Support Surface Materials and Design Innovation:
Preserving Integrity and Longevity in a Hospital Environment

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ABSTRACT

Preserving support surface integrity prevents infections and reduces replacements. This study explores how materials and construction techniques prevent damage, inhibit contamination and enhance longevity. Hospital support surfaces were inspected for damage to top covers and internal components. Surfaces with holes or tears allowing fluid ingress were identified. After removing the top covers, internal components were checked for damage, staining and compression to assess contamination control and longevity. Inspections of 1,022 surfaces from various manufacturers were conducted across 89 facilities. Of these surfaces, 123 contained innovative construction materials. Zero surfaces with the innovative construction required full replacement and only 17% (21) required new top covers. Of the 899 without innovative construction, 74% (667) sustained internal damage requiring full surface replacement and an additional 8% (74) required top cover replacement. An innovative support surface containing construction materials and methods to limit fluid ingress and improve durability included the following: a top cover material that is highly chemically-resistant, while it still maintains 4-way stretch and breathability; radio-frequency welded seams, instead of sewn, to eliminate holes that allow fluid ingress; and Agiliti's proprietary CoreShield™, that protects the internal components of the surface should the top cover become damaged. Innovative support surface construction decreased the risk of cross-contamination by eliminating fluid ingress and increased longevity — requiring less frequent costly full-surface replacements.

INTRODUCTION

National safety organizations are currently calling for surveillance of hospital support surfaces due to reports of contamination. The Food and Drug Administration (FDA) recommends regular inspections of mattress top covers and internal surfaces for damage and fluid ingress.[1] Centers for Disease Control and Prevention (CDC) guidelines state "mattress covers should be replaced when torn; the mattress should be replaced if it is visibly stained."[2] Also, The Joint Commission now requires hospital-wide infection prevention and control programs for the surveillance of healthcare associated infections (HAIs).[3] These directives and guidelines have resulted from studies that have shown that hospital support surfaces contaminated by fluid ingress were linked to an increase in healthcare-associated infections.[4-11]

Early breakdown of support surfaces has been linked to harsh chemical cleansers and improper cleaning procedures utilized in hospitals. These improper cleaning and disinfecting procedures have recently led to an FDA recall of a major hospital mattress manufacturer's support surfaces due to top cover damage allowing fluid ingress.[12] Most hospital mattresses today are manufactured with materials that do not withstand the harsh chemicals required

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to properly clean and disinfect hospital equipment. FDA's Code of Federal Regulations part 820 related to medical device design controls requires manufacturers to design products that can withstand the environment in which they are being used.

Construction materials and manufacturing methods should ensure support surfaces, as a class I or class II exempt medical device, can endure rigorous cleaning procedures with harsh chemicals and intensive patient use. Evaluation of various mainstream support surfaces, including those constructed with innovative materials and manufacturing methods, was warranted to understand their impact on fluid ingress and durability.

CLINICAL PROBLEM ADDRESSED

Healthcare-associated infections are the most frequent healthcare adverse event.[13] One in 31 patients in the United States (US) contracts a HAI every day. HAIs are categorized as never events that result in increased length of stay, cost of care, and negatively impact reimbursement. According to the CDC, **the total cost of HAIs to hospitals in the US is approximately $28.4 billion annually.[14]**

Hospital support surfaces are at higher risk for infection transmission due to their direct contact with patients.[15] Studies have shown that support surfaces can serve as pathogen reservoirs and have been responsible for the spread of infections throughout hospital units.[4-11] **One study showed that patients were 5.83 times more likely to contract a HAI if the previous occupant of their hospital bed had an infection.[16]**

Support surface contamination has been identified as the causative source for many HAI outbreaks over many studies for many years. An Enterobacter outbreak in an intensive care unit (ICU) was associated with contaminated mattresses in a van der Mee-Marquet et al. study. While the top covers appeared intact during initial inspection, once removed, staining from fluid ingress was found on the internal foam where patients had been placed and along the sewn seams of the top covers.[11] Another bacterial outbreak in a burn unit was associated with support surfaces. Pseudomonas aeruginosa transmission was attributed to the compromised support surfaces after top cover damage that allowed fluid intrusion was revealed. The bacteria survived in the support surface foam for more than two months.[17] In another report, a patient admitted to a clean hospital room noticed a blood-like fluid seeping from the mattress. This led to an inspection of 656 mattresses throughout the facility with 177 found to have substantial internal damage.[10]

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In addition to intensive patient use, support surface contamination is further exacerbated by top cover damage and/or breakdown due to the use of harsh chemical cleaning agents and improper cleaning and disinfecting procedures *(Figure 1)*, which may allow for fluid ingress.[1] Hospital cleaning procedures require vigorous cleaning around mattress seams and soiled areas with harsh, unapproved chemicals for use on polyurethane coated material, leading to top cover breakdown and fluid permeability. Often these harsh disinfectants and cleansers are left on the top cover and not washed off once the indicated kill time was met. Leaving harsh chemicals on top cover fabrics breaks them down quickly, degrades their waterproofing, which then allows fluids to penetrate. The intact appearance of support surface top

Figure 1: Top Cover Damage

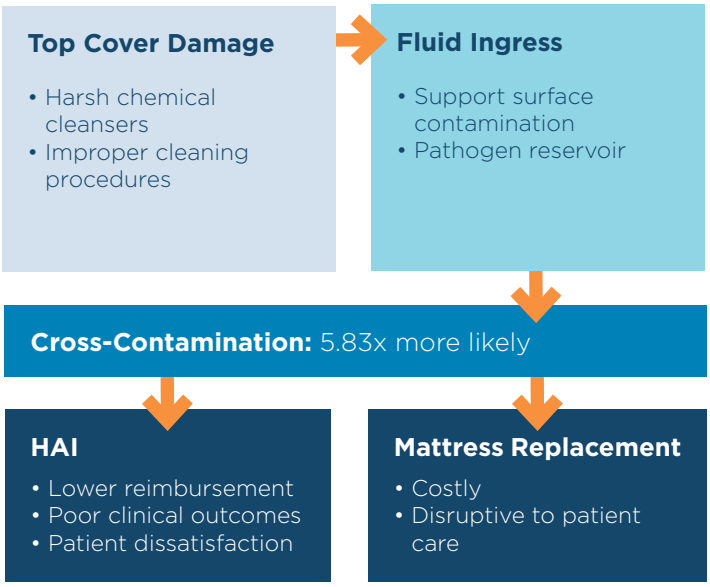
Top cover damage due to chemical disinfectants and the utilization of top cover materials that cannot withstand the harsh hospital environment.

covers can disguise contamination that can only be found through internal component inspection. This fluid ingress allows the internal components to harbor bacteria.[18]

From 2011 through 2016, the **FDA received more than 700 reports of hospital bed mattress covers that failed to prevent blood or body fluids from leaking into the mattress,** and the FDA communicated concern that fluid ingress due to top cover damage may be extensive and not regularly caught by hospital staff.[1,19] Due to the large number of reported compromised surfaces, the FDA has released guidance to healthcare providers recommending regular inspection of support surfaces for damage or wear, including routinely removing the top cover to inspect the internal components. When found, damaged or stained mattresses should be removed, and damaged or worn top covers should be immediately replaced.[1]

The cascade of events *(Figure 2)* from compromised support surfaces starts with damage from the intensive patient environment and harsh chemical cleansers. Once the top cover is damaged, allowing fluid intrusion, the internal components can harbor pathogens that can spread to subsequent bed occupants. This leads to increased facility costs including treatment for HAIs, frequent mattress replacements, and decreased reimbursement due to poor clinical outcomes and patient dissatisfaction.

Figure 2: Cascade of Compromised Support Surfaces

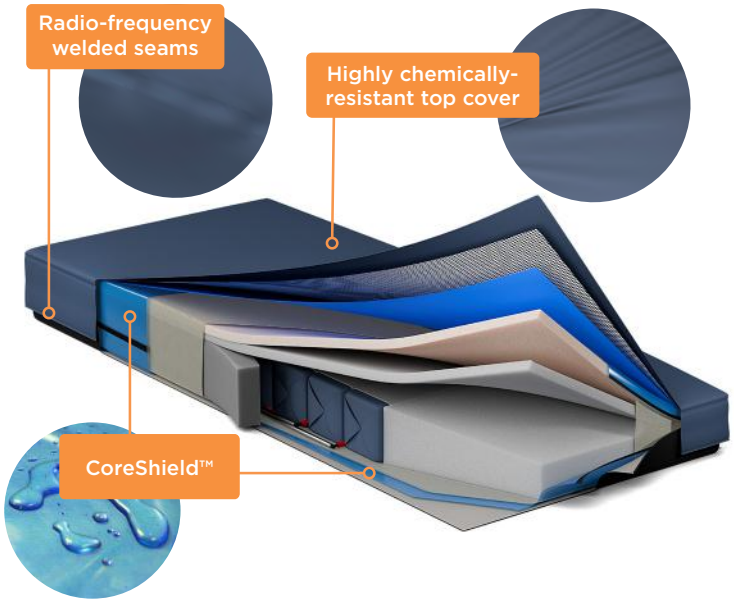


METHODOLOGY

Most current hospital mattresses are constructed with top cover materials that breakdown from exposure to harsh chemical cleansers used in hospitals. This damage allows fluids to contaminate the support surface core increasing the risk for HAIs.

Innovative Materials and Design *(Figure 3)*
Material and design scientists at Agiliti have developed patent-pending material specifically formulated for support surface top covers for use in the hospital environment to prevent HAIs and pressure injuries (PIs). The material is highly chemically-resistant, withstanding harsh disinfecting chemicals while maintaining integrity and not allowing fluids and other contaminants to enter the surface.

Figure 3: Innovative Support Surface Materials and Design

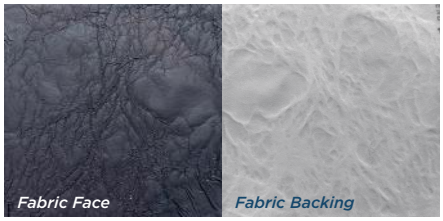


At the same time, the top cover material possesses superior 4-way stretch characteristics for increased immersion. Similarly, a strategic balance has been achieved with microclimate management (MCM), increasing thermal control, breathability and evaporative capacity to decrease the risk of pressure injuries. Targeted coefficient of friction helps prevent patient migration down in bed, yet still allows for boosting and lateral transfers of patients.

The material chemistry has been highly engineered to allow for robust radio-frequency (RF) weld capability. Agiliti's RF-Welding Specialists have industry-leading, proprietary techniques that bond material together

Figure 4: Innovative vs. Non-Innovative Design Materials

Typical Construction



Standard Top Cover Fabric
Major acute support surface manufacturer's top cover immersed in bleach for five days — resulting in full delamination.

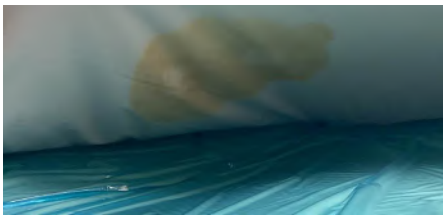
Sewn Seams
Traditional sewing methods punch thousands ofholes into the fabric — creating openings for fluid ingress along every seam.

No CoreShield™
Typical design allows any fluid ingress to immediately damage internal components — likely requiring full asset replacement.

Innovative Construction

Specially Formulated Top Cover Fabric
(4-Way Stretch, Breathable, Waterproof)
Top cover immersed in bleach for ten days — resulting in no delamination.

RF-Welded Seams
RF-welding avoids holes altogether — joining fabrics using radiofrequency.



CoreShield
Welded shield liner protects the internal components from potential fluid ingress and damage — likely requiring only top cover replacement.

on a molecular level resulting in superior seam strength. RF-welded seams instead of sewn seams, eliminate the holes which allow fluid ingress and seal the entire outside of the support surface preventing fluids and contaminants from entering.

Top covers can be damaged from excessive use causing tears and micro-holes allowing fluid to compromise the internal components. Agiliti's proprietary CoreShield™ protects the inner components of the surface should the top cover become damaged, eliminating the risk of fluid contaminating the internal components and the support surface becoming a source of HAIs.

CoreShield is a high-tech, stretchable medical grade film that safeguards internal components, adding a layer of fluid protection to extend the life of the surface and reduce the risk of HAIs. CoreShield also aids in the reduction of shear forces with patient movement. It has been specifically formulated to constructively interact with other surface materials within the support surface to reduce the risk of PIs.

An Optimal Support Surface for the Hospital Environment

Material and Design Scientists at Agiliti have combined these industry-leading materials and construction techniques to meet user needs of preventing HAIs and PIs while increasing surface longevity for increased ROI. Top cover fabric is often thought to be mutually exclusive of either highly chemically resistant or breathable. With Agiliti's pioneered, patent-pending fabric formulation both microclimate management and durability are achieved with the same fabric. This fabric in combination with Agiliti's CoreShield technology extends the lifespan of the support surface while

A Support Surface Audit Data Collection Form Was Utilized To Gather Surface Integrity Data

Top cover inspection included assessment of damage including:

- external top cover defects,
- patches,
- cuts/tears/holes,
- zipper integrity, and
- any micro-holes found with LED lighting.

Internal component inspection included assessment of damage including (if accessible via zipper):

- assessing the fire barrier integrity,
- presence of fluid ingress, and
- erosion of the support materials.

**For surfaces without internal access, a paper towel test was conducted, which applied pressure to a paper towel placed on the top cover to assess for the presence of fluid*

minimizing the risk of hospital-associated infections and pressure injuries evidenced by recent mattress inspections.

Mattress Inspections

A convenience sample of support surfaces was examined to understand the impact of different construction techniques on fluid ingress and support surface longevity. Surfaces from different manufacturers of various materials, designs and manufacturing processes were evaluated for the impact on fluid ingress and longevity within the hospital setting. Support surfaces included were foam based because foam is not able to be cleaned and disinfected once contaminated, unlike full air surfaces.

Upon selection, each support surface was inspected externally and internally. Manufacturer, model and year manufactured were noted. Inspections were conducted in accordance with relevant regulations governing support surfaces.[1]

Agiliti offers a variety of mattress audit support and options including a support surface audit guide, a support surface audit app, or onsite staff support.

Audit resources available at this link:
https://resources.agilitihealth.com/support-surface-audit-tools-and-resources/

FINDINGS

Mattress Inspection Outcomes

A total of 1,022 support surfaces from various manufacturers, with an average age of 5.7 years, were inspected across 89 facilities. All surfaces had been utilized in a hospital environment, many from different manufacturers within the same hospital thereby being subject to the same harsh chemicals used across their top covers. Among the 1,022 surfaces inspected, 123 surfaces were equipped with innovative materials and construction consisting of highly chemically-resistant top cover fabric showing no signs of chemical degradation, intact radio-frequency welded seams that prevented fluid ingress, and CoreShield™ that protected all internal components, when the top cover was compromised.

None (0%) of the Agiliti innovative surfaces had internal damage requiring full surface replacement, with only 21 surfaces (17%) requiring new top covers. In contrast, among the remaining 899 surfaces without innovative construction, 667 surfaces (74%) required full surface replacement due to top cover and internal damage and 741 surfaces (82%) had damaged top covers. Significantly fewer surfaces required replacements with the innovative materials and construction compared to the non-innovative surfaces ($p<0.01$). *(Table 1)*

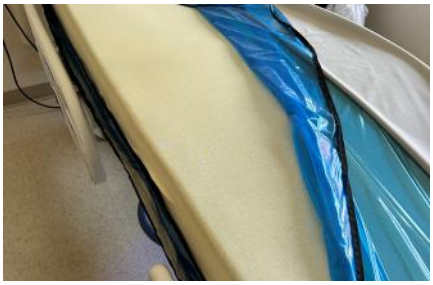
"None (0%) of the innovative surfaces had internal damage requiring full surface replacement, with only 21 surfaces (17%) requiring new top covers."

Top cover damage seen on non-innovative surfaces encompassed tears, micro-holes, damaged zippers and degradation of waterproofing from chemical cleansers. In contrast, the top cover of the Agiliti manufactured support surfaces showed no chemical degradation and intact waterproofing, while RF-welded seams prevented fluid ingress. Among damaged top covers, most non-innovative surfaces had significant staining from fluid ingress and compromised fire barriers. The Agiliti-manufactured surfaces showed no internal damage, as the CoreShield protected all internal components, when the top cover was compromised from physical damage.

Table 1: Compromised Support Surfaces by Manufacturer

Manufacturer	Agiliti	B	C	D
Total Surfaces Inspected	123	53	252	594
Average Age	5.5 years	6.8 years	6.4 years	5.6 years
Damage	**Agiliti**	**B**	**C**	**D**
Top Cover Damage	21 (17%)	46 (87%)	215 (85%)	480 (81%)
Fluid Ingress and Internal Damage	0 (0%)	38 (72%)	184 (73%)	445 (75%)

Figure 5: Internal Component Damage Without and With Innovative Materials and Construction

Damage to Non-Innovative Surfaces		No Damage to Innovative Surfaces	
	**Construction:** Unprotected fiberglass fire barrier breaks down over time and is chemically treated **Result:** No longer offers fire protection		**Construction:** Protected and fiberglass-free fire barrier **Result:** Remains intact over time ensuring adequate fire protection.
	**Construction:** Unprotected interior components **Result:** Fluid ingress and contamination of interior components, requires full replacement of the surface for patient safety		**Construction:** Welded shield protected interior components **Result:** The welded shield prevents fluid ingress to interior components if top cover would become damaged, preventing full replacement

DISCUSSION & ANALYSIS

The non-innovative surfaces' contamination rate in this study — 74% in 5.8 years — is in line with the recent study that showed 50% of acute care support surfaces were compromised within 3.8 years with an increase in failure odds of 67.6% with each additional year of age.[20] These non-innovative surfaces displayed extensive fluid infiltration similar to that which was reported in many studies to cause cross contamination and increase HAIs. Studies have been published regarding fluid ingress and cross contamination since the early 2000s. **HAI outbreaks have been linked to hospital support surfaces, and hospital acquired antimicrobial resistant infection rates have remained increased since COVID.[4-11,21]**

The COVID pandemic also impacted hospital cleaning procedures. Harsh chemical cleansers were required to kill resistant organisms and have remained in use post-pandemic. High staff turnover and decreased staffing levels have created training deficiencies and time restraints resulting in manufacturer-recommended cleaning processes not being followed correctly. Additionally, manufacturer cleaning instructions can be unclear or lack complete information, as seen by the recent top cover recall from a major support surface manufacturer.[12] These conditions have led to harsh chemicals not being rinsed from surfaces after their designated kill time, causing premature degradation of the top cover waterproofing from manufacturers using non-innovative materials and manufacturing processes.

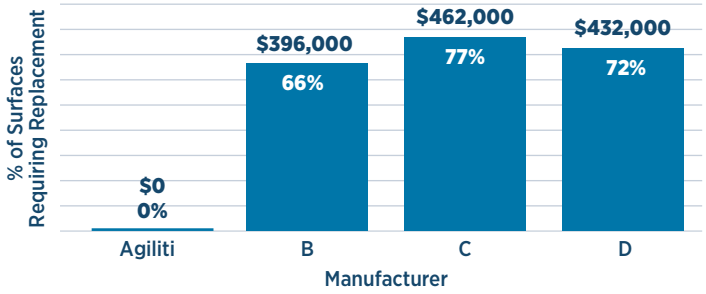
The Agiliti support surface construction in this study is essential to reduce the risk of fluid ingress that has been shown to cause HAIs and bring patients harm. The highly chemically resistant top cover showed no signs of degradation, and CoreShield™ protected internal components when the top cover was compromised from extensive patient and clinical use. This study demonstrates the importance of incorporating innovative materials and construction to enhance support surface durability and decrease costly full support surface replacements.

"This study demonstrates the importance of incorporating innovative materials and construction to enhance support surface durability and decrease costly full support surface replacements."

Return on Investment

Applying the results from this study to an average hospital with 400 beds demonstrates that after 5 years, a hospital that owned non-innovative surfaces would incur costs of $444,000 (296 replacement support surfaces at an approximate cost of $1500 per surface) to fully replace their contaminated support surfaces (74% of all their owned mattresses). Conversely, if the same facility owned innovative (Agiliti-manufactured) surfaces, they would only incur significantly less costs of $13,600 (68 replacement top covers at an average cost of $200 each) to replace top covers only. This results in a $430,400 cost savings to the hospital over 5 years. The Agiliti surface design shows a substantial cost savings due to its ability to withstand the harsh hospital environment. These costs are merely replacing surfaces, not encompassing the costs of HAIs and poor patient satisfaction which can be substantially higher.

Figure 6: Additional Spend Required for Patient Safety
In a 400 Bed Hospital by Year 5



Designing Products for the Harsh Hospital Environment

Good product design principles include understanding the use case and environments where products are intended to be utilized. Medical devices are intended for use in medical environments where harsh chemical cleansers are required to kill harmful pathogens and prevent cross contamination. Furthermore, medical staff have a primary responsibility to the patient, not the equipment they utilize for patient care. The hospital environment is harsh. The users are harsh. Designing support surfaces to retain their integrity within the hospital environment is a challenge, but it is a responsibility of surface manufacturers. Agiliti support surface materials and design have proven over time to withstand the harsh hospital environment and provide not only cost benefits, but even more so, benefit the patient.

KEY TAKEAWAYS

- **Innovative Design and Manufacturing:** Hospital mattresses often face early degradation due to harsh chemical cleansers, leading to internal component breakdown and potential infection risks from fluid penetration. However, mattresses made with advanced materials provide greater protection by resisting chemical damage, preserving their integrity and minimizing contamination and the risk of hospital-acquired infections (HAIs).
- **Manufacturing Responsibility:** Designing support surfaces to retain their integrity within the hospital environment is a challenge, but it is a responsibility of surface manufacturers as it maintains the best interest of patients and consumers.
- **Return on Investment:** Investing in support surfaces manufactured with innovative and advanced materials yielded a 0% need for full surface replacement vs. the 74% full replacement rate of the non-innovative support surfaces. Investing in an audit program will lead to finding hospital mattresses that are damaged sooner leading to a decreased risk of harm to the patient.

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Kristen is a master's prepared physical therapist and a certified wound specialist through the American Board of Wound Management. She is currently the Vice President of Product Management and Clinical Affairs for Agiliti Health. Kristen is a current Panel Member, and past board liaison, of the National Pressure Injury Advisory Panel (NPIAP) as well as the Chair of the Support Surface Standards Initiative (S3I) Committee. Kristen has presented at national and international conferences and is published in the areas of wound care, support surfaces, and pressure injury prevention.

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Neil Craney is a Registered Nurse who spent his bedside career in intensive care. While working in industry, he actively collaborates with healthcare teams to implement evidence-based practices and cutting-edge technologies aimed at improving pressure injury prevention and treatment. He is a current Panel Member of the National Pressure Injury Advisory Panel.

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Megan Hermann is a Physical Therapist with a Doctorate in Physical Therapy and certification in Safe Patient Handling and Mobility (CSPHA). Megan has extensive experience in acute care settings, specializing in early mobility interventions. A passionate advocate for evidence-based practices, she is actively engaged in researching and presenting advancements in support surface construction and development, aiming to optimize pressure injury treatment and prevention, patient safety, and reduced risk to patients.

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