

Vortex Surgical Inc

12/28/2025

URGENT: MEDICAL DEVICE RECALL

Product Name	Catalog Number	Affected Lot(s)
25GA Laser Probe Flex-Tip	VS0130.25	2411024

Attention:



Dear Device Customer,

Purpose of this Letter

The purpose of this letter is to advise you that Vortex Surgical Inc is voluntarily recalling:

Product Name	Catalog	Lot	Pouch UDI	Box UDI	Expiration (YYYY/MM/DD)
25GA Laser Probe Flex-Tip	VS0130.25	2411024	00810123480111	00810123480265	2027/12/01

According to our records you have received:

Catalog	Boxes	Lot
VS0130.25	10	2411024

Please complete the response on page 3 of this document and email it back to ARitts@VortexSurgical.com as soon as possible. Please note if there are no boxes in inventory with a zero (0).

Reason for Recall

Reason for the voluntary recall is Vortex Surgical has become aware from a single customer complaint that there may be voids located in the seal of the Tyvek pouches associated with the catalog number and lots listed above. The seal issue is only related to the lots listed. Other lots of product may be utilized in place of the affected lots.

Risk to Health

A compromised sterile barrier has potential of bioburden contamination which could lead to infection.

Vortex Surgical Inc

12/28/2025

Actions to be taken by the Customer

Discontinue use of product listed above. Return the product for Vortex Surgical to evaluate the seals. Please use UPS account 23623Y to ship unused products to Vortex Surgical Inc for replacement or refund at:

Attn: Andrew Ritts Recall Tyvek Seal
Vortex Surgical Inc.
4 Research Park Dr.
Suite 124
St. Charles, MO 63304

Product and distribution information: The seal issue is only related to the lots listed. Other lots of product may be utilized in place of the affected lots.

Product and Distribution Information Table				
Product Names, Unique Device Identifier	Catalog Number	Lot/Serial Number	Expiration Date (YYYY/MM/DD)	Quantity
25GA Laser Probe Flex-Tip UDI Pouch 810123480111 UDI Box 810123480265	VS0130.25	2411024	2027/12/01	10 boxes

Actions have been implemented to improve training of individuals associated with sealing and inspecting seals to prevent reoccurrence. The sealer associated with the issue is being updated to include a guard to prevent reoccurrence.

For questions please contact:

Andrew Ritts
Director of Regulatory Affairs
636-778-4350
ARitts@VortexSurgical.com
From 8 AM to 5 PM CST

Attachments: Acknowledgement and Product Replacement Forms (separate sheets)

Authorized by: 

Signature 

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.

Vortex Surgical Inc

12/28/2025

MEDICAL DEVICE RECALL RETURN RESPONSE

Acknowledgement and Receipt Form

Response is Required

Customer Information:

Lameris Ootech

info@lameris-group.nl

Da Vincilaan 7, WC Ede 6716, Netherlands

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I have read and understand the recall instructions provided in the <Date letter sent> letter.

Yes _____ No _____

Any adverse events associated with recalled product? Yes _____ No _____

If yes, please explain:

Affected Product Information: Include information that is applicable for affected product.

Affected Product Information Table					
Product/Brand Names, UDI	Manufacturer's Product #/ Catalog #	Lot/Serial # shipped to Customer	Quantity in inventory	Quantity destroyed	Quantity returned
25GA Laser Probe Flex-Tip UDI Pouch 810123480111 UDI Box 810123480265	VS0130.25	2411024			

Vortex Surgical Inc

12/28/2025

Return Response Box:

Please provide any additional information, if applicable.

Questions:

Please have Customer Service contact me.

Signature of Receipt _____

Name/Title	
Telephone	
Email address	

PLEASE EMAIL COMPLETED RESPONSE FORM TO: ARitts@VortexSurgical.com

ATTN: Andrew Ritts

OR MAIL TO: Vortex Surgical Inc
4 Research Park Dr.
Suite 124
St. Charles MO, 63304