



AD-TECH[®] MEDICAL INSTRUMENT CORPORATION

DATE: April 30, 2019
VIA: Email
SUBJECT: Notification to Ad-Tech LSB Style Anchor Bolt Users - DFU Updates
TO: Valued Ad-Tech Customer

The Ad-Tech Post Market Surveillance program has received user feedback from some customers related to LSB Style Anchor Bolts breaking when excessive force is experienced. Although the occurrence rate is very low, Ad-Tech has decided to provide instructions on what to do should this type of device failure be experienced.

An update will be added to the *Use* section of the LSB Series Anchor Bolt Directions For Use (DFU) to provide steps to be taken in the event of a device failure (anchor bolt breakage). A clarification will also be added to the DFU stating, "Not Intended for Implantation (21 CFR 860.3(d): ≥ 30 days)".

The steps to be taken should you encounter an anchor bolt breakage are as follows:

- Stop use immediately and monitor the patient.
- Attempt to remove the retained portion of the bolt using the LSB Anchor Bolt Wrench.
- If unable to use the wrench for removal, use other medical equipment available (e.g. clamp) to remove the retained portion.
- If still unable to remove the retained portion of the bolt, additional surgical intervention may be required.

We strive to provide the most safe and effective monitoring devices and accessories for our users and patients. We are writing to ensure you are informed about the clarifications that will be made to the directions related to the steps to be taken in the event of a device failure and duration of use.

Best Regards,

Lisa Theama
Chief Operating Officer
Ad-Tech Medical Instrument Corporation