

TheraworxTM

When Clean Is Not Enough.



Clean.

Protect.

Hydrate.

When Clean Is Not Enough.

What is Theraworx™?

Theraworx™ is a skin cleansing solution clinically formulated with the Silver Advantage and is designed to cleanse and nourish the skin without the harshness of alcohol. The **Theraworx™** solution is considered all natural and utilizes three distinct mechanisms to provide its cleansing properties:

Cleans - Removes dirt while leaving the natural oils behind

Protects - Moisturizers help defend against Dryness

Hydrates - Aloe, Vitamin E and Beta Glucan provide skin nourishment

Its unique cleansing action and ability is coupled with clinically significant amounts of skin healthy natural compounds that enrich and nourish the skin.

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Theraworx™
SILVER ADVANTAGE

When Clean Is Not Enough.

Full Disclosure Statement

Theraworx™ is a patented formulation clinically designed to assist patients, health care professionals and individuals with topical cleansing needs. The formulation is unique and different from other topical cleansers currently available.

Theraworx™ is to be considered as an adjuvant to first line remedies for patients with chronic skin conditions requiring diligent hygiene and would benefit from a cleanser with minimal topical irritation.

Theraworx™ is to be considered as a hand wash with unique attributes designed to hydrate and protect the skin in settings where hands are to be washed throughout the day.

Theraworx™ is to be considered when water and / or rinsing are not feasible or indicated.

When **Theraworx™** is used to clean the skin cultures are affected. Washing with **Theraworx™** will result in significant log reduction of a broad range of bacteria, fungi and viruses, however, **Theraworx™** is not to replace first line antiseptics in the pre-surgical arena but can be used as a pre-antiseptic wash or post-antiseptic wash. **Theraworx™** is not to be positioned as an antiseptic but rather a skin cleanser. **Theraworx™** may be considered as a cleansing option when individuals show sensitivities to other products in this class or when cleansing needs to occur in areas of the body where other products are not indicated or optimal.

While regular hand washing is recommended as a safeguard against infections it should be noted that hand washing is a safeguard only and not a guarantee. Individuals who wash their hands with **Theraworx™** should not consider themselves covered and understand it is a safeguard only.

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Executive Summary

Microbial Testing

1.0 Objective

- 1.1 The objective of this summary is to briefly delineate the scope of testing that has been conducted to assure the safety and effectiveness of the Theraworx™ platform.

2.0 Scope

- 2.1 The scope of this report shall cover the original testing completed as part of the patented process (2002), as well as all subsequent antimicrobial and biocompatibility testing recently conducted.

3.0 References

- 3.1 AATCC Method 100: Antibacterial Finishes on Textile Materials: Assessment of
- 3.2 ISO/DIS 10993: Biological evaluation of Medical Devices- Part I: Evaluation and Testing

4.0 Attachments

- 4.1 Test reports available upon request.

5.0 Definitions

- 5.1 Theraworx™ - A patented, anti-microbial skin-nourishing and cleansing solution.

6.0 Testing Data

6.1 Original Testing

6.1.1 Antimicrobial Activity Testing

Testing was conducted by Microbiological Consultants, Inc. on behalf of Harod Enterprises, Inc. on January 15, 1998.

| Test Organism | ATCC No. | Initial Inoculum | Percent Reduction |
|------------------|----------|--------------------|-------------------|
| E. Coli | 11229 | 2.32×10^3 | >99.9% |
| S. aureus (MRSA) | 33591 | 1.06×10^3 | >99.9% |
| C. albicans | 10231 | 1.06×10^4 | >99.9% |

6.1.2 Antimicrobial Efficacy Testing

Testing was conducted by Microbiological Consultants, Inc. on behalf of Harod Enterprises, Inc. on June 12, 2000

| Test Organism | ATCC No. | Initial Inoculum | Percent Reduction |
|----------------|----------|--------------------|-------------------|
| E. faecalis | 29212 | 1.36×10^4 | >99.9% |
| Herpes Simplex | 33591 | 6.6×10^4 | >99.9% |

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Executive Summary

Microbial Testing

6.1.3 Antiviral Efficacy Testing

Testing was conducted by Microbiological Consultants, Inc. on behalf of Harod Enterprises, Inc. on July 3, 2000

| Test Organism | Initial Inoculum | Percent Reduction |
|----------------|-----------------------|-------------------|
| Influenza A | $1.0 \times 10^{4.5}$ | >99.9% |
| Herpes Simplex | $1.0 \times 10^{4.5}$ | >99.9% |

6.2 Antimicrobial Testing

6.2.1 AATCC Method 100 Antimicrobial Testing:

Testing was conducted by Apptec Laboratories on behalf of Avadim, LLC between September 5, 2007 through June 12, 2008.

| Test Organism | ATCC No. | Initial Inoculum | Percent Reduction |
|------------------|----------|-------------------|-------------------|
| C. albicans | 10231 | 1.1×10^5 | >99.9% |
| M. luteus | 49732 | 1.1×10^5 | >99.9% |
| C. ammoniagenes | 6872 | 1.7×10^5 | >99.9% |
| S. epidermidis | 12228 | 1.3×10^5 | >99.9% |
| S. aureus (MRSA) | 33591 | 1.3×10^5 | >99.99% |
| A. baumannii | 15308 | 1.4×10^6 | >99.99% |
| E. faecalis | 51575 | 1.4×10^6 | >99.99% |
| E. coli | 8739 | 1.6×10^6 | >99.99% |
| P. aeruginosa | 9027 | 1.2×10^6 | >99.99% |
| C. difficile | 9689 | 2.4×10^7 | >99.99% |

6.2.2 Antimicrobial Efficacy Duration Study

Testing was conducted by St. John's Research Institute on behalf of Avadim, LLC on November 14, 2007. This study was based upon a one-time application of collegen and re-inoculated at various time periods.

| Time | Test Organism | Initial Inoculum | Percent Reduction |
|-------------|------------------|-------------------|-------------------|
| 15 minutes | S. aureus (MRSA) | 3.0×10^5 | >99% |
| 30 minutes | S. aureus (MRSA) | 3.0×10^5 | >99% |
| 60 minutes | S. aureus (MRSA) | 3.0×10^5 | >99% |
| 120 minutes | S. aureus (MRSA) | 3.0×10^5 | >99% |
| 180 minutes | S. aureus (MRSA) | 3.0×10^5 | >99% |

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Microbial Testing

6.3 Biocompatibility Testing

6.3.1 Outline

Theraworx™ has been subject to in vitro and in vivo biocompatibility testing (ISO Intracutaneous Reactivity Test, ISO Acute Systemic Injection Test, ISO Guinea Pig Maximization Sensitization Test, and MEM-Elution using L-929 Mouse Fibroblast Cells(ISO) (Cytotoxicity)). These tests support the safe use of Theraworx™ in contact with breached or compromised skin.

6.3.2 MEM Elution Using L-929 Mouse Fibroblast Cells (ISO) (Cytotoxicity)

6.3.1.1 Reference: ISO 10993-1

6.3.1.2 Report No. 66958

6.3.1.3 Date Tested: November 9,2007

6.3.1.4 Conducted By: Apptec Laboratories

6.3.1.5 Results: Test was considered valid as the control results were within acceptable parameter. The test article PASSED and is considered NON-TOXIC under the test conditions employed.

6.3.3 ISO Intracutaneous Reactivity Test

6.3.2.1 Reference: ISO 10993-1

6.3.2.2 Report No. 66959

6.3.2.3 Date Tested: December 10,2007

6.3.2.4 Conducted By: Apptec Laboratories

6.3.2.5 Results: The test article is considered a NON-IRRITANT.

6.3.4 ISO Acute Systemic Injection Test

6.3.3.1 Reference: ISO 10993-1

6.3.3.2 Report No. 101611

6.3.3.3 Date Tested: February 11,2008

6.3.3.4 Conducted By: Apptec Laboratories

6.3.3.5 Results: No potential toxic effects as a result of a single-dose systemic injection were observed; test article PASSED the test.

6.3.5 ISO Guinea Pig Maximization Sensitization Test

6.3.4.1 Reference: ISO 10993-1

6.3.4.2 Report No. 101612

6.3.4.3 Date Tested: March 13, 2008

6.3.4.4 Conducted By: Apptec Laboratories

6.3.4.5 Results: None of the test animals challenged with the test article extracts were observed with a sensitization response greater than "0". Test article did NOT elicit a sensitization response.

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Comparison of the Early Antibacterial Efficacy of Theraworx and Theraworx Plus Skin and Wound Cleansers

Roger Huckfeldt MD, Phillip Finley MS

St. John's Medical Research Institute, Springfield, Missouri

Early antibacterial action of skin and wound cleansers against resistant bacterial strains is an increasing important need. Much of the reported efficacy with wound care products is based on testing over a 24 period even though the use of these products are limited to substantially shorter periods of time. Theraworx was designed as a skin healthy cleanser and has been found to possess antibacterial characteristics as well. Theraworx Plus adds the accepted antibacterial properties of Benzalkonium Chloride to the cleansing characteristics of the Theraworx solution. This in vitro study was performed to determine the early bactericidal capabilities of both solutions.

Procedure: Modifications of Method 100 testing were performed to allow evaluation at time intervals appropriate for duration of contact when used as a skin and wound cleanser. Sterile non-woven fabric was cut into one inch squares and pre-moistened with the Theraworx or Theraworx Plus. Known concentrations of Methicillin Resistant Staphylococcus Aureus were added to saturate the fabric samples. The samples were then incubated at room temperature for 30 seconds, 60 seconds or 120 seconds. Immediately following the timed exposure, the fabric was placed into broth containing an appropriate neutralizer and agitated for one minute. Ten microliters of the solution was then plated onto blood agar and incubated at 37 degrees for 24 hours. Quantitative analysis was then performed and log reduction calculated. This entire procedure was then repeated with Pseudomonas Aeruginosa.

Results: Quantitative analysis results are presented in the table below.

| Bacteria tested | Solution tested | 30 seconds | 60 seconds | 120 seconds |
|-----------------|-----------------|------------------|------------------|------------------|
| MRSA | Theraworx | >log 3 reduction | >log 3 reduction | >log 4 reduction |
| | Theraworx Plus | >log 3 reduction | >log 3 reduction | >log 4 reduction |
| Pseudomonas | Theraworx | >log 3 reduction | >log 3 reduction | >log 4 reduction |
| | Theraworx Plus | >log 3 reduction | >log 3 reduction | >log 4 reduction |

Summary: Theraworx and Theraworx Plus provide >99.9% efficacy at 30 seconds and 60 seconds exposure to MRSA and Pseudomonas aeruginosa and >99.99% efficacy at 120 second exposure. This bactericidal activity is sufficient for both skin and wound cleansing.

Abstract: John A. Boswick, M.D. Burn and Wound Symposium; Maui HI, February 2009

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The Development of an All Natural Solution Designed to Enhance and Nourish Skin While Providing Advanced Antimicrobial Protection

Roger Huckfeldt, M.D.; Debbie Mikkelsen, R.N.; Phillip Finley, M.S.;

Cindy Lowe, C.R.R.P.; Jennifer Robertson, R.N.

ST. JOHN'S RESEARCH INSTITUTE, SPRINGFIELD MISSOURI

The progression of bacterial resistance has forced health care workers and researchers to search for new methods of control of these pathogens. Many popular skin cleansers utilize alcohol as the killing agent resulting in discomfort to opened skin, dry skin surfaces and short duration of action. These often result in poor compliance. Wound cleansers often employ chemical means of antimicrobial protection that are not cell friendly. High risk arenas including hospitals, acute care centers, chronic care centers, prisons, sports participants and schools are left with less than ideal choices. Environments with limited resources such as commonly seen in battlefield and disaster situations are also incompletely addressed.

Theraworx™ is a solution initially designed and patented to provide a product promoting skin health in chronic care facilities. After studying the antimicrobial pattern of this solution in our lab we began investigation into the potential for this solution and have proceeded with the development of this product. Microbiologic testing performed by us and confirmed by an outside laboratory show broad spectrum coverage. Log reduction studies identify >99.9% efficacy for a host of gram negative and gram positive bacteria including MRSA, CA-MRSA, VRE, Pseudomonas, Streptococcus, E.coli and a composite culture of bacteria and spores of C. difficile. The same log reduction was identified for Candida albicans and activity against Herpes Simplex 1 and Influenza A viruses was confirmed. Zone of inhibition studies show statistically significant larger zones as compared to another silver wound cleanser currently available and silver nylon fabric when tested against MRSA. Duration of action studies using a collagen based delayed inoculation study with MRSA show that even at three hours post Theraworx™ application log reduction studies indicate a >99% efficacy. Theraworx™ contains several ingredients recognized to be skin healthy. Aloe, Allantoin, Beta Glucan and Vitamin E provide skin nourishment and promote cell growth and enhance the skin's immune function. Given the lack of chemicals in the solution it is safe for all skin types without discomfort even in areas of opened skin.

Theraworx™ represents a breakthrough in effective management of skin and wounds compromised by bacterial growth or bacterial contamination including antibiotic resistant strains. It is very cost effective and now commercially available. It is being used in hospitals as a waterless bathing system for high risk patients, hand protection in hospitals and sports facilities, veterinary practices as well as others. Current IRB approved investigations are underway to evaluate Theraworx™ in MRSA decolonization, surgical site preparation, and wound healing.

[abstract] In: Proceeding of the John A. Boswick Burn and Wound Care Symposium; 2008 Feb 18-22; Maui HI.

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SILVER ANTISEPTIC

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St. John's Hospital Replaces Basin Baths with Theraworx to Fight Superbugs

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<http://www.infectioncontrolday.com/>
Posted on: 06/19/2008

SPRINGFIELD, Mo. — In a shift in patient hygiene and personal bathing procedures, St. John's Hospital, a member of the Sisters of Mercy Health System, has made far-reaching changes to stop the threat of healthcare-associated infections (HAIs) such as MRSA, C. difficile and VRE. Instead of the traditional bedside basin bath or using alcohol-based sanitizers on patients, nurses and staff now use an all-natural skin cleanser and protectant called Theraworx™ to bathe and fortify patients' skin against the growing threats posed by so-called superbugs.

Following extensive testing by independent labs and the St. John's Medical Research Institute, critical-care nurses began using the Theraworx waterless bathing system on high-risk patients in late 2007 in the neuron-trauma unit. In-vitro testing proved the all-natural, alcohol-free solution is greater than 99.99 percent effective against a broad array of organisms. It provides coverage against MRSA, Clostridium difficile, vancomycin-resistant Enterococcus, Candida albicans and an array of bacteria, fungi and viruses, even after three hours.

After a successful 240 patient-day pilot study found Theraworx highly effective, it has become the primary patient bathing system used in St. John's ICUs, including medical and surgical floors. Following an enthusiastic reception by nurses and patients alike, the medical staff in the orthopedic and general surgery units asked to expand use of the bathing system in their wards. St. John's will likely provide the bathing system at other Sisters of Mercy Health System's facilities in the near future.

"When we considered how we could really protect patients, we took an in-depth look at the infection risks associated with the basin bath. We realized the soap-and-water bath is a conduit for colonization and we needed a superior method to clean and boost patient safety," noted William Sistrunk, MD, infectious disease specialist and medical director of infection prevention at St. John's Health System. "Both patients and nurses were overwhelmingly positive about how effective Theraworx has performed and how good it feels on their skin. We know it provides residual efficacy for compliance, plus the peace of mind that we're not spreading contamination."

Theraworx has shown to be quite effective with its skin moisturizing, re-hydrating and nourishing properties, while helping protect wounds against invasive germs. The pH-balanced solution contains natural reinforcing ingredients that nurture the skin and promote the body's native mechanism for killing bacteria. Alcohol-based products evaporate instantly and provide no sustained protection. Lab tests have confirmed the long-lasting duration of action of Theraworx, which retains its effectiveness for hours, plus it is certified non-toxic and a non-irritant, unlike alcohol.

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Theraworx™
SISTERS OF MERCY HEALTH SYSTEM

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St. John's Hospital Replaces Basin Baths with Theraworx to Fight Superbugs (cont.)

St. John's officials were aware of staff and patient concerns over the increased potential for HAIs. The hospital ranks better than average or at par in fighting infections when compared to other Missouri hospitals according to state criteria and reporting. However, facing coming changes in regulatory, compliance and reimbursement policies the 866-bed referral medical center took this proactive step in the battle against dangerous antibiotic-resistant bacteria, viruses and fungi to demonstrate leadership in infection control and an even higher level of commitment to patient safety and protection.

"The focus of the research institute has always been to identify acute care issues and find solutions that do not currently exist. After we investigated the patient bathing and skin care environments in hospitals we realized that there had to be a better, healthy choice," said Dr. Roger Huckfeldt, medical director at St. John's Medical Research Institute and partner in Avadim LLC, which produces Theraworx. "We're confident that the preliminary trial findings validate the changes we instituted at St. John's. We want to share and further our knowledge, experience and the benefits of Theraworx with infection control professionals to aid in the fight against HAIs."

The patented Theraworx formulation and family of products contain no skin-drying alcohols, glycols or harsh ingredients. The waterless bathing system is available on pre-moistened soft cloths in either total-body bath or personal clean-up sizes. The single-use, four-ply non-woven cloths eliminate the need for towel and laundry service in hospital settings, as well as control cross contamination upon disposal. For individual use when there is no access to soap and water, there is a convenient 2-ounce bottle that provides approximately 150 applications, and an economy-sized 8-ounce bottle, both fitted with a foaming non-aerosol pump top.

Source: Theraworx

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Recent Clinical Work

Head to head comparison with Chlorhexidine - Data on file currently in editorial review:
Non clinical setting full body bath comparing pre and post cultures at set time intervals.

Head to head with Ethyl Alcohol -Data on file currently in editorial review: Hand Wash
study comparing cultures at set time intervals up to one hour.

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Bathing System

Product Codes

Bathing System

Reorder Number

HX-8808

A patented one-step method of cleansing, conditioning and treating the skin without challenges associated with basin bathing for non-ambulatory settings, patients with access difficulties and difficult caregiver settings.

- All new admissions, transfers and discharges
- Traditional bed-bound patients with or without history of contractures
- Chronic odor
- High Risk Patients
- Stroke & Alzheimer's patients
- Combative, resistant, and non-compliant patients with respect to bathing
- Intubated patients
- Paraplegics, quadriplegics
- Non self sufficient patients



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8 oz. Foaming Cleanser

Product Codes

8 oz Foaming Skin Cleanser

Reorder Number

HXC-08Z

The all natural, ph balanced solution is non-irritating to the skin. This can encourage hygiene compliance for patients that require routine cleansing in sensitive areas of the body including: axilla, perineum, and the face. Developed for chronic conditions, it has hundreds of cleansing applications in one bottle.

- Obese patients with skin folds prone to yeast issues
- Hydradenitis
- Chronic folliculitis
- Atopic dermatitis
- Sebhorreic dermatitis
- Psoriasis
- Cellulitis
- Decubitis
- Vascular insufficiency related ulcers
- Macularpapular Rash
- Hives and post herpetic neuralgia
- Non-rinse shampoo
- 600 applications in one bottle



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SLAYERSM BY NATURE

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2 oz. Foaming Cleanser

Product Codes

2 oz Foaming Skin Cleanser

Reorder Number

HXC-02Z

The 2 oz foamer possesses the same patented formulation technology with individual portability. Clinical benefits for healthcare professional hand cleansing in high risk patient settings.

- ICU Professionals
- Isolation
- Cath Labs
- Emergency
- Extended Care Units
- Emergency Medical Technicians
- All nursing staff - (neoprene holder available)
- 150 Applications



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SILVER ANTIBACTERIAL

When Clean Is Not Enough.

2 oz. Spray

Product Codes

2 oz Cleansing Spray

Reorder Number

HXS-02Z

No touch delivery of the patented Theraworx technology when patient comfort and cleansing is a must.

- Cleansing for Decubiti wound stages 1 and 2
- Central Line, PICC, IV dressing Changes
- Pacemaker incision cleansing without agitation
- Wound dressing changes
- Photo toxic/photo allergic reactions
- UV/Radiation recall
- Hemorrhoidectomy cleansing
- Anal Fissure cleaning
- Pre- Casting Cleansing
- Cast cleansing maintenance
- Post Cast removal
- Pre and Post Suture removal topical spray
- Post antiseptic cleansing — Betadine, povidone iodine CHG
- Cleansing around: J tubes, Chest Tubes, Tracheostomy Care, Ports, G tubes etc.
- Macularpapular Rash
- No Touch Wound Care
- Extremely sensitive and irritated skin
- C-Section Staple Cleansing



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SILVER ANTIBACTERIAL

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Specialty Care Pack / Urinary Care Pack

| Product Codes | Reorder Number |
|----------------------------|----------------|
| Specialty Care Pack | SCP-8802 |
| Urinary Catheter Care Pack | UCP-8802 |

Convenient 2 cloth system for personal hygiene when patient needs require diligent attention.

- Functioning Elderly Incontinent patient concerned with chronic odor
- Cleansing areas of the skin with dried blood or scabs
- Pre Cardiovascular Catheter Cleansing (prior to antiseptic step)
- Post Cardiovascular Catheter Cleansing
- Pre minor surgery cleansing – moes, ACL, Carpal Tunnel, Excisions
- Pre and post percutaneous stent procedures
- Stormy cleansing
- Pre Foley insertion cleansing
- Post Foley insertion
- Cleansing for the urinary infected patient
- Incontinent Dermatitis
- Geriatric Diaper associated rashes
- Genital excoriation
- Coccyx ulcer cleansing
- Percutaneous nephrolithotomy
- Suprapubic catheter cleansing
- Urinalysis collection



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Swabs

Product Codes

Reorder Number

Theraswab (1 per pack)

HXT-01

Theraworx™ Liquid filled swabs with foam tip applicator for skin cleansing purposes around difficult areas to reach.

- Traches
- Vascular catheters
- Ports
- PICC lines
- Urinary catheters
- Wounds
- Staples and Sutures
- Skeletal pin sites
- External Fixator
- Nores Swabbing (Cleansing)

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Theraworx™
STERILIZED
BY GAMMA RAY



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Hand Tubs

Product Codes

18 oz Foamer

Reorder Number

HXC-018Z

Institutional size packaging for the healthcare professional areas requiring repeat or pre and post cleansing throughout the day. Utilized in areas where wall mounts are not applicable.

- Nursing stations
- Patient contractures throughout the day
- Pharmacy areas
- Exam rooms
- Nursing carts
- Physician/nursing lounges
- Non alcohol patient areas
- Infirmaries
- Dining Areas
- Med Carts
- All visitor entrances
- All High Risk and Isolation residents
- 1,500 Applications



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Wall Mounted Foamers

Product Codes

Wall Mount

Reorder Number

HXC-033Z

Manual wall mounts specifically designed for precise delivery of the Theraworx solution with replacement technology.

- High traffic healthcare station areas
- Carpeted areas (alcohol not recommended)
- Protocol Defined areas
- Patient and visitor entry areas
- Patient Contact areas
- Public Restrooms
- 2,600 Applications



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SILVER
ANTIBACTERIAL

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Pricing & Terms

| Product Codes | Reorder Number | | |
|----------------------------|----------------|--|--|
| Bathing System | HX-8808 | | |
| Specialty Care Pack | SCP-8802 | | |
| Urinary Catheter Care Pack | UCP-8802 | | |
| 8 oz Foaming Skin Cleanser | HXC-08Z | | |
| 2 oz Foaming Skin Cleanser | HXC-02Z | | |
| 2 oz Cleansing Spray | HXS-02Z | | |
| Perioperative Pack | POP-100 | | |
| Theraswab (1 per pack) | HXT-01 | | |
| 18 oz Foamer (Tubs) | HXC-018Z | | |
| Wall Mount | HXC-033Z | | |

Terms to be finalized.