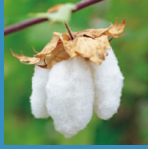


Reducing Fiber and Lint Contamination during Endovascular and Surgical Procedures

Why is it important and how to prevent it



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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

AFFILIATION/FINANCIAL RELATIONSHIP	COMPANY
Employment	Medtronic
Scientific Advisory Board / Stock	Syntervention

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Cotton lint is a documented source of foreign body contamination





Cotton plant fibers, cellulose, are not digestible by tissue macrophages.

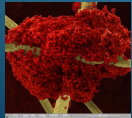
Lint from cellulose introduced to the body initiate an inflammatory response.

Significant complications are associated with cotton fiber and lint contamination.

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Clinical Complications during Diagnostic, Interventional and Surgical Procedures

When introduced into the body, cellulose in cotton lint can lead to:



- Thrombus formation
- Embolism
- Inflammation
- Granulomas
- Adhesions
- Restenosis
- Infection
- Tissue necrosis

Jandoff K, Weyand K, Hartwork D, et al. Foreign body reactions secondary to cellulose lint fibers. The Am J Surg. 2004;147:298-300. | Shandy JA, Bard MA, Green AN. Surgical sponges: a cause of granuloma and adhesion formation. Ann Surg. 1967;165:128-134. | Bookstein JJ, Arach K. Experimental investigation of hypercoagulant conditions associated with angiography. J Vasc Med Biol. 1995;6(2):137-204. | Tenker MA, Teicher I, Burdman D. Cellulose granulomas and their relationship to microbial obstruction. Am J Surg. 1977;133:134-139.

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The Culprits:

Cellulose in the Cotton-Manufactured Products We Use Every Day







Cotton Gauze Telfa Pad Cotton Towels Raytec Sponges Lap Sponges

- A standard cath lab tray includes 50 gauze and 8 surgical towels = 4,220,000 lint particles
- A standard surgical tray includes 5 lap sponges and 8 cotton towels = 3,355,000 lint particles

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How lint is introduced to the patient

AIRBORNE DIRECT CONTACT FLUIDS





4x4 Cotton Gauze


Cotton-manufactured products readily release lint into the air

Contact with cotton products or transferred from gloves, devices, and instruments

Saline used to flush a device or irrigate a wound

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Coronary Embolization of a Gauze Fragment: A Cautionary Case Report (2005)



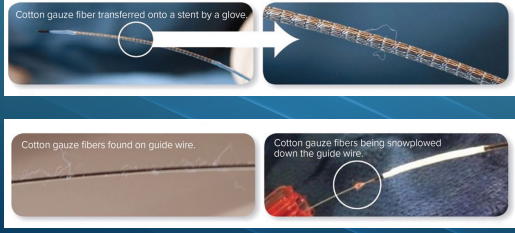
"Acute coronary thrombosis during coronary angiography due to cotton fiber injected into the coronary artery.

Cotton gauze was being soaked in the flush bowel and flush was drawn up and injected into the guiding catheter."

Coronary Embolization of a Gauze Fragment: A Cautionary Case Report
Michael Fischl, MD, and Craig R. Narins, MD

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Lint is transferred by direct contact



Cotton gauze fiber transferred onto a stent by a glove.

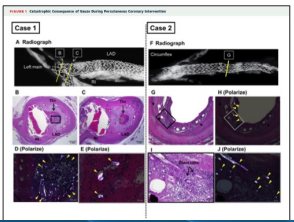
Cotton gauze fibers found on guide wire.

Cotton gauze fibers being snowplowed down the guide wire.

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Catastrophic Consequence of Gauze During PCI

Hiroyoshi Mori, MD, Robert Kutys, MS, Maria Romero, MD, Renu Virmani, MD, Aloke V. Finn, MD, 2017 JACC

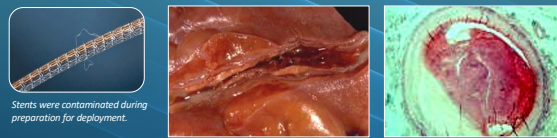


Catastrophic Consequence of Gauze During Percutaneous Coronary Intervention

"Autopsy revealed proximal left anterior descending artery thrombus with evidence of gauze in the lumen and surrounding inflammation as the likely cause."

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Foreign Body Contamination during Stent Implantation



Stents were contaminated during preparation for deployment.

- 42% of stent thrombosis had lint and glove powder enmeshed within the thrombi.
- Foreign particulates covered with inflammatory cells were large enough to clog capillaries in which they lodged.

Whelan D, Van Beusekron H, Van Der Giessen W. Foreign body contamination during stent implantation. Catheterization and Cardiovascular Diagnosis. March 1997; 40 (3): 328-332.

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Unintended Delivery of Surgical Towel Fibers into a Vein Graft During Cardiac Catheterization

Jasper et al. Cardiovasc Revasc Med. 2019

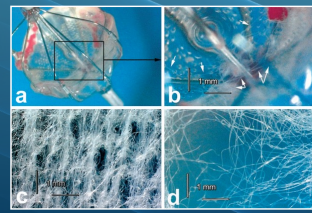
- Intraluminal filling defect formed during coronary SVG intervention
- Thromboaspiration performed and removed blue filamentous material representing fibers from blue surgical towels used on sterile field



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Distal Embolization: A Threat to the Coronary Artery?

Glenn Van Langenhove, Leonidas Diamantopoulos, Evelyn Regar, David P. Foley, Jan Tuijn, Stephane G. Carlier and Patrick W. Serruys, Circulation 2000.



Example of Cotton Fiber Embolization

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Foreign Body Embolization in Cerebral Angiography

62-year-old woman presented with subarachnoid hemorrhage. Following angiography, the patient developed new cerebral infarction and died.

(A) CT scan 2 days after angiography, demonstrating cerebral infarctions

(B) Cerebral artery containing recent thrombus and a particle of polyvinyl alcohol

(C) Small leptomeningeal artery demonstrating acute cellular reaction and thrombosis

(D) under polarized light, strongly birefringent hollow fibers characteristic of cotton

Shannon P. Billbao JM, Marotta T, Terbrugge K. Inadvertent foreign body embolization in diagnostic and therapeutic cerebral angiography. *AJNR Am J Neuroradiol.* 2006;27(2):278-282.

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Cotton-manufactured products CAN NOT be used in the clean room.

The FDA requirements for manufacturing devices no longer benefit the patient when the device is exposed to foreign body contaminants in diagnostic, interventional, and surgical procedures.

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How do we prevent lint contamination? Alternatives to cotton-manufactured products.

LINT-FREE MEDICAL DEVICE FOAM WIPER

The SWIPER hydrophobic wiper removes blood and contrast from catheters and guidewires.

ULTRA LOW-LINT SURGICAL TOWEL

SWASHER towels are lightweight, highly absorbent and minimize transfer of lint.

LINT-FREE RADIOPAQUE SURGICAL FOAM SPONGE

The SWICKER hydrophilic sponge for continuous use in open, laparoscopic, and robotic surgical procedures.

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Examples of lint-free and ultra-low-lint products in clinical use

SWIPER wiping guide wire

SWICKER Sponge 3x3 used to tamponade a wound.

SWICKER Sponge and SWASHER Towel used in femoral endarterectomy.

SWICKER Sponge 9x9 used as a sling in a CABG procedure.

SWICKER Digit used as an instrument holder.

SWICKER Digit used in an AV access graft repair.

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Summary

- Lint from cotton-manufactured products is a well-documented source of foreign body contamination in diagnostic, interventional, and surgical procedures.
- Complications from lint contamination are significant, but underreported and underappreciated. (We just can't see it).
- To increase patient safety, we should modernize and prioritize the use of lint-free and low-lint products in our procedural workflow.

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