URGENT – PRODUCT RECALL
Ref: #FCA-146

Edwards Lifesciences EZ Glide™ Aortic Cannula
Model Numbers EZC21A, EZC21TA, EZC24A, EZC24TA, EZF21A, EZF21TA, EZF24A, EZF24TA, EZS21A, EZS21TA, EZS24A, and EZS24TA

Possibility of Cannula Separation – Action required

25 Oct 2019

Attention: Risk Management Department
cc: Chief of Cardiac Surgery, Director of Operating Room Services
cc: Chairman Medical Board and relevant Head of Departments

RE: Edwards Lifesciences EZ Glide aortic perfusion cannula

Dear Valued Customer,

Edwards Lifesciences would like to advise you of action to be taken by users of EZ Glide aortic perfusion cannula (UDI code 00690103172119) used for perfusion in cardiopulmonary bypass procedures. The affected model numbers are EZC21A, EZC21TA, EZC24A, EZC24TA, EZF21A, EZF21TA, EZF24A, EZF24TA, EZS21A, EZS21TA, EZS24A, and EZS24TA.

Edwards Lifesciences has initiated a recall of the EZ Glide product after receiving three (3) reports that an EZ Glide cannula separated from its connector, causing a breach of the cardiopulmonary bypass (CPB) circuit and loss of blood. In each case, the report suggests that the separation occurred without any significant force being applied to the joint. Although the occurrence rate is 0.0034%, and all patients had successful surgical outcomes, in the interests of patient safety and transparency, Edwards is notifying customers of the events and requesting return of EZ Glide devices. Figure 1 shows the EZ Glide device and the location of the connector, cannula, and where the two components are bonded together.

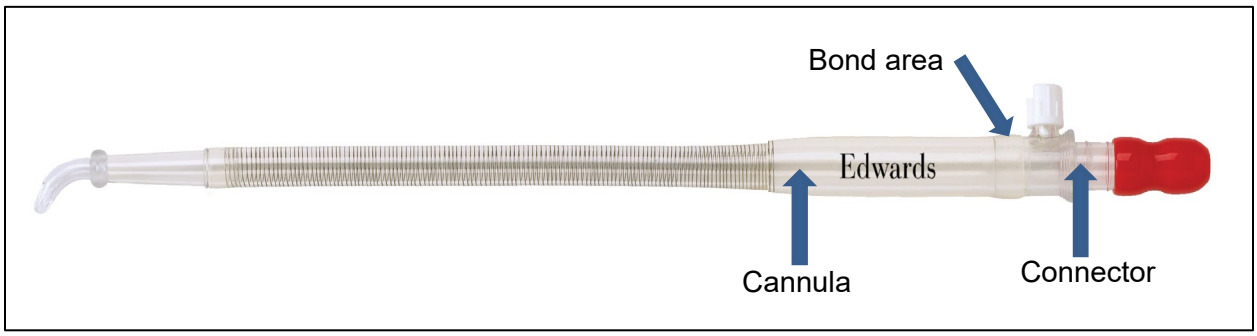
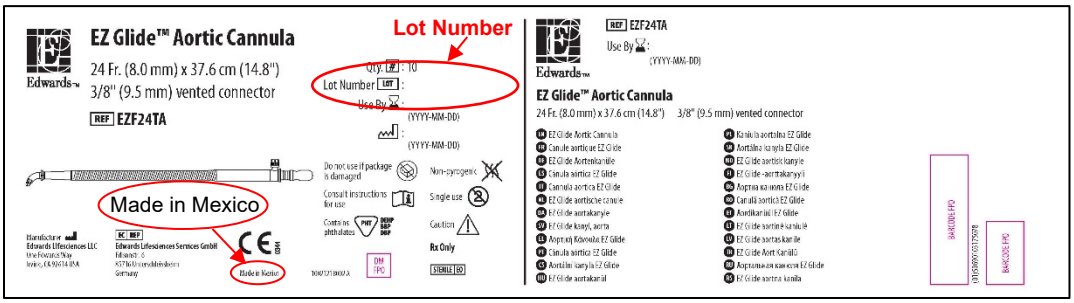


Figure 1. EZ Glide Aortic Cannula Device

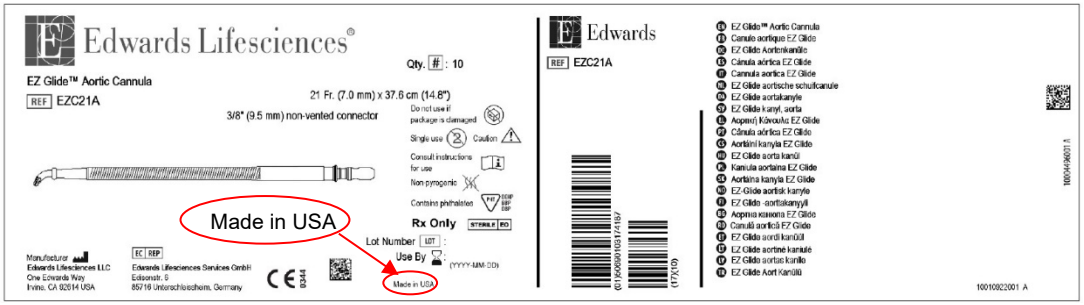
Below please find a description of the affected product, the potential hazard, instructions for return, and potential mitigations.

Affected Product

Lot numbers of EZ Glide cannula listed in Attachment A are affected by this recall. The package for affected units is labeled “Made in Mexico.” See label illustrations below.



Note: Packages labeled “Made in USA” are not subject to recall. See label illustrations below.



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Potential Hazard

During use the flow in these cannulae is very high. A separation of this type can result in significant blood loss. There is also a risk of air embolism and ischemic events. As a result of the potential risk of serious injury posed by this issue, we are requesting that you return all affected inventory.

Customer Instructions

1. Review this field safety notice to understand the potential hazard, and return all unused inventory as instructed.
2. Complete and return the Product Reconciliation Form to Customer Service:
   a) Record the quantity of any affected EZ Glide aortic perfusion cannula in your possession,
   b) Segregate and quarantine affected product until returned,
   c) Determine the quantity of EZ Glide aortic perfusion cannula used by subtracting the quantity on hand from the quantity shipped to you,
   d) Contact Customer Service to arrange return of affected devices, and
   e) Return affected devices to Edwards with the Return Goods Authorization (RGA) provided.
3. Complete and return the attached Acknowledgement Form within five (5) business days of receiving this notice to Customer Service at [redacted] or respective Edwards Sales Representative.
4. Distribute this notice within your organization or to any organization where the potentially affected devices have been transferred. If you have further distributed this product, notify your customers to the user level. Report any EZ Glide separation to Edwards Lifesciences.

Potential Shortage and Mitigations

EZ Glide will not be available until we correct the issue. Please take this into consideration as you manage your practice. We recommend use of an alternative device from Edwards or another provider (e.g., Medtronic, LivaNova, etc.). Questions regarding future availability of EZ Glide may be directed to Edwards Customer Service at [redacted].

Should you elect to use the EZ Glide device in your inventory, we suggest grasping each side of the bond area and applying a firm pull before use to confirm the bond is secure. We also recommend maintaining visibility of the device throughout the procedure. Potential mitigations in the event of cannula separation include ensuring a backup device or 3/8” x 3/8” connector is available.

Clinical or procedural questions may be directed to Blesson Varghese, SEA BU Director at [redacted], 662-239-8020.

Your assistance is appreciated and necessary to ensure that this notice is reviewed, and that the response forms and affected devices are returned promptly.

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Edwards has communicated this Field Safety Notice to appropriate regulatory authorities. Please report any adverse events or quality problems associated with the use of the EZ Glide to Edwards or to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

We appreciate your attention and apologize for the inconvenience caused by this matter. We are working diligently to ensure availability of replacement devices. If you have questions, please call or email Edwards Customer Service at 662 239 8040 (Yosita), Email: [redacted]

Sincerely,

[redacted]

Sunita Das
Director I Quality Assurance
Edwards Lifesciences

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ATTACHMENT A

URGENT – PRODUCT RECALL – Ref: #FCA-146

Edwards Lifesciences EZ Glide Aortic Cannula
Model Numbers EZC21A, EZC21TA, EZC24A, EZC24TA, EZF21A, EZF21TA, EZF24A, EZF24TA, EZS21A, EZS21TA, EZS24A, and EZS24TA

AFFECTED LOT NUMBERS

Lot Number	Lot Number	Lot Number	Lot Number
203876	207654	217024	226788
205724	207655	217025	226938
205775	208823	217048	227494
205868	208893	218185	227886
205920	208894	218457	228009
205921	209901	218539	228259
205922	209904	219090	228549
206369	210110	219212	228558
206372	210111	219561	229051
206373	212032	220146	229054
206374	212033	220151	229827
206768	212034	220157	230690
206769	212035	220802	230894
206770	212258	220803	231105
206771	212280	222841	231109
206772	212959	222913	231111
206773	213506	222914	231291
206774	213914	222915	231485
206775	214214	223174	232109
206776	214216	224233	232437
206777	214716	224235	234138
206778	214717	224662	
207319	214961	224707	
207320	215239	225306	
207321	215495	225884	
207322	216123	225885	
207323	216196	226188	
207324	216627	226596	
207636	216628	226597	
207638	216632	226691	

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Acknowledgement Form

URGENT – PRODUCT RECALL

Edwards Lifesciences Edwards Lifesciences EZ Glide Aortic Cannula
Reference: FCA-146

25 Oct 2019

Reason for action: Possibility of Cannula Separation with the EZ Glide Aortic Cannula

This acknowledgement form confirms that we understand the information in the Urgent Product Recall Notice for action #FCA-146. We have shared this information with all appropriate clinical staff at our institution and we will ensure return of any unused affected product.

☐ I confirm receipt of the Field Safety Notice and that its content was read and understood.

Hospital:	Hospital Ship To #:	Hospital Address:

Printed Name of Person Responding: _____

Title: _____ Department: _____

Telephone: _____ Fax: _____ Email: _____

Signature: _____ Date: _____

Please email this Acknowledgement Form to the attention of: Edwards Customer Service, at [redacted] or respective Edwards Sales Representative.

Please complete the Product Reconciliation Form below, then contact customer service at Yosita Sawangpong, Phone: 662 239 8040, Email: [redacted] to arrange for return of product to Edwards.

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Product Reconciliation Form

URGENT – PRODUCT RECALL

Edwards Lifesciences Edwards Lifesciences EZ Glide Aortic Cannula
Reference: FCA-146

Reason for action: Possibility of Cannula Separation with the EZ Glide Aortic Cannula

Hospital:	Hospital Ship To #:	Hospital Address:

Model Number	(A) Quantity Shipped to Hospital	(B) Quantity on Hand to be Returned to Edwards
Column TOTAL:		
	Quantity Used (A total – B total):	

Please return this completed Reconciliation Form to respective Edwards Sales Representative or Edwards Customer Service at Yosita Sawangpong, Phone: 662 239 8040, Email: [redacted] Attn: Customer Service

Returned Goods Authorization (RGA) Number: _____

Completed by (print):	
Signature:	Date: