

The efficacy you need.
The healthy skin you want.



PURELL® Waterless Surgical Scrub

Frequent scrubbing with harsh ingredients can cause skin irritation.

The U.S. Food and Drug Administration (FDA) requires that surgical scrubs provide rapid antimicrobial action and persistence. To achieve this persistent effect, some hand hygiene products rely on a combination of active ingredients that may irritate skin when used frequently. With most surgical staffs scrubbing in 10 to 15 times per day, it's easy to see why skin irritation is one of the most important issues they face on a daily basis.





It's time to wash your hands of ingredients which may be harsh to the skin.

There's a new way to scrub in. PURELL® Waterless Surgical Scrub is designed to meet and exceed FDA surgical scrub requirements* *without* the addition of ingredients which may be harsh to the skin. Our unique formulation uses alcohol as the only active ingredient, plus inactive ingredients that make the alcohol work even harder. Together, they provide the germ kill and persistent activity critical to the surgical environment — and critical to meeting FDA and AORN requirements.

- CHG-free formulation
- Includes five skin conditioners that help maintain healthy skin
- Compatible with latex, neoprene and polyisoprene gloves
- Requires only two applications and dries quickly

For a surgical clean that's mild to the skin, turn to the name you trust — PURELL Waterless Surgical Scrub.

waterless

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

Proven Persistent Activity

Innovation made simple

PURELL® Waterless Surgical Scrub provides the immediate kill and persistence you expect, but does it without CHG. A unique *Advanced Alcohol* formulation allows it to work with alcohol as the only active ingredient, making PURELL Waterless Surgical Scrub kinder to skin while providing all the effectiveness you need.

High alcohol content has been proven to kill both resident and transient bacteria immediately upon contact. And when combined with a patent-pending blend of inactive ingredients, that alcohol works even harder.

The result is an *Advanced Alcohol* formulation that weakens even the hardest-to-kill germs on contact, penetrates the skin more completely than alcohol alone to reach more resident bacteria, and creates a pH-balanced environment that helps inhibit germ recovery and regrowth.



persistent

Although alcohol evaporates rapidly from the skin, studies have shown that bacterial counts continue to decline for some time after alcohol exposure. This occurs because bacteria damaged sublethally will die over time if not promptly inoculated onto culture medium. Because of this post-exposure effect, additional inactive ingredients are not necessary to meet requirements established by the Centers for Disease Control and Prevention (CDC), the Association of periOperative Registered Nurses (AORN) and the FDA. In fact, Figure 1 demonstrates that the persistence of PURELL® Waterless Surgical Scrub (as measured by the log reductions at six hours on days 1, 2 and 5) was equal to or better than the 4% CHG control product.

Meets and Exceeds FDA Regulatory Requirements*

Figure 1
In Vivo Surgical Scrub Study:
Immediate and Persistent Antimicrobial Activity

PURELL® Waterless Surgical Scrub (two applications of 2 mL) vs. 4% CHG Reference Product

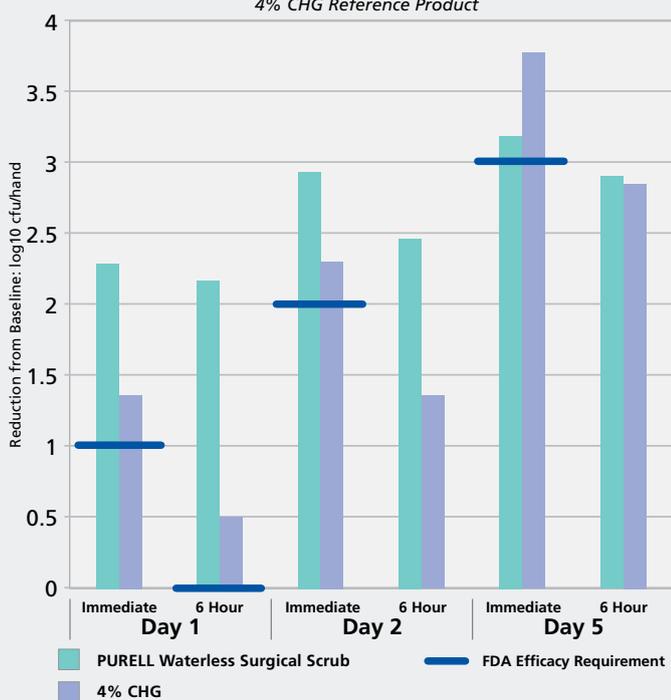
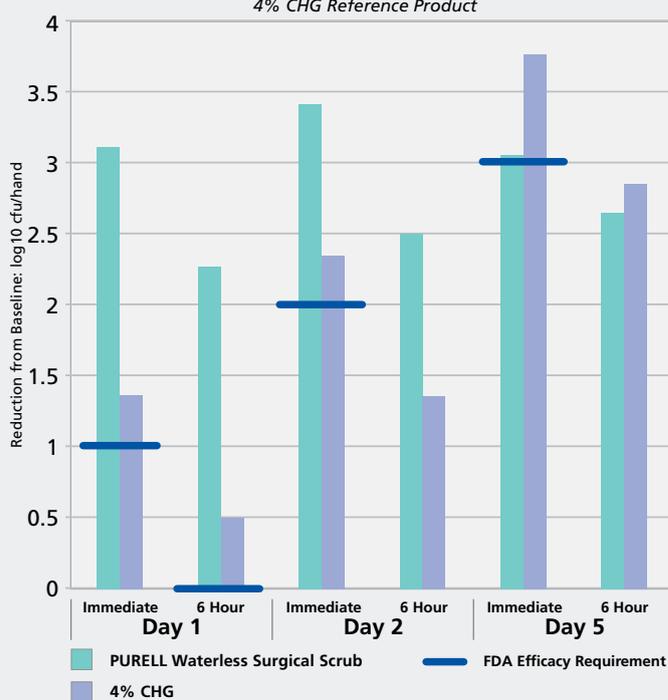


Figure 2
In Vivo Surgical Scrub Study:
Immediate and Persistent Antimicrobial Activity

PURELL® Waterless Surgical Scrub (three applications of 2 mL) vs. 4% CHG Reference Product



Conducted at an independent third-party clinical laboratory, study #BSL#050716-102, March 23, 2006.

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

Conclusion:

PURELL Waterless Surgical Scrub meets and exceeds the FDA's* six-hour persistent activity requirement.

efficacy

Proven Antimicrobial Efficacy

It not only kills germs, it inhibits regrowth

Surgical scrubs were developed for several critical purposes. While significantly reducing resident microorganisms and eliminating transient microorganisms from the hands of surgical team members, they slow microbial repopulation, which helps to reduce the potential transfer of microorganisms into a surgical wound.

PURELL® Waterless Surgical Scrub has been proven to perform each of these functions while providing rapid antimicrobial kill of a broad spectrum of microorganisms. In fact, it's been tested thoroughly 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].

Table 1

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

*Clinical isolate

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

Conducted at an independent third party clinical laboratory, study #BSL#051211-201, March 23, 2006.

Challenge Microbe	ATCC No.	Exposure (Seconds)	Percent Reduction
<i>Pseudomonas aeruginosa</i>	27853	15	99.9999%
<i>Salmonella choleraesuis</i> Serotype Choleraesuis	10708	15	99.9999%
<i>Salmonella choleraesuis</i> Serotype Enteritidis	13076	15	99.9999%
<i>Salmonella choleraesuis</i> Serotype Typhimurium	14028	15	99.9999%
<i>Serratia marcescens</i>	14756	15	99.9999%
<i>Shigella dysenteriae</i>	13313	15	99.9999%
<i>Shigella sonnei</i>	11060	15	99.9999%
<i>Staphylococcus aureus</i>	6538	15	99.9999%
<i>Staphylococcus aureus</i>	29213	15	99.9999%
<i>Staphylococcus aureus</i> (MRSA)	33591	15	99.9999%
<i>Staphylococcus aureus</i> (MRSA,PVL+)	120805Nr Sa384*	15	99.9999%
<i>Staphylococcus epidermidis</i>	12228	15	99.9999%
<i>Staphylococcus haemolyticus</i>	43253	15	99.9999%
<i>Staphylococcus hominis</i>	27845	15	99.9999%
<i>Staphylococcus saprophyticus</i>	49453	15	99.9999%
<i>Streptococcus pneumoniae</i>	33400	15	99.9999%
<i>Streptococcus pyogenes</i>	19615	15	99.9999%

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

In Vitro Time-Kill Studies

Fifteen-second time-kill evaluations were performed at an independent third-party laboratory against 50 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 15 seconds. Standard plate-counting techniques were used to enumerate viable challenge microorganisms.

(Table 1)

Conclusion:

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



In Vivo Surgical Scrub Study

According to FDA Tentative Final Monograph (TFM) for Health Care Antiseptic Drug Products testing requirements, surgical scrubs must provide both immediate kill and a “persistent” effect. PURELL® Waterless Surgical Scrub was tested according to FDA guidelines at a third-party independent clinical testing laboratory. Subjects used the product a total of 11 times over a five-day period to measure the reduction of resident hand microflora. The product met the FDA minimum performance requirements for surgical hand scrub antiseptics which are a 1-log (90%) reduction immediately after the first wash on day one, a 2-log (99%) reduction immediately after the first wash on day two, and a 3-log (99.9%) reduction immediately after the first wash on day five. Furthermore, the bacteria count did not exceed baseline within six hours (under glove occlusion) on day one.

(Table 2)

Table 2

Day	Sample	PURELL® Waterless Surgical Scrub		4% CHG Reference Product	FDA Acceptance Criteria ^{1,2}
		Three applications of 2 mL	Two applications of 2 mL	Two 3-minute scrubs with 5 mL product and brush	
		log ₁₀ Reduction			
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

¹ N/A: Not applicable ² FDA acceptance criteria = bacterial cell count does not exceed baseline within six hours on the first day
 Conducted at an independent third-party clinical laboratory, study #BSL#050716-102, March 23, 2006.

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 1-log reduction on day one, a 2-log reduction on day two, a 3-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

Conclusion:

PURELL Waterless 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 Waterless Surgical Scrub met the day five requirement of a 3-log (99.9%) reduction in microbial hand flora on day one.

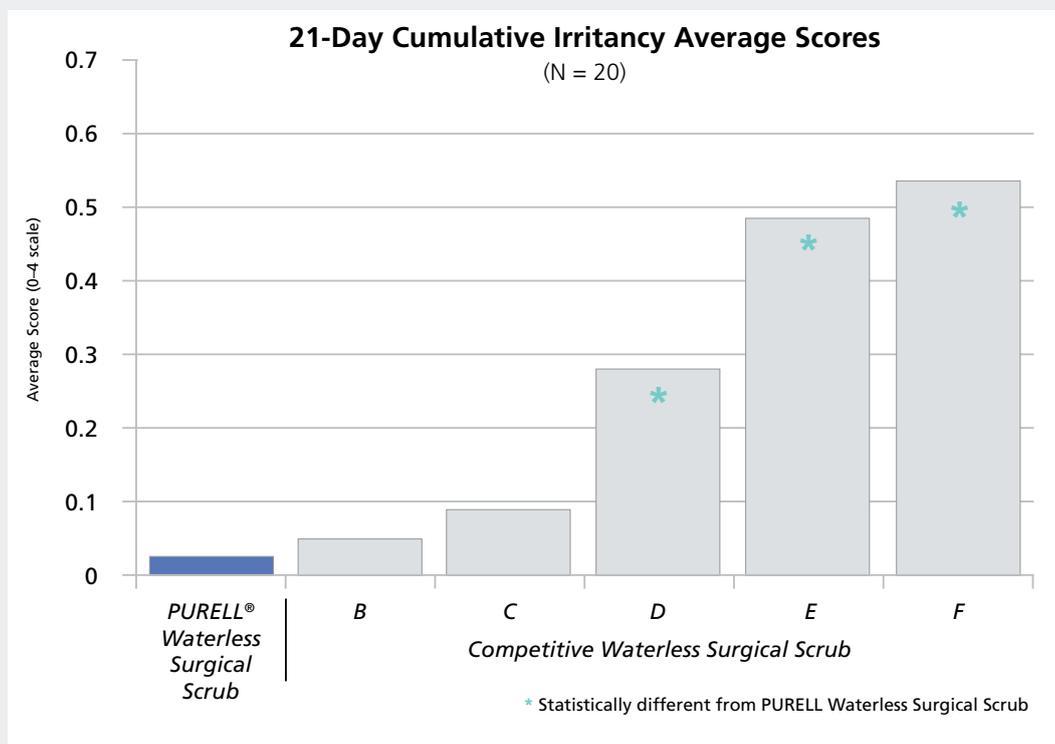


mild

Proven to Be Mild

Makes dry, irritated skin a thing of the past

It is essential for healthcare workers to maintain healthy skin on the job to reduce the probability of increased colonization and the spread of infectious agents. However, frequent scrubbing can lead to dry, irritated and damaged hands. Following industry standards, a 21-day evaluation of skin irritation potential in humans was performed by applying product (PURELL® Waterless Surgical Scrub) daily, five days per week, for 21 days to the same site. The average obtained score was 0.02 on a scale of 0–4, with 0 indicating that no irritation occurred.



Conducted at an independent third-party clinical laboratory, study #RCTS#2003, April 7, 2006.

User Acceptance: Clinical Field Testing

With a patent-pending silky-smooth formulation, PURELL Waterless Surgical Scrub is free of dyes and fragrances. It also contains five skin-conditioning agents that leave hands feeling soft and moisturized without any stickiness or residual buildup. And since it evaporates quickly, it saves time and allows staff to quickly get into the OR.

Conclusion:

PURELL Waterless Surgical Scrub has a low potential for skin irritation and allergic contact dermatitis. Twenty-One-Day Cumulative Irritation Test data showed that PURELL Waterless Surgical Scrub is significantly less irritating than three of the competitive products tested.



Compatible with Gloves and CHG

Following the ASTM D5151-99 standard, glove samples were immersed in the product for a period of two hours and then examined for leaks. The control samples were not exposed to the product. PURELL® Waterless Surgical Scrub was tested on 100 control gloves and 100 gloves made of latex, polyisoprene and two brands of neoprene. Results indicated that PURELL Waterless Surgical Scrub does not impact the integrity of latex, neoprene or polyisoprene surgical gloves.

An additional compatibility study to measure the effects of PURELL Waterless Surgical Scrub on the antimicrobial properties of a known CHG Surgical Scrub indicated that PURELL Waterless Surgical Scrub is compatible with CHG.

compatible

Compatibility Study to Measure the Effects of PURELL® Waterless Surgical Scrub on the Antimicrobial Properties of a 4% CHG Surgical Scrub Formulation

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

Conducted at an independent third-party clinical laboratory, study #Smithers#062-13141, February 14, 2006.

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 two-hour time point. Therefore, the test product is compatible with products containing CHG and gloves.

PURELL® Waterless Surgical Scrub Dispensing Systems

Dependable performance with every pump

The new generation of PURELL Waterless Surgical Scrub dispensing systems is engineered for reliability and easy servicing. With an innovative, sleek design, the PURELL Waterless Surgical Scrub LTX™ dispenser system offers the durability and versatility you need while providing greater user experience and optimal performance.

This dispenser is designed to release 2mL of product in one actuation of the dispenser, the exact amount of product needed for each hand and arm in the scrub process and to meet and exceed FDA surgical scrub requirements.

Just place your hands below the PURELL Waterless Surgical Scrub LTX touch-free dispenser and it will release two pumps of product helping you be surgery ready in record time. And with guaranteed reliability, you'll enjoy all the benefits of a touch-free system without worrying if the dispenser is working properly.

simple

Smart, trouble-free electronics

PURELL Waterless Surgical Scrub LTX™ dispenser uses patent-pending technology to optimize energy use. That means it's engineered to use a minimal amount of energy per actuation – eliminating the need to change batteries during the life of the dispenser in most installations. The batteries are also pre-installed to make system activation simple.

Sustainability

At GOJO, we design all of our products with ease of use and sustainability in mind. That's why we made it simple to install the refills. Plus, the removable pump makes recycling more convenient than ever.

GOJO SMART-FLEX™ Bottles

Our bottles are made with durable, recyclable PET material to provide crystal clarity. They also use 30% less material than bottles made with rigid HDPE.

Guaranteed performance

The LTX system carries the GOJO Lifetime Performance Guarantee. Our dependability promise even includes the batteries in the LTX touch-free system.

Easy to maintain

A large sight window, skylight and clear refill bottles work together to offer at-a-glance checking of refill status. And with our GOJO® LOCK OR NOT™ Technology, the cabinet can be opened using either of the dual side latches, or by removing the key inside to convert it to a locking cabinet.

Available Accessories:

Wall Spacer — Offsets the dispenser from the wall to help prevent contamination from any germs on the wall.

Surgical Sink Bracket — Enables the dispenser to be mounted on a sink to support a scrubbing environment familiar to your staff.

AT-A-GLANCE™ Service REFILL ALERT™ — Help maintain your dispensing system with AT-A-GLANCE Service REFILL ALERT. Flag is in the down position, indicates the dispenser is equipped with product; flag is up to indicate that the dispenser needs to be refilled.



Wall Spacer



Surgical Sink Bracket



AT-A-GLANCE
Service REFILL ALERT

Get a FREE Product Trial*

We're so sure that you'll love PURELL® Waterless Surgical Scrub that we're willing to let you try it for free! After several uses, you'll see for yourself that it provides the surgical clean and germ kill you need while keeping your skin healthy and smooth. Get your free product trial today!

To receive your free trial of PURELL Waterless Surgical Scrub, call **1-800-321-9647**, e-mail healthcaretrial@gojo.com or visit healthcare.GOJO.com/surgical-scrub-trial.

*Some restrictions apply. See healthcare.GOJO.com for details.



**WATERLESS
SURGICAL SCRUB**



Directions for Use:

APPLY TO CLEAN, DRY HANDS

Step 1

- Clean under your nails with a nail pick.¹

APPLICATION 1 (RIGHT HAND)

Step 2

- Dispense 2 mL of product (dispenser will automatically actuate twice) into the palm of your right hand.

Step 3

- Dip fingertips of left hand into the product and work under nails.

Step 4

- Spread remaining product evenly over your left hand and forearm.
- Pay attention to all skin surfaces including the nails, cuticles and web area in between fingers.

APPLICATION 2 (LEFT HAND)

Step 5

- Repeat steps 2, 3 and 4 for the opposite hand and arm.
- Allow hands and arms to completely air dry before applying glove (approximately one minute).

IF DESIRED OR REQUIRED BY YOUR OPERATING ROOM PROTOCOL, A THIRD APPLICATION CAN BE USED FOR YOUR HANDS.

¹ Healthcare personnel should keep natural fingernails no more than one-quarter inch (0.64 cm) long

PURELL® Waterless Surgical Scrub	Order Number	Case Pack*
PURELL Waterless Surgical Scrub 1200 mL LTX Refill	1907-02	2
PURELL Waterless Surgical Scrub 1200 mL TFX Refill	5485-04	4
PURELL Waterless Surgical Scrub 1000 mL TFX Refill	5483-04	4
PURELL Waterless Surgical Scrub 2 fl. oz. bottle	9686-24	24

Dispensing Options and Accessories	Order Number	Case Pack*
PURELL Waterless Surgical Scrub LTX™ Dispenser	1932-04	4
PURELL Waterless Surgical Scrub TFX™ Dispenser	2785-12	12
PURELL Waterless Surgical Scrub TFX Surgical Sink Bracket	2782-06	6
PURELL Waterless Surgical Scrub TFX Wall Spacer	2781-06	6
PURELL Waterless Surgical Scrub AT-A-GLANCE™ Service REFILL ALERT™	2101-24	24
PROVON® Nail Cleaners (150 nail cleaners per box; 6 boxes per case)	6180-06	6

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



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