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Edwards Lifesciences

URGENT: MEDICAL DEVICE NOTIFICATION

Product: EZ Glide Aortic Cannulae

Reference Appendix A for Impacted Products

08 Nov 2024

Edwards Lifesciences FCA#188

Dear Valued Customers and Distributors:

Edwards Lifesciences is voluntarily notifying customers of a potential issue regarding the EZ Glide Aortic Cannulae.

Intended Use:

Aortic perfusion cannulae are intended for perfusion of the aorta during short-term (<6 hours) cardiopulmonary bypass procedures.

Aortic perfusion cannulae may be used in pediatric or adult populations based on the flow rate requirements and individual patient anatomy.

Description of the Problem:

Edwards Lifesciences has received customer complaints associated with EZ Glide Aortic Cannulae minor leakage at the connector. The investigation revealed a manufacturing issue causing a potential small leak path in the connector during perfusion that may lead to minimal blood leakage consisting of drips or oozing blood. None of the complaints have resulted in any serious injury or illness.

Risk to Health:

There have been no associated injuries or blood transfusions required. All cases were completed without complications or injuries as a result of the leak.

Only the lots listed in Appendix A are impacted. The manufacturing issue has been resolved, and newly manufactured devices are not impacted by this potential issue.

Edwards Lifesciences LLC

One Edwards Way • Irvine, CA USA • 92614

Phone: 949.250.2500 • Fax: 949.250.2525 • www.edwards.com



Field Corrective Action # 188

Actions to be Taken:

- No product return is necessary.
- You may continue to use this product; however, if you experience this issue, you may contact customer service per the information below for a replacement device.
- Please distribute this notice within your organization or to any organization where the potentially impacted product has been transferred.
- Please post a copy of this notice near and/or with affected devices.
- Complete and email acknowledgement form to CustomerService_MY@edwards.com, within 15 days from receipt of this notification.
- Contact Edwards Lifesciences Customer Service at +603-2289 3788 if you have further questions.

Actions to be Taken for Distributors:

In addition to the actions above, please forward this customer communication to any of your customers who have purchased the impacted product.

Transmission of the Product Correction Notice:

This notice needs to be passed on to all individuals within your organization who need to be aware of this correction. Please transfer this notice to other organizations if the impacted product has been transferred or distributed to other facilities.

Your assistance is appreciated and necessary to ensure that this notice is reviewed and understood. Edwards Lifesciences is responsible for any reporting to the applicable Regulatory Authorities.

Adverse Event Reporting in the US:

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Sincerely,

Amy Li
Vice President , Quality



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Appendix A: Field Corrective Action # 188

Table 1: UDI Numbers

Product Name	UDI - Unit	UDI - Box
EZC21A	0690103174182	0690103174187
EZS21A	0690103172096	0690103172091
EZC21TA	0690103174199	0690103174194
EZF21TA	0690103175097	0690103175092
EZF21A	0690103175080	0690103175085
EZS21TA	0690103172102	0690103172107
EZC24A	0690103714401	0690103714406
EZS24A	0690103172119	0690103172114
EZC24TA	0690103714418	0690103714413
EZS24TA	0690103172126	0690103172121
EZF24A	0690103175066	0690103175061
EZF24TA	0690103175073	0690103175078

Table 2: Impacted Lots by Model

EZC21A						
391136	395877	401161	401162	401160	400120	405092
406884	407404	412973	413866	414709	417262	417265
419860	419861	420606	423540	423561	423562	422572
429046	433816	433244	434261	435606	435904	436714
440602	440603	442143				
EZS21A						
384889	384887	384883	386801	391223	395875	398476
400118	405146	408036	408039	411041	411043	417246
417239	420466	420467	423563	423564	427535	428178
428177	435901	437698	437699	440318	440319	443026
EZC21TA						
383800	383802	386803	386840	389990	389991	393997
394000	395874	397568	397569	398185	398188	398177
400126	400127	400128	401182	405916	412974	412760
413867	414710	415896	415921	415897	415898	416562
421681	421682	422569	424410	424411	424163	429408
429044	429490	429489	430266	432769	433521	433523
440446	440612	443027	443028			



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EZF21A						
384881	390383	393996	400124	406003	408635	411025
411030	418391	418429	419303	419304	425519	434115
435608	436721	438407	438408	442132		
EZS21TA						
386134	386135	386459	387784	388262	387788	391957
391958	395878	398477	401712	406248	409990	409991
413289	413065	412988	413865	413465	413286	418433
419676	421679	421680	424412	429498	429499	431074
431076	433814	436718	438409	442129		
EZF21TA						
387782	391206	393008	408643	411207	416564	417210
417226	420585	425518	428173	428182	431079	433804
440317	444830					
EZC24A						
387783	390382	393010	398200	403093	405871	407877
411047	415920	422567	425099	425176	433815	435902
437702	440619	444825				
EZS24A						
384894	386800	390384	393994	398479	409989	411045
416566	419677	423565	428179	434256	437700	443025
EZC24TA						
393009	406246	407758	411414	416561	422570	422568
422571	426006	426171	426173	426242	426243	427537
427541	430144	437701	440620			
EZS24TA						
382872	387778	391944	393995	398205	401715	406255
408024	414797	414798	414799	418431	428199	432551
438405						
EZF24A						
394001	397336	400125	421506	436584	436588	438406
EZF24TA						
409179	418430	420586	427446	427304	427539	430340

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**URGENT: MEDICAL DEVICE CORRECTION
ACTION REQUIRED**

**Field Corrective Action # 188
Product: EZ Glide Aortic Cannulae
CUSTOMER ACKNOWLEDGEMENT FORM**

To: << Customer Name >>
<< Customer Address >>

Attention: Risk Management Department
cc: Chairman Medical Board and relevant Head of Departments

Please review and verify your inventory in the table below for your impacted devices.

- Provide all requested contact information below.
- E-mail the completed form to CustomerService_MY@edwards.com, within 15 days from receipt of this notification.
- Contact Edwards Lifesciences Customer Service at +603-2289 3788 have further questions.

Name (Print):	
Hospital Name:	
Title/Dept.	
Telephone Number:	
E-mail:	
Signature/Date:	