November 2nd, 2026

URGENT Medical Device Recall
FA-26-004
Mini-Blade and Lamellar Blade products

Dear Valued Customer,

Beaver-Visitec International, Inc. (BVI) is voluntarily recalling certain lots of BVI Mini-Blade and Lamellar Blade products distributed to the market, and is writing to inform you of the steps we ask you to take.

Reason for Recall

As part of our ongoing product quality monitoring, BVI identified a seal integrity issue affecting certain units of the products listed in the table below. The issue may result in an “open seal” condition, in which sterility cannot be guaranteed. The condition has been confirmed through physical investigation, including visual inspection and dye penetration testing.

Risk to Health

An open seal compromises the integrity of the sterile barrier and results in loss of product sterility. Use of a product with an open seal may therefore expose the patient to a non-sterile product and may result in an increased risk of infection.

To date, BVI has received one complaint associated with the open seal and has not received any reports of adverse health outcomes related to this issue.

Because the open seal condition does not occur in every product, BVI is requesting customers to review their existing stock of the affected lots . Place under quarantine identified SKUs and LOTs, do not use or further distribute product subject to this notification. Follow steps indicated in section Action Required.

Affected products

SKU (Product No.)	Device Name	Device Description	UDI	Manufactured Lots
364820	Beaver® Mini-Blade® (rounded tip sharp on one side)	Bulk Sterile version of BEAVER6400 for BVI kit packer customers. Ophthalmic blade intended for incisions and excisions made from stainless steel and polystyrene	00886158004455	6094705, 6096316, 6097790, 6098264, 6103527,6103775, 6104214, 6104911, 6106609.
364822	Beaver® Mini-Blade® Contains 100 Blades BEAVER6700	Bulk Sterile version of BEAVER6700 for BVI kit packer customers. Ophthalmic blade intended for incisions and excisions made from stainless steel and polystyrene	00886158004479	6097147.
364823	Beaver® Mini-Blade® Contains 100 Blades BEAVER6900	Bulk Sterile version of BEAVER6400 for BVI kit packer customers. Ophthalmic blade intended for incisions and excisions made from stainless steel and polystyrene. Straight, sharp all around, 180 degree cutting surface, double bevel blade.	00886158004486	6093979, 6095885, 6098085, 6098402, 6098861, 6100219, 6102697, 6103231, 6103314, 6103524, 6103773, 6104365.
BEAVER6400	Beaver® Mini-Blade® (rounded tip sharp on one side)	Ophthalmic blade intended for incisions and excisions made from stainless steel and polystyrene	00886158004394	6094706, 6095455, 6096317, 6097599, 6097789, 6099696, 6101055, 6101974, 6103529, 6103774, 6104213, 6104249, 6104910, 6105255, 6105454, 6106256.

SKU (Product No.)	Device Name	Device Description	UDI	Manufactured Lots
BEAVER6700	Beaver® Lamellar Blade, sharp all around	Ophthalmic blade intended for incisions and excisions made from stainless steel and polystyrene. Smaller alternative to #15 general blade.	00886158004417	6095225, 6096605, 6098263, 6099066, 6100914, 6102220, 6105764, 6106164.
BEAVER6900	Beaver® Mini-Blade®	Ophthalmic blade intended for incisions and excisions made from stainless steel and polystyrene. Straight, sharp all around, 180 degree cutting surface, double bevel blade	00886158004424	6093400, 6093401, 6094203, 6094304, 6095224, 6095886, 6096607, 6098084, 6098862, 6099697, 6100071, 6100218, 6101525, 6102021, 6102696, 6103017, 6103230, 6103313, 6103523, 6103772, 6104364, 6105028, 6105159.

Actions required

Our records indicate that you may have received one or more potentially affected products. Affected serial numbers are listed in Attachment 1. We kindly request your cooperation with the following steps:

1. Immediately review your current inventory of the affected product(s) listed in Attachment 1 and quarantine them from stock.
2. Do not use or distribute products from the affected batches.
3. Review the enclosed Customer Response Form (CRF) to confirm receipt of this notice and your understanding of the required actions. Indicate in the CRF how many units you have quarantined.
4. Return the completed Customer Response Form to BVIMinibladeOUS@sedgwick.com.
5. Return ALL quarantined product from the affected batches to our company via pre-paid postal labels, which will be supplied to you by our recall team.
6. This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred/distributed.
7. If you distributed the product further, BVI request you to forward the copy of the notice to your customers. Have your customers complete and return the Customer Response Form along with the existing stock to your organization for reconciliation purposes. Distributors are asked to return ALL quarantined product from the affected batches to BVI via pre-paid postal labels, which will be supplied to you by our recall team. There is no requirement to return your customer response forms to BVI, you should maintain these on file at your facility. Return only your final consolidated response form.

BVI is committed to providing high quality products to you and apologizes for any inconvenience this field correction may cause. Please report all device-related incidents to the manufacturer, distributor or local representative, and the National Competent Authority, if appropriate.

For questions regarding credit, please contact our customer service department by email and include in the subject line: 00945244.

Sincerely,

Amarjit Gill
Amarjit Gill (Oct 27, 2026 09:35:09 GMT)

Amarjit Kaur Gill
Vice President, Global Quality Assurance

URGENT Medical Device Recall
FA-26-004
Customer Response Form

Please complete and return this Customer Response Form within fourteen (14) days from the issuance date.

STEP 1 Acknowledgement

☐ I confirm that I have read and understood the information provided in this notice. I confirm that the notice has been distributed to all relevant users of the affected products under my responsibility.

STEP 2 Product status

☐ I confirm that the available stock was checked and no products from the affected batches have been identified.

OR

☐ I confirm that the available stock was checked and products have been quarantined and are awaiting product return disposition. Summary of products is recorded in the attached Appendix 1.

STEP 3 Customer data

Customer name: _____

Address: _____

Telephone: _____

Contact name: _____

Title: _____ Email: _____

Date completed: _____

Signature: _____

STEP 4

Please return the completed Response Form and Appendix 1, if applicable, to BVI by emailing it the attached to BVIMinibladeOUS@sedgwick.com

Appendix 1 – Stock Inspection Results Form

Please complete the applicable row for each product/lot identified and quarantined.
If a specific product/lot was not identified in your stock, please leave that row blank.

SKU (Part No.)	Lot No.	Quarantined Quantity
364820	6094705	
364820	6096316	
364820	6097790	
364820	6098264	
364820	6103527	
364820	6103775	
364820	6104214	
364820	6104911	
364820	6106609	
364822	6097147	
364823	6093979	
364823	6095885	
364823	6098085	
364823	6098402	
364823	6098861	
364823	6100219	
364823	6102697	
364823	6103231	
364823	6103314	
364823	6103524	
364823	6103773	
364823	6104365	
BEAVER6400	6094706	
BEAVER6400	6095455	
BEAVER6400	6096317	
BEAVER6400	6097599	
BEAVER6400	6097789	
BEAVER6400	6099696	
BEAVER6400	6101055	

SKU (Part No.)	Lot No.	Quarantined Quantity
BEAVER6400	6101974	
BEAVER6400	6103529	
BEAVER6400	6103774	
BEAVER6400	6104213	
BEAVER6400	6104249	
BEAVER6400	6104910	
BEAVER6400	6105255	
BEAVER6400	6105454	
BEAVER6400	6106256	
BEAVER6700	6095225	
BEAVER6700	6096605	
BEAVER6700	6098263	
BEAVER6700	6099066	
BEAVER6700	6100914	
BEAVER6700	6102220	
BEAVER6700	6105764	
BEAVER6700	6106164	
BEAVER6900	6093400	
BEAVER6900	6093401	
BEAVER6900	6094203	
BEAVER6900	6094304	
BEAVER6900	6095224	
BEAVER6900	6095886	
BEAVER6900	6096607	
BEAVER6900	6098084	
BEAVER6900	6098862	
BEAVER6900	6099697	
BEAVER6900	6100071	
BEAVER6900	6100218	
BEAVER6900	6101525	
BEAVER6900	6102021	
BEAVER6900	6102696	

SKU (Part No.)	Lot No.	Quarantined Quantity
BEAVER6900	6103017	
BEAVER6900	6103230	
BEAVER6900	6103313	
BEAVER6900	6103523	
BEAVER6900	6103772	
BEAVER6900	6104364	
BEAVER6900	6105028	
BEAVER6900	6105159	