baseline within 6 hours on the first day



### Conclusion:

PURELL Surgical Scrub met or exceeded the FDA's in vivo efficacy criteria for surgical scrub products at all points measured with as little as two applications of 2 mL (Table 2). In fact, when three applications of 2 mL were used, PURELL Surgical Scrub met the Day 5 requirement of a **99.9% reduction in microbial hand flora on Day 1.**

### Guideline criteria for surgical scrubs in the United States:

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

“...requires that products for surgical hand scrubs provide a one-log reduction on day one, a two-log reduction on day two, a three-log reduction on day five, and show persistent activity for at least six hours on the first test day.”

CDC MMWR Recommendations and Reports Oct. 25, 2002/vol. 51/ No. RR-16:

“Surgical hand antisepsis using either an antimicrobial soap or an alcohol-based hand rub with persistent activity is recommended before donning sterile gloves when performing surgical procedures.” (Recommendations: 3C)

AORN Recommended Practices for Surgical Hand Antisepsis/Hand Scrubs:

“An FDA-compliant, surgical hand antiseptic agent (i.e., surgical hand scrub/ rub) approved by the facility's infection control personnel should be used for all surgical hand antisepsis/ hand scrubs.

Definitions:

FDA – Food and Drug Administration

CDC – Centers for Disease Control and Prevention

AORN - Association of periOperative Registered Nurses

## Proven Persistent Activity

Not only must a surgical scrub hand antiseptic provide rapid antimicrobial action, this antimicrobial action must have a sustained effect over time. Some have argued that formulas consisting only of alcohol could not provide a persistent effect and that alcohol requires an additional active such as chlorhexidine gluconate (CHG) for persistence. But this is no longer the case. With the emergence of new technology, and the development of a patent-pending formulation PURELL Surgical Scrub (with 70% ethyl alcohol) provides excellent persistent activity lasting hours.

Although alcohol evaporates rapidly from the skin, studies have demonstrated that bacterial counts continue to decline for some time after exposure to alcohol.<sup>1,2</sup> This effect can be explained by sublethal damage to some bacteria which will kill the bacteria over time if they are not promptly inoculated onto culture medium. Because of this post-exposure effect, CHG is no longer needed to meet FDA, CDC, and AORN requirements. In fact as Figure 1 demonstrates, the persistence of PURELL Surgical Scrub (as measured by the log reductions at 6 hours on days 1, 2, and 5) was equal to or better than the 4% CHG control product.

### Conclusions:

PURELL Surgical Scrub meets or exceeds the FDA requirements for a Surgical Scrub including **6 hour persistence** activity. The persistence of PURELL Surgical Scrub (as measured by the log reductions at 6 hours on days 1, 2, and 5) was equal to or better than the 4% CHG control product.

Figure 1:

**In vivo Surgical Scrub Study:  
Immediate and Persistent Antimicrobial Activity**  
PURELL® Surgical Scrub (2 applications of 2 mL) vs. 4% CHG Reference Product

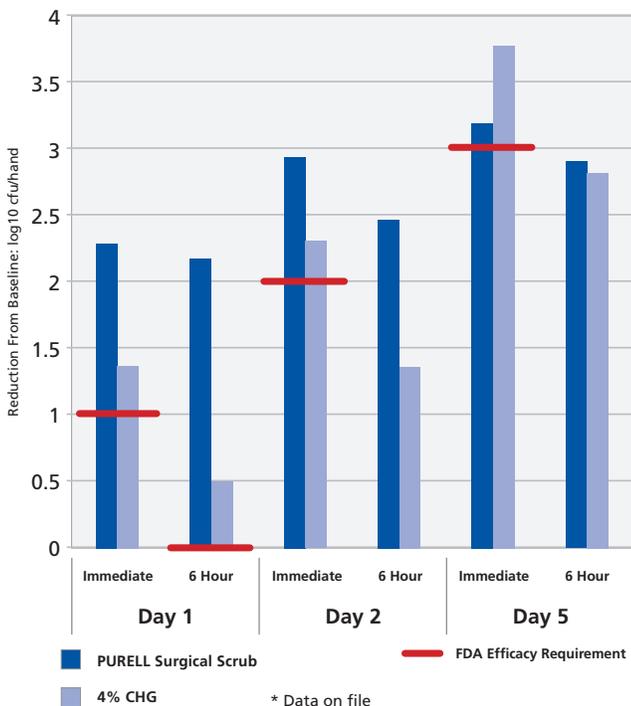
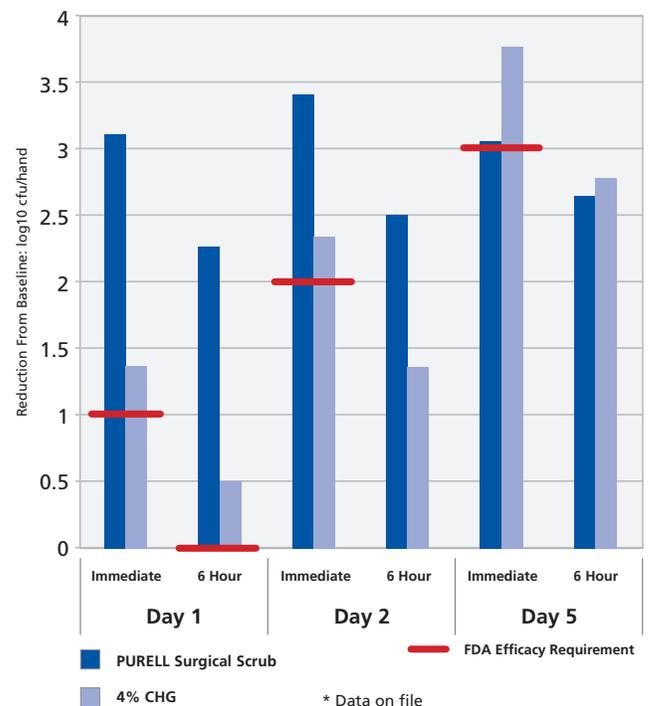


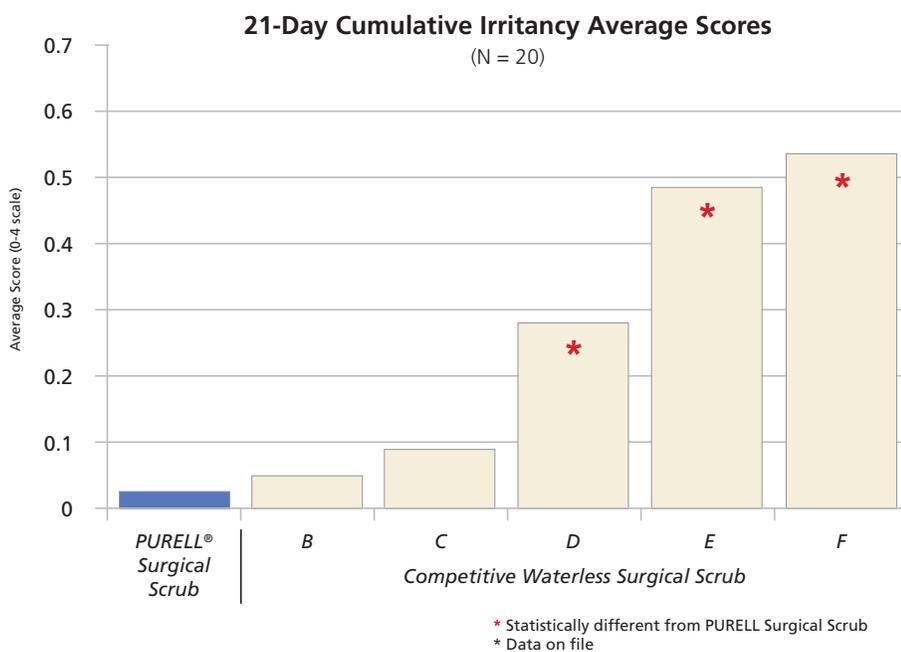
Figure 2:

**In vivo Surgical Scrub Study:  
Immediate and Persistent Antimicrobial Activity**  
PURELL® Surgical Scrub (3 applications of 2 mL) vs. 4% CHG Reference Product



## Proven To Be Mild

Frequent and repeated scrubbing can lead to dry, irritated and damaged hands. Maintaining healthy skin is essential to keep healthcare workers at their job and to reduce the probability of increased colonization and the spread of infectious agents. Following industry standards, a 21 day evaluation of skin irritation potential in humans was carried out applying fresh product (PURELL Surgical Scrub) daily, for 5 days per week, for 21 days to the same site. The average score obtained was 0.02 on a scale of 0 – 4; with 0 indicating that no sensitization occurred.



### Conclusion:

**Mild.** PURELL Surgical Scrub has a low potential for skin irritation and allergic contact dermatitis. The data for the first 21-Day Cumulative Irritation Test for PURELL Surgical Scrub have been analyzed for statistical significance against five competitive waterless surgical scrub products. Statistically, PURELL Surgical Scrub is significantly less irritating to the skin than three of five competitive surgical scrubs tested.

## User Acceptance: Clinical Field Testing

PURELL Surgical Scrub's patent-pending silky-smooth formulation is dye-free, fragrance-free and contains five skin-conditioning agents that leave hands feeling soft and moisturized without the feeling of stickiness or residual build up. And does not interfere with gloving. PURELL Surgical Scrub evaporates quickly, saves time and gets operating room staff into the OR quicker.



## Compatible

**Gloves:** Following the ASTM D5151-99 standard, glove samples were immersed in product for a period of 2 hours and then examined for leaks. The control samples were not exposed to product. 100 control gloves and 100 gloves were tested with PURELL Surgical Scrub on each of three glove types. Tested were 100 each of latex, polyisoprene, neoprene and a second brand of neoprene surgical gloves. Results indicated that PURELL Surgical Scrub does not impact the integrity of latex, neoprene or polyisoprene surgical gloves.

\* Data on file

**CHG:** A compatibility study to measure the effects of PURELL Surgical Scrub on the antimicrobial properties of a known CHG Surgical Scrub indicated that PURELL Surgical Scrub is compatible with CHG.

### Compatibility Study to Measure the Effects of PURELL® Surgical Scrub On the Antimicrobial Properties of One Surgical Scrub Formulation

	Baseline	Log Reduction Immediate	Log Reduction at 2 hours
PURELL Surgical Scrub followed by use of CHG Surgical Scrub	5.47	5.06	5.01
CHG Surgical Scrub followed by use of PURELL Surgical Scrub	5.98	5.98	5.98
CHG Surgical Scrub (control test)	5.66	4.11	5.06



#### Conclusion:

The results with the test product are not significantly lower than the log reduction for the control at the immediate time point and at the 2 hour time point. Therefore the test product is compatible with CHG containing products.

\* Data on file

## Formulated Without CHG?

While chlorhexidine gluconate (CHG) is found in many wash off hand hygiene products, it can be harsh on skin. CHG is a commonly known cause of irritant contact dermatitis and frequent use can lead to dry skin. Additionally, allergic reactions to CHG, while rare, can range from contact dermatitis and urticaria to dyspnea and anaphylactic shock.

Several species of gram-negative bacteria have demonstrated either natural or acquired resistance to CHG including *P. aeruginosa*, *P. mirabilis*, *P. aeruginosa*, and *S. marcescens*. Furthermore some strains of MRSA have been found to carry CHG resistance which can be transferred to other bacteria. Occasional outbreaks of nosocomial infections have been traced to contaminated solutions of CHG.<sup>3</sup>

Considering the demonstrated persistence of PURELL Surgical Scrub, the potential side effects of CHG (as a wash-off) and not fully understanding the potential side effects of CHG as a leave-on, CHG would not add sufficient value to PURELL Surgical Scrub to compensate for these risks.

## PURELL Surgical Scrub Dispensing Systems... *the Choice is Yours.*

Our state-of-the-art dispensing systems are easy to install, easy to use and easy to maintain. The 1200 mL refill provides more scrubs than traditional dispensing bottles in the market today.



### PURELL Surgical Scrub TFX™ Touch Free Dispenser

With the PURELL TFX Touch Free Dispensing System, there is nothing to touch or push. Just place hands below. It takes hand hygiene to a whole new level.

Reliability is guaranteed. You get all the benefits of touchless without the worry of whether or not your dispenser is working.

- Skylight makes it easy to see when it's time to reload
- Turns off automatically when dispenser is opened
- 30,000 uses from three standard C-size alkaline batteries which are included
- Fully ADA compliant
- UL / CE registered
- Sanitary-sealed, collapsible bottle refill keeps germs out
- Fresh dispensing valve with every refill
- 300 scrubs per refill (4 mL per scrub)



### PURELL Surgical Scrub Foot Pump Dispenser

The PURELL Surgical Scrub Foot Pump Dispenser offers durable construction and easy-to-load, large capacity refills. With an extra-large site window and skylight there is less need for refilling – and fewer out-of-soap complaints.

- Skylight makes it easy to see when it's time to reload
- Sanitary-sealed, collapsible bottle refill keeps germs out
- Fresh dispensing valve with every refill
- Holds 1200 mL sealed refill in a remarkably small footprint
- Requires filling half as often, saving time and money
- Ideal for high traffic, high volume locations where frequent servicing is difficult or impractical
- Permanently attached foot pump that stays in place
- Easy to use and reliable



### Directions for Use:

- A) Clean under the nails with a nail pick. Nails should be maintained with a 1 millimeter free edge
- B) Place 2 mL of product into palm of one hand, dip fingertips of opposite hand into the product and work under nails
- C) Spread remaining product evenly over the hands and lower 2/3 of one forearm paying particular attention to the nails, cuticles, and interdigital spaces
- D) Place 2 mL of product into opposite hand and repeat steps B and C
- E) Allow to air dry completely before gloving

PURELL® Surgical Scrub Alcohol-based, waterless and brushless	Order Number	Case Pack
PURELL Surgical Scrub TFX™ Dispenser	2785-12	1
PURELL Surgical Scrub 1200 mL TFX Refill	5485-4	4
PURELL Surgical Scrub Foot Pump Dispenser	6120-01	1
PURELL Surgical Scrub 1200 mL Refill	6185-03	3

PROVON® Antimicrobial Skin Cleanser w/ 2% CHG	Order Number	Case Pack
PROVON® Antimicrobial Skin Cleanser with 2% CHG - 32 fl oz Bottle	4104-12	12
PROVON Foot Pump Dispenser	4298-06	6
PROVON Nail Cleaners (150 nail cleaners per box; 6 boxes per case)	6180-06	6

**To order PURELL® Surgical Scrub, contact your distributor or call GOJO at 1-800-321-9647.**

- Lowbury, E.J.L.; Lilly, H.A.; Ayliffe, G.A.J., Preoperative Disinfection of Surgeons Hands: Use of Alcoholic Solutions and Effects of Gloves on Skin Flora, British Medical Journal, Vol. 4, 1974, pp. 369-372.
- Lilly, H.A.; Lowbury, E.J.L.; Wilkins, M.D.; Zaggy, A., Delayed Antimicrobial Effects of Skin Disinfection by Alcohol, Journal of Hygiene (Cambridge), Vol. 82, 1979, pp. 497-500.
- Centers for Disease Control and Prevention, Guideline for Hand Hygiene in Health-Care settings. MMWR Morb. Mortal. Weekly Rep. October 25, 2002 / Vol. 51 / No. RR-16.



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