AD-TECH® MEDICAL INSTRUMENT CORPORATION

Urgent Field Safety Notice

Drill Sleeve Guide
FSCA-identifier 02-05-2018-00001
Type of action: Field Safety Notice (FSN)

Date: May 2, 2018

Customer Information
Name
Address
City/State/Zip

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-63-090-2.4N	107104 710220	2/24/2017	2/1/2019	2
		111423 716180	10/17/2017	8/1/2019	1

Description of the problem:
Ad-Tech Medical Instrument Corporation is recalling all DSG-6.3-090-2.4N products from the following lots:

- 111423 716180
- 113775 719190
- 113776 719190
- 114390 715001
- 114724 711101
- 115000 714201
- 115847 712211
- 116389 712121
- 117146 810110
- 105176 613121
- 107104 710220

On April 25, 2018, Ad-Tech Medical Instrument Corporation decided to voluntarily recall drill sleeve guides from the lots listed above, which are intended to be used only with the 2.4mm diameter Cranial Drill Bit. This recall has been initiated due to identifying a potential trend with the raw material drill sleeve guide coming from a specific supplier and lot. 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. An injury associated with this severity is not expected to result in death, but could result in a moderate injury requiring medical intervention. The severity was determined by assessing the potential harms associated with the potential hazardous situation in which a drill sleeve guide causes a drill bit to seize during surgery. In these instances, the procedure is suspended until the drill can be removed from the guide or various components can be replaced. Accordingly, there is the potential that additional medical intervention would be required if the surgery has to be rescheduled.

Advise on action to be taken by the user:

- Immediately examine your inventory and quarantine any unopened/unused product subject to recall. Since the devices are reusable, if you have any of these products 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.
- Place a no charge purchase order with Ad-Tech Customer Support for any replacement drill sleeve guides needed.
- Please send acknowledgement of this letter as soon as possible to your Ad-Tech Clinical Specialist:
    - FAX: 262-634-5668
    - Telephone: 262-634-1555
    - Email: customersupport@adtechmedical.com

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Contact reference person:

- Contact Information: Monday through Friday, 7:00 AM to 5:00 PM, Central Time.
  FAX: 262-634-5668
  Toll Free: 1-800-776-1555
  Email: customersupport@adtechmedical.com

- EU contact information:
    - M Devices/E.C. Rep Ltd
      Telephone: (44) 1704 544 944
      FAX: (44) 1704 544 050
      Email: Janet.Borgerson@ecrep.com

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

Customer Information
Name
Address
City/State/Zip

DRILL KITS

I have read and understand the recall instructions provided in the May 2, 2018 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	107104 710220		
		111423 716180		

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 Customer Service contact me

Signature of Receipt _____

Name/Title	
Telephone	
Email Address	

PLEASE FAX COMPLETED RESPONSE FORM TO: 262-634-5668, Attention Customer Support
OR MAIL TO: AD-TECH MEDICAL INSTRUMENT CORPORATION, 400 Oakview Parkway, Oak Creek, WI 53154
OR EMAIL TO: customersupport@adtechmedical.com