



## URGENT Field Safety Notice Immediate Action Required

### Affected International Products

BVI Malosa® Single Use Instrument Procedure Packs, Various part numbers

Part Number	Description	Affected Lot Numbers
MMK100/2	Malosa Medical Refractive Kit	3235253, 3264748, 3295823, 3301979, 3309015, 3312569, 3356836, 3387543
MMK110/3	Malosa Medical Corneal Kit	3228591, 3358240
MMK5652	Malosa Medical Cataract Kit	3272756, 3290981, 3293855
MMK5655	Malosa Medical Cataract Kit	3271236, 3292034
MMK5657	Malosa Medical Cataract Kit	3272231, 3287445, 3332952, 3347553
MMK5658	Malosa Medical Cataract Kit	3272232, 3287444, 3300565, 3332953
MMK5661	Malosa Medical Cataract Kit	3332955
MMK5679	Malosa Medical Cataract Kit	3375835, 3376248, 3378947, 3386611
MMK5680	Malosa Medical Cataract Kit	3377759
MMK833/2	Malosa Medical Cataract Kit	3228634, 3233542, 3237894, 3241237, 3251075, 3252250, 3258046, 3261706, 3272267, 3274728, 3292638, 3296840, 3323887, 3348318, 1801052693
MMK834/1	Malosa Medical Cataract Kit	3228645, 3237895, 3241238, 3251076, 3252251, 3286239, 3289074, 3292639, 3309855, 18801053240
MMK863/1	Malosa Medical Cataract Kit	3228651, 3239031, 3251086, 3252176, 3253625, 3257027, 3258631, 3271233, 3287366, 3289198, 3297004, 3300583, 3305877, 3307386, 3309740, 3313262, 3322016, 3323196, 3323889, 3328216, 3331631, 3356864, 3360732, 3361772, 3368632, 3377304, 3381522, 18801022417, 18801042985
MMK865/1	Malosa Medical Cataract Kit	3233746, 3237898, 3238880, 3248603, 3251087, 3252177, 3263629, 3272860, 3282189, 3287665, 3299646, 3300567, 3308324, 3313275, 3322266, 3328958, 3331123, 3357818, 3361675, 3377757, 3386609, 18801042986
MMK884	Malosa Medical Refractive Kit	3234120, 3255268, 3261518, 3278550, 3282314, 3282994, 3326272, 3331632, 3348295, 3350319, 3359471, 3371559, 3380161, 18801046466, 18801050826, 18801053322
MMK919	Malosa Medical Cataract Kit	3263022, 3273856, 3365736
MMK925	Malosa Medical Cataract Kit	3282176, 3311458, 3312802, 3334379, 3351207, 3355549, 3366542, 3377617, 3380825, 3386325, 18801050827, 18801051699
MMK927	Malosa Medical Cataract Kit	3285718, 3290925, 18801051984
MMK950	Malosa Medical Cataract Kit	3289537, 3292641
MMK952	Malosa Medical Cataract Kit	3292629

**BVI is requesting evidence that affected product has been destroyed.**



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MMK954	Malosa Medical Cataract Kit	3303230, 3326209, 3330178
MMK957	Malosa Medical Cataract Kit	3320139, 3323142, 3329277, 3337600, 3339963, 3344908, 3348588, 3349734, 3352552, 3354442, 3362605, 3365008, 3366603
MMK958	Malosa Medical Cataract Kit	3326791, 3329443
MMK959	Malosa Medical Refractive Kit	3320470, 3328948, 3348256, 3364418
MMK960	Malosa Medical Cataract Kit	3324392, 3328944, 3337050, 3346497, 3348298, 3349758, 3351331, 3356827, 3360739, 3362192, 3366702, 3368522, 3376002, 3380171
MMK965	Malosa Medical Cataract Kit	3338522
MMK981	Malosa Medical Cataract Kit	3386347
MMSP0330	Malosa Medical Cataract Kit	3246901
MMSP0336	Malosa Medical Cataract Kit	3250310
MMSP0347	Malosa Medical Cataract Kit	3254186
MMSP0356	Malosa Medical Refractive Kit	3255779
MMSP0380	Malosa Medical Cataract Kit	3272210
MMSP0394	Malosa Medical Cataract Kit	3281061
MMSP0402	Malosa Medical Cataract Kit	3293016
MMSP0407	Malosa Medical Cataract Kit	3298532, 3307607, 3308232
MMSP0418	Malosa Medical Refractive Kit	3301307
MMSP0466	Malosa Medical Cataract Kit	3310484
MMSP0492	Malosa Medical Refractive Kit	3311371
MMSP0493	Malosa Medical Refractive Kit	3311372
MMSP0494	Malosa Medical Cataract Kit	3312117
MMSP0495	Malosa Medical Cataract Kit	3312123
MMSP0504	Malosa Medical Cataract Kit	3323163
MMSP0506	Malosa Medical Cataract Kit	3324488
MMSP0514	Malosa Medical Cataract Kit	3329336
MMSP0521	Malosa Medical Cataract Kit	3332813
MMSP0522	Malosa Medical Cataract Kit	3332819
MMSP0547	Malosa Medical Cataract Kit	3347693
MMSP0598	Malosa Medical Cataract Kit	3362215
MMSP0600	Malosa Medical Cataract Kit	3363406
MMSP0607	Malosa Medical Cataract Kit	3364817

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## **URGENT Field Safety Notice**

### **Immediate Action Required**

BVI Malosa® Single Use Instrument Procedure Packs, Various part numbers

<b>MMSP0618</b>	<b>Malosa Medical Cataract Kit</b>	<b>3370690</b>
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Dear Valued Customer,

This letter advises you that Beaver-Visitec International Ltd. (BVI) is voluntarily recalling all lots of the parts listed above that utilize the same tray and pouch configuration for the BVI Malosa® Single Use Instrument Procedure Kits. BVI has identified the potential for Malosa cataract, cornea, or refractive surgery kit packaging to have small holes that may not be clearly visible. BVI has self-identified this matter through internal testing. Additionally, BVI has received no trends or signals from post market surveillance of these kits and is taking this action out of an abundance of caution. The affected kits have been manufactured between October 2016 to October 2021.

BVI Malosa® Single Use Instrument Procedure Kits are intended for use in ocular surgeries indicated for refractive and cataract surgery. The devices within the kit are patient contacting.

Fig: 1 BVI Malosa® Single Use Instrument Procedure Kit Example



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## **URGENT Field Safety Notice**

### **Immediate Action Required**

BVI Malosa® Single Use Instrument Procedure Packs, Various part numbers

#### **Risks to Health**

Health effects include the potential for postoperative infection and/or inflammation which are potentially sight-threatening if gone unnoticed.

#### **Actions Required by You**

Our records show you received one or more affected product. You can recognize affected product by the part number printed on the device label of one of the affected parts.

#### **PLEASE perform the following actions:**

1. **Immediately examine your inventory and destroy product from these lots that are subject to recall according to your local procedures.**

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. **Please enter the following information on the enclosed BRF:** part number(s), lot number(s) and quantity(ies) of device(s) destroyed.
3. **Return the completed BRF and evidence of destruction** of affected product to BVI by emailing the attached to [BVIMalosa@Sedgwick.com](mailto:BVIMalosa@Sedgwick.com).

If you have questions regarding this FSN, please contact Stericycle Inc. at +44 20 7660 1541 (Mon.-Fri. 8:00 am - 5:00 pm GMT).

BVI values your business and is committed to taking the actions necessary to prevent reoccurrence. Please direct any questions regarding alternative product or credit to our customer service department by email [ROWCustomerSupport@bvimedical.com](mailto:ROWCustomerSupport@bvimedical.com) and please include in the subject line: Master Case PIR 279909.

Sincerely,

A handwritten signature in black ink, appearing to read "Aminah Crawford".

Aminah Crawford  
Regulatory Compliance Manager, Regulatory & Medical Affairs  
Beaver-Visitec International, Inc. (BVI)

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## **URGENT Field Safety Notice**

### **Immediate Action Required**

BVI Malosa® Single Use Instrument Procedure Packs, Various part numbers  
CC: Robin L. Rowe, MSc, RAC

**BVI is requesting evidence that affected product has been destroyed.**



# URGENT Field Safety Notice

## Immediate Action Required

BVI Malosa® Single Use Instrument Procedure Packs, Various part numbers

Please complete and return this Business Response Form no later than  
**November 30, 2021**

Please check the appropriate response(s)

### STEP 1

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 have attached evidence that the following quantities and lots of the BVI Malosa® Single Use Procedure Pack have been destroyed.

Part Number	Description	Lot(s) Destroyed	Qty of Lot(s) Destroyed
MMK100/2	Malosa Medical Refractive Kit		
MMK110/3	Malosa Medical Corneal Kit		
MMK5652	Malosa Medical Cataract Kit		
MMK5655	Malosa Medical Cataract Kit		
MMK5657	Malosa Medical Cataract Kit		
MMK5658	Malosa Medical Cataract Kit		
MMK5661	Malosa Medical Cataract Kit		
MMK5679	Malosa Medical Cataract Kit		
MMK5680	Malosa Medical Cataract Kit		
MMK833/2	Malosa Medical Cataract Kit		
MMK834/1	Malosa Medical Cataract Kit		
MMK863/1	Malosa Medical Cataract Kit		
MMK865/1	Malosa Medical Cataract Kit		
MMK884	Malosa Medical Refractive Kit		
MMK919	Malosa Medical Cataract Kit		
MMK925	Malosa Medical Cataract Kit		

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### **Immediate Action Required**

BVI Malosa® Single Use Instrument Procedure Packs, Various part numbers

Part Number	Description	Lot(s) Destroyed	Qty of Lot(s) Destroyed
MMK927	Malosa Medical Cataract Kit		
MMK950	Malosa Medical Cataract Kit		
MMK952	Malosa Medical Cataract Kit		
MMK954	Malosa Medical Cataract Kit		
MMK957	Malosa Medical Cataract Kit		
MMK958	Malosa Medical Cataract Kit		
MMK959	Malosa Medical Refractive Kit		
MMK960	Malosa Medical Cataract Kit		
MMK965	Malosa Medical Cataract Kit		
MMK967	Malosa Medical Refractive Kit		
MMK981	Malosa Medical Cataract Kit		
MMSP0330	Malosa Medical Cataract Kit		
MMSP0336	Malosa Medical Cataract Kit		
MMSP0347	Malosa Medical Cataract Kit		
MMSP0356	Malosa Medical Refractive Kit		
MMSP0380	Malosa Medical Cataract Kit		
MMSP0394	Malosa Medical Cataract Kit		
MMSP0402	Malosa Medical Cataract Kit		
MMSP0407	Malosa Medical Cataract Kit		
MMSP0418	Malosa Medical Refractive Kit		
MMSP0466	Malosa Medical Cataract Kit		
MMSP0492	Malosa Medical Refractive Kit		
MMSP0493	Malosa Medical Refractive Kit		
MMSP0494	Malosa Medical Cataract Kit		
MMSP0495	Malosa Medical Cataract Kit		
MMSP0504	Malosa Medical Cataract Kit		
MMSP0506	Malosa Medical Cataract Kit		
MMSP0514	Malosa Medical Cataract Kit		
MMSP0521	Malosa Medical Cataract Kit		
MMSP0522	Malosa Medical Cataract Kit		
MMSP0547	Malosa Medical Cataract Kit		

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### **Immediate Action Required**

BVI Malosa® Single Use Instrument Procedure Packs, Various part numbers

<b>Part Number</b>	<b>Description</b>	<b>Lot(s) Destroyed</b>	<b>Qty of Lot(s) Destroyed</b>
<b>MMSP0598</b>	<b>Malosa Medical Cataract Kit</b>		
<b>MMSP0600</b>	<b>Malosa Medical Cataract Kit</b>		
<b>MMSP0607</b>	<b>Malosa Medical Cataract Kit</b>		
<b>MMSP0618</b>	<b>Malosa Medical Cataract Kit</b>		

[please proceed to Step 2]

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## **URGENT Field Safety Notice**

### **Immediate Action Required**

BVI Malosa® Single Use Instrument Procedure Packs, Various part numbers

#### **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: \_\_\_\_\_

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

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

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#### **STEP 3**

Please return this completed Response Form to BVI either by

- Fax to +44 2088196285, or
- Email the attached to [BVIMalosa@Sedgwick.com](mailto:BVIMalosa@Sedgwick.com)

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

**BVI is requesting evidence that affected product has been destroyed.**