



## URGENT Field Safety Notice

FA-23-002

Immediate Attention Required

**Conventional Crescent Knife 2.5mm, 55 degrees bevel up**

**Catalog #: 373807**

**LOT#: 6054027**

**UDI# 30886158000571**

25 August 2023

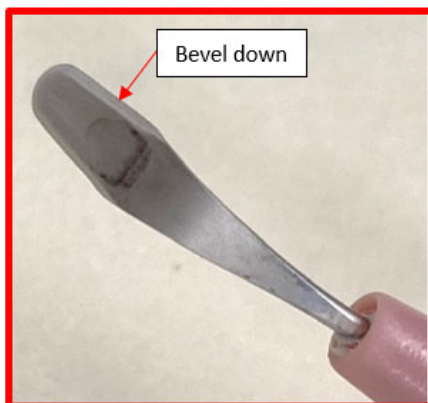
Dear Valued Customer,

This letter advises you that BVI is voluntarily recalling one lot of Cat# 373807, of the Conventional Crescent Knife 2.5mm, 55 degrees bevel-up.

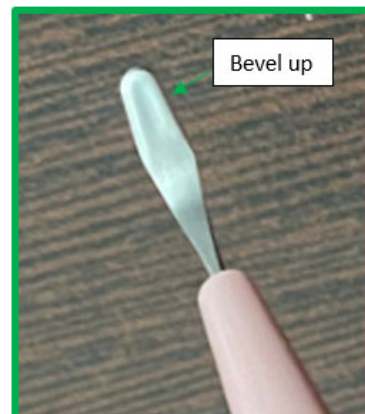
The Conventional Crescent Knife is intended to make ocular incisions and indicated for cataract surgery. This knife is a bevel-up knife (meaning the knife's cutting edge is on the top of a knife when looking down on it) and will create an incision that arcs downward upon entering the eye. In contrast, a bevel down knife, with the cutting edges on the bottom of the blade will make the incision arc upward.

### Reason for the Voluntary Recall

BVI has received feedback from a singular customer that one lot of Part Number 373807, Conventional Crescent Knife 2.5mm, 55 degrees bevel-up contains a bevel down blade. BVI determined the following lot is affected: 6054027.



**Figure 1.** Crescent knife with incorrect bevel orientation (down)



**Figure 2.** Crescent knife with correct bevel orientation (up)



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### Risk to Health

Inadvertently, using a bevel down blade instead of a bevel-up blade causes the surgeon to make an unintended incision architecture. A careful, observant surgeon is likely to notice the incorrect blade orientation under the microscope prior to use. However, when unnoticed, the unintended incision architecture potentially leads to an incision leakage. When incision leakage goes unnoticed, a watertight wound closure may not be achieved and thereby increasing the risk for anterior chamber fluid egress or ocular surface fluid ingress. Health effects include infection, iris prolapse, and intraocular pressure (IOP) fluctuations

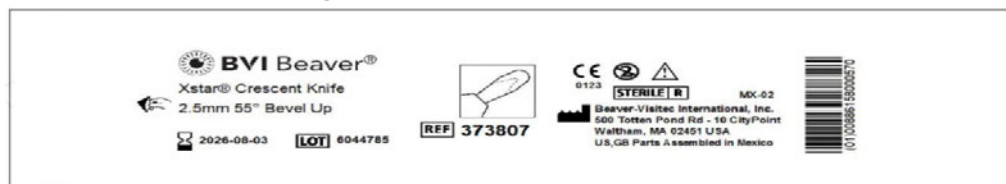
### Actions Required by You

Our records show you received one or more affected product. You can recognize the affected product by determining whether the lot number printed on the device label is one of the affected lots.

Figure 1, REF 373807 Box Label



Figure 2, REF 373807 Pouch Label





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PLEASE perform the following actions:

1. **Immediately examine your inventory and determine if the blades on the knives are bevel-up as intended or bevel down. Only destroy the knives in your inventory that have the incorrect bevel orientation (bevel down).** 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. **Review the enclosed Business Reply Form (BRF)** and indicate whether you have the affected product in your possession.
3. **Please enter the following information on the enclosed BRF:** part number(s), lot number(s) and quantity(ies) of device(s) destroyed.
4. **Return the completed BRF and evidence of destruction** of affected product to BVI by emailing the attached to [BVICrescentKnife@Sedgwick.com](mailto:BVICrescentKnife@Sedgwick.com)

BVI values your business and apologizes for the inconvenience this may have caused. Please direct any questions regarding credit to our customer service department by email and include in the subject line: **Master Case PIR 00474923.**

Country	Customer Service Email
UK	<a href="mailto:UKCustomerSupport@bvimedical.com">UKCustomerSupport@bvimedical.com</a>
FR	<a href="mailto:serviceclient@bvimedical.com">serviceclient@bvimedical.com</a>
DE/ AT	<a href="mailto:Kundendienst@bvimedical.com">Kundendienst@bvimedical.com</a>
IT	<a href="mailto:servizioclienti@bvimedical.com">servizioclienti@bvimedical.com</a>
ROW	<a href="mailto:ROWCustomerSupport@bvimedical.com">ROWCustomerSupport@bvimedical.com</a>

Sincerely,





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Please complete and return this Business Response Form no later than  
September 08, 2023

Please check the appropriate response(s)

### STEP 1

I have read the information related to this matter and I have **none** of the affected product on hand  
[please proceed to Step 2]

or

I have read the information related to this matter and I have attached evidence that the following quantities and lots of the REF # 373807 Conventional Crescent Knife 2.5mm, 55 degrees with the **incorrect bevel orientation**, have been destroyed.

Lot 6054027, Quantity \_\_\_\_\_

[please proceed to Step 2]

### STEP 2

Your company name: \_\_\_\_\_

Address: \_\_\_\_\_

BVI Customer Account # (if known) \_\_\_\_\_

**If purchased through a distributor, please let us know the following information**

Distributor Name: \_\_\_\_\_

Telephone: \_\_\_\_\_

Contact name: \_\_\_\_\_



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Title: \_\_\_\_\_ Email: \_\_\_\_\_

Please enter the date you completed this form: \_\_\_/\_\_\_/\_\_\_\_\_

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#### **STEP 3**

Please email this completed Response Form, along with evidence that affected product has been destroyed, to BVI at [BVICrescentKnife@Sedgwick.com](mailto:BVICrescentKnife@Sedgwick.com)

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