



URGENT Field Safety Notice

BVI Visitec® Nucleus Hydrodissector [Sauter] Cannula .40 x 22mm (27G x 7/8 in) REF#: 585786 Lot 6008126

June 25, 2019

Dear Customer,

Beaver-Visitec International, Inc. (BVI) is issuing this Field Safety Notice to inform you of a mislabelled Hydrodissector Cannula. We are providing this notification, so you can check your inventory immediately.

Details on Affected Devices:

BVI Visitec® Nucleus Hydrodissector [Sauter] Cannula, .40 x 22mm (27G x 7/8 in)
REF#: 585786 (Portion of the lot may be Incorrectly labelled as REF# 585793)
Lot #: 6008126

Description of the Problem:

Mislabelling: You ordered REF# 585786, Nucleus Hydrodissector [Sauter], “.40 x 22mm (27G x 7/8 in)”, and you received the correct device of REF# 585786 associated with Lot # 6008126. However, part of the lot # 6008126 may be mislabelled with an erroneous REF# 585793, Nucleus Hydrodissector, “.40 x 22mm (27G x 7/8 in)”.

The intended purpose

The cannula is intended to irrigate and/or aspirate ophthalmic solutions and liquids in or out of the eye, single-use.

Health Hazard Assessment: It has been determined by a BVI medical expert that there is none/negligible health risk (hazard) in the event this product is used. The detection of the problem would be readily noticed during setup and prior to use.



Advise on Action to be Take by the User:

1. **Immediately examine your inventory and quarantine product from this lot subject to recall.**

REF	Lot Number
585786	6008126

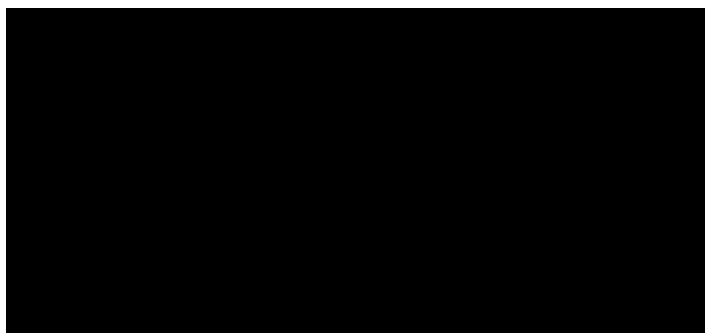
If you have further distributed this product, please identify your customers and notify them of this product recall. Consider all potential users of this product in your user supply chain. You may be supported by including a copy of this recall notification letter.

2. Complete the **Attachment 1: Response Form** enclosed **IMMEDIATELY**, as evidence of the product being returned, and BVI will credit your account OR complete the response form **even if you do not have product** to return.
3. Return the **Attachment 1: Response Form** to BVI by e-mail to UKCustomerSupport@bvimedical.com
4. **Return ALL quarantined product from the affected lot** to our company by contacting the BVI Customer Service at the respective number below:

TEL: + 49 622 16479854 Option 3

We value your business and apologise for any inconvenience this may cause.

Sincerely,



Beaver-Visitec International, Inc. (BVI)



Attachment 1 - Response Form
BVI Visitec® Nucleus Hydrodissector Cannula
.40 x 22mm (27G x 7/8 in)
REF#: 585786, Lot#: 6008126

Please complete and return this response form
no later than July 20th, 2019

Please check the appropriate response(s)

STEP 1:

Evaluate your inventory for **BVI Visitec® Nucleus Hydrodissector Cannula**
.40 x 22mm (27G x 7/8 in) REF#: Bulk 585786, Lot#: 6008126

Please check ALL appropriate boxes.

- ☐ I have read and understand the recall instructions provided in the June 25, 2019 letter.
- ☐ 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 (TEL: +49 622 16479854 Option 3) . 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

Please **e-mail this completed Response Form by July 20th, 2019**
UKCustomerSupport@bvimedical.com

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