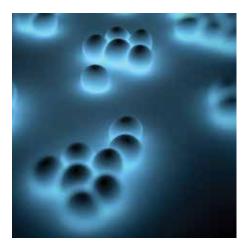
PREVENTION OF BI-DIRECTIONAL MICROBIAL CONTAMINATION OF PATIENTS AND TABLES DURING SURGICAL PROCEDURES:

EFFICACY OF DISPOSABLE, IMPERVIOUS, ANTIMICROBIAL LINENS



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BACKGROUND

Healthcare-associated infections (HAIs) are adverse events occurring in a patient during the process of care in a hospital or other healthcare facility which was not present or incubating at the time of admission. HAIs are one of the top ten healthcare associated events in the world.¹ On any given day, approximately 1 in 31 hospital patients have at least one HAI.² The Centers for Disease Control and Prevention (CDC) reports that in the United States (US), reportable acute care hospital HAIs account for more than 2 million infections annually.³

HAIs result in prolonged hospital stays, long-term disability, massive additional costs for health systems, excessive costs for patients and their families, and unnecessary deaths. HAIs have a significant economic impact on hospitals with direct medical costs of \$28.4 billion per year. The impact on society is estimated to be \$12.4 billion in early deaths and lost productivity. ⁴ Surgical site infections (SSIs) alone have a profound impact on the health of patients. SSIs are a substantial cause of morbidity, prolonged hospitalization, unplanned readmissions after surgery and death. Estimations are that 157,500 SSIs occur in the US per year and are associated with nearly 1 million additional inpatient-days. SSIs incur the greatest attributable cost of all HAI types, estimated at \$3.3 billion annually.⁵



BI-DIRECTIONAL ROUTES OF LINEN AND MATTRESS CONTAMINATION



Operating room (OR) linen, tables and mattresses may become contaminated in a variety of bi-directional manners.

- **Patients to surfaces Sheets and mattresses represent** the highest-touch elements for a hospitalized patient. The most significant source of pathogenic organisms contaminating textiles is colonized or infected patients. ⁶ It is important to note that patients are not typically screened for infections prior to surgery. Patient secretions including blood, skin, stool, urine, vomitus, and other body tissues and fluids contaminate textiles and fabrics resulting in high numbers of organisms. Natural fibers constituting reusable surgical linens serve as an excellent substrate for microbial adherence due to the organic material that provides a strong base for bacterial attachment.⁷ Reusable linens provide minimal barrier protection from strike-through to surfaces below such as the OR table and mattress which can result in these environmental surfaces acting as a reservoir for bacterial proliferation. 29,30
 - Healthcare Workers to surfaces to patient -Transmission of organisms from a healthcare worker (HCW) to a patient or to items in the surrounding environment is well documented. Identified routes for transmission of pathogenic organisms are from the hands of HCWs or via contaminated apparel to a patient by direct contact during breaks in the sequence of the chain of infection.^{8,9}

- Laundering/post-laundering handling of linen to patients - Variations in established industrial laundering and handling processes may lead to the continued survival of pathogens on textiles.⁶ The variables inherent in the laundry process include:
 - Wash cycle temperatures and chemistry. Regardless of the process used, textiles are rendered "hygienically clean" but not sterile; in addition, there currently is no standardized test methodology for the validation of laundering processes for the decontamination of healthcare textiles.
 - Laundry facility structure and mechanicals. Adherence to proper inspection and maintenance of both the laundry facilities' physical properties and equipment.
 - **Post-laundry handling.** Breaks in post-laundering practices may spread organisms throughout clean areas of laundry facilities by worker recontamination, or by omissions in regular cleaning and disinfecting of all laundry areas.¹⁰
 - Transportation and storage. Contamination of clean linen during transport in carts or trucks or during storage.¹¹
- Mattress surface to patient Microscopic holes, tears, or even zippers on mattress covers or inadequate cleaning of mattresses and tables can allow fluid penetration which poses risk of cross-contamination to future patients. Neither reusable linens nor nonantimicrobial disposable linens prevent pathogenic organisms from migrating from the OR table or mattress to the patient surface.²⁹

Despite adherence to recommended commercial laundry cleaning processes, multiple studies have identified the survival of pathogens on linen.¹² Reports on hospital outbreaks related to post-processed laundry include growth of organisms in biofilm-laden facility roof vents, ¹³ evaporative coolers, ¹⁴ door seals of washing machines, ¹⁵ and dispersion of organisms during preparation or breakdown of patient beds or procedure tables.¹⁶ An investigation conducted that examined the attribution of contamination of linen post-laundering to outbreaks, such as those due to the fungi *Rhizopus* spp., reported rates of 42% among laundered linen samples, 45% of linen bins, 100% of line delivery trucks, and 78% of storage rooms.¹⁷ No conclusions were made as to which stage of the laundering process the linens were contaminated. In evaluating the level for microbial contamination of clean bed linen, researchers reported that 53% of bacterial isolates (present in 38% of textile samples) identified potential opportunistic pathogens. The organisms identified included Staphylococcus spp., Pseudomonas spp., Burkholderia cepacia, and Stenotrophomonas maltophilia.¹² Pathogens such as spores of C. difficile have survived industrial detergent and disinfection-level temperatures.¹⁸

Additional studies detailing the survival of bacteria, fungi, and viruses on textiles and associated healthcare outbreaks are summarized in research conducted by Owen and Laird.⁶

OR tables, mattresses, and mattress covers may become laden with pathogenic organisms via direct contact with blood or body fluids. Padding materials within the mattresses themselves may absorb the contaminants when penetration occurs through undetected holes or tears of the surface material. In assessing the condition of 727 beds and mattresses in 4 US hospitals, it was identified that 72% were damaged, 47% were recommended for replacement of the mattress cover, and 25% required entire replacement of the cover and core. Of the 183 beds needing replacement of the entire mattress, 174 (95%) had large areas of staining visibly present.²² Food and Drug Administration (FDA) alerts issued since 2013 have warned healthcare institutions of hundreds of reported occurrences of body fluid contamination of mattress covers and cores abetted by damage such as tears, cuts, punctures, abrasions, or staining.²³ Such occurrences pose an infection risk to subsequent patients and HCWs who come into contact with the surfaces, regardless of the use of a barrier in between.

LIMITATIONS OF ENVIRONMENTAL CLEANING IN THE OPERATING ROOM

Studies have indicated that although environmental cleaning protocols have been widely established in healthcare institutions, limitations in their implementation have demonstrated continued contamination of surfaces after disinfection. Such limitations may apply significantly to OR settings as factors such as constraints on resources, rapid turnover, and practice compliance come into play. The principal factors cited in the literature that contribute to inadequate surface disinfection include:

- Inconsistent cleaning practices The diversity of invasive procedures in ORs increases the risk of patient infection. A systematic review of 35 published studies underscored that environmental cleaning therefore becomes a critical practice in preventing transmission of pathogens.¹⁹
- Factors beyond Environmental Services (EVS) worker education and training – A literature review of 31 published studies indicated that education/training was not the only factor in positive cleaning outcomes; other factors were categorized as attitudes and perceptions, beliefs and opinions, perceived barriers, and practices.²⁰
- Monitoring methods lack standardization Monitoring of cleaning practices aside from traditional visual inspection, e.g., microbiological sampling, are not commonly performed in OR settings.²¹

PROTECTIVE CHARACTERISTICS OF INNOVATIVE SURGICAL TABLE LINENS

Improvement in the care of mattresses, particularly in high-exposure settings such as surgical suites, requires continuous application of recommended care practices and consideration of technologies that reduce body fluid exposure to surfaces. Currently available table linens can be divided into several basic categories: reusable cloth, disposable non-woven fabric reinforced with an impervious backing, and disposable non-woven fabric with an additional super absorbent material reinforced with an impervious backing.

The weight of evidence on contamination of mattresses, coinciding with the potential survival of pathogenic organisms and limitations in the application of effective environmental disinfection, gives considerable support that an important approach in reducing infection risk involves the use of an innovative fourth category of surgical table sheets, namely a **disposable**, **non-woven fabric with additional super absorbent material**, **reinforced with an antimicrobial**, **impervious backing (STAT-BLOC™ disposable antimicrobial linens**, **Ansell**).

Characteristics and testing methods are detailed as follows:

 Antimicrobial properties - Textile-based active antimicrobial technology assists in preventing crosscontamination by reducing the bioburden of potential contaminating organisms. In-vitro testing of disposable/ impervious/antimicrobial table covers indicated an overall reduction of >99.8% of MRSA, E. coli, and CRE.
²⁶ Virucidal activity using Human Coronavirus strain 229E (ATCC 3VR-740) was studied to ascertain the effectiveness against the family of lipid enveloped Coronaviruses, which includes SARS-CoV-2, the cause of COVID-19. Test results indicated that antimicrobial table sheets reduced potential infectivity of Coronavirus 229E by an average of 2.0 log10 (99.00%) which is categorized as good antiviral activity in accordance with international microbial laboratory standards.²⁷ The antimicrobial compound used, triclosan, a halogenated phenoxy phenol, has been demonstrated to provide broadspectrum antibacterial and antifungal activities. Due to these properties, triclosan enhanced products have seen extensive use in the healthcare industry. ²⁸

- Protection against bacterial migration Testing to evaluate bacterial migration utilized a methodology that included an OR table contaminated with a mixed coliform bacterial suspension, overlay of sections of different types of table covers, and a hydroconductive fiber acting as a patient surrogate. Microbiologic testing indicated that both a reusable cloth table cover and a non-antimicrobial disposable table cover allowed bacterial migration, while no bacterial transfer was detected using the STAT-BLOCTM disposable, impervious, antimicrobial table cover. ²⁴
- 3. Prevention of strike-through Fluid repellency is an important feature of surgical table linens in addressing the minimization of infective microorganism dose onto underlying surfaces such as mattresses. A study designed to test the ability of OR table sheets to prevent strike-through contamination of mattress surfaces utilized placement of mixed enteric organisms onto marked areas of test products covering an uncontaminated OR mattress. Inoculum was allowed to dwell for a period of 2- and 4-hours. Cultures taken of the mattress immediately below the marked areas were incubated per standard microbiologic testing methods. Results indicated that only two colonies of bacteria grew under the STAT-BLOC™ table cover at the 2- and 4-hour periods. It should be noted that, at baseline, two colonies of bacteria were detected on the table so no new bacteria grew under the STAT-BLOC[™] table sheet. However, organism growth identified under the cloth cover demonstrated large concentrations of bacteria at both 2- and 4-hours.²⁵

ENVIRONMENTAL TESTING SUPPORTING EFFICACY OF STRIKE-THROUGH CHARACTERISTICS

Ansell has conducted environmental testing to compare bioburden levels on OR mattresses in facilities using reusable fabric linens to bioburden levels on mattresses in facilities where STAT-BLOC™ linens are used. Testing of mattress surfaces was conducted using ATP (Adenosine Triphosphate) technology (Hygiena, ATP monitoring system through Hygiena® EnSURE® Touch) after patient use and after cleaning. Data gathered over a 43-month period in 14 hospitals located across the US indicated that OR mattress surfaces in facilities using STAT-BLOC[™] linens had an average ATP measurement 67.7% lower than measurements of mattresses in facilities using fabric linens.²⁹

ANSELL STAT-BLOC™ LINENS (ANTIMICROBIAL DISPOSABLE LINENS)

Facility Number	Total # of Operating Rooms Tested	Average RLU – Mattress*
1	12	16.44
2	8	52.16
3	2	322
4	5	30.67
5	3	93.56
6	17	75.58
7	4	112.58
Total	51	65.21

REUSABLE LINENS

Facility Number	Total # of Operating Rooms Tested	Average RLU – Mattress*
1	10	141.73
2	26	123.97
3	20	100.67
4	30	344.56
5	25	89.8
6	9	43.91
7	10	180.35
Total	130	202.49

* Relative Light Units. The standard readout value given by luminometers in ATP testing. Outliers in both data sets have been removed.

CONCLUSION

Environmental contamination of hospital surfaces and the subsequent creation of sources for potential pathogen transfer and development of HAIs is an issue of national importance. This white paper provides published evidence and scientific testing results on survival of organisms on textiles, infection outbreaks traced to contaminated laundry sources, increased risk of cross-contamination from mattresses when using reusable linens, and added protection from antimicrobial linens versus non-antimicrobial linens.

The paper also examines the efficacy of antimicrobial disposable table linens in preventing pathogen migration or strike-through in a bi-directional manner from contaminated mattresses to a patient and from a colonized/infected source to table or mattress surfaces.

The use of disposable, non-woven linens with additional super absorbent material, reinforced with an antimicrobial, impervious backing mitigates issues relating to the contamination of OR tables coinciding with the potential survival of pathogenic organisms. Further, antimicrobial disposable linens help address limitations in the application of effective environmental disinfection.

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