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Making Surgery Safer

XODUS MEDICAL, INC.
September 20, 2019

Urgent: Medical Device Voluntary Recall

Cautery Tip Cleaner

Hospital Services Limited
Unit 1A, Block 4A
Blanchardstown Corporate Park,
Blanchardstown, Dublin, D15 YW26
Ireland
Attn: Recall Coordinator

Dear Sir or Madam,

The purpose of this letter is to advise you that Xodus Medical, Inc is voluntarily recalling the Cautery Tip Cleaner product for a specified manufacturing time frame.

Description of items under voluntary recall:

- Cautery Tip Cleaner
- Product Numbers 30500
- The Cautery Tip Cleaner is a single use device used to clean uncoated cautery blades of eschar build-up.

Reason for the Voluntary Recall:

Xodus Medical has received complaints of some devices where the sterile barrier of some devices may have been affected. Xodus Medical has confirmed instances where the pouch seal was compromised on some of the reported product. In no instance has it been reported to Xodus Medical that a compromise in the sterile barrier has resulted in injury or illness. The compromised seals were discovered prior to use.

The issue can be identified through inspection of the Tyvek pouch. In some instances, the pouch seal has been cut causing the seal width to be less than the required minimum (6mm) per BS EN 868-5 or the pouch seal is open. Secondly, the product contained within the pouch may be partially sealed into the Tyvek seal itself.

Note: There is an extremely low health risk associated with this issue. The associated health risk may be contamination for the patient. The issue is easily identifiable, thereby preventing use of the product.

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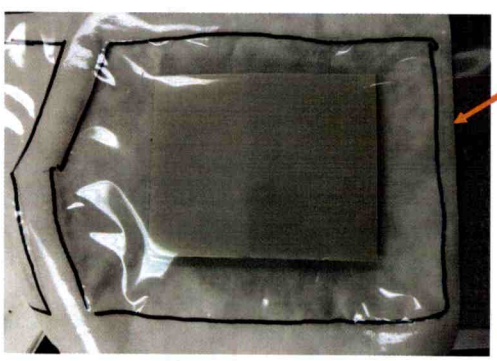
Actions to be taken:

- Please **immediately** check your inventory and quarantine affected stock on hand. It has been determined by Xodus Medical that the product can be inspected for the suspected issue and segregated accordingly.
    - Please note, the list of affected products and lot numbers included in this letter are specific to your purchases from Xodus Medical.
- The following process shall be undertaken in order to segregate any affected inventory. The existing inventory shall be inspected and any affected product quarantined and destroyed.
    - The Tyvek pouch shall be inspected for the seal integrity as described above. the pouch seal has been cut causing the seal width to be less than the required minimum (6mm) per BS EN 868-5 or the pouch seal is open. Secondly, the product contained within the pouch may be partially sealed into the Tyvek seal itself.
    - Please see the photos below to provide guidance to the specific condition called out above.



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- Unaffected product shall be distributed with no further action necessary.
- For any product that is quarantined and must be destroyed:
    - Xodus Medical requires documentation of the affected inventory that is found to be affected and destroyed. Information regarding the following shall be documented and provided to Xodus Medical.
        - Product Number; Quantity Affected; Method of Destruction; Evidence of Destruction
        - Evidence of destruction can be photos or videos of product being destroyed
    - Upon Xodus receipt of this information and confirmation of destruction of any affected product, Xodus Medical shall issue a credit for the affected and subsequently destroyed product.
- Please **immediately** complete the attached Acknowledgement form even if you do not have any affected stock, and return the acknowledgement to Xodus Medical at the following:
    - *Email – PLloyd@XodusMedical.com or*
    - *Fax +1 724-337-1131*
- If you have supplied any potentially affected product to another organization, please advise that organization of this voluntary recall and contact us so we can follow up with them.
- In case product is in transit, display this letter in a prominent place for 36 months from date of your receipt.

Product and Distribution Information:
The following table shall indicate the product information subject to the voluntary recall.

Product Number	Description	Affected Lot Number	Manufacturing Dates	Quantity (Cases)	Quantity (Eaches)
30500	Cautery Tip Cleaner	17JAN23	1/23/2017	20	4,000
30500	Cautery Tip Cleaner	17FEB27	2/27/2017	20	4,000
30500	Cautery Tip Cleaner	17APR03	4/03/2017	14	2,800
30500	Cautery Tip Cleaner	17APR14	4/14/2017	6	1,200
30500	Cautery Tip Cleaner	17MAY24	5/24/2017	1	200
30500	Cautery Tip Cleaner	17MAY24A	5/24/2017	19	3,800

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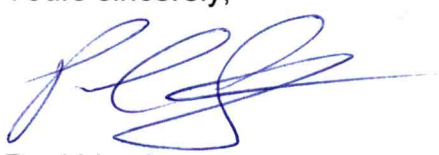
For further information please call Paul Lloyd, Vice President, Global QA/RA & Technology, Xodus Medical; +1 724-337-5500; PLloyd@XodusMedical.com. Availability of Paul Lloyd for questions via phone, email or fax is Monday-Friday, 8AM-5PM Eastern Standard Time.

Thank you for your assistance in helping us to manage this voluntary recall.

Yours sincerely,



Paul Lloyd
Vice President, Global QA/RA & Technology
Xodus Medical, Inc.
PLloyd@XodusMedical.com
+1 724-337-5500

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MEDICAL DEVICE RECALL RETURN RESPONSE

Acknowledgement and Receipt Form

Response is Required

Hospital Services Limited
Unit 1A, Block 4A
Blanchardstown Corporate Park,
Blanchardstown, Dublin, D15 YW26
Ireland
Attn: Recall Coordinator

Description of items under recall

- **Cautery Tip Cleaner**

Affected Product:

Product Number	Description	Affected Lot Number	Manufacturing Dates	Quantity (Cases)	Quantity (Eaches)
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30500	Cautery Tip Cleaner	17MAY24	5/24/2017	1	200
30500	Cautery Tip Cleaner	17MAY24A	5/24/2017	19	3,800

I have read and understand the recall instructions provide in the September 20, 2019 letter. Yes _____ No _____

Any adverse events associated with the recalled product? Yes No

If yes, please explain:

_____

_____

_____

On behalf of this organization I acknowledge receipt of the Urgent Medical Device Recall notice date September 20, 2019 relating to the above product.

Name		**Date**	
Position		**Signature**	
Organization			

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Affected Stock

If you have **no affected** stock tick this box [ ]

If you have affected stock please complete the table below

Product	Batch/Lot/Date	Qty
	TOTAL AFFECTED PRODUCT	

Has your organization supplied potentially affected product to any other organisation?
[ ] No
[ ] Yes (please supply names and contact information of the organizations)

Name/Title	
Telephone	
Email Address	

Completed forms are to be returned by email or fax to:

- Paul Lloyd, Vice President, Global QA/RA & Technology
- Fax +1 724-337-1131
- Email: PLloyd@XodusMedical.com