

## **URGENT Field Safety Notice (FSN)**

### **Immediate Action Required**

#### **MICROPURE 123 and ISOPURE123 increased resistance during injection**

FSN Ref: FSN-24-010

FSCA Ref: FA-24-010

FSN Type: New

December 18, 2024

**Dear Valued Customer,**

We are writing to inform you of a Field Safety Corrective Action (FSCA) concerning intraocular lenses ISOPURE 123 and MICROPURE 123 (IOLs) delivered in preloaded cartridges. These acrylic lenses are designed for implantation in the capsular bag after a cataract removal and serve to replace the optical function of the cataractous natural crystalline lens.

#### **Reason for the Notification**

BVI has become aware that, on occasion, increased resistance during injection of preloaded intraocular lenses (IOL) is observed. The increased resistance may result in users exerting excessive force causing the jamming of the injector or IOL.

We would like to emphasize that the IOL product itself performs according to its intended purpose. Specifically, in the vast majority of cases, the injection force observed remains within normal operating parameters

#### **Risk to Health**

Post-market data evaluated to date indicates that the most common consequence is a stuck IOL/injector, which prevents implantation progression and necessitates the use of a second device. However, in rare instances, excessive force during injection can cause IOL surface damage (scratches) with possible further procedure complications. Avoiding excessive injection force helps users prevent potential harm to the patient.

## Action Required

Our records show you received one or more affected products. You can determine if the affected product is in your possession by reviewing batch number(s) present in Table 1, Attachment I. Batch numbers may be found on the product labelling. The batch number is derived from the first five or six digits of the serial number (SN) printed on the label. We kindly request your cooperation in the following steps to address the situation at hand:

1. Ensure that MICROPURE 123, and ISOPURE 123 lenses are used according to their current Instructions for Use (IFU) found here <https://ifu.bvimedical.com/>.  
**In addition, if excessive resistance is encountered while pushing the plunger, discontinue use immediately. Discard the product and switch to another IOL.**
2. Ensure this notice is distributed to all users of the affected products and relevant personnel in your organization.
3. If you have further distributed this product, please notify your customers about this situation. Consider all potential users of this product in your distribution chain. You are encouraged to use a copy of this notification letter when contacting your customers.
4. Review the enclosed Business Reply Form (BRF) and confirm the acknowledgement of the letter.

Please **immediately complete and return** the attached Business Reply Form.

BVI values your business and will continue to provide quality products. If you have any questions regarding this matter, don't hesitate to contact us.

Sincerely,



Agnieszka Drzewiecka  
Global CVP Manager

## Response Form

**Please complete and return this response form no later than January 20<sup>th</sup>, 2025.**

### STEP 1

☐ I have read the information related to this matter and understand this product FSN. I confirm the notice has been distributed to all users of the affected products.

### STEP 2

Customer name: \_\_\_\_\_

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

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

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

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

Date completed: \_\_\_\_\_

### STEP 3

Please **return the completed Response Form** to BVI by **January 20<sup>th</sup>, 2025** emailing the attached to [BVIPreloadedIOL@sedgwick.com](mailto:BVIPreloadedIOL@sedgwick.com)

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

## Attachment I

| Table 1 - Batch numbers for affected series |        |        |        |        |        |        |        |
|---------------------------------------------|--------|--------|--------|--------|--------|--------|--------|
| 24FPED                                      | 24GCLB | 24GFFB | 24HCIB | 24HSN  | 24HTG  | 24HCWC | 24JETD |
| 24FRHE                                      | 24GYKE | 24GTDC | 24HXTD | 24HSQB | 24HXG  | 24HDCD | 24GQMB |
| 24FNJE                                      | 24GCLE | 24GJEC | 24HRVD | 24HBRB | 24HPI  | 24HZYD | 24GXDE |
| 24FPGF                                      | 24GOLE | 24GRHE | 24HOCB | 24HHRB | 24HWSC | 24HNJE | 24HPB  |
| 24GCE                                       | 24HXL  | 24GVHE | 24HOIB | 24HKCC | 24HATC | 24HVJE | 24HQF  |
| 24GOW                                       | 24HDO  | 24GGIE | 24HAJB | 24HEGC | 24HEVC | 24HHKE | 24HHH  |
| 24GVW                                       | 24IIXC | 24GJIE | 24HPVD | 24GVY  | 24HAXC | 24HMLE | 24HFSB |
| 24GDGB                                      | 24GUYD | 24GNIE | 24HUVD | 24GRGC | 24HIBD | 24HQLE | 24HUSB |
| 24GGLE                                      | 24GQZD | 24GPJE | 24HDXD | 24GTTD | 24HOUD | 24HCME | 24HUTC |
| 24GWLE                                      | 24HHZ  | 24GXJE | 24ISG  | 24GXUD | 24IWG  | 24HOME | 24HKUC |
| 24HDL                                       | 24HNZ  | 24FAG  | 24IQJ  | 24HMC  | 24IECE | 24IO   | 24HOUC |
| 24HEED                                      | 24HZZ  | 24GUCB | 24ITJ  | 24HYD  | 24IICE | 24IUQ  | 24HSWC |
| 24HCGE                                      | 24HCAB | 24GCDB | 24GYEC | 24HSH  | 24JPDF | 24HEMB | 24HEZC |
| 24FSAC                                      | 24HOAB | 24GCFB | 24GCFC | 24HTGC | 24JKTD | 24HEVD | 24HMZC |
| 24FAAD                                      | 24HOSD | 24GJFB | 24GJDD | 24GPTD | 24JPUD | 24HMYD | 24HTBD |
| 24FJAD                                      | 24IBQC | 24GPGB | 24GXSD | 24HEC  | 24ISY  | 24IIH  | 24HNRD |
| 24FYAD                                      | 24FBDD | 24GVBC | 24GUUD | 24HTC  | 24IRNB | 24IMH  | 24IEB  |
| 24FHCD                                      | 24FAGF | 24GDCC | 24GAVD | 24HQD  | 24IFPB | 24ICL  | 24IGC  |
| 24FAED                                      | 24FJHF | 24GHCC | 24HMB  | 24HRP  | 24INAE | 24IEN  | 24ILYC |
| 24GJE                                       | 24FTHF | 24GOCC | 24HVQ  | 24HPQB | 24IABE | 24ILN  | 24JIK  |
| 24GKLE                                      | 24GDX  | 24GTGE | 24HHR  | 24HYQB | 24JYFD | 24IYW  | 24HTI  |
| 24GEME                                      | 24GMXC | 24GFHE | 24HMEC | 24HQEC | 24JWTD | 24IOZ  | 24HMRB |
| 24HNJ                                       | 24HNF  | 24HKCE | 24HSIB | 24INMF | 24HLIF | 24IMM  | 24HOFC |
| 24HZM                                       | 24HDK  | 24FHE  | 24HJWD | 24JAOB | 24IAK  | 24IQM  | 24HQXC |
| 24FJZB                                      | 24HKK  | 24FQF  | 24HAYD | 24FQFF | 24IUM  | 24ISEE | 24HUXC |
| 24FMPC                                      | 24HPO  | 24FFAD | 24HCHF | 24GVFC | 24IXM  | 24IWEE | 24HQZC |
| 24FXPC                                      | 24IDQB | 24FLDD | 24HDIF | 24GCGC | 24ION  | 24HDI  | 24HOAD |
| 24FQDD                                      | 24IEAE | 24FOFD | 24HPIF | 24GGGC | 24IMX  | 24HGCD |        |
| 24FYHF                                      | 24IKAE | 24FKGF | 24HTIF | 24GUXC | 24IQY  | 24HLKE |        |
| 24GEEB                                      | 24FFED | 24FUGF | 24IFH  | 24GBWD | 24IXLB | 24HAOE |        |
| 24GZFB                                      | 24FCFF | 24GVFB | 24IQH  | 24GTDE | 24IYJ  | 24IS   |        |
| 24GLCC                                      | 24FZGF | 24GJKB | 24HXGB | 24HYI  | 24IUK  | 24IWAB |        |
| 24GVCC                                      | 24GEKC | 24GREC | 24HWIB | 24HJQ  | 24IEM  | 24IYC  |        |
| 24GDXC                                      | 24GSLE | 24GBHE | 24HYJB | 24HNQ  | 24IVW  | 24JSL  |        |

|        |        |        |        |        |        |        |
|--------|--------|--------|--------|--------|--------|--------|
| 24GBKE | 24HZJ  | 24GVIE | 24HSUD | 24HXR  | 24IRZ  | 24JZL  |
| 24GFKE | 24HDN  | 24FICF | 24IQI  | 24HEDC | 24IBLB | 24HGKB |
| 24IAS  | 24HLO  | 24FHDF | 24IMJ  | 24GGWD | 24IONB | 24HGWD |
| 24FSGB | 24HVP  | 24GJHC | 24IWJ  | 24HHF  | 24GKCD | 24HZWD |
| 24FQPC | 24HTR  | 24GNHC | 24JWTB | 24HRK  | 24HVVH | 24HYGF |
| 24FEFD | 24FIBB | 24GIXD | 24HQJB | 24HIDC | 24HJS  | 24HEHF |
| 24GEKB | 24GBUD | 24GLXD | 24HUJB | 24HCFC | 24HWCC | 24IHI  |
| 24GYKC | 24HHI  | 24GGZD | 24HSKB | 24HXGC | 24HADC | 24IULB |
| 24GIXC | 24HZK  | 24GKZD | 24HYSD | 24HJHC | 24HIEC | 24HXF  |
| 24GEDD | 24HHL  | 24HGY  | 24HKTD | 24HNHC | 24HSFC | 24HBG  |
| 24GPGE | 24HZQ  | 24HSY  | 24HKXD | 24HQTC | 24HIGC | 24HBH  |
| 24GNKE | 24HDR  | 24FXBD | 24HMXD | 24IRQ  | 24HMTD | 24HEH  |
| 24HRJ  | 24HVQB | 24GHGB | 24HEYD | 24GMLB | 24HCUC | 24HMCV |
| 24HLL  | 24HGCC | 24GRBC | 24HMHF | 24GBMB | 24HWUC | 24HQB  |
| 24HHN  | 24HEEC | 24GDDC | 24HABB | 24GKGC | 24HKWC | 24HKCD |
| 24FEZB | 24HYEC | 24GXDC | 24HGEB | 24GQXC | 24HETC | 24HALE |
| 24FVZC | 24HGFC | 24GFEC | 24HDHB | 24HHO  | 24HSYC | 24HGNE |
| 24FOAD | 24FUOD | 24GJHE | 24HGHB | 24HXO  | 24HMBD | 24HIHF |
| 24FRCD | 24GCJC | 24GNHE | 24HSTD | 24HZP  | 24HBRD | 24HKHF |
| 24FYFD | 24GMYD | 24GZHE | 24HWUD | 24HCQ  | 24HVYD | 24HZHF |
| 24FHFF | 24HDY  | 24GDIE | 24HIYD | 24HFS  | 24HJJE | 24IBX  |
| 24GZW  | 24HEBB | 24FJFD | 24HAHB | 24GYY  | 24HZJE | 24IPX  |
| 24GRCC | 24HXX  | 24GRIE | 24HIIB | 24GCZ  | 24HYLE | 24ITX  |
| 24GTWC | 24HEZ  | 24HGE  | 24HOKB | 24GWEC | 24HKME | 24IFY  |
| 24HVK  | 24HWZ  | 24HVE  | 24HELB | 24GOFC | 24KBWB | 24INY  |
| 24HTL  | 24HSAB | 24HJM  | 24HQLB | 24GOGC | 24HBJ  | 24IKZ  |
| 24HRM  | 24HIBB | 24HFP  | 24HLUD | 24GDTD | 24HSSC | 24KYY  |
| 24HVM  | 24HCCB | 24HNP  | 24HWHF | 24GDWD | 24HQVC | 24GHFC |
| 24HKZ  | 24HIDB | 24HFQ  | 24HHIF | 24HVC  | 24HUV  | 24HZE  |
| 24HMBB | 24HFIB | 24HLR  | 24GAFC | 24HIE  | 24HGWC | 24HWI  |
| 24HUBB | 24HVT  | 24HQDC | 24GKFC | 24HDG  | 24HOYC | 24HMQB |
| 24HYBB | 24FDIF | 24HYDC | 24GYFC | 24GHLB | 24HGAD | 24HFHC |
| 24HSCB | 24GLW  | 24HBEC | 24GWWC | 24GUEC | 24HSAD | 24HGUC |
| 24HEDB | 24GKJC | 24HUEC | 24GATD | 24GLTD | 24HDZD | 24HAVC |
| 24FGDD | 24GOKC | 24HKFC | 24GGUD | 24GLDE | 24HKZD | 24HYVC |
| 24GGAB | 24GTSD | 24IWMF | 24GQUD | 24GQKE | 24HSZD | 24HOWC |
| 24GSKB | 24HFM  | 24HIJB | 24GQVD | 24HPL  | 24HFJE | 24HWWC |
| 24GJUD | 24HVN  | 24HMJB | 24HAC  | 24HBM  | 24HSME | 24HAZC |

|        |        |        |        |        |        |        |
|--------|--------|--------|--------|--------|--------|--------|
| 24GPDE | 24HBS  | 24HWKB | 24HYC  | 24HTO  | 24HEXC | 24HACD |
| 24GXGE | 24GVIC | 24HILB | 24HHG  | 24HOCC | 24HMXC | 24JBRF |
| 24HJJ  | 24GZIC | 24HYLB | 24HPH  | 24HWHB | 24HCYC | 24GUCD |
| 24HNK  | 24GQYD | 24IMI  | 24HBP  | 24HCKB | 24HGYC | 24HQC  |
| 24HZN  | 24GYYD | 24HADB | 24GUVD | 24HRSD | 24HWYC | 24HLG  |
| 24GNZD | 24HOY  | 24HGSD | 24HID  | 24HCTD | 24HKAD | 24HKSB |
| 24HAY  | 24HGAB | 24HKSD | 24HLE  | 24HIUD | 24HWAD | 24HSUC |
| 24HAZ  | 24FOHE | 24HUSD | 24HJP  | 24HDWD | 24HABD | 24HIVC |
| 24HTZ  | 24GZCC | 24HGTD | 24HRQ  | 24HHXD | 24HEBD | 24HJRD |
| 24HWAB | 24GHDC | 24HOTD | 24HPR  | 24IJJ  | 24HWBD | 24HRJE |
| 24HXDB | 24GPDC | 24HAUD | 24HSCC | 24HBMB | 24KEJB | 24HDKE |
| 24HAVD | 24GZIE | 24HEUD | 24HMDC | 24IZG  | 24HNWD | 24HALB |
| 24HMVD | 24GDJE | 24HRWD | 24HADC | 24IJX  | 24ICH  | 24IEJ  |
| 24FHCB | 24GHJE | 24HVWD | 24HLGC | 24IAZ  | 24IIN  | 24IYK  |
| 24FVFF | 24GLJE | 24FLDB | 24HBHC | 24IUZ  | 24IXX  | 24IGL  |
| 24FEHF | 24GJKE | 24GUJC | 24GSFC | 24ILNB | 24IYKB | 24ICPB |
| 24FOHF | 24HFJ  | 24GQWC | 24GXTD | 24IHDE | 24IZMB | 24GFFC |
| 24GWLb | 24HVJ  | 24GPSD | 24GEUD | 24JXED | 24IDNB | 24GZWC |
| 24GUKE | 24HNM  | 24GMUD | 24HCD  | 24KAZ  | 24IQAE | 24HSB  |
| 24GAME | 24ILHB | 24GEVD | 24HMD  | 24HQXD | 24GXDD | 24HLI  |
| 24HLN  | 24FKDF | 24HFD  | 24HCE  | 24HTXD | 24HDS  | 24HRRB |
| 24FMCD | 24GFJC | 24HUD  | 24HOE  | 24HWXD | 24HKNE | 24HWFC |
| 24FWCD | 24GIYD | 24HDF  | 24GIVD | 24HOHF | 24ICD  | 24HAGC |
| 24FKED | 24GCZD | 24HPG  | 24GMVD | 24HSHF | 24IABB | 24HOSC |
| 24FUED | 24HKY  | 24HHK  | 24HIC  | 24ICI  | 24ILBD | 24HITC |
| 24FTFD | 24HQZ  | 24HWCB | 24HTF  | 24IUI  | 24IOBD | 24HYTC |
| 24FLFF | 24HKAB | 24HADB | 24HZH  | 24IAM  | 24JSJ  | 24IHNB |
| 24FFGF | 24GODB | 24HOHB | 24HPN  | 24IFX  | 24JAK  | 24JRED |