Barbed Sutures and the Potential Risk of Small Bowel Obstruction

Report a Concern

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Issue:	Medical Devices, New safety information
Audience:	Healthcare Professionals, Hospitals
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Issue | Who is affected | Report health or safety concerns

Audience

Healthcare professionals in hospitals, including hospital chiefs of medical staff, departments of surgery, emergency medicine, family medicine and other relevant departments.

Key messages

- Health Canada is aware of international reports of small bowel obstruction (SBO) associated with the use of barbed (knotless) suture devices used in various abdominal or pelvic surgeries. The barbed suture can hook onto the small intestine and potentially cause a post-operative blockage.
- Healthcare professionals are advised to consider barbed sutures as a possible explanation in surgical cases showing post-operative signs/symptoms of SBO when these devices have been used during closure.
- Health Canada is working with relevant medical device manufacturers to update the labelling for barbed suture devices to include this safety information.

Issue

A Health Canada safety review confirmed a potential risk of small bowel obstruction (SBO) associated with the use of barbed (knotless) sutures used in surgical wound closure.

Products affected

Medical Device Name	Manufacturer	Device Licence Numbers
V-LOC 180 Wound Closure Devices	Covidien LLC	81056, 85189, 89650, 90982
Quill Knotless Tissue-Closure Devices	Surgical Specialties Mexico	79116, 87496, 87896, 90848
Stratafix Spiral Knotless Tissue Control Devices	Angiotech Puerto Rico	95456, 95457, 95459
	Ethicon LLC	90875, 97348
	Surgical Specialities Mexico	87496, 87896

Background information

Barbed sutures are knotless wound-closure devices used for soft tissue approximation in instances similar to those where traditional sutures are used. Barbs along the length of the suture thread grasp tissue at numerous points along the wound margins, locking the device into place and eliminating the need to tie the suture device off with a knot. Benefits of using this type of device may include reduced suturing or operative time, reduced cost, reduced blood loss, and more even distribution of tension across the suture line. Barbed sutures have been marketed in Canada since 2009. They are available in various types of thread materials (absorbable and non-absorbable) and are currently sold in Canada by four different manufacturers.

Despite the potential advantages of using barbed (knotless) sutures, Health Canada is aware of cases of small bowel obstruction (SBO) associated with the use of these devices. The mechanism of injury in the reported incidents was usually described as a cut end or barb of the suture becoming adherent to underlying small bowel or mesentery and producing an impingement or kinking and a transition point. This could lead to bowel infarction and significant morbidity.

In the 27 literature cases of SBO associated with barbed sutures that were reviewed at the time of Health Canada's assessment, the complication was noticed anywhere between 1 day and 4 months following the operation using barbed sutures, with an average of 18 days. Multiple types of abdominal and pelvic surgeries were implicated in the reported cases. Approximately half of the cases involved barbed sutures being used to approximate peritoneal edges, and all cases required additional surgery to correct. Bowel ischemia, necrosis, and significant morbidity were reported in one case. To date no Canadian cases of SBO related to barbed sutures have been identified.

There is some suggestion in the medical literature that either cutting the end of the suture flush with the tissue or using accessory devices (adhesion barriers, suture clips) over the cut suture end may mitigate the risk of SBO, but this has not been well studied. Some of the reported cases of SBO occurred despite the use of accessory devices or despite the barbed suture end being cut flush with the tissue surface.

Who is affected

Information for consumers

A suture is a stitch or row of stitches used to hold the edges of a wound or of body tissues together after an injury or surgery. Barbed sutures have numerous thorn-like barbs along the length of the thread that lock the suture in place, eliminating the need for knots to tie the suture.

There have been some international reports of intestinal blockage when a portion of barbed suture used during some recent surgeries hooked onto part of the small intestine, causing small bowel obstruction (SBO).

Patients should contact their healthcare professionals if they have symptoms following abdominal surgeries that may suggest SBO such as vomiting, abdominal pain, and inability to pass gas or stool.

Information for healthcare professionals

Post-market reports have demonstrated that barbed suture material has been associated with the post-surgical development of small bowel obstruction (SBO) including volvulus, bowel infarction and significant morbidity.

The root cause of these incidents appears to relate to the ends of the suture or barbs hooking onto adjacent small bowel and/or mesentery.

Even in cases where the suture has been cut flush with the tissue surface, the free lead end of the suture may advance further above the surface as healing tissues retract. This may result in the above complications.

Surgeons should be aware of this safety information when considering the use of barbed sutures in abdominal and pelvic surgeries.

Care should be taken to avoid barbed suture ends adjacent to the peritoneum in extra-peritoneal tissue closure.

Healthcare professionals are advised to consider barbed sutures as a possible explanation in surgical cases showing post-operative signs/symptoms of SBO when these devices were used during closure

Action taken by Health Canada

Health Canada is working with medical device manufacturers to update the safety information (labelling) for all barbed sutures to include details about this potential risk. Health Canada is also communicating this important safety information to Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians website. This communication will be further distributed through the MedEffect™ e Notice email notification system.

Health Canada will continue to monitor safety information involving barbed sutures, as it does for all health products on the Canadian market, to identify and assess potential harms. Health Canada will take appropriate and timely action if and when any new health risks are identified.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any case of small bowel obstruction or other serious or unexpected side effects in patients receiving barbed sutures should be reported to the device manufacturer or Health Canada.

Any suspected adverse incident can be reported to:

Regulatory Operations and Regions Branch
HEALTH CANADA
Address Locator: 2003D
Ottawa, Ontario K1A 0K9
Telephone: Regulatory Operations and Regions Branch Hotline: **1-800-267-9675**

The Health Product Complaint Form (FRM-0317) can be found on the Health Canada Web site.

For other health product inquiries related to this communication, contact Health Canada at:

Marketed Health Products Directorate (MHPD)
E-mail: mhpd_dpsc@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

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