



COOK (CANADA) INC.
165 MOSTAR STREET
STOUFFVILLE, ON L4A 0Y2
PHONE: 905.640.7110 TOLL FREE: 877.640.7110
WWW.COOKMEDICAL.COM

September 19, 2018

ATTN: DIRECTOR OF PURCHASING and/or RISK MANAGEMENT

Re: PRODUCT RECALL - Cook Zenith Alpha™ Spiral-Z Endovascular Leg

Dear Sir or Madam:

Cook (Canada) Inc. has learned from one of our manufacturers, William Cook Europe (WCE), of a fractured Zenith Alpha Abdominal Endovascular Graft that was delivered to your facility. We are sending this communication to advise you that WCE is launching a voluntary product recall.

The Zenith Alpha Abdominal Endovascular Graft is indicated for the endovascular treatment of patients with abdominal aortic or aortoiliac aneurysms having morphology suitable for endovascular repair. Our records indicate that you have received the following affected product.

Product Name	Reference Part Number	Global Product Number	Lot Number
Zenith Alpha Abdominal Endovascular Graft	ZISL-20-59	G35976	8344185

Action to Be Taken:

Please fill in the attached Customer Response form to acknowledge your receipt of this Product Recall notice. Our records indicate that the affected product has been returned. Please confirm that the affected product is no longer in your inventory.

Should you have any questions or concerns, please feel free to contact me directly at greg.leblanc@cookmedical.com / (905) 640-7110, or your Sales Representative. We regret any inconvenience that this situation may cause, and thank you for your co-operation.



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Sincerely,

Cook (Canada) Inc.



Greg LeBlanc, M.Sc., RAC
Director, Regulatory Affairs and Quality Systems

Encl. – Customer Response Form
Customer Specific Product Spreadsheet



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Customer Response Form

Please complete the following information in order to confirm your facility's receipt of the attached Product Recall regarding the Cook Zenith Alpha™ Spiral-Z Endovascular Leg.

PLEASE PRINT

Customer Account #: _____

Customer/Facility Name: _____

Street Address: _____

City, Province: _____

Postal Code: _____

Completed By: _____

Department: _____

Phone Number: _____

Please confirm the following:

____ We do not have any affected product remaining in our inventory

Please fax the completed form to (905) 640-6847 or scan and e-mail it to can.regulatory@cookmedical.com

If you have any further questions, please contact our Customer Relations Department at 1-800-457-4500 or 1-812-339-2235.

Signed: _____ Date: _____