



COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
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TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2020FA0005

Date: 11Aug2020

Urgent Field Safety Notice

Zenith Alpha® Abdominal Endovascular Graft

For Attention of: Chief Executive / Risk Management / Purchasing

Contact details of local representative (name, e-mail, telephone, address etc.)

Cook Medical Europe Ltd.
O'Halloran Road
National Technology Park
Limerick, Ireland

E-mail: European.FieldAction@CookMedical.com

Phone: Please refer to the attached Country Contacts List

For any further information or support concerning the information within this FSN please contact your local Cook Medical Sales Representative or Cook Medical Europe Ltd.



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Zenith Alpha® Abdominal Endovascular Graft

Risk addressed by FSN

Information on Affected Devices	
1.	<p>1. Device Type(s)</p> <p>The Zenith Alpha® Abdominal Endovascular Graft (ZIMB) is part of a modular system consisting of the following components: a bifurcated main body component (ZIMB) and two iliac legs (ZISL). The graft modules are constructed of woven polyester fabric sewn to self-expanding nitinol stents with braided polyester and monofilament polypropylene suture, providing a conduit that is intended to exclude the aneurysm from blood flow.</p>
1.	<p>2. Commercial name(s)</p> <p>Zenith Alpha® Abdominal Endovascular Graft</p>
1.	<p>3. Primary clinical purpose of device(s)</p> <p>The Zenith Alpha® Abdominal Endovascular Graft is indicated for the endovascular treatment of patients with abdominal aortic or aorto-iliac aneurysms having morphology suitable for endovascular repair.</p>
	<p>4. Device Catalogue number(s) specific affected lot numbers</p> <p>Refer to attached list of affected lot numbers</p>
Reason for Field Safety Corrective Action (FSCA)	
2.	<p>1. Description of the product problem</p> <p>Cook Medical has identified that specific lots of the Zenith Alpha® Abdominal Endovascular Graft (ZIMB main body) may contain excess glue within the handle of the delivery system, resulting in an inability to fully deploy the graft via the standard method or troubleshooting deployment method provided in the IFU.</p> <p>Cook has received two complaints for this issue. The procedures were able to be completed successfully without any serious adverse effects to the patient.</p>
2.	<p>2. Hazard giving rise to the FSCA</p> <p>Potential adverse events that may occur if an affected product is used include a prolonged procedure and/or open surgical repair.</p> <p>Devices already implanted are not affected by this recall. The Reply Form is still required to be returned for these devices.</p>
2.	<p>3. Background on Issue</p> <p>Based on two customer complaints, Cook Medical has identified that specific lot numbers of these devices may contain excess glue within the handle of the delivery system.</p>

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Type of Action to mitigate the risk			
3.	<p>1. Action To Be Taken by the User</p> <p> <input checked="" type="checkbox"/> Identify Devices <input checked="" type="checkbox"/> Quarantine Devices <input checked="" type="checkbox"/> Return Devices <input checked="" type="checkbox"/> Other </p> <p>Please complete the enclosed Reply Form. Where product is indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Reply Form. Returned Product should be addressed to:</p> <p>Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler GERMANY</p> <p>Credit will be provided for the returned affected products where applicable.</p>		
3.	<p>2. Particular considerations for: Implantable device</p> <p>Is follow-up of patients or review of patients' previous results recommended? No</p> <p>Devices already implanted are not affected by this recall. The Reply Form is still required to be returned for these devices.</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">3. Is customer Reply Required? Form is attached specifying deadline for return</td> <td style="text-align: center; width: 30%;">Yes</td> </tr> </table>	3. Is customer Reply Required? Form is attached specifying deadline for return	Yes
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General Information					
4.	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">1. FSN Type</td> <td style="width: 50%;">New</td> </tr> </table>	1. FSN Type	New		
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4.	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">2. Further advice or information already expected in follow-up FSN?</td> <td style="width: 50%;">No</td> </tr> </table>	2. Further advice or information already expected in follow-up FSN?	No		
2. Further advice or information already expected in follow-up FSN?	No				
4.	<p>3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">a. Company Name</td> <td style="width: 50%;">William Cook Europe</td> </tr> <tr> <td>b. Address</td> <td>Sandet 6 4632 Bjaeverskov Denmark</td> </tr> </table>	a. Company Name	William Cook Europe	b. Address	Sandet 6 4632 Bjaeverskov Denmark
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b. Address	Sandet 6 4632 Bjaeverskov Denmark				
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.				
4.	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">5. List of attachments/appendices:</td> <td style="width: 50%;">List of affected lots Reply form Country Contacts List</td> </tr> </table>	5. List of attachments/appendices:	List of affected lots Reply form Country Contacts List		
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4.	6. Name/Signature	
		Thomas Hessner Kirk Manager, Regulatory Reporting, Quality Assurance William Cook Europe

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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2020FA0005 - Affected Lot Numbers
Medical Device Recall for Zenith Alpha® Abdominal Endovascular Graft

Reference Part Number (RPN)	Order Number (GPN)	Lot Numbers
ZIMB-22-108	G35989	9182141, 9983461, 10010790, 10136649, 13023971
ZIMB-22-118	G35990	10077065
ZIMB-22-70	G35986	9170948, 9196501, 9196502, 9311502, 9415647, 10156546, 10275239, 10337923
ZIMB-22-84	G35987	9100087, 9100089, 9118160, 9124830, 9132423, 9182145, 9403140, 9415636, 9415637, 9964029, 9964055, 9974798, 9974799, 10153964, 10153965, 10337925
ZIMB-22-98	G35988	9108371, 9163902, 9406786, 10136631, 10275243
ZIMB-24-108	G35995	9338301, 9854089, 9936720, 9936722, 9939734, 9939736, 9945749, 9945751, 9945753, 10318498
ZIMB-24-118	G35996	9100111, 9163853, 9959252, 9995361, 9999386, 10275245
ZIMB-24-128	G35997	9136557
ZIMB-24-70	G35992	9084499, 9118179, 9118180, 9163859, 9184781, 9196487, 9196590, 9300915, 9311508, 9338304, 9978260, 9978261, 9983464, 10291632, 13023978
ZIMB-24-84	G35993	9084507, 9118182, 9118183, 9118406, 9118409, 9163906, 9181250, 9196491, 9196593, 9279116, 9292346, 9321079, 9321083, 9324519, 9324521, 9330492, 9330493, 9338306, 9365311, 9409601, 9409602, 9409604, 9959219, 9964025, 9964027, 9964028, 9983471, 10017280, 10044210, 10141902, 10141911, 10175395, 10175409, 10291637, 10291638, 10305523, 10305524, 10332829, 10340274, 10340279, 13008932, 13011201, 13020521, 13035543, 13041249, 10056663XX, NS9088555
ZIMB-24-98	G35994	9076897, 9080500, 9080501, 9084510, 9084512, 9100134, 9100135, 9102515, 9118415, 9173828, 9321095, 9365312, 9373635, 9415651, 9964064, 9969873, 9974816, 10052850, 10077067, 10098962, 10151099, 10186652, 13041251
ZIMB-26-108	G34381	9100142, 9163915, 9373477, 9904753, 9915021, 9930826, 9936725, 9936733, 9936734, 9953748, 10010796, 10010836, 10025525, 10108021, 10175397, 10299712, 10309872, 13023989, 13023990
ZIMB-26-118	G34382	9286115, 10105275, 10299413, 13011587, 13023992

Reference Part Number (RPN)	Order Number (GPN)	Lot Numbers
ZIMB-26-70	G35998	9100151, 9217933, 9373479, 9373646, 9419035, 9425597, 9425598, 9915028, 9915029, 9915030, 9995377, 9999389, 10025531, 10077068, 13011591, 13015424, 13021170, 13023993, 13027639
ZIMB-26-84	G35999	9076909, 9076928, 9088530, 9118164, 9124843, 9196498, 9303243, 9303253, 9314216, 9321168, 9415652, 9415653, 9936744, 9978265, 10010848, 10025534, 10130408, 10130411, 10139153, 10153985, 10225101, 10227951, 10282883, 10331451, 13008934, 13008935, 13011595, 13023997, 13030103, 13035545, 13035546, 13035549, 13090261, 10139146X
ZIMB-26-98	G36030	9076932, 9088524, 9100103, 9108359, 9124922, 9170952, 9170972, 9181256, 9209904, 9307498, 9307687, 9307688, 9321171, 9321173, 9376513, 9376514, 9376516, 9425605, 9425607, 9978273, 9999333, 10017283, 10056684, 10105282, 10113546, 10144804, 10153990, 10153991, 10153992, 10227946, 10231315, 10309875, 10331463, 10331489, 10331490, 13011600, 13015425, 13027049, 13090267
ZIMB-28-108	G34387	9040730, 9869684, 9920813, 9920814, 9920817, 9951131, 9969884, 9969885, 9983493, 9999335, 10022608, 10044216, 10056686, 10108037, 10307420, 10332830, 13010195, 13011603, 13044015, 13188317
ZIMB-28-118	G34388	9064897, 9303288, 9412815, 9415641, 9425608, 9923193, 9969889, 10010800, 10031214, 10047286, 13011606, 13041262
ZIMB-28-128	G34389	9193964, 9383486, 9915023, 9971444, 9974773, 10119913, 10119918, 10305544, 13027650
ZIMB-28-70	G34384	9037693, 9056000, 9064899, 9064901, 9088565, 9167748, 9212286, 9217990, 9226370, 9307689, 9330495, 9330496, 9331479, 9338361, 9338362, 9415633, 9415638, 9415643, 9425610, 9425613, 9930818, 9964070, 9966894, 10037025, 10139135, 10139159, 10283657

Reference Part Number (RPN)	Order Number (GPN)	Lot Numbers
ZIMB-28-84	G34385	9046402, 9136667, 9167751, 9190117, 9193974, 9212287, 9217995, 9226355, 9279120, 9303293, 9303294, 9311539, 9314218, 9324565, 9324566, 9324569, 9376519, 9383491, 9383496, 9415665, 9423252, 9425615, 9425636, 9425640, 9909088, 9911870, 9948685, 9948691, 9966896, 9966900, 9969905, 9986400, 9999343, 10022614, 10022616, 10044217, 10044219, 10047287, 10051143, 10052841, 10052868, 10068425, 10105284, 10154429, 10175398, 10175399, 10271375, 10288149, 10297330, 10325658, 10337931, 13010196, 13011613, 13021173, 13027655, 13050699, 13101560, 10141924X
ZIMB-28-98	G34386	9037752, 9046415, 9055991, 9064922, 9124929, 9124932, 9136670, 9143825, 9218000, 9234946, 9283231, 9373486, 9373488, 9376523, 9383415, 9383501, 9425633, 9911865, 9911867, 9913326, 9913327, 9920819, 9920820, 9948687, 9948692, 9956372, 9982267, 10007633, 10059719, 10059720, 10136638, 10332808, 13008942, 13010340, 13021175, 13021177, 13078502, 13101562
ZIMB-30-108	G34393	9212304, 9307494, 9307701, 9361542, 9904221, 9911853, 9911860, 9966907, 9969909, 9978296, 9982268, 9999348, 10013746, 10129802, 10156556, 10223556, 13078507, 13078509, 9904230X, NS9218007
ZIMB-30-118	G34394	9040636, 9056086, 9415666, 9959246, 9999350, 10001828, 10013748, 10132963, 10156542, 10156558, 10163202
ZIMB-30-128	G34395	9136542, 9283236, 9307703, 10047290, 10156560, 13020527, 13199408
ZIMB-30-70	G34390	9423255, 9904219, 9992839, 10007637, 10007638, 10037030, 10156561, 10327926, 13012746, 9933334X
ZIMB-30-84	G34391	9053445, 9056095, 9060405, 9150335, 9185031, 9185032, 9185034, 9190254, 9292350, 9292355, 9334354, 9338287, 9404792, 9426588, 9930856, 9971412, 9971451, 10044221, 10051128, 10059685, 10098974, 10156565, 10156567, 10315171, 10315172, 13030115, 13030117, 13050689, 13094868
ZIMB-30-98	G34392	9037765, 9060395, 9060412, 9060414, 9193801, 9206515, 9212249, 9242441, 9933350, 9974777, 9982278, 9986414, 10007647, 10017296, 10037041, 10062767, 10062768, 10062770, 10119927, 10119928, 10119929, 10136643, 10156538, 10271379, 10315173, 10331468, 10343161, 13030124, 13032866, 13078512, 13105397, 10052870X

Reference Part Number (RPN)	Order Number (GPN)	Lot Numbers
ZIMB-32-108	G34400	9034048, 9060448, 9159951, 9159952, 9167820, 9283243, 9383406, 9945758, 9982284, 9983455, 9986419, 10126202, 10156568, 10337935
ZIMB-32-118	G34401	9143871, 9391316, 9917748, 9948669, 9982251, 9995331, 10136646, 13011206, 13014574
ZIMB-32-128	G34402	9037772, 9159955, 9361554, 9423265, 10156570
ZIMB-32-84	G34397	9040645, 9136551, 9159958, 9159959, 9159962, 9167828, 9193807, 9193809, 9239290, 9239292, 9242443, 9301043, 9330500, 9373494, 9391318, 9406725, 9406728, 9917759, 9951141, 9982291, 9986422, 9995339, 10007656, 10007660, 10013759, 10017297, 10017298, 10051126, 10051157, 10062699, 10062781, 10073701, 10077029, 10110453, 10156572, 10288184, 10297335, 10299417, 10307043, 13098184, 13105403
ZIMB-32-98	G34399	9060391, 9060393, 9088571, 9132417, 9201608, 9214705, 9217930, 9234937, 9234938, 9234939, 9286012, 9286110, 9307514, 9324523, 9406730, 9406733, 9406735, 9423268, 9936717, 9936719, 9974787, 9986425, 9999375, 10007664, 10013762, 10062785, 10077088, 10113555, 10126227, 10163191, 10163203, 10167625, 10335581, 13010201, 13030131, 13030132, 13030133, 13082901, 13105407
ZIMB-36-108	G34406	9130033, 9150330, 9159890, 9365255, 9386647, 9406737, 9406738, 9995345, 9999376, 10139139, 13030135, 13074793, 13082903
ZIMB-36-118	G34407	9132489, 9376500, 10129806, 10151121
ZIMB-36-128	G34408	9915031, 10090273
ZIMB-36-84	G34404	9132418, 9132427, 9132428, 9132496, 9184767, 9303240, 9330504, 9330505, 9406742, 9904232, 9974792, 10077064, 10307049, 13035572
ZIMB-36-98	G34405	9132500, 9391321, 9959249, 10110457, 10166133, 10167626, 10297331, 10331476



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Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2020FA0005
FSN Date	11 August 2020
Product/ Device name	Zenith Alpha® Abdominal Endovascular Graft
Product Code(s) and Lot number(s)	Please refer to the attached list of affected lot numbers

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation	
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.
<input type="checkbox"/>	I have affected devices to return - enter Lot number and quantities in table below.
<input type="checkbox"/>	No affected devices are available for return.
Print Name	
Signature	
Date	

4. Return acknowledgement to sender	
Email	European.FieldAction@CookMedical.com
Customer Helpline	Please refer to the attached Country Contacts List
Fax	+ 353 61 239294
Deadline for returning the customer reply form	Please return this form within 5 business days of receipt



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If you are returning any affected product, please indicate the part number, lot number and quantity:

Product Part Number	Product Lot Number	Quantity

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.