ViVO Surgical
Beyond Surgery

15th March 2024

Urgent Field Safety Notice

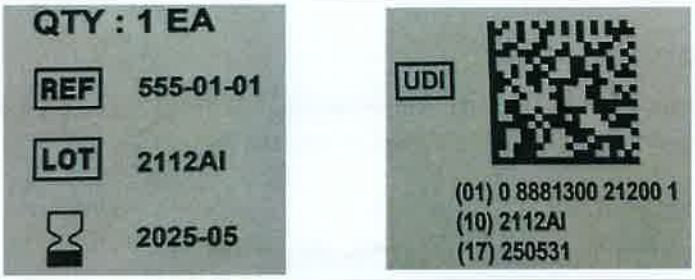
Dear customers,

Vivo Surgical Private Limited is initiating a voluntary product recall for the following affected KLARO® In Vivo Surgical Lighting product lots:

Table 1: Affected Product and Product Lots

Product Model	Product Description	Product Lot
555-01-01	KLARO® In Vivo Surgical Lighting	2112AI
555-01-01	KLARO® In Vivo Surgical Lighting	2104AG
555-01-01	KLARO® In Vivo Surgical Lighting	2108AH

Table 2: Pictorial Information of Affected Product Lot

Type of Label	Label Information
Tray (2112AI)	
Tray (2104AG)	
Tray (2108AH)	

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Description Of The Issue:

We received a product-related complaint for the KLARO® In Vivo Surgical Lighting device, involving the splitting open of the top and bottom enclosures of the device. This complaint did not result in any harm or adverse effects to the patient or end-user. However, as a precautionary measure, Vivo Surgical Private Limited would now require your assistance to return the affected lots as mentioned in Table 1 above.

Actions to be taken by the recipients of this recall:

1) Please inform all affected users / organizations of this Voluntary Medical Device Recall.
2) Examine inventory and storage immediately to determine if there are any affected products on hand.
3) Immediately quarantine any affected products that remain unused and cease all further sales, distribution, and use of the affected products.
4) Complete and sign the Medical Device Recall Acknowledgement Form within 3 business days of receiving this letter and return it via email to regulatory@vivo-surgical.com.
5) This notice must be shared with all appropriate personnel, including end-users, both within your organization or externally where the potentially affected devices have been distributed.
6) Kindly contact Vivo Surgical Private Limited to return ALL affected products.

Please assist us in meeting our regulatory obligations by completing and emailing the attached Medical Device Recall Acknowledgement Form. A response is required even though you may not have any affected products on hand.

Market Impact:

This recall is strictly specific to products listed in Table 1. Unaffected devices will continue to be accessible on the market for purchase based on availability.

Action Taken by Vivo Surgical Private Limited:

1) Vivo Surgical Private Limited is removing potentially affected products from the market.
2) Vivo Surgical Private Limited has stopped shipment of the affected product.

For further information or inquires, please contact us at +65 6677 0395 or send us an email at regulatory@vivo-surgical.com.

We apologize for the inconvenience caused and seek your kind cooperation and understanding on this matter.

VIVO SURGICAL PTE LTD
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Dr Kevin Koh
Chief Executive Officer
Vivo Surgical Private Limited