



REDEFINING THE STANDARD OF CARE



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Agenda

- Market Need
- Product Overview
- Milestones & Results
- Q&A

MARKET NEED

Why DermaTherapy®?

- **Number affected:** 2.5 million patients suffer from pressure ulcers per year.
- **Cost:** Pressure ulcers cost \$9.1 – \$11.6 billion per year in the US. Cost of individual patient care ranges from \$20,900 to \$151,700 per pressure ulcer. Medicare estimated in 2007 that each pressure ulcer added \$43,180 in costs to a hospital stay.
- **Death:** About 60,000 patients die as a direct result of a pressure ulcer each year.
- **Lawsuits:** More than 17,000 lawsuits are related to pressure ulcers annually. It is the second most common claim after wrongful death, and greater than falls or emotional distress. (Average Settlement ~ \$250,000)

Overlooked

Healthcare bedding has changed very little in the last half century. Patients usually sleep on poly/cotton or 100% cotton.

These cotton fabrics have no special properties, despite our individual healthcare needs.

While billions of dollars are spent attempting to prevent and treat pressure ulcers, little attention is given to the single items with which people have the most contact—the **bedding** and **gowns**.

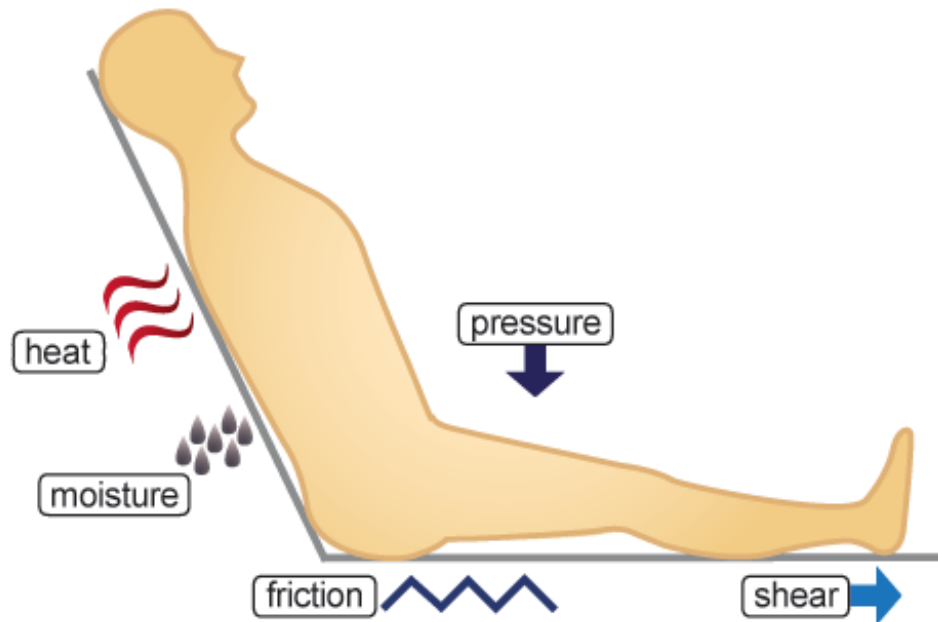


A SYSTEM OF BED LINENS
AND PATIENT APPAREL SHOULD
BE AN INTEGRAL PART OF THE
THERAPEUTIC PROCESS IN
HEALTHCARE INSTITUTIONS.

PRODUCT OVERVIEW

Microclimate Control

Problem: Factors Causing Skin Damage



Solution: Improve Microclimate

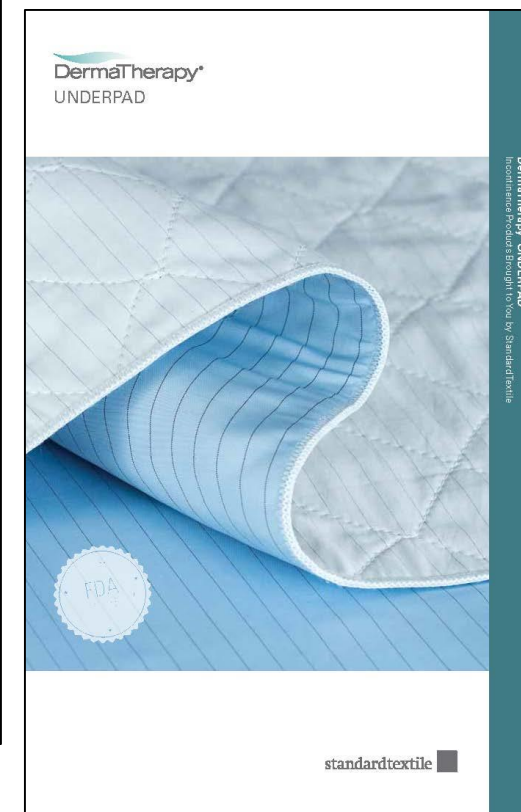
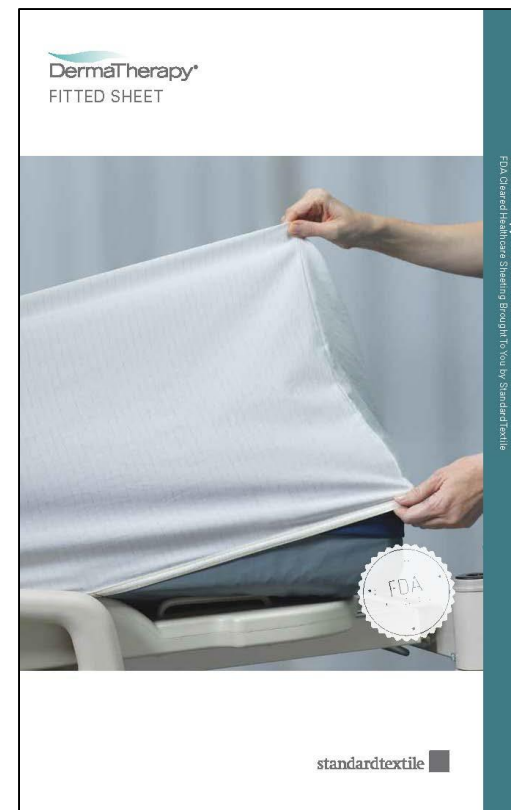
- Reduce Friction
- Prevent Shear
- Control Moisture
- Dissipate Heat
- Minimize Bioburden

Therapeutic Linen Solution

DermaTherapy® is the next generation of healthcare linen products engineered to provide therapeutic properties that optimize the microclimate around the patient to prevent the breakdown of skin and promote healing. DermaTherapy in comparison to standard cotton or poly/cotton linen is:

- Smoother
- Drier
- Cleaner
- Cooler

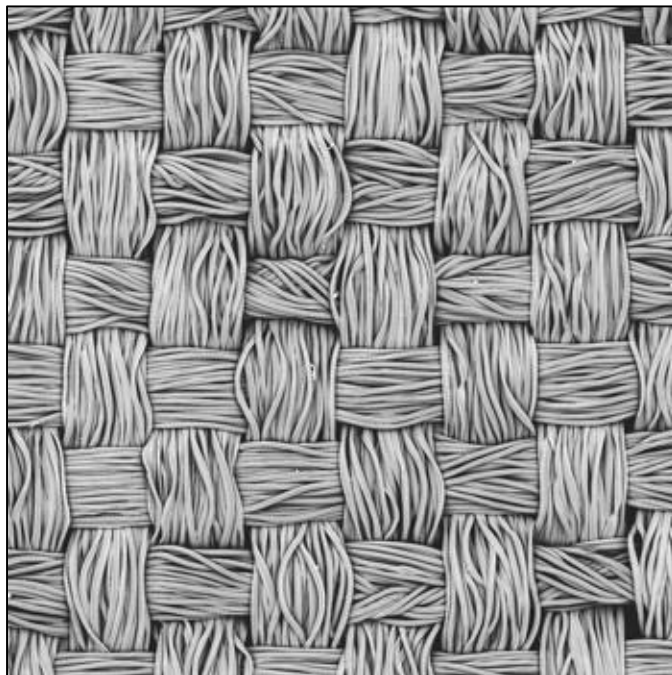
All are important factors in wound care.



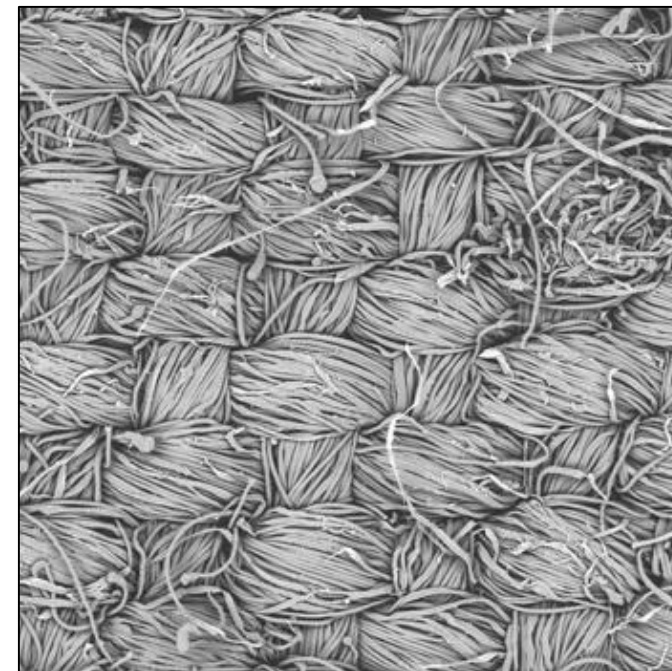
Smoother – Reduces Shear and Friction

DermaTherapy is woven with continuous filament yarns that are free of short, protruding fibers or pills that can create friction and cause irritation. The result is a silk-like sleep surface that is non-irritating and friendly to the patient's skin.

Skin slides smoothly across the sleep surface to minimize abrasion and prevent shear.



Silk-Like Therapeutic Linen

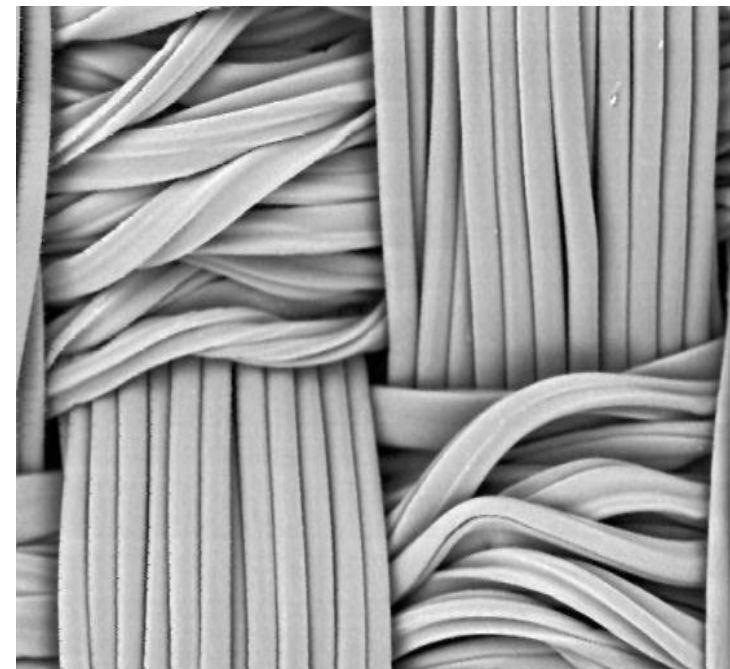
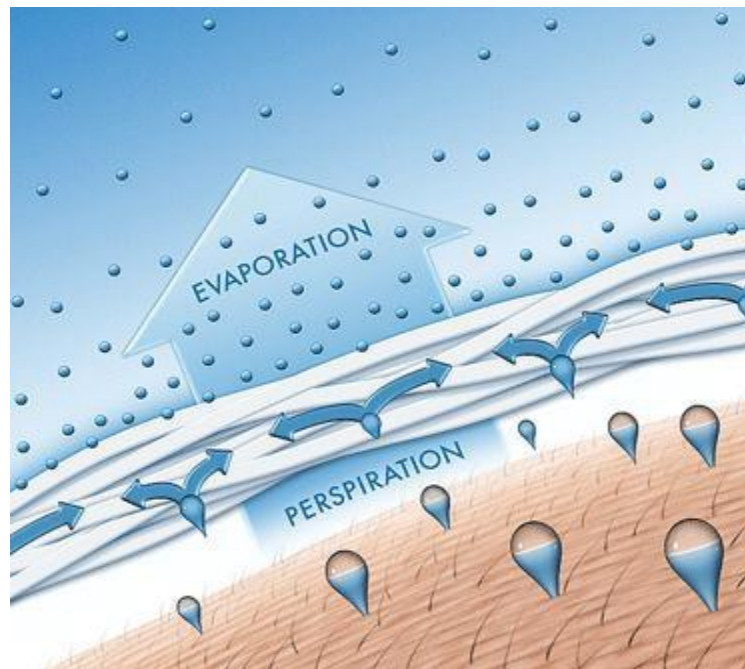


Polyester/Cotton

Drier – Controls Moisture

The DermaTherapy fabric is woven of fibers with unique cross sections that create thin micro-channels to wick moisture away and quickly dry the skin.

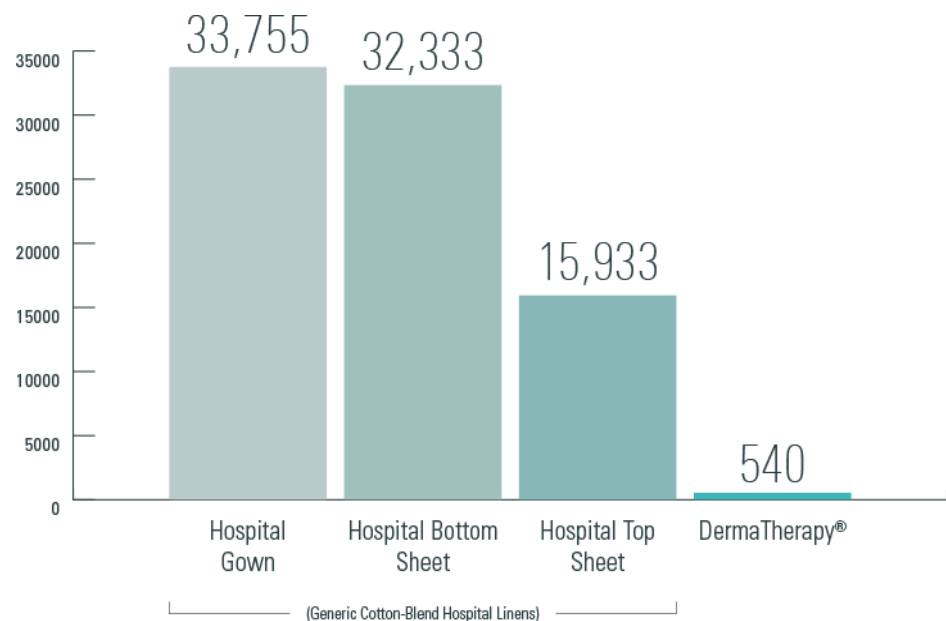
Evaporation takes place on the fabric—**not on the skin.** Reducing the potential for moisture associated skin damage.



Cleaner – Minimizes Bioburden

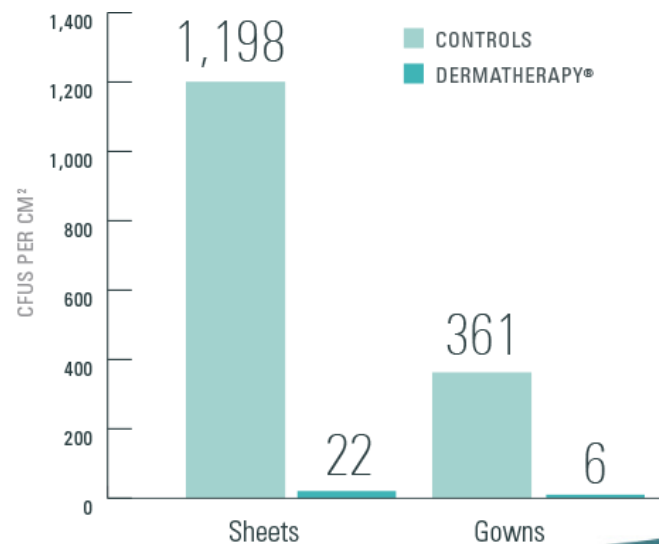
Virtually no lint means:

- No transfer of fibers and lint to open wounds.
- No airborne particle contamination, reduces particle count by 98% over poly/cotton bedding



Built-in Antimicrobial means:

- Significantly decreases growth of bacteria on textile
- Reduces potential cause of infections
- Minimizes odor caused by bacteria growth

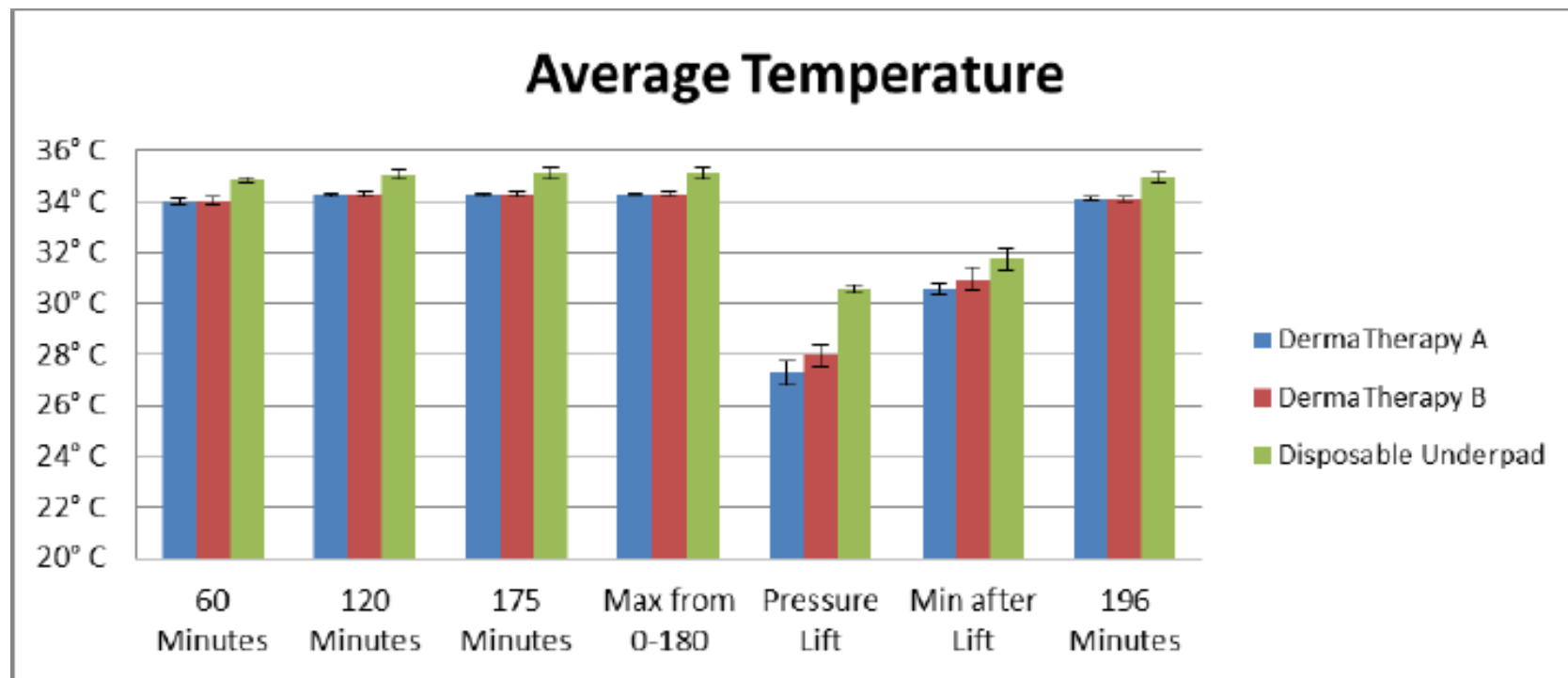


Cooler – Dissipates Excess Heat

Tests conducted at an independent lab indicate the DermaTherapy underpad stays cooler and releases heat better than disposable underpads.

A 1° Celcius reduction in skin temperature results in a 10% – 15% drop in metabolic demand.

When cutaneous heat buildup occurs with external loading, tissue loading impedes the delivery of blood and nutrients at a time when the need for both is heightened.



DermaTherapy® Technology Summary

- Patented fabric engineering reduces friction by **35% versus poly/cotton**
- Continuous filament yarns with micro-channels **wicks 40% faster** and **dries 60% faster** than poly/cotton
- The highly breathable quick drying fabric keeps patient cooler and more comfortable, **reducing metabolic demand** in the skin
- Fabric engineering and fiber content **eliminate lint**, a potential vector causing infection in open wounds
- Surgical-grade antimicrobial on the fabric **reduces bio burden by 99%**

RESULTS AND MILESTONES

Documented Clinical Results

In trials, involving over 21,000 patients at risk for pressure ulcers:

- Reductions in the incidence of HAPU development averaged **66%** when using DermaTherapy® as compared with conventional bedding.
- Reductions in the incidence of total pressure ulcers for patients at discharge averaged **20%**. when using DermaTherapy® as compared with conventional bedding.
- Reductions in the patients' length of stay averaged **0.24** days.



Trial Results: University of Michigan

- Trial period 9 months: Feb 2015 – Nov 2015
- Trial Units 24 beds CVICU and 20 Beds SICU
- Trial Results 50% Reduction in HAPU
- Presented poster at NTI Conference
- Made decision to convert all critical care units to DermaTherapy products in 2016

University of Michigan Health System

Evaluation of Specialty Linens to Reduce Pressure Ulcers in High Risk Intensive Care Unit Patients

Regi Freeman, MSN, RN, ACNS-BC; Andrew Smith, BSN, RN; Sharon Dickinson, MSN, RN, CNS-BC, ANP, CCRN; Candace Friedman, MPH, CIC
Cardiovascular Intensive Care Unit & Surgical Intensive Care Unit, University of Michigan, Ann Arbor, MI

Purpose

Change

Evaluation

- To evaluate the impact of using specialty linens on the incidence of pressure ulcers in high risk patients.
- Cardiovascular Intensive Care Unit (CVICU) and Surgical Intensive Care Unit (SICU) patients are at high risk for pressure ulcers.
- CVICU and SICU have the highest unit acquired pressure ulcer rates at UMHS.
- On average CVICU and SICU have around 60 unit acquired pressure ulcers per year per unit on the National Data Base for Nursing Quality Indicators (NDNQI) skin day (total 120).
- Pressure ulcers cost approximately \$30,000 per ulcer, for which the hospital may or may not receive any reimbursement.
- Based on admission and pressure ulcer data in CVICU, proposing a 33% reduction in pressure ulcers, a total of at least 1160 patients (about 9 months of data) would be needed to show a significant reduction in pressure ulcers.
- Our goal of a 33% reduction in pressure ulcers would reduce CVICU pressure ulcers by 20 in a year, which would be a savings of \$600,000.
- By duplicating this in another high risk ICU we have proposed an additional reduction of 20 pressure ulcers over 9 months.
- Total pressure ulcer reduction could be 40 ulcers, a savings of \$1,200,000.

The specialty linen was trialed on 24 beds in CVICU and 20 beds in SICU. The linens including sheets, under pads, gowns, and pillow cases were evaluated from February to November 2015.

Funding to support the increase in linen costs was supplemented by a \$40,000 Fostering Innovation Grant (FIG) from the institution and the Laundry Operational Budget of \$43,000.

- Data was compared for a 9 month period prior to implementation (4/2014-1/2015) and 9 month period post implementation (2/2015-1/2016).
- NDNQI skin day data indicated an overall decrease in pressure ulcers, particularly in sacral/coccyx/buttock pressure ulcers.
- Data collection of electronic medical record documentation indicated a downward trend in documented pressure ulcers.
- No increase in falls has been noted with use of these linens; a concern raised due to the slipperiness of the linens.
- Anecdotally, pressure ulcers and incontinence associated dermatitis has been noted to heal during the trial period in contrast to the pre-implementation period, when healing was not a routine finding.
- After initial start-up inventory adjustments, the linen has been found to be more durable than traditional blended linen. The washing, drying and finishing of this specialty linen is more labor intensive. However, per Linen Services, the value to our patients outweighs this consideration.
- Cost analysis based on matched All Patient Refined Diagnosis Related Groups (APRDRG) at our institution indicated patients with pressure ulcers on average stay 11.5 days longer for a direct cost increment of \$63,370 per case.

Synthesis

Implementation Strategies

Significance

- Multiple interventions have been utilized in both CVICU and SICU to reduce pressure ulcers with limited results.
- These high risk patients have multiple risk factors impacting pressure ulcer development.
- Evidence supports the use of specialty linens and beds to address the microclimate surrounding patient's skin and reduce pressure ulcers.
- By addressing the microclimate, friction, shear, moisture, and heat can be minimized.
- Specialty synthetic silk-like fabric linen that is drier and smoother than conventional cotton textiles was selected for use in this high risk patient population.

A plan including the following factors was implemented in February 2015:

- Distribution, storage, collection, and laundering of specialty linens.
- Nursing education including benefits, bed making, use in chairs, and positioning.
- Patient and family education.
- Education of other departments and multidisciplinary teams who work with CVICU and SICU.
- Prior to implementation a multidisciplinary group collaborated to determine trial details for a smooth roll out.

- Total pressure ulcers were reduced by 25 ulcers and sacral, coccyx, buttock pressure ulcers were reduced by 20 on NDNQI skin days during the trial.
- Total cost saving based on NDNQI skin day pressure ulcers was \$1,584,400 during the trial period with a 287.5 reduction in patient days on average.
- Reducing pressure ulcers in high risk patients reduces health care costs and decreases length of stay.
- The use of specialty linens can impact pressure ulcer rates in particular sacral, coccyx, and buttock pressure ulcers.
- An increase in the cost of linens is minimal in comparison to the potential for improved outcomes for patients and health care costs.
- The specialty linens have laundered well and outlast the current cotton textiles used by the rest of the institution. Thus the increase in cost may be offset by the durability of the specialty linens.


References

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Account Update: University of Michigan Health

- UofM trial study was published in the Nov 2017 issue of American Journal of Critical Care.
- **Study reports annual potential savings of \$3,929,312 due to reduction in the incidence of pressure injuries.**

Pressure Injury Management



SPECIALTY LINENS AND PRESSURE INJURIES IN HIGH-RISK PATIENTS IN THE INTENSIVE CARE UNIT

By Regi Freeman, RN, MSN, ACNS-BC, Andrew Smith, RN, BSN, CCRN, Sharon Dickinson, RN, MSN, CNS-BC, ANP, CCRN, Dana Tschannen, RN, PhD, Shandra James, RN, DNP, and Candace Friedman, MPH

Background The cardiovascular and surgical intensive care units had the highest unit-acquired pressure injury rates at an institution. Patients in these units had multiple risk factors for pressure injuries. Various interventions had been used to minimize pressure injuries, with limited results.

Objectives To evaluate the effect of specialty linens on the rate of pressure injuries in high-risk patients. The specialty linen was a synthetic silklike fabric that addressed the microclimate surrounding the patient, with the purpose of minimizing friction, shear, moisture, and heat.

Methods The specialty linen was tried on 24 beds in the cardiovascular intensive care unit and 20 beds in the surgical intensive care unit, including sheets, underpads, gowns, and pillow cases. Data obtained from a retrospective review of electronic health records were compared for 9 months before and 10 months after specialty linens were implemented.

Results Total unit-acquired pressure injury rates for both units combined declined from 7.7% (n=166) before to 5.3% (n=95) after the intervention. The intervention was associated with a significant reduction in posterior (coccyx, sacrum, back, buttock, heel, and spine) pressure injury rates, from 5.2% (n=113) before to 2.8% (n=51) after specialty linens were implemented ($P < .001$).

Conclusion Addressing the microclimate, friction, and shear by using specialty linens reduces the number of posterior pressure injuries. The use of specialty linens in addition to standard techniques for preventing pressure injuries can help prevent pressure injuries from developing in high-risk patients in intensive care units. (*American Journal of Critical Care*. 2017;26:474-481)

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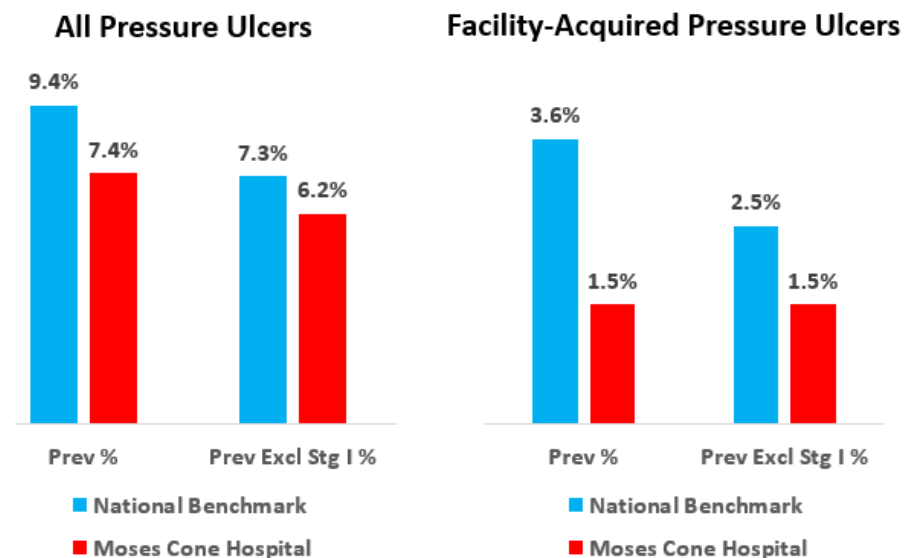
Trial Results: Mayo Clinic

- Conducted trial in 4 critical care units, Dec. 2015 – June 2016
- **Results: 85% Reduction in PU's (Some of the best results we have seen during any trial!)**
- Made decision to convert to DT product in 2017.



Account Update: Cone Health

- On DermaTherapy® since 2012
- Cone Health System documents reoccurring annual clinical savings of \$4.9 million.
- 2015 Hill-Rom study determined **Cone Health has one of the lowest pressure ulcer incidence rates in the country.**



Trial Results: Liberty Healthcare

- Owner of over 26 Skilled Nursing and Rehabilitation Facilities located in North Carolina
- Trial period 3 months: March 2017 – May 2017
- Tried at 4 Facilities, Totaling 489 Beds
- Trial Results
 - March: 71% reduction in PU's, 40.8 PUs
 - April: 58% reduction in PU's, 30.9 PUs
 - May: 60.5% reduction in PU's, 47.8 PUs
- Estimated savings of \$8,000 per pressure ulcer.

Account Update: Liberty Healthcare

- Based on tremendous trial results, decided to convert all 26 facilities to DermaTherapy in 2017
- Facilities using all DT product except gown.
- Average facility is 125 beds, initial startup orders are approximately \$35,000
- Great LTC reference!
- They are excited about promoting use of DermaTherapy to their Acute Care partners

Published Trial Results

- Specialty Linens and Pressure Injuries in High-Risk Patients in the Intensive Care Unit, *American Journal of Critical Care*, November 2017
- A Retrospective, Nonrandomized, Before-and-After Study of the Effect of Linens Constructed of Synthetic Silk-like Fabric on Pressure Ulcer Incidence. *J Ostomy Wound Management* 2013; 59(4):28-33.
- Prospective, Nonrandomized Controlled Trials to Compare the Effect of a Silk-Like Fabric to Standard Hospital Linens on the Rate of Hospital-acquired Pressure Ulcers. *J Ostomy Wound Management* 2012; 58(10):14-31.
- A Randomized, Controlled Study to Assess the Effect of Silk-like Textiles and High-absorbency Adult Incontinence Briefs on Pressure Ulcer Prevention. *J Ostomy Wound Management* 2012; 58(12):18–24.

NPUAP Guideline

2014 Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline

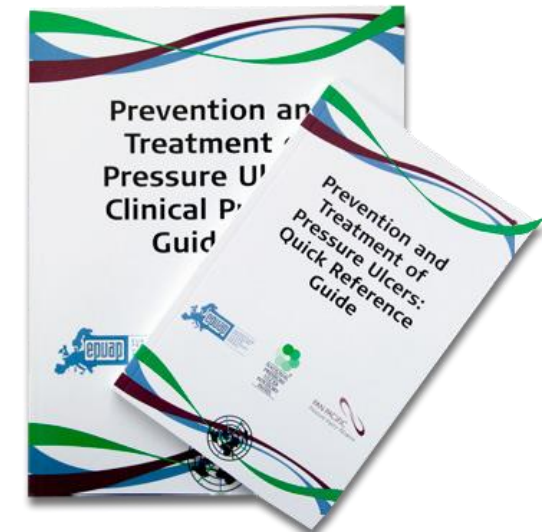
- Emerging Therapies for the Prevention of Pressure Ulcers

Fabrics and Textiles

“Consider using silk-like fabrics rather than cotton or cotton-blend fabrics to reduce shear and friction.”

Strength of Evidence = B, recommendation is supported by direct scientific evidence from properly designed and implemented clinical series on pressure ulcers in humans

Strength of Recommendation: One thumb up, probably do it



FDA Clearance for Prevention of Pressure Ulcers!

510(k) SUMMARY K152884

- Date Prepared: June 15, 2016

Subject Device:

- Device Name: DermaTherapy® Bed Linens
- Common Name: Bed linens
- Regulation: Class I Medical Device

Indications for Use:

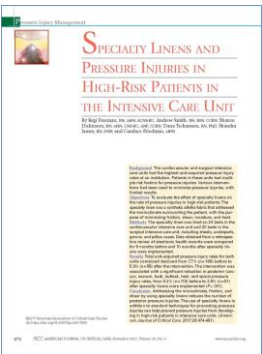
- The DermaTherapy® Bed Linens help to reduce the likelihood of patients developing pressure ulcers by reducing moisture, friction and shear on the patient's skin.



Unique in the Market

DermaTherapy® has the unique distinction of being the only patented bed linen with the following credentials:

- **Published Clinical Trial Results:** Ostomy Wound Management Journal has published three DermaTherapy® clinical trials: October 2012, December 2012, and April 2013, documenting improved clinical outcomes.
- **Recommendation for use from National Pressure Ulcer Advisory Panel (NPUAP):** “Consider using silk-like fabrics rather than cotton or cotton blend fabrics to reduce shear and friction.”
- **FDA 510(k) Clearance as a Class I Medical Device:** “The DermaTherapy® Bed Linens help to reduce the likelihood of patients developing pressure ulcers by reducing moisture, friction and shear on the patient’s skin.”



DermaTherapy Utilization: Highest Impact

Units:

- Critical Care
- Oncology
- Skilled Nursing
- Rehab
- Burn

Patient Profile:

- Critically ill
- Have Compromised Skin
- Elderly
- Non-ambulatory
- Incontinent

DermaTherapy Products: Highest Impact

Items:

Fitted Sheet and Underpad will have the greatest impact on preventing pressure ulcers and improving existing skin damage.

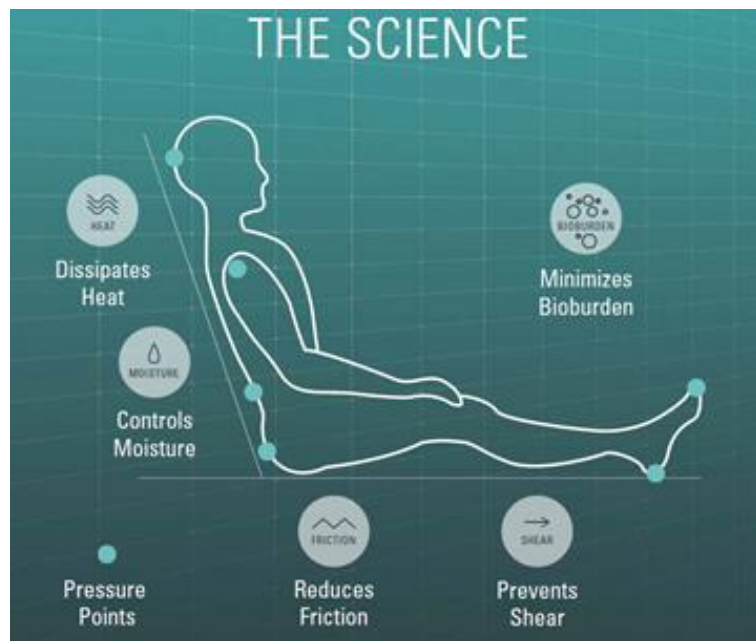
- Support surfaces are covered
- Easier patient positioning
- Lower comparative cost

Other DT Items (Pillowcase, Flat Sheet, Patient Gowns) will amplify the clinical results.



DT Value Proposition: Facility

- Reduction in facility-acquired pressure injuries and associated costs.
- Reduction in bio-burden, a potential cause of facility-acquired infections.



- Reduction of odors caused by the growth of bacteria.
- Improved treatment of existing skin damage.
- Improved skin condition for patients at discharge.
- Decrease in Worker's comp claims, due to easier repositioning.
- Reusable DT underpads can significantly reduce costs associated with disposable underpads and patient positioning devices
 - Lower cost per use
 - Eliminate need for drawsheets
 - Reduce amount of medical waste



DermaTherapy®

Questions?



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