Sender:	**To:**
From the Materiovigilance Manager LSO MEDICAL	**Local Materiovigilance Correspondent/Directors**
Surname - First name: DECARPIGNY Anne-Sophie	**From the healthcare facility:**
Tel. : 03.20.67.90.00	
Fax : 03.20.04.46.24	

Date : Loos, 24/07/2025 **Total number of pages: 5** *(including this one)*

LSO ref. RC-25-03-04 / MV-25-03-01 / FSN202501**ter** ANSM ref. R2507918

This document contains important information to ensure the continued safe and proper operation of your device.
Please review the following information with all your staff who need to be aware of it. It is important to understand the implications.
Please keep this letter for your records.

Subject: Updated Field Safety Notice - Product Recall Extension

Madam, Sir,

As part of the follow-up to FSCA R2507918, we hereby inform you of the **extension of the recall scope** for medical devices of Ringlight Fiber range, due to a **confirmed risk of distal cap detachment**, potentially linked to **variations in fixation performance observed on certain productions**.
According to our traceability status, your facility is concerned by this safety notice.
This urgent safety information concerns all distributors, users and relevant staff of healthcare establishments using and distributing the above-mentioned products.
The relevant competent authorities have been informed of this FSN.

Reason for extending the recall
New technical elements, consolidated with our subcontracting partners, have made it possible to:

- Correlate a fixing defect to a change in formulation of a component used to fix the cap.
- Identify a significant variability in operator gestures, uncontrolled following this change.

Identification of Products Concerned - Enlargement of the field of application

Legal Manufacturer: LSO Medical - FR-MF-000009080

RINGLIGHT FIBERS RANGE			
Product name	*UDI code*	*Reference*	*Lots concerned*
RINGLIGHT FIBER PROBE IR 1,8mm	03760227850129	ORLF000003	*L00107673, L00107674, L00107697, L00107701, L00107753, L00107768, L00107771, L00107809, L00107864, L00107865, L00107878, L00107889, L00107923, L00108001, L00108257, L00108259, L00108265, L00108267, L00108382, L00108593, L00108970,* *L00109038, L00109094, L00109095, L00109103, L00110387, L00110529, L00110595, L00110607, L00110619, L00110632* ***Scope extension :*** ***L00107989, L00108912, L00109023, L00109089, L00109628, L00110396, L00110446, L00110451, L00110457, L00110458, L00110536, L00110552, L00110573, L00110630, L00110631, L00113901, L00114295, L00114078***
RINGLIGHT FIBER PROBE IR_SB 1,8mm	03760227850327	ORLF000003_ SB	***Scope extension :*** ***L00107412, L00109795, L00109865, L00109868, L00109991, L00110007, L00110021, L00110127, L00112218, L00112279, L00112280, L00112431, L00112629, L00112979***
RINGLIGHT SLIM FIBER PROBE IRH 1,0mm	03760227850266	ORLF000005	*L00107223, L00107360, L00107422, L00107463,* *L00109344, L00109450, L00109472, L00111011* ***Scope extension :*** ***L00107176, L00107199, L00107295, L00107302, L00107341, L00107395, L00107420, L00107576, L00107640, L00109145, L00109247, L00109252, L00109287, L00109329, L00109367, L00109415, L00109417, L00109431, L00110865, L00110866, L00110867, L00110870, L00110896, L00110913, L00110942, L00110947, L00111014,***

RINGLIGHT FIBERS RANGE			
Product name	*UDI code*	*Reference*	*Lots concerned*
			L00111021, L00111022, L00112576, L00112632, L00113050, L00113109, L00113111, L00113141, L00113150, L00113151, L00113160, L00113245, L00113291, L00113292, L00113344, L00113790, L00113818, L00113931, L00113940, L00114019, L00114021, L00114072

Description of the Problem and Associated Risks

LSO Medical has identified a **recurring issue** of cap detachment on certain fibers from the Ringlight range. This phenomenon is linked to fixation defects occurring under specific conditions, following a formulation change introduced in December 2024.
To date, LSO Medical has identified an overall occurrence rate of **fewer than 1 case per 1,000 fibers** (ratio of confirmed incidents to total volumes), which reflects a **rare but recurring** phenomenon.

Potential risks include:

- An alteration in the diffusion of laser energy, which may affect the effectiveness of venous occlusion.
- A risk of retention of a foreign body in the vein, which may require additional intervention to extract the detached cap.

Risk reduction: Safety measures already in place

The Ringlight Fiber device integrates several mechanisms that help limit the risks associated with this event:

- Detection by the Back Reflection system
  - The Back Reflection system, integrated into ENDOTHERME 1470 and LumeSeal_SB lasers, is designed to detect an anomaly in the transmission of the laser beam in the event of a modification of the fiber.
  - An alert can be triggered if an energy transmission problem is detected, allowing the practitioner to intervene immediately.

- IFU instructions for Post-Procedure Visual Inspection
  - According to the product instructions for use (IM EMB 62-M-en dated 26.11.2024 - article 18 and IM EMB 72-D-en dated 29.11.2024 – article 27), it is required to visually check the fiber after the procedure in order to verify the integrity of the silica protective cap.
  - If there is any doubt about the integrity of the fiber before or after the procedure, it is recommended not to use the device and to contact LSO Medical.

These mechanisms help to limit the impact of the identified problem and ensure patient safety when using the device.

Actions requested from users

In agreement with the French National Agency for the Safety of Medicines and Health Products (ANSM) and as a preventive measure, we ask you to:

1. Immediately cease use of affected units and place any remaining stock in quarantine.
2. Return the affected products to LSO Medical, in accordance with the recall instruction.
3. Please report to LSO MEDICAL and the relevant competent authority any incident that may occur with the affected devices in connection with this issue.

In agreement with the French National Agency for the Safety of Medicines and Health Products, and as a precautionary measure, we ask you:

- To acknowledge receipt upon reading this document by returning the “coupon – response – information” below.
- To inform users and people to whom you have distributed the products of this safety information.

Patient safety
To date, **no serious events** have been reported. This action is aimed at preventing any potential risk.

We are at your disposal for any information concerning this document and you can contact the LSO MEDICAL Materiovigilance Manager on 03.20.67.90.00.

Please be assured that our priority is to guarantee a high level of safety and quality. LSO Medical apologizes for any inconvenience this issue may cause.

Yours sincerely

Materiovigilance Manager
Anne-Sophie DECARPIGNY

<u>In all cases</u>: Return by e-mail to Fsn202501@lsomedical.com

REPLY COUPON - INFORMATION CERTIFICATE

FSN202501ter

Customer Name:

- « I confirm receipt of the FSN202501ter dated 24/07/2025, having read it and understood its contents ».
- « I acknowledge having informed the persons concerned ».

Date :

Name : **Quality :**

Signature : **Stamp :**

It is important that your organization takes the action described in the warning sheet and confirms receipt of it.

Your organization's response is the proof we need to monitor the progress of corrective measures.