AD-TECH® MEDICAL INSTRUMENT CORPORATION

Urgent Field Safety Notice

MR Supplement Information
FSCA-identifier 11-06-2019-00001
Type of action: Field Safety Notice (FSN)

Date: June 11, 2019

Attention Valued Customer:

Details on affected supplemental information:

Catalog

- MKTG-3006 Product Catalog (a new version of the Product Catalog for your use is included with this recall correspondence)

Attachment/Files:

- Subdural MRI Certification
- Subdural – MRI Testing – Schneider
- Subdural – RF Heating – Kanal
- Depth Electrode MRI Certification
- Depth – MRI Testing – Schneider
- Depth – RF Heating – Kanal

Journal Articles:

- Carmichael_NI_2010
- Carmichael_NI_2012
- Vulliemoz_NI_2011

PLEASE NOTE: This is a recall of the supplemental information, NOT the physical devices.

Description of the problem:
Ad-Tech Medical Instrument Corporation is recalling supplemental information (stated above) that may have been sent to customers in response to their questions regarding the use of all subdural electrodes, depth electrodes, and anchor bolts in an MR environment. These devices have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the devices in the MR environment is unknown.

The severity was determined by assessing the hazards associated with the use of these devices in the MR environment. In instances through which devices are exposed to an MR environment, the impact of any induced magnetic forces or torque, induced heating, or the generation of imaging artifacts (limiting the ability of imaging to provide clinical data for surgical decisions) has not been assessed. Imaging artifacts could prevent the capability of imaging techniques to inform surgical intervention, potentially delaying surgical procedures.

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

Furthermore, the application of unintended mechanical or thermal energy could cause irreversible tissue damage. Therefore, the potential exists that the use of these devices in an MR environment could lead to serious (irreversible) injury or death to the patient or user and/or very severe negative impact on the environment.

Advise on action to be taken by the user:

- Immediately examine your records for any documentation subject to this recall. In addition, if you may have further distributed this documentation, please identify your customers or personnel/departments and notify them immediately of this recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.
- Please complete the associated response form to acknowledge that you understand that the devices are not approved for use as described in the recalled supplemental information.
- Acknowledge that the supplemental information has been properly destroyed and/or disposed of.
- Please send the completed response form to the Ad-Tech Regulatory Team:
    - FAX: 262-634-5668
    - Telephone: 262-634-1555
    - Email: Regulatory@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: 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: Kathl Barlow 6/17/2019

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

MR Supplemental Information Recall

By signing this acknowledgment and receipt form, you agree that:

- You have read and understand that subdural electrodes, depth electrodes, and anchor bolts are not approved for use in the MR environment as described in the supplemental information.
- You have properly disposed of any supplemental information (i.e., MRI Certification memos, articles, emails, etc.) that you may have received.

Have there been any adverse events associated with recalled supplemental information?

Yes__ No__

If yes, please explain:

_____
_____
_____
_____
_____
_____
_____

Return Response Box:

Please provide any additional information, if applicable.

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Distributors:

I have identified and notified my customers that were provided, or may have been provided, this supplemental information (**specify date and method of notification**); <or>

Attached is a list of customers who received/may have received this supplemental information. Please notify my customers.

Questions: (when applicable)

☐ Please have Ad-Tech's Regulatory Team contact me

Signature of Receipt _____

Name/Title	
Hospital/Company Representing	
Hospital/Company Address	
Telephone	
Email Address	

PLEASE FAX COMPLETED RESPONSE FORM TO:
262-634-5668 ATTENTION: AD-TECH REGULATORY TEAM

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

OR EMAIL TO:
Regulatory@adtechmedical.com