AD-TECH® MEDICAL INSTRUMENT CORPORATION

Urgent Field Safety Notice

Drill Sleeve Guide
FSCA-identifier 22-08-2019-00001
Type of action: Field Safety Notice (FSN)

Date: September 10, 2019

MS. LONE JACOBSEN
CEPHALON A/S
SUNDSHOLMEN 29
NOERRESUNDBY, DK-9400
DENMARK

Attention Valued Customer:

Details on affected devices:

Product and Distribution Table					
Product Name	**Manufacturer's Catalog Number**	**Lot Number**	**Distribution Date**	**Expiration Date**	**Quantity**
Drill Sleeve Guide	DSG-6.3-090-2.4N	813170	4/25/2019	2020-07-01	1
Drill Sleeve Guide	DSG-6.3-090-2.4N	714201	2/19/2018	2019-10-01	1

Description of the problem:
On August 22, 2019, Ad-Tech Medical Instrument Corporation decided to voluntarily recall all drill sleeve guides which are intended to be used only with the 2.4mm diameter Cranial Drill Bit. This recall has been initiated due to an investigation being performed that has identified potential issues with both of our raw material suppliers. The inner diameter of the drill sleeve guide raw material was found to be under tolerance, potentially resulting in the drill bit seizing in the guide during surgery. Although these devices do not make patient contact and are not expected to result in death, this issue could result in a delay in procedure.

The worst-case severity has been determined to be Moderate. This deficiency is not expected to result in death, but there is a possibility an additional surgery could be required if a drill bit seizes within a guide and replacements are not available on-hand. A delayed or additional surgery constitutes additional medical intervention. There is no further impact to the patient, as once the drill bit becomes stuck within the guide, neither the drill sleeve guide nor the drill bit can further interact with the patient.

400 WEST OAKVIEW PARKWAY, OAK CREEK, WI 53154
Phone: 262-634-1555 | Email: adtech@adtechmedical.com
Fax: 262-634-5668 | Website: www.adtechmedical.com
Toll Free (U.S.A.): 800-776-1555

Actions to be taken by the Customer:

- Immediately examine your inventory and quarantine any product subject to recall. Since the devices are reusable, if you have any of this product in stock with an unknown lot number, please return those as well. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter. Please return product subject to recall to:
    - Ad-Tech Medical Instrument Corporation
      400 West Oakview Parkway
      Oak Creek, WI 53154
- Contact an Ad-Tech Customer Support Specialist for a Return Material Authorization (RMA) number
- Replacements will not be provided
- Credit will be issued for all non-expired returned product
- Please send acknowledgement of this letter as soon as possible to Ad-Tech's Regulatory Department:
    - FAX: 262-634-5668
    - Telephone: 262-634-1555
    - Email: Regulatory@adtechmedical.com
- EU contact information:
    - E C Rep Ltd
      Telephone: (44) 1704 544 944
      FAX: (44) 1704 544 050
      Email: Janet.Borgerson@ecrep.ie

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

Authorized by:

Kathleen Barlow

Signature:

Title:

Regulatory Team Representative and CAPA/Complaints Manager

AD-TECH® MEDICAL INSTRUMENT CORPORATION

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form
Response is Required

MS. LONE JACOBSEN
CEPHALON A/S
SUNDSHOLMEN 29
NOERRESUNDBY, DK-9400
DENMARK

DRILL SLEEVE GUIDES

I have read and understand the recall instructions provided in the September 10, 2019 letter.
Yes__ No__

Any adverse events associated with recalled product? Yes__ No__

If yes, please explain:

_____
_____
_____
_____
_____
_____
_____

Affected Product Information:

Affected Product Information Table				
Product Name	**Catalog Number**	**Lot Number**	**Quantity In Inventory**	**Quantity Returned**
Drill Sleeve Guide	DSG-6.3-090-2.4N	813170		
Drill Sleeve Guide	DSG-6.3-090-2.4N	714201		

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Return Response Box:

Please provide any additional information, if applicable.

Distributors:

I have checked my stock and have quarantined inventory consisting of _____ units.

I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**); <or>
Attached is a list of customers who received/may have received this product. Please notify my customers.

Questions: (when applicable)

☐ Please have someone from the Regulatory Department contact me

Signature of Receipt _____

Name/Title	
Telephone	
Email Address	

PLEASE FAX COMPLETED RESPONSE FORM TO: 262-634-5668, ATTENTION: REGULATORY DEPARTMENT
OR MAIL TO: AD-TECH MEDICAL INSTRUMENT CORPORATION, 400 WEST OAKVIEW PARKWAY, OAK CREEK, WI 53154
OR EMAIL TO: Regulatory@adtechmedical.com