FEATHER SAFETY RAZOR CO.,LTD.
■OVERSEAS TRADE DIVISION■
3-70, OHYODO MINAMI 3-CHOME,
KITA-KU, OSAKA 531-0075, JAPAN
PHONE:+81-6-6458-1638 FAX:+81-6-6458-1611
[E-mail] overseas@feather.co.jp
[URL] http://www.feather.co.jp/

Field Safety Notice: FSN-2023-09-27

Date: 2023.09.27

Product:	**MICRO FEATHER DISPOSABLE OPHTHALMIC SCALPEL WITH PLASTIC HANDLE**

Dear Customer,

This letter is to inform you of a **Field Safety Corrective Action** initiated by the manufacturer FEATHER SAFETY RAZOR CO., LTD., JAPAN for the affected **Ophthalmic Knives**.

The Competent (Regulatory) Authority of your country has been informed about this Field Safety Corrective Action.

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Contact Details of European Representative and Importer

Company:	pfm medical ag
Address:	Wankelstraße 60, 50996 Köln, Germany
Phone:	+49(0)2236/9641-220
Fax:	+49(0)2236/9641-51
E-mail:	recall@pfmmedical.com

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1. Information on Affected Devices

1. 1. Device Type(s)

A sterile, manual ophthalmic knife constructed as a one-piece handle and scalpel blade (not an exchangeable component).

1. 2. Commercial Name(s)

MICRO FEATHER DISPOSABLLE OPHTHALMIC SCALPEL WITH PLASTIC HANDLE

1. 3. Primary Clinical Purpose of Device(s)

This device is an ophthalmic surgical instrument to make an incision into eyes and their surrounding tissues to make the surgeon accessible to the involved areas.

1. 4. Device Model/Catalogue/Part Number(s)

P-700 (REF 200200700), P-715 (REF 200200715), P-722 (REF 200200722), P-730 (REF 200200730), P-745 (REF 200200745) and USP-745 (REF 200500745).

1. 5. Affected Lot Number Range

Type / REF	Lot No.
P-700 / 200200700	22080676, 23010718, 23030568, 23040527, 23060379
P-715 / 200200715	22040348, 22040940, 22040971, 22050258, 22050558, 22050640, 22061029, 22070588, 22070932, 22071016, 22080605, 22080657, 22090309, 22090580, 22110377, 22111070, 22111175, 22111185, 22120244, 22120360, 23010505, 23010580, 23020604, 23020914, 23020955, 23020988, 23030183, 23030281, 23031091, 23040914, 23041009, 23050569, 23061029, 23061184
P-722 / 200200722	22050353, 22060845, 22070495, 22080687, 22080791, 22120377, 22120408, 23020614, 23060274
P-730 / 200200730	22040454, 22040657, 22050332, 22070618, 22070693, 22070777, 22080946, 22081019, 22090392, 22090491, 22090496, 22110681, 22110682, 22120576, 22121054, 23010303, 23010873, 23010955, 23011025, 23011126, 23020656, 23020768, 23020779, 23030372, 23060522
P-745 / 200200745	22040458, 22050728, 22061061, 22070710, 22080802, 22090322, 22100265, 22111064, 22121065, 23030297, 23040627, 23040673, 23050274
USP-745 / 200500745	22050669, 22050727

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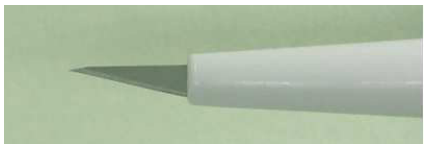
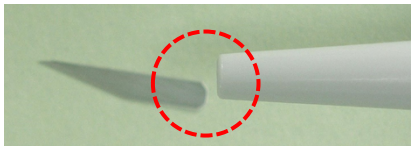
2. Reason for Field Safety Corrective Action (FSCA)

2. 1. Description of the Product Problem

The manufacturer found out that the plastic handle of the product changes over time for some reason, resulting in weakening of the fixing strength which can cause the blade to fall out of the handle.

Normal	Defective
	

2. 2. Hazard giving rise to the FSCA

The product problem may cause an injury or harm to the patient or user.
It may also lead to the interruption or delay of surgical procedures.

2. 3. Probability of Problem arising

Internal tests on aged goods have shown that the probability of the defect occurring increases after approx. 6 months.

2. 4. Predicted Risk to Patient/Users

The possibility of serious health hazard to the patient/user is very low because the device is used in a medical institution under the supervision of health care professional and the defect is either noticed before the procedure or, due to the sharpness of the blade and the very low cutting resistance, the procedure can be performed even if the blade is loose.

2. 5. Background on Issue

Feather came aware of the defect by customer complaints. To date, there have been no reports of incidents associated with the defect. The manufacturer has initiated a root cause analysis for the product defect. Since the defect occurred after the changeover of the production process in 2022, it could be isolated to the affected batches.

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3. Type of Action to mitigate the Risk	
3.	**1. Action to be taken by the Customer**
	☒ Identify Device ☒ Quarantine Device ☒ Arrange the return or, after consultation with the supplier, arrange for destruction
3.	**2. Is Customer Reply Required?**
	The completed reply form is required as proof and for reimbursement.
3.	**3. Action Being Taken by the Manufacturer**
	☒ Product Removal ☒ Corrective / preventive measure to eliminate the product defect

Name/Signature	Satoshi Mitsuishi Satoshi Mitsuishi, PRRC

Attachment: Reply Form

Reply Form – Field Safety Notice, FSN-2023-09-27

<Insert Logo of Supplier>	<Insert Supplier Contact Details>

Dear Customer,

You were supplied with article batches affected by the attached Field Safety Notice.

Customer / User	<to be included>
Product	**Micro Feather Disposable Ophthalmic Scalpel with Plastic Handle** manufactured by FEATHER SAFETY RAZOR CO., LTD., JAPAN
Affected articles, batch no.	See product safety notice "FSN-2023-09-27".

We require the following information from you as proof and for reimbursement purposes.

Please tick as appropriate!

I herewith confirm that

I have received the Field Safety Notice, understand its contents and have forwarded the FSN to all users and customers who have received affected products.

☐ I have identified and blocked the following affected batches and arranged for them to be returned to pfm medical.

☐ I have identified and blocked the following affected batches and that subsequently the products were destroyed and disposed of in accordance with national requirements **(Certification of Destruction).**

☐ I no longer have any products of the affected batches in stock.

Please list here the products that are returned or have been destroyed.

REF	Article Description	LOT	Quantity

Remarks:

Signature:
Name:
Date:

Please return the response form to

<Insert Supplier Contact Details>