

Urgent Field Safety Notice

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

Date: September 10, 2019

JAMIE ATKINS
 SEVERN HEALTHCARE
 42 KINGFISHER COURT
 HAMBRIDGE ROAD
 NEWBURY, BERKSHIRE, RG145SJ, UK

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-90-2.3N | 417250 | 7/21/2014 | 2016-05 | 2 |
| Drill Sleeve Guide | DSG-90-2.3N | 417280 | 10/31/2014 | 2016-08 | 1 |
| Drill Sleeve Guide | DSG-90-2.3N | 511130 | 10/8/2015 | 2017-03 | 1 |
| Drill Sleeve Guide | DSG-90-2.3N | 511130 | 11/9/2015 | 2017-03 | 1 |
| Drill Sleeve Guide | DSG-6.3-090-2.4N | 515211 | 2/26/2016 | 2017-11 | 1 |
| Drill Sleeve Guide | DSG-6.3-090-2.4N | 618010 | 8/4/2016 | 2018-01 | 2 |
| Drill Sleeve Guide | DSG-6.3-090-2.4N | 812050 | 5/18/2018 | 2020-05 -01 | 4 |

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.

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:
 - EC 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



**MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form**

Response is Required

JAMIE ATKINS
SEVERN HEALTHCARE
42 KINGFISHER COURT
HAMBRIDGE ROAD
NEWBURY, BERKSHIRE, RG145SJ, UK

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-90-2.3N | 417250 | | |
| Drill Sleeve Guide | DSG-90-2.3N | 417280 | | |
| Drill Sleeve Guide | DSG-90-2.3N | 511130 | | |
| Drill! Sleeve Guide | DSG-90-2.3N | 511130 | | |

| | | |
|--------------------|------------------|--------|
| Drill Sleeve Guide | DSG-6.3-090-2.4N | 515211 |
| Drill Sleeve Guide | DSG-6.3-090-2.4N | 618010 |
| Drill Sleeve Guide | DSG-6.3-090-2.4N | 812050 |

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)

D 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, ATENTION: REGULATORY DEPARTMENT
OR MAIL TO: AD-TECH MEDICAL INSTRUMENT CORPORATION, 400 WEST OAKVIEW PARKWAY, OAK CREEK, WI 53154

OR EMAIL TO: Regulatory@adtechmedical.com