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

URGENT: Medical Device Recall Notification

AFFECTED PRODUCT: Flat Panel Fluoroscopy Registration Fixture

January 16, 2024

Dear Valued Customer,

Globus Medical is advising customers to stop using the Flat Panel Fluoroscopy Registration Fixture, Globus Medical has decided to initiate a voluntary recall. This recall is being conducted because a calibration error is associated with the Flat Panel Fluoroscopy Fixture when it is used with ExcelsiusGPS® for fluoroscopy workflows, leading to inaccurate navigation which may result in device misplacement and patient harm.

Reason for Voluntary Recall

Globus Medical is notifying all customers with the Flat Panel Fluoroscopy Registration Fixture that we have received an increased rate of complaints associated with use of this registration fixture. To date, Globus Medical has received 11 complaints with reports of 2 adverse events associated with screw misplacement.

Potential Risks to Health

When the Flat Panel Fluoroscopy Registration Fixture is used with ExcelsiusGPS® to input medical images using the fluoroscopy workflow, incorrect registration of patient image can occur, leading to misplaced implant or instrument which may result in tissue damage, and lead to complications such as a dural tear, cerebrospinal fluid leak, nerve root irritation, loss of sensation, paralysis, vascular injury, visceral injury, and pedicle fracture.

Affected Units

All distributed devices listed below.

Part Number	Description	Serial #	UDI
6203.2100	Flat Panel Fluoro Fixture Kit	FPFF-0101	(01)00193982465155(11)230623(21)FPFF-0101
		FPFF-0102	(01)00193982465155(11)230623(21)FPFF-0102
		FPFF-0103	(01)00193982465155(11)230623(21)FPFF-0103
		FPFF-0104	(01)00193982465155(11)230726(21)FPFF-0104
		FPFF-0105	(01)00193982465155(11)230726(21)FPFF-0105
		FPFF-0106	(01)00193982465155(11)230726(21)FPFF-0106
		FPFF-0107	(01)00193982465155(11)230726(21)FPFF-0107
		FPFF-0108	(01)00193982465155(11)230726(21)FPFF-0108
		FPFF-0109	(01)00193982465155(11)230726(21)FPFF-0109

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Required Action for Users

Customers are instructed to immediately return the Flat Panel Fluoroscopy Registration Fixture and complete the attached Response Card.

Report any adverse events believed to be associated with the Flat Panel Fluoroscopy Registration Fixture to Globus Medical.

Follow-up Actions by Globus Medical

The US Food and Drug Administration has been notified of this product recall. Globus Medical has determined that an error is associated with the Flat Panel Fluoroscopy Fixture when it is used with ExcelsiusGPS® for fluoroscopy workflows, leading to inaccurate navigation which may result in device misplacement. Globus is working to correct the calibration process and taking actions to prevent recurrence.

Adverse incidents are to be reported to the relevant regulatory authorities. In the EU, reports are submitted to the respective National Competent Authorities by means of the Manufacturer Incident Report (MIR). The MIR can be found on the European Commission Medical Devices website: https://ec.europa.eu/docsroom/documents/41681. In the UK, refer to Medical devices: guidance for manufacturers on vigilance - GOV.UK (www.gov.uk).

For Questions and Support:

Globus Medical Contact	Contact Information	Areas of Support
Globus Medical Complaint Handling Unit	Fax: 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.

Attachment: Customer Response Form

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URGENT: Medical Device Recall

ExcelsiusGPS® Flat Panel Fluoroscopy Registration Fixture

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

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):

_____

_____

_____

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.

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Number of units to return _____

[Please contact Globus Customer Service at 1-866-456-2871 for Return Authorization. Contact your local Globus Sales Representative to coordinate the return of the Flat Panel Fluoroscopy Fixture.)

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

Completed By:	Title:
Signature:	Date:
Phone:	Fax:
Email:	
Preferred Form of	☐ Phone ☐ Fax ☐ Email

Return Response Box:

Please provide any additional information, if applicable.