



Beaver-Visitec International, Inc.

Date 02/19/2019

URGENT: MEDICAL DEVICE RECALL

Beaver® Micro Knife 5.0mm 30°, 10/box

REF # 0001522, Lot 180615

Attention to Customer

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Beaver-Visitec International, Inc. ("BVI") is voluntarily recalling a one (1) lot #180615, of its Beaver® Micro Knife 5.0mm 30°. The Beaver® Micro Knife 5.0mm 30°, REF: 0001522. The Micro Knife is a sharp pointed tip intended for ophthalmic, ears, nose & throat (ENT) and other forms of surgery stab incisions and other microsurgical techniques. You are receiving this letter because you are identified as a potential customer who has purchased the Beaver® Micro Knife 5.0mm 30° from the affected lot number 180615. We began shipping the affected lot of this product on August 07th, 2018. **PLEASE NOTE: NO OTHER BVI PRODUCTS ARE INVOLVED IN THIS ACTION.**

Based on a recent investigation, BVI confirmed that Beaver® Micro Knife 5.0mm 30° [REF: 0001522] lot 180615, contains a misprinted expiration date on the peel pack (Figure 1). Both were printed as "180615", which is the lot number. The Lot number is correct.



Figure 1

BVI is requesting that you take the following actions necessary to return the affected product to BVI.



Please follow these Instructions:

1. **Immediately examine your inventory and quarantine product from this lot subject to recall.** If you have further distributed this product, please identify your customers and notify them of this product recall. Consider all potential users of this product in your user supply chain. You may be supported by including a copy of this recall notification letter.

Part Number	Lot Number
0001522	180615

2. Complete and return the enclosed **Product Recall Notice Response & Return Form IMMEDIATELY** as evidence of the product being returned and we will credit your account OR complete the response form **even if you do not have product** to return. Please include a copy of the completed **Response & Return Form** with your shipment in the address provided below.
 - a. Fax 866-906-4304 or email a copy to ClaimsUS@bvimedical.com
3. **Return ALL quarantined product from the affected lot** to our company utilizing the **Return Merchandise Authorization sticker** label return (Figure 2) that is included in this letter. You may use the prepaid BVI FedEx number for your return.

Return the completed form with your quarantined product identified to:
---Return Merchandise---
Beaver-Visitec International, Inc.
Attn: QIC Team – SF74660-0001522
3550 Roy Orr Blvd. Ste. 180
Grand Prairie, TX 75050

Please use BVI FedEx account 122227600 when shipping the returns back to Grand Prairie

Fax 866-906-4304 or email a copy to ClaimsUS@bvimedical.com

Figure 2. Return Merchandise Authorization sticker

If you have any specific product replacement questions you may contact our Customer Service Team at:

ClaimsUS@bvimedical.com or call 866-906-8080 from 8 A.M. to 6 P.M. EST (Monday-Friday)

This voluntary recall is being made with the knowledge of the US Food and Drug Administration (FDA). We value your support and sincerely apologize for the inconvenience this has caused you.

Sincerely,

Regina Shih
 VP Regulatory & Quality
 Beaver-Visitec International, Inc.



Attachment A - RECALL RETURN RESPONSE FORM

RECALL

Beaver® Micro Knife 5.0mm 30°

Lot Number: 180615

Please complete and return this response form **no later than March 15th, 2019**

REF# 0001522

LOT# 180615

STEP 1: Evaluate your inventory for *Beaver® Micro Knife 5.0mm 30°, Lot Number: 180615*

Please check ALL appropriate boxes.

I have read and understand the recall instructions provided in the _____ letter.
<date>

I have checked my stock and have quarantined inventory consisting of _____
<units or boxes>.

Indicate disposition of recalled product:

returned _____/held for return;
(specify quantity, date and method)

destroyed _____
(specify quantity, date and method)

I am providing photographic evidence of the destroyed lots and would like credit or replacement product and will contact BVI Customer Service [Attach Photos with Attachment 1].

I have identified and notified my customers that were shipped or may have been shipped this product by _____
(specify date and method of notification);



STEP 2: Complete the form

Name: _____

Title: _____

Tel. number: () _____

Firm name: _____

Email: _____

Address: _____

City/state: _____

STEP 3: Return the Form

BVI USA customers please **return this completed Response Form by March 15**

2019 to BVI by one of these methods:

- Fax to 866-906-4304,
- Mail back in the self-addressed and stamped envelope provided by BVI, or
- Email the attachment to ClaimsUS@bvimedical.com.

*****Thank you for your assistance in this
matter*****