



COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
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FSN & FSCA Ref: 2020FA0004

Date: 27May2020

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.)
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<p>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</p>

<p>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.</p>
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Zenith Alpha® Abdominal Endovascular Graft

Risk addressed by FSN

Information on Affected Devices		
1.	1. Device Type(s)	
	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.	
1.	2. Commercial name(s)	
	Zenith Alpha® Abdominal Endovascular Graft	
1.	3. Primary clinical purpose of device(s)	
	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.	
	4. Device Catalogue number(s) specific affected lot numbers	
	REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN) LOT NUMBERS
	ZIMB-26-108	G34381 10199454, 10199470, 10208616, 10216004, 10222621, 10225098, 10225099, 10236495, 10248188, 10248189, 10261154, 10262338, 10262339, 10262340, 10205533X
	ZIMB-26-118	G34382 10208618, 10208619, 10215770, 10222622, 10236497, 10241031, 10242503
	ZIMB-26-128	G34383 10258804, 10265109
	ZIMB-28-70	G34384 10222636, 10238909, 10245880, 10250361, 10250362, 10250363, 10262345, 10262346, 10269483
	ZIMB-28-84	G34385 10199450, 10199475, 10199477, 10199478, 10204345, 10204346, 10205525, 10205526, 10205527, 10205528, 10205529, 10205539, 10211497, 10211498, 10211499, 10211500, 10215409, 10215414, 10216007, 10222637, 10222638, 10223547, 10225108, 10233563, 10235877, 10236429, 10238903, 10238910, 10238911, 10238912, 10238913, 10238914, 10238915, 10238916, 10241502, 10245881, 10247235, 10247236, 10247237, 10249321, 10250365, 10250366, 10250367, 10250368, 10250369, 10250370, 10250371, 10250372, 10250373, 10250374, 10269485, 10269486, 10271376, 10271377, 13041265, 10222639X, 10241034X
	ZIMB-28-98	G34386 10205516, 10205530, 10205531, 10205532, 10211501, 10211502, 10211503, 10212862, 10212863, 10223551, 10223552, 10223553, 10223554, 10223555, 10225109, 10225110, 10228473, 10233106, 10233553, 10233554, 10233555, 10233556, 10236430, 10238918, 10238919, 10238920, 10238921, 10251228, 10251229, 10251230, 10251231, 10251232, 10251233, 10251234, 10252366, 10291801, 10291802

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ZIMB-28-108	G34387	10208631, 10208632, 10208633, 10211492, 10211493, 10222630, 10222631, 10222632, 10222633, 10225104, 10225105, 10225106, 10225107, 10241033, 10248204, 10248205, 10248206, 10248207, 10248208, 10250358, 10250359, 10265111, 10240704X
ZIMB-28-118	G34388	10207216, 10207217, 10210137, 10211495, 10222634, 10222635, 10248209, 10248210
ZIMB-28-128	G34389	10200936, 10205562, 10211496, 10248211, 10248212, 10258806, 10262344
ZIMB-30-70	G34390	10210135, 10210962, 10215769, 10230974, 10233544, 10269488, 10269698
ZIMB-30-84	G34391	10199451, 10199455, 10199473, 10199479, 10200943, 10204343, 10205561, 10212864, 10212865, 10212866, 10216009, 10223561, 10223562, 10223563, 10223564, 10223565, 10233557, 10247239, 10247240, 10247241, 10249322, 10251246, 10251247, 10251248, 10251249, 10251250, 10251251, 10265114, 10269699, 10271378
ZIMB-30-98	G34392	10204339, 10205522, 10205523, 10205524, 10205555, 10215763, 10223566, 10233558, 10233559, 10233560, 10233561, 10238925, 10247242, 10247243, 10251253, 10251254, 10251255, 10251256, 10251257, 10264837, 10264838, 10265115, 10265116, 10265117, 10265118, 10265120
ZIMB-30-108	G34393	10225111, 10251236, 10251237, 10258796, 10258800, 10258801, 10262347, 10265112, 10265113, 10291806, 10251238X
ZIMB-30-118	G34394	10211476, 10212875, 10216008, 10251240
ZIMB-30-128	G34395	10233545, 10269487
ZIMB-32-70	G34396	10223574, 10231109, 10233542, 10261156, 10265127
ZIMB-32-84	G34397	10210963, 10212857, 10215767, 10223575, 10223576, 10223577, 10223578, 10225117, 10233546, 10233547, 10233548, 10247246, 10247247, 10247248, 10265128, 10265129, 10265130, 10269700, 10269701, 10269702, 10269703, 10269704
ZIMB-32-98	G34399	10199458, 10199459, 10199468, 10205517, 10205518, 10212867, 10215765, 10225118, 10225119, 10233552, 10236432, 10238928, 10238929, 10238930, 10271382, 10307044
ZIMB-32-108	G34400	10212859, 10216010, 10223570, 10247244, 10249323, 10251259, 10251260, 10258798, 10258799, 10264840, 10265121, 10265122, 10265123, 10271380
ZIMB-32-118	G34401	10210961, 10223572, 10223573, 10225116, 10247245, 10265124, 10265125
ZIMB-32-128	G34402	10215412
ZIMB-36-70	G34403	10261157, 10267914
ZIMB-36-84	G34404	10199452, 10199476, 10200938, 10212872, 10212873, 10215768, 10216011, 10225123, 10225124, 10231326, 10249325, 10258797, 10258803, 10261149, 10261150, 10261151, 10261158, 10261159, 10267915, 10269707, 10269708, 10271385
ZIMB-36-98	G34405	10199460, 10200940, 10204344, 10207218, 10207219, 10210136, 10212869, 10212871, 10222048, 10225125, 10225126, 10225127, 10225128, 10231327, 10231328, 10233549, 10233550, 10233551, 10238933, 10238934, 10241038, 10269710, 10271386, 10271387
ZIMB-36-108	G34406	10225120, 10231324, 10233543, 10238783, 10238932, 10241037, 10258802, 10269705, 13051084
ZIMB-36-118	G34407	10200939, 10207215, 10212868, 10222049, 10225121, 10231325
DEMO-ZIMB	G34959	10186895, 10186898, 10211629, 10211630, 10211631, 10211633, 10273391, 10273393, 10273395, 10273396
ZIMB-22-70	G35986	10208608, 10211485, 10215996, 10228479, 10248181, 10265103, 10267913, 10269479, 13051062
ZIMB-22-84	G35987	10215762, 10215997, 10222615, 10228481, 10228482, 10236484
ZIMB-22-118	G35990	10208604
ZIMB-24-70	G35992	10227949, 10230972, 10231302, 10231303, 10231304, 10236489, 10236490, 10242494, 10242495, 10248182, 10250348, 10262332, 10262333, 10262334, 10262335, 10262336, 10269480, 10271371, 13056932
ZIMB-24-84	G35993	10199469, 10200941, 10204340, 10204347, 10208611, 10208612, 10208613, 10211488, 10211489, 10215998, 10215999, 10216000, 10216001, 10222617,

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			10222618, 10233541, 10236427, 10236491, 10236492, 10238904, 10238905, 10242498, 10242499, 10247472, 10248183, 10248184, 10248185, 10248186, 10250349, 10250350, 10265106, 10265107
	ZIMB-24-98	G35994	10200935, 10205519, 10205520, 10205521, 10205540, 10208614, 10208615, 10216002, 10216003, 10222619, 10222620, 10227944, 10227947, 10235868, 10235873, 10236493, 10236494, 10242500, 10242501, 10242502, 10250352, 10262337, 10265108, 13056937
	ZIMB-24-108	G35995	10231107, 10252364, 10252365, 10262330, 10262331, 10265105
	ZIMB-24-118	G35996	10222616, 10236487
	ZIMB-26-70	G35998	10204342, 10208620, 10208621, 10216005, 10222623, 10222624, 10236500, 10236501, 10242506, 10248191, 10262341, 10262342, 10262343
	ZIMB-26-84	G35999	10199457, 10200937, 10200942, 10204348, 10204349, 10205534, 10205535, 10205536, 10205537, 10205538, 10205556, 10208623, 10211490, 10211491, 10222625, 10231311, 10231312, 10231313, 10233562, 10235874, 10236503, 10236504, 10236505, 10236506, 10236507, 10236508, 10236509, 10238907, 10242507, 10242508, 10242509, 10242510, 10242511, 10242512, 10248192, 10248193, 10248194, 10248196, 10248197, 10248198, 10248199, 10250354, 13056938, 10248195X
	ZIMB-26-98	G36030	10199453, 10199456, 10199461, 10204341, 10204350, 10205557, 10208625, 10208627, 10208628, 10208629, 10208630, 10216006, 10222626, 10222627, 10222628, 10222629, 10225102, 10225103, 10231316, 10235871, 10236428, 10241032, 10242513, 10242514, 10242515, 10242516, 10248200, 10248201, 10248202, 10248203, 10250355, 10250356, 10250357

Reason for Field Safety Corrective Action (FSCA)

2.	1. Description of the product problem
	Cook Medical has identified that the product specific lot numbers listed above may contain a damaged bushing within the delivery system, which could potentially result in difficulty or an inability to fully deploy the graft via the standard method provided in the IFU. Based on customer complaints Cook Medical has received for this issue, the troubleshooting deployment method within the IFU has been able to be used successfully
2.	2. Hazard giving rise to the FSCA
	Potential adverse events that may occur if an affected product is used include a prolonged procedure and minimally invasive endovascular intervention. Devices already implanted are not affected by this recall.
2.	3. Background on Issue
	Based on customer complaints Cook Medical has identified that specific lot numbers of these devices may contain a damaged bushing.

Type of Action to mitigate the risk

3.	1. Action To Be Taken by the User
	<input checked="" type="checkbox"/> Identify Devices <input checked="" type="checkbox"/> Quarantine Devices <input checked="" type="checkbox"/> Return Devices <input checked="" type="checkbox"/> Other


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	<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.</p>	
3.	<p>3. Is customer Reply Required? Form is attached specifying deadline for return</p>	Yes

General Information						
4.	1. FSN Type	New				
4.	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>a. Company Name</td> <td>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
a. Company Name	William Cook Europe					
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.	5. List of attachments/appendices:	Reply form Country Contacts List				
4.	6. Name/Signature	 Thomas Hessner Kirk Manager, Regulatory Reporting, Quality Assurance William Cook Europe				

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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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