URGENT MEDICAL DEVICE RECALL

FA-22-005

Immediate Attention Required

Beaver® Arthro-Lok Pointed Tip Curve L 4mm Blade

Beaver®Artho-LOK Pointed Tip Curve L 4mm Blade
Catalog#: 376780
LOT#: 6034831,6039837
UDI# 00886158001249

30 September 2022

Dear Customer/Distributor,

This letter advises you that Beaver-Visitec International is voluntarily recalling two lots of Catalog# 376780, Beaver®Artho-LOK Pointed Tip Curve L 4mm Blade. The affected products were manufactured on May 28, 2020, and February 02, 2021. The Beaver®Artho-LOK Pointed Tip Curve L 4mm Blade is indicated for orthopedic surgery and is not intended for ophthalmic procedures. These blades are sold individually packaged in boxes of 6.

Reason for the Voluntary Recall

BVI has received two complaints from customers that two lots of Catalog # 376780, Beaver®Artho-LOK Pointed Tip Curve L 4mm Blades were shipped with incorrect configuration of the blades in the package. The blades were confirmed to curve to the right instead of curving to the left as intended. BVI determined the following lots are affected: 6034831,6039837. According to the product specification, the correct configuration should be as follows:

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Figure 1. Correct configuration for PN 376780

Figure 2. Incorrect configuration for PN 376780

Risk to Health

Inadvertently using a Beaver®Artho-LOK Pointed Tip Curve 4mm Blade that is curved right instead of curved left may cause unintended tissue damage during the procedure. If noticed prior to procedure, an appropriate replacement blade must be sought and/or minor variation (adjustment) of surgical technique may be made to avoid incorrect procedural steps. An observant surgeon and/or staff is likely to notice the incorrect curve prior to use.

Actions Required by You

Our records indicate that you received one or more affected products. You can recognize affected product by the part and lot number printed on the device label.

Please perform the following actions:

1. **Immediately examine your inventory and quarantine product from these lots that are subject to recall.** If you have further distributed this product, please notify your customers by initiating a sub-recall. Consider all potential users of this product in your user supply chain. You are encouraged to use a copy of this recall notification letter when contacting your customers.
2. Complete the enclosed Business Response Form (BRF) and indicate whether or not you have affected product to return. Please return the business response form to beavervisitec2765@sedgwick.com even if you no longer have product on hand.

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3. Please enter the following information on the enclosed BRF: company name, lot number(s) and quantity(ies) of device(s) that are being returned.
4. If you have any questions regarding this Field Action, please contact BVI Sedgwick at 866-382-8606 or beavervisitec2765@sedgwick.com.
5. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
6. If you have affected product, please return product with copy of BRF to:

   Return your product to SEDGWICK using the enclosed UPS pre-paid return label:

   Attn: Event 2765 Sedgwick

   2670 Executive Drive, Suite A
   Indianapolis, IN 46241

A credit will be provided to consignees who have replied with confirmation of receiving affected product. Please direct any questions regarding credit to our customer service department by email ClaimsUS@bvimedical.com and include in the subject line: Master Case PIR 00371817.

BVI values your business and is committed to taking the actions necessary to prevent reoccurrence and assure patient safety.
Sincerely,

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