



## **URGENT: Medical Device Recall Notification**

AFFECTED DEVICES: Cannula A, 9mm x 250mm

23 January 2024

Dear Valued Customer:

Globus Medical has initiated a recall of all lots of ExcelsiusGPS® Cannula A, 9mm x 250mm. This recall is being conducted because these devices may not be rendered sterile.

### **Reason for Voluntary Recall:**

Devices may not be rendered sterile due to an internal gap that may be present on some devices causing increased difficulty cleaning prior to steam sterilization.

To date, Globus Medical has received 4 reports of difficulty cleaning the I.D. due to the presence of a gap. No adverse events were associated with the reported issue.

### **Affected Lots:**

All lots of part number 6143.2844, Cannula A 9mm x 250mm, are subject to this recall. Refer to the table beginning on page 3.

### **Potential Risks to Health:**

There is an increased risk for infection, inflammation, local toxicity, systemic toxicity, sensitivity, and cross-contamination. No special follow-up visits are necessary.

### **Required Action for Customers:**

Customers are instructed to stop using Cannula A immediately, quarantine them according to your internal procedures, return the affected cannulas to Globus Medical, and complete the attached Response Card.

Report adverse events believed to be associated with the affected cannulas to Globus Medical immediately.



Valley Forge Business Center  
2560 General Armistead Avenue Audubon, PA 19403  
Phone: 610.930.1800 Fax: 610.930.2042  
Order Fax: 610.930.2041  
www.globusmedical.com

**Follow-up Actions by Globus Medical:**

The US Food and Drug Administration and the National Competent Authority of your country has been notified of this action.

Through an internal investigation, this was identified to be a design issue isolated to this cannula.

**For Questions and Support:**

Globus Medical Contact	Contact Information	Areas of Support
Globus Medical Complaint Handling Unit	Fax: +1 (610) 300-1342 Email: recall@globusmedical.com	Recall Related Questions

**Please complete and return the enclosed Response Form via fax or email.**

Globus Medical is committed to serving your product needs and our primary objectives are patient safety, exceptional product reliability, and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Daniel S Paul  
Senior Vice President, Corporate Quality & IT  
Globus Medical, Inc.

**Affected Lots (all lots)**

Part	Description	Lot	UDI
6143.2844	Cannula A 9mm x 250mm	FSB136AA	(01)00889095998498(10)FSB136AA
		FSB121AA	(01)00889095998498(10)FSB121AA
		FSB241AA	(01)00889095998498(10)FSB241AA
		FSB207AA	(01)00889095998498(10)FSB207AA
		FSB136AA	(01)00889095998498(10)FSB136AA
		FSB121AA	(01)00889095998498(10)FSB121AA
		FSB110AA	(01)00889095998498(10)FSB110AA
		FSB073AA	(01)00889095998498(10)FSB073AA
		FSA286CA	(01)00889095998498(10)FSA286CA
		FSA286BA	(01)00889095998498(10)FSA286BA
		FSA286AA	(01)00889095998498(10)FSA286AA
		FSA263DA	(01)00889095998498(10)FSA263DA
		FSA263EA	(01)00889095998498(10)FSA263EA
		FSA263CA	(01)00889095998498(10)FSA263CA
		FSA263AA	(01)00889095998498(10)FSA263AA
		FSA263BA	(01)00889095998498(10)FSA263BA
		FSA160AA	(01)00889095998498(10)FSA160AA
		FSA160BA	(01)00889095998498(10)FSA160BA
		FSA105BA	(01)00889095998498(10)FSA105BA
		FSA105AA	(01)00889095998498(10)FSA105AA
		FSA053AA	(01)00889095998498(10)FSA053AA
		FSY319AA	(01)00889095998498(10)FSY319AA
		FSY279BA	(01)00889095998498(10)FSY279BA
		FSY279AA	(01)00889095998498(10)FSY279AA
		FSY272AA	(01)00889095998498(10)FSY272AA
		FSY230AA	(01)00889095998498(10)FSY230AA
		FSY098AA	(01)00889095998498(10)FSY098AA
		FSY098CA	(01)00889095998498(10)FSY098CA
		FSY098BA	(01)00889095998498(10)FSY098BA
		FSY048AA	(01)00889095998498(10)FSY048AA
FSX093AA	(01)00889095998498(10)FSX093AA		
FSX205AA	(01)00889095998498(10)FSX205AA		
FSX141BA	(01)00889095998498(10)FSX141BA		



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Part	Description	Lot	UDI
6143.2844	Cannula A 9mm x 250mm	FSX141CA	(01)00889095998498(10)FSX141CA
		FSX141AA	(01)00889095998498(10)FSX141AA
		FSX093AA	(01)00889095998498(10)FSX093AA
		FSX063AA	(01)00889095998498(10)FSX063AA
		FSX041AA	(01)00889095998498(10)FSX041AA
		FSX041BA	(01)00889095998498(10)FSX041BA
		FSW142AA	(01)00889095998498(10)FSW142AA
		FSW094AA	(01)00889095998498(10)FSW094AA



**URGENT: Medical Device Recall – ExcelsiusGPS® Cannula A (P/N 6143.2844)**

**RESPONSE FORM**

Please assist us in making this Medical Device Recall Notification follow-up process efficient and convenient for you by completing and returning this form to Globus Medical via email or fax. This serves as confirmation that you have received and understand this notification. A coversheet is not required to fax this response form.

**FAX:** +1 (610) 300-1342

**Email:** [recall@globusmedical.com](mailto:recall@globusmedical.com)

**NOTE:** [If you have responded already, you do not have to respond again.](#)

I have read and understand the recall instructions provided in the letter. Yes  No

Any adverse events associated with recalled product? Yes  No

If yes, please explain (attach additional sheets if needed):

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**Was this device used? (If yes, please indicate the quantities used.)**

**Recalled Devices for Return**

- I have checked my inventory and have determined that **NONE** of the recalled devices are available to be returned.
- I have checked my inventory and have recalled devices to return to Globus Medical.

Number of units to return \_\_\_\_\_

*[Please contact Globus Customer Service at +1(866) 456-2871 for Return Authorization and return it to Globus Medical]*

Device Part #(s):	
Device Lot #(s):	
Facility Name:	
Facility Address:	



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Completed By:	Title:
Signature:	Date:
Phone:	Fax:
Email:	
Preferred Form of	<input type="checkbox"/> Phone <input type="checkbox"/> Fax <input type="checkbox"/> Email

**Return Response Box:**

Please provide any additional information, if applicable.