

COOK®

Cook Medical Europe

 O'Halloran Road,
 National Technological Park,
 Limerick, Ireland.

Phone: + 353 61 334440

Fax: + 353 61 334441

Urgent Field Safety Notice

Commercial name of the affected product: Zenith Alpha Abdominal Endovascular Graft

Manufacturer : William Cook Europe

Cook Reference Number: 2019FA0005

Type of action: Field Safety Corrective Action (FSCA) – Recall of specific lots

Date: 25 April 2019

Attention: Health Care Provider / Chief Executive / Risk Management / Purchasing

Details on affected devices:

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN) PREFIX	ORDER NUMBER	LOT NUMBER
Zenith Alpha Abdominal Endovascular Graft	ZIMB	See Attachment 1	See Attachment 1

Description of the problem:

Cook Medical has identified that specific lots of the Zenith Alpha Abdominal Endovascular Graft may contain a damaged grey safety lock knob, which could potentially result in difficulty or an inability to fully deploy the graft via the standard or troubleshooting method provided in the Instruction for Use. Therefore, Cook Medical has determined to initiate a voluntary recall of the lots listed in Attachment 1.

Potential adverse events that may occur if an affected product is used include a prolonged procedure and open surgical intervention.

Devices already implanted are not affected by this recall.

Intended use for the affected products:

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.

Advise on action to be taken by the user:

1. Examine your inventory immediately to determine if you have affected product(s), and quarantine affected product(s). Immediately cease all distribution and use of these products.
2. Return the affected product(s) to Cook Medical with a copy of the Customer Response Form to receive a product credit.

NOTE: Unaffected products that are returned will not be credited.

3. Please complete the attached Customer Response Form within 5 business days of receiving this Field Safety Notice and return it to Cook Medical as directed on the form.

Transmission of this Field Safety Notice:

This notice must be shared with appropriate personnel, including down to the user level, within your organization or with any organization where the potentially affected devices have been transferred.

We apologize for any inconvenience this may cause. If you need any further information or support concerning this information, please contact your local Cook Medical Sales Representative.

Contact reference person:

Thomas Hessner Kirk
Team Lead, Regulatory Reporting
Regulatory Affairs
William Cook Europe
Bjaeverskov, DENMARK

We recognize this situation is a disruption to your normal operations and we sincerely apologize. Thank you again for your immediate assistance in this matter. Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@cookmedical.com, phone +353 61 334440).

We confirm that this notice has been notified to the appropriate Regulatory Agency.



Thomas Hessner Kirk
Team Lead

Reference Part Number (RPN)	Global Product Number (GPN)	Lot Numbers
ZIMB-22-108	35989	9221784, 9228731, 9232249, 9246529, 9272685, 9272835, 9276029, 9276400, 9303245, 9373623, 9406776, 9466908, 9506559, 9525188, 9557569, 9566160, 9566211, 9575380, 9620378, 9620379, 9620382, 9625916, 9625917, 9636371, 9640584, 9663986
ZIMB-22-118	35990	9406777, 9522416, 9566161, 9575382, 9625918, 9656992
ZIMB-22-128	35991	9557570, 9566162, 9575383, 9625919, 9625920, 9656978
ZIMB-22-70	35986	9221629, 9232247, 9276401, 9303246, 9373624, 9394051, 9403262, 9406778, 9406779, 9406780, 9453299, 9466909, 9466910, 9482147, 9486290, 9486313, 9506616, 9522418, 9522419, 9525189, 9529047, 9534284, 9555442, 9555453, 9555475, 9566214, 9572229, 9575386, 9592482, 9592485, 9594196, 9594205, 9609105, 9617443, 9617445, 9625921, 9625922, 9625923, 9636298, 9636330, 9640585, 9642977, 9650113, 9650114, 9394051X, NS9584273, NS9584274, NS9584275, NS9584276, NS9584277, NS9584278, NS9584279, NS9584280, NS9584281, NS9584282
ZIMB-22-84	35987	9214951, 9221781, 9221785, 9221786, 9221787, 9228739, 9232238, 9232239, 9232250, 9234942, 9239302, 9239303, 9246530, 9272665, 9272686, 9272687, 9272836, 9276402, 9276403, 9391303, 9403123, 9403124, 9403125, 9403126, 9403127, 9403128, 9403129, 9403130, 9403131, 9403132, 9403133, 9403134, 9403136, 9403137, 9403138, 9403139, 9404632, 9404633, 9406719, 9406720, 9406721, 9406781, 9406782, 9406783, 9464235, 9522423, 9529049, 9529050, 9529051, 9557572, 9561001, 9566215, 9575388, 9581884, 9594197, 9594206, 9598741, 9602905, 9605694, 9605695, 9625893, 9625896, 9625924, 9625925, 9625926, 9636372, 9640586, 9642978, 9656979, 9656994, 9272665X, 9403130X, 9522423X, NS9239300, NS9239301
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ZIMB-24-108	35995	9228740, 9242449, 9386592, 9386660, 9386661, 9386662, 9466913, 9466914, 9466915, 9605686, 9623874, 9623879, 9625845, 9640513, 9640514, 9671040, 9671042, 9671043, 9671044, 9242450
ZIMB-24-118	35996	9228741, 9228742, 9403263, 9419802, 9470240, 9506618, 9515086, 9557574, 9561003, 9566217, 9575392, 9609106, 9623930, 9625929, 9629885, 9640589, 9640590, 9656981, 9660204, 9663989
ZIMB-24-128	35997	9373626, 9557564, 9557575, 9569073, 9575332, 9578369, 9629871, 9629886, 9640591, 9656995, 9373626X
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Reference Part Number (RPN)	Global Product Number (GPN)	Lot Numbers
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ZIMB-26-108	34381	9217948, 9217949, 9217950, 9226365, 9228749, 9228750, 9246541, 9246542, 9246543, 9248835, 9248836, 9373644, 9391463, 9391464, 9394054, 9394055, 9403268, 9403269, 9403270, 9474596, 9525196, 9529066, 9529067, 9529068, 9534296, 9534297, 9557578, 9602871, 9650039, 9650040
ZIMB-26-118	34382	9232389, 9246544, 9525197, 9525198, 9566166, 9578388, 9587407, 9625900, 9629891, 9640558, 9642981
ZIMB-26-128	34383	9228753, 9232390, 9248837, 9396561, 9525171, 9525200, 9525202, 9557579, 9566167, 9578390, 9594198, 9594209, 9594210, 9629892, 9629893, 9640600, 9642982, 9642983, 9660205, 9664012
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ZIMB-28-70	34384	9279026, 9279027, 9386653, 9478700, 9482119, 9486299, 9508745, 9508746, 9508747, 9515128, 9515129, 9515130, 9515131, 9522379, 9525248, 9534303, 9534304, 9566174, 9566175, 9569119, 9569122, 9569123, 9578412, 9578413, 9578414, 9578415, 9578416, 9578417, 9578418, 9587421, 9587422, 9594219, 9598729, 9602925, 9602926, 9602927, 9602928, 9602930, 9605704, 9623925, 9623926, 9623934, 9623935, 9623936, 9623937, 9633334, 9636299, 9636340, 9636341, 9636342, 9636343, 9640565, 9640566, 9647073, 9647074, 9647097, 9647098, 9647099, 9647100, 9656986, 9515130X

Reference Part Number (RPN)	Global Product Number (GPN)	Lot Numbers
ZIMB-28-84	34385	9276033, 9276034, 9279028, 9279110, 9279118, 9279119, 9279121, 9279122, 9279123, 9279124, 9279125, 9279126, 9279127, 9365243, 9365244, 9365245, 9370230, 9370231, 9370232, 9370238, 9370239, 9370240, 9370241, 9370242, 9386654, 9461549, 9461553, 9464246, 9466882, 9470221, 9470222, 9474577, 9474578, 9478701, 9478702, 9478703, 9478704, 9478705, 9478706, 9478707, 9478708, 9478709, 9482120, 9482121, 9482122, 9482124, 9482125, 9482126, 9482127, 9486300, 9486301, 9486302, 9506575, 9506576, 9506577, 9506578, 9506579, 9506581, 9508748, 9508749, 9508750, 9512178, 9515062, 9515063, 9515132, 9517941, 9517965, 9517966, 9517968, 9517969, 9517970, 9517974, 9561011, 9566155, 9566176, 9566177, 9569135, 9569136, 9572239, 9572240, 9575340, 9581850, 9581851, 9581852, 9584258, 9584260, 9587392, 9587393, 9587394, 9587395, 9587424, 9587425, 9587426, 9587427, 9587428, 9587429, 9587430, 9587431, 9592483, 9594200, 9594220, 9594221, 9598730, 9602931, 9602932, 9605706, 9605707, 9605708, 9605709, 9605710, 9605711, 9609111, 9609112, 9620381, 9620391, 9620392, 9620393, 9620394, 9625904, 9629879, 9633299, 9633302, 9633303, 9633304, 9633305, 9633306, 9633307, 9633308, 9633309, 9633335, 9636344, 9636345, 9636346, 9636347, 9640567, 9640568, 9640569, 9640570, 9640571, 9647075, 9647101, 9647102, 9647103, 9647104, 9647105, 9647106, 9647107, 9647108, 9650089, 9650090, 9653860, 9653884, 9653885, 9653886, 9653887, 9653888, 9653889, 9653890, 9653891, 9276034X, 9370230X
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ZIMB-30-108	34393	9276036, 9276037, 9276038, 9276039, 9283232, 9283233, 9283234, 9283235, 9391306, 9396541, 9396620, 9426572, 9464251, 9466885, 9466886, 9466887, 9474579, 9478713, 9478714, 9482132, 9512187, 9515065, 9517988, 9517989, 9517990, 9517991, 9529012, 9529014, 9534329, 9561012, 9566178, 9572252, 9572253, 9572254, 9575343, 9575344, 9584261, 9594223, 9594224, 9594225, 9594226, 9605691, 9605712, 9605713, 9605714, 9605715, 9609113, 9620395, 9620396, 9623938, 9625895, 9625905, 9636348, 9636349, 9636350, 9640572, 9640573, 9640574, 9640575, 9647076, 9647109, 9647110, 9647111, 9647112, 9647113, 9650091, 9650092, 9650093, 9653861, 9653892, 9660211, 9664015
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ZIMB-30-128	34395	9276040, 9400632, 9426580, 9517944, 9517998, 9557566, 9560987, 9566179, 9594229, 9605717, 9609114, 9611322, 9617438, 9620397, 9642971, 9653893, 9656987, 9656988, 9656993, 9656996
ZIMB-30-70	34390	9276041, 9283222, 9283237, 9283238, 9365246, 9386600, 9386601, 9426581, 9426582, 9466889, 9478715, 9478716, 9529018, 9557567, 9560988, 9561014, 9572261, 9575346, 9594230, 9594231, 9609115, 9611323, 9625906, 9625907, 9633310, 9636353, 9647116, 9647117, 9653862, 9653863, 9653894

Reference Part Number (RPN)	Global Product Number (GPN)	Lot Numbers
ZIMB-30-84	34391	9276021, 9279005, 9279006, 9365247, 9365248, 9365249, 9365250, 9365251, 9365252, 9386602, 9386657, 9391309, 9391310, 9396543, 9396544, 9400672, 9426584, 9426585, 9464257, 9470225, 9478717, 9482133, 9482134, 9515067, 9518002, 9518003, 9518004, 9522380, 9529019, 9529020, 9529021, 9534274, 9566180, 9566181, 9569080, 9572262, 9572263, 9572264, 9572265, 9572266, 9572267, 9572268, 9581857, 9581858, 9581859, 9581860, 9581861, 9581862, 9594233, 9594234, 9594235, 9594236, 9594237, 9594238, 9594239, 9594240, 9609116, 9609117, 9609118, 9609119, 9609120, 9609121, 9609122, 9611324, 9611325, 9611326, 9620398, 9620399, 9620400, 9620401, 9620402, 9620403, 9620404, 9623939, 9633311, 9636354, 9636355, 9636356, 9636357, 9640576, 9640577, 9647079, 9647118, 9647119, 9647120, 9647121, 9650094, 9650095, 9650096, 9656989, 9660214, 9660215, 9664020
ZIMB-30-98	34392	9283224, 9283239, 9283240, 9365253, 9391314, 9396546, 9464258, 9474583, 9478691, 9478718, 9478719, 9478720, 9478721, 9486305, 9486306, 9512191, 9512192, 9515068, 9515069, 9515070, 9515071, 9517945, 9518013, 9518015, 9522381, 9522382, 9522383, 9522384, 9529022, 9529023, 9529024, 9529025, 9529026, 9529027, 9555457, 9555458, 9555459, 9555460, 9555461, 9566184, 9572271, 9572272, 9572273, 9572274, 9572275, 9572276, 9575347, 9578358, 9581846, 9581863, 9581864, 9581865, 9581866, 9581867, 9581868, 9594242, 9594243, 9594244, 9594245, 9594246, 9609100, 9609123, 9609124, 9620405, 9620406, 9620407, 9620408, 9620409, 9620410, 9629880, 9633312, 9633313, 9633314, 9633315, 9633316, 9633317, 9636284, 9636358, 9640522, 9640578, 9640579, 9640580, 9647080, 9647081, 9650097, 9650098, 9650099, 9650100, 9650101, 9650108, 9653864, 9653899, 9653900, 9653901, 9663993, 9663994, 9663995, 9664021, 9664022, 9664023, 9664024, 9664025
ZIMB-32-108	34400	9386604, 9386605, 9478722, 9478723, 9482135, 9486308, 9512193, 9515073, 9522385, 9522386, 9525174, 9529028, 9561015, 9561016, 9566186, 9572281, 9575348, 9578359, 9581869, 9581870, 9584267, 9594202, 9594249, 9594250, 9609101, 9609125, 9609126, 9609127, 9611327, 9620411, 9620412, 9386604X, 9478723X
ZIMB-32-118	34401	9478724, 9478725, 9522388, 9557568, 9560989, 9561017, 9566187, 9569086, 9572283, 9572284, 9575349, 9578360, 9598725, 9602900, 9602902, 9602903, 9611328, 9611329, 9611330, 9620413, 9647082, 9647083, 9650056, 9650102, 9650103, 9656968, 9656969, 9671109, 9671112
ZIMB-32-128	34402	9412948, 9466894, 9522390, 9560991, 9566188, 9569087, 9611331, 9620414, 9633318, 9650104, 9650105, 9650109, 9656970, 9656971, 9671110, 9671111
ZIMB-32-70	34396	9276043, 9276044, 9515075, 9522391, 9560992, 9561020, 9575350, 9611315, 9611332, 9611333, 9620415, 9625908, 9625909, 9636359, 9636360, 9650110, 9656972
ZIMB-32-84	34397	9276023, 9276045, 9276298, 9276299, 9276300, 9276301, 9361560, 9386610, 9386611, 9400693, 9464262, 9464263, 9592449, 9592451, 9592452, 9592453, 9592454, 9592455, 9592456, 9592457, 9592458, 9592459, 9592460, 9592461, 9598718, 9598719, 9598720, 9598721, 9598722, 9605683, 9605684, 9605685, 9609072, 9609073, 9609074, 9609075, 9623875, 9623876, 9623877, 9623878, 9625846, 9633256, 9640512, 9671029, 9671030, 9671032, 9671033, 9386610X, 9386613
ZIMB-32-98	34399	9276302, 9276303, 9276304, 9276305, 9276306, 9276307, 9365254, 9370212, 9386614, 9386615, 9386616, 9386642, 9386643, 9386645, 9415644, 9461576, 9478729, 9478730, 9486310, 9486311, 9515076, 9515078, 9515079, 9515080, 9522394, 9522395, 9522396, 9522397, 9522398, 9525176, 9525177, 9529029, 9529031, 9529032, 9529033, 9529044, 9560994, 9560995, 9561022, 9566189, 9566191, 9566192, 9566194, 9575352, 9575353, 9575354, 9575355, 9575356, 9575357, 9584268, 9598734, 9598735, 9611334, 9611335, 9611336, 9611337, 9611338, 9620416, 9623927, 9623941, 9623942, 9623943, 9623944, 9623945, 9623946, 9625910, 9629881, 9633319, 9633320, 9633321, 9633322, 9633323, 9633324, 9633325, 9636361, 9636362, 9642972, 9642973, 9642974, 9653865, 9656973, 9656974, 9656975, 9656976, 9656977, 9656991, 9664000

Reference Part Number (RPN)	Global Product Number (GPN)	Lot Numbers
ZIMB-36-108	34406	9376505, 9376506, 9376507, 9376580, 9376581, 9383408, 9383409, 9461581, 9522401, 9560996, 9566198, 9575358, 9575359, 9575360, 9575361, 9581871, 9581872, 9592484, 9594203, 9611340, 9611342, 9611344, 9611346, 9633326, 9633327
ZIMB-36-118	34407	9376508, 9376509, 9376582, 9376583, 9560997, 9566199, 9609087, 9609102, 9609103, 9611347, 9611348, 9620380, 9623928, 9623947, 9623948, 9636363, 9636364, 9647084, 9650057, 9650058, 9653829, 9653866, 9653867, 9660202, 9664002, 9664003, 9664029, 9664030
ZIMB-36-128	34408	9560998, 9566200, 9609104, 9611349, 9611350, 9623949, 9636365, 9650059, 9653868, 9664004, 9664031, 9664782
ZIMB-36-70	34403	9555469, 9566201, 9569088, 9575365, 9575366, 9581873, 9623950, 9629882, 9633328, 9636366, 9642975, 9647085, 9650042, 9650046, 9650047, 9650051, 9650060, 9653869, 9653870, 9663988, 9664005, 9664032, 9664033
ZIMB-36-84	34404	9365288, 9365289, 9376585, 9376586, 9376587, 9466898, 9560999, 9566206, 9575371, 9578361, 9581874, 9581875, 9598738, 9611351, 9611352, 9611353, 9611354, 9611355, 9623929, 9623951, 9623952, 9623953, 9623954, 9636367, 9640581, 9640582, 9642976, 9650106, 9650107, 9650111, 9660203, 9664006, 9664007, 9664008, 9664009, 9664034, 9664035
ZIMB-36-98	34405	9365290, 9365291, 9376589, 9376590, 9380004, 9383412, 9386651, 9566153, 9566158, 9566210, 9575374, 9575376, 9575377, 9581877, 9584270, 9605692, 9605693, 9611357, 9611358, 9611359, 9611360, 9623955, 9623956, 9623957, 9623958, 9625911, 9625912, 9633329, 9633330, 9633331, 9633332, 9636368, 9636369, 9640583, 9650112, 9653871, 9653872, 9653873, 9664010, 9664011, 9664780, 9664781



Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
Phone: + 353 61 334440
Fax: + 353 61 334441

FIELD ACTION CUSTOMER RESPONSE FORM

1. SECTION 1

Field Action reference no.: 2019FA0005
Affected device: Zenith Alpha Abdominal Endovascular Graft

Please indicate the following:

Customer Number (As Indicated on the attached product list): _____

Customer Name: _____

Street Address: _____

City, ZIP: _____

Completed by: _____

Department: _____

Phone Number: _____

(Please Print)

Please indicate which of the following applies to your facility:

- None of the affected product remains in our inventory
- We are returning our remaining inventory, please see details listed below

****If you are a distributor, have your customers been notified of this Field Safety Corrective Action?**

- Yes No

