

REMOVAL NOTIFICATION

PRODUCT PART #	AR-8973-01
PRODUCT NAME (COMMON NAME)	Outrigger Targeting Guide
LOT/BATCH#	051838
PRODUCT DESCRIPTION	FibuLock Outrigger Targeting Guide
INTENDED USE	The Outrigger Targeting Guide, AR-8973-01 is an instrument that is intended to insert the FibuLock Nail into a fibula fracture.
REASON FOR REMOVAL	Potential for blockage of the Hub Attachment Tube
DATE REMOVAL INITIATED	December 17 th , 2019

REQUIRED
ACTION
BY RECIPIENT

- 1. Immediately discontinue use, sale, and distribution of the product.
- 2. Direct Customers:
 - a. Please contact Arthrex Product Surveillance at 866-267-9138 or <u>complaints@arthrex.com</u>. Our Product Surveillance Specialists are available to answer questions regarding credit for affected devices in your possession.
 - b. You do not need to notify any patients of this product removal.
- 3. Arthrex Agencies:
 - Please contact Arthrex Field Logistics Services at <u>FLS@arthrex.com</u> as soon as possible to arrange for return of the affected product.
 - You do not need to notify any patients of this product removal.
- 4. Arthrex Subsidiaries (APAC):
 - a. Please contact Arthrex Product Surveillance at 866-267-9138 or <u>complaints@arthrex.com</u>. Our Product Surveillance Specialists are available to answer questions regarding credit for affected devices in your possession.
 - You do not need to notify any patients of this product removal.
- If you have any questions about this product removal, please contact Arthrex Product Surveillance at 866-267-9138 or complaints@arthrex.com.



REMOVAL NOTIFICATION

Arthrex, Inc. remains committed to providing you with the highest quality products and services. We apologize for any inconvenience this removal may cause. Thank you for your continued support of Arthrex products.

Sincerely

Tuesday, December 17, 2019

William Potter / Director, Quality Systems and Regulatory Compliance Arthrex, Inc.
1370 Creekside Blvd
Naples, FL 34108