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**Edwards Lifesciences**  
**URGENT FIELD SAFETY NOTICE**

Field Corrective Action #188

Product: EZ Glide Aortic Cannulae

**Reference Appendix A for Impacted UDI / Lot Numbers**

<<MM/DD/YYYY>>

Edwards Lifesciences FCA#188

<Customer #>

Attention: Risk Management

<Firm Name>

<Address>

<City/state/zip>

**Dear Valued Customers and Distributors:**

Edwards Lifesciences (SRN: US-MF-000007139) 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 ( $\leq 6$  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.



## 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 follow the standard complaint reporting process.
- 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 [XXX@edwards.com](mailto:XXX@edwards.com), within 15 days from receipt of this notification.
- Contact Edwards Lifesciences Customer Service at [XXX-XXX-XXXX](tel:XXX-XXX-XXXX) if you have further questions.

### Actions to be Taken for Distributors:

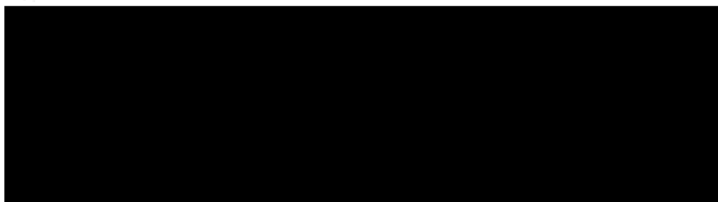
In addition to the actions above, please forward this customer communication to any of your customers who have purchased the impacted product.

### Transmission of the Field Safety Notice:

This notice needs to be passed on to all individuals within your organization who need to be aware of this notice. 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.

Sincerely,





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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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## Appendix A Continued: Field Corrective Action # 188

| 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 |



**URGENT FIELD SAFETY NOTICE  
ACTION REQUIRED**

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

Reference Appendix A for Impacted UDI / Lot Numbers

**CUSTOMER ACKNOWLEDGEMENT FORM**

<Customer #>  
Attention: Risk Management  
<Firm Name>  
<Address>  
<City/state/zip>

**Dear Customers and Distributors:**

- Please review the content of this field safety notice.
- Provide all requested contact information below.
- E-mail the completed form to [XXX@edwards.com](mailto:XXX@edwards.com), within 15 days from receipt of this notification.

Contact Edwards Lifesciences Customer Service at [XXX-XXX-XXXX](tel:XXX-XXX-XXXX) if you have further questions.

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