




**URGENT:**

**VOLUNTARY PRODUCT  
RECALL NOTIFICATION**

AR-8550BT Recall Notification Page 1 of 2

<p><b>PRODUCT PART #</b></p>	<p style="text-align: center;"><b>AR-8550BT</b></p> 	
<p><b>PRODUCT NAME (COMMON NAME)</b></p>	<p style="text-align: center;"><b>Burr, Oval, 12 Flute, 5.5mm x 13cm</b></p>	
<p><b>LOT/BATCH #</b></p>	<p style="text-align: center;"><b>10211276</b></p>	<p style="text-align: center;"><b>10202784</b></p>
<p><b>PRODUCT DESCRIPTION</b></p>	<p><b>The Arthrex Burr devices are rotary cutting devices for use in arthroscopic surgical applications for the resection of bone.</b></p>	
<p><b>INTENDED USE</b></p>	<p><b>These devices are indicated for resection of osseous tissues in both large and small articular cavities during arthroscopic procedures.</b></p>	
<p><b>REASON FOR PRODUCT RECALL</b></p>	<p><b>Devices may generate excessive heat during use.</b></p>	
<p><b>DATE RECALL INITIATED</b></p>	<p style="text-align: center;"><b>January 14, 2019</b></p>	

<p><b>REQUIRED ACTION BY RECIPIENT</b></p>	<ol style="list-style-type: none"> <li>1. Immediately discontinue use, sale, and distribution of the affected product.</li> <li>2. Direct customers:             <ol style="list-style-type: none"> <li>a) Please contact Arthrex Product Surveillance at 866-267-9138 or <a href="mailto:complaints@arthrex.com">complaints@arthrex.com</a>. Our Product Surveillance Specialists are available to answer questions regarding credit for affected devices in your possession.</li> <li>b) You do not need to notify any patients of this product recall.</li> </ol> </li> <li>3. Arthrex Agencies:             <ol style="list-style-type: none"> <li>a) Please contact <a href="mailto:FLS@arthrex.com">FLS@arthrex.com</a> as soon as possible to arrange for return of the affected product.</li> <li>b) You do not need to notify any customers as Arthrex will be notifying customers directly.</li> </ol> </li> <li>4. If you have any questions about this product recall, please contact Arthrex Product Surveillance at 866-267-9138 or <a href="mailto:complaints@arthrex.com">complaints@arthrex.com</a>.</li> </ol>
--------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------



**URGENT:**

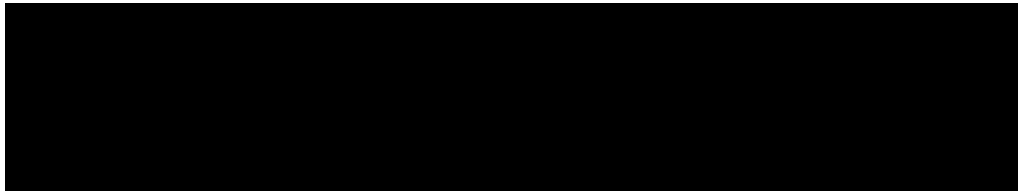
**VOLUNTARY PRODUCT  
RECALL NOTIFICATION**

AR-8550BT Recall Notification Page 2 of 2

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

*Sincerely,*

*January 14, 2019*



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