

The Catastrophic Impact of Cotton Fiber Contamination in Surgical Procedures

New fiber-free products address an under-recognized danger to patients



During surgical procedures, patients are exposed to foreign body contaminants in the form of fiber and lint shed from essential tools like cotton gauze, non-adherent pads, radiopaque surgical sponges, and lap pads. Despite the prevalence of cotton as an almost universal component of these medical supplies, something as seemingly insignificant as cotton lint poses a serious threat to patients. It is an under-appreciated cause of complications, readmissions, and other associated costs.

Cotton fibers and lint trigger a fierce inflammatory reaction

The introduction of any foreign material into the body leads to an inflammatory response in which immune system cells accumulate and attack the foreign material to degrade it.¹ Cotton fiber contaminants induce a greater inflammatory reaction than synthetic polymers or metals.² Cotton fibers are almost entirely made of cellulose, an organic compound that provides structure to the cell walls of plants.³ Cellulose is the most abundant organic

“ Cotton fiber contaminants induce a greater inflammatory reaction than synthetic polymers or metals ”²

compound on earth, yet it cannot be broken down and absorbed by the human body.⁴ Adhesions, thrombi, and foreign-body granulomas (i.e. gossypibomas) can occur when immune cells envelope and form a physical barrier around indigestible foreign materials like cellulose fibers to isolate them from the rest of the body.^{5,6} These formations may be asymptomatic and cause no issues, or they can lead to a variety of complications, including death.^{6,7,8}

Adhesions

Adhesions are bands or sheets of abnormal fibrous connections that anchor normally slippery organs together or to the abdominal wall. They are a common side effect of abdominal surgeries, with 9 out of every 10 patients developing adhesions.⁹ Most of these adhesions will clear on their own while those that remain may result in pain, constrained movement, disrupted organ function and life-threatening conditions like intestinal blockage.⁹

In a review of 211 patients who underwent laparotomy surgery for long-term postoperative pain, adhesions were identified as the major cause of pain in 90% of the patients. 70% of the patients adhesions were caused by foreign body reactions. Cellulose was found to be the cause of more than 60% of these foreign bodies.¹⁰

In addition to minimizing foreign body contamination, protection of the slippery membrane around abdominal organs is vital to the prevention of adhesion formation

where contact between the denuded surfaces of organs has been found to be the primary cause of inflammation and adhesion formation.¹¹ Current cotton tools are abrasive, causing irritation and trauma to sensitive tissues while easily shedding indigestible cellulose fibers and lint, making adhesions a challenge to prevent; and once they occur, they tend to re-occur.¹²

Retained foreign body granulomas (Gossypiboma)

Foreign body granulomas that form around retained cellulose fibers is called gossypiboma. It is estimated that retained foreign bodies occur every 1 in 100 to 1 in 1000 surgeries with gossypiboma accounting for 80% of these instances.¹³ They may take years to present symptoms, are often misdiagnosed as tumors or abscesses, and are treated with unnecessary procedures, resulting in significant morbidity and cost \$1 billion annually in surgical corrections and legal fees.⁷

Measures to prevent gossypiboma have included published standards by the organizations like the Association of periOperative Registered Nurses (AORN) requiring diligent pre- and post-surgery sponge counts before wound closure begins. Despite these time-consuming efforts by operating room staff to prevent gossypiboma, inherent limitations in the design (and radiopacity) of surgical sponges and lap pads makes this an ongoing quality issue for hospitals.¹⁴

Infections

It doesn't take a whole retained sponge to cause the complications characterized, as even the shed fibers cause local to expanded reactions depending on a multitude of parameters such as the number and size of fibers; location in the body; chemical residues like inks, dyes, and detergents; and the presence of endotoxins.⁹ Particulate in the OR can become a vector for infection as pathogens attach to the lint shed from surgical products and may be deposited directly on the patient or the surgical field.⁹ Verkkala, et al, found that replacing cotton in the surgical suite with synthetic low-linting materials significantly reduces particulate and bacterial contamination.¹⁵

Even the presence of sterile cotton fibers within a wound significantly reduces the patient's resistance to infection by distracting immune cells, allowing bacteria to become established.¹⁶ Elek and Cohen found that the foreign body reaction to a single sterile cotton suture enhanced the virulence of staphylococci by 10,000 times.¹⁶ This

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increased risk of infection is why many organizations like the Association for the Advancement of Medical Instrumentation (AAMI), AORN, and The American College of Surgeons (ACS) have emphasized the use of low-linting materials used during surgical procedures.⁹

Cellulose fiber-free options to prevent contamination

For over 12 years, Syntervention, Inc. of Rocky Mount, NC, has been designing products to reduce fiber and lint contamination, save procedure time, and reduce costs to the hospital. Syntervention currently offers the cellulose and fiber-free SWICKER® Radiopaque Surgical Foam Sponge.

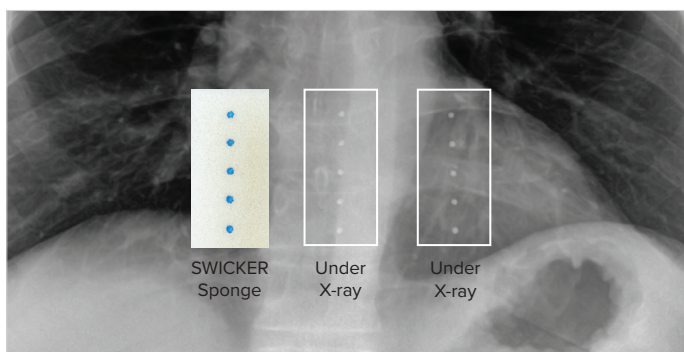


More than just a sponge, its unique design allows it to be used in open surgeries (incision or trauma), closed surgical cases (laparoscopic), and can also be used for wound care and patient hygiene. These radiopaque foam surgical sponges are available in multiple sizes allowing physicians to choose the size and thickness based on the incision type or absorbency requirements of the procedure.

The SWICKER sponge is made of a flexible foam that can be used rolled, folded, or flat. While cotton surgical sponges become hard and less malleable when saturated, the foam sponge maintains its pliability and will not deform. To help control bleeding, the fiber-free sponge can be rolled and placed internally in a patient where it will apply gentle pressure as it tries to return to its original shape. It is ideal for organ isolation, instrument padding for stable retraction, and to position or pad the extremities. The foam material is highly absorbent and retains fluids well, while being easy to clear by wringing or surgical suction device. Unlike a cotton surgical sponge, the

SWICKER can be left in position to keep organs hydrated and reduce irritation to sensitive tissues, while using a surgical suction device to clear sections of the sponge as needed.

The SWICKER maintains the rhythm of laparoscopic procedures, as it can be easily placed and retrieved through a Trocar without removing the Trocar from the patient. This is useful for cleaning instruments and the Trocar during the procedure for better visualization. The SWICKER foam sponge also replaces the abrasive high-linting cotton sponges used for resection during laparoscopic procedures.



Patented biocompatible radiopaque ink dots provide exceptional visibility under X-ray.

An estimated \$62.00 per minute is wasted looking for lost sponges in the operating room, not to mention the cost of an X-ray.¹⁷ In conjunction with manual counting of sponges, some hospitals have deployed the use of barcode scanning of each individual sponge pre- and post-operation or wand scanning of radiofrequency identified chipped sponges (RFID). These technologies

help to prevent retained sponges, yet are not fool proof as they are an extra responsibility subject to human error.¹⁴ When developing the SWICKER surgical foam sponge, Syntervention recognized the importance of reducing the amount of sponges used during medical procedures. Its unique ability to be used continuously in the same procedure allows for less sponges, as few as two per case, simplifying the sponge count, reducing the costly risk of accidental sponge retention, and cellulose fiber contamination. Managing less inventory allows facilities to minimize the expenses of shipping costs, storage space, and medical waste disposal.



SWICKER reduces overall sponge count and biohazardous waste expenses by giving the physician the ability to swap between one “working” and one “waiting” sponge.

A new standard of care

Cellulose fiber and lint contamination is responsible for costly corrective treatments, extended hospital stays, and legal fees.⁷ Syntervention is dedicated to changing the standard of care from the traditional high-linting cotton medical tools to fiber and cellulose-free medical foam technology.

President and Founder, Syntervention Norman Furbush

Norm Furbush spent six years on active duty in the US Navy as a Hospital Corpsman working in the ICU/CCU and then served with the US Marines while attending Cardio-Pulmonary school in Bethesda, MD.

Norm was honorably discharged in 1988 and took his hands on experience to the cardiac catheterization lab at Children’s Hospital DC where he spent 12 years as the Chief Technologist focused on interventional cardiology.

Over his 40 year career, Norm has held various roles in the medical device industry and provided procedure coverage for clinical research and physician training.

Since founding Syntervention in 2010, Norm has been designing products and promoting techniques to reduce fiber and lint contamination, save procedure time, and reduce costs to the hospital.

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