Field safety notice

Sender :	**Addressee :**
From the Medical Device Vigilance Correpondent of LSO MEDICAL	**Local Medical Device Vigilance Correspondent / Managers**
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Date : Loos, the June 14th 2024

Total number of pages: 4 *(including this page)*

FSN202401

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

Subject: Information on the use of surgical instruments with Ringlight optical fibers and associated restrictions on use.

Dear Sir or Madam,

We are writing to inform you of a field safety notice.
According to our traceability status, your establishment is affected by this safety notice.
This urgent safety information concerns all distributors, users and relevant personnel in healthcare establishments that use and distribute the above-mentioned products.

Identification of the medical devices concerned

RINGLIGHT FIBERS RANGE			
Product name	*UDI Code*	*Reference*	*Batch concerned*
RINGLIGHT FIBER PROBE IR 1,8mm / RINGLIGHT FIBER PROBE IR 1,8mm 3Y	03760227850129 / 03760227850136	ORLF000003 ORLF000003_3Y	*All batches*
RINGLIGHT SLIM FIBER PROBE IRH 1.0mm / RINGLIGHT SLIM FIBER PROBE IRH 1.0mm 3Y	03760227850266 / 03760227850273	ORLF000005 ORLF000005_3Y	*All batches*
RINGLIGHT FIBER PROBE IR 1.8mm FUSED	03760227850297	ORLF000007	*All batches*
RINGLIGHT SLIM FIBER PROBE IRH 1.3mm FUSED	03760227850280	ORLF000006	*All batches*
RINGLIGHT FIBER PROBE IR_SB 1,8mm	03760227850327	ORLF000003_SB	*All batches*
RINGLIGHT SLIM FIBER PROBE IRH_SB 1.0mm	03760227850334	ORLF000005_SB	*All batches*
RINGLIGHT SLIM FIBER PROBE IRH_SB 1.3mm FUSED	03760227850341	ORLF000007_SB	*All batches*
RINGLIGHT FIBER PROBE IR_SB 1.8mm FUSED	03760227850358	ORLF000006_SB	*All batches*

Field safety notice

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Description of the problem including identified causes

LSO Medical wishes to inform its customers of a reminder of the restrictions of use concerning the products listed above.

Ringlight fibers are sterile, single-use disposables intended for use during endovenous procedures with the Endotherme 1470 and LumeSeal_SB lasers in the treatment of varicose veins.

As specified in the Ringlight fibers instructions for use IM EMB 62 version J-en dated 31/03/2020 and Ringlight _SB fibers IFU IM EMB 72 version B dated 30/08/2023:

1. Point 10 of version J-en of Ringlight fibers: "*Ringlight fibers have to be inserted, applied and removed very carefully in order to avoid the suction of air into the vascular system, and to avoid mechanical damage of the fiber*".
2. Point 7 of version B-en of Ringlight_SB fibers "*Ringlight SnakeBack fibers must be inserted, used and removed with the utmost care, to prevent air from being drawn into the vascular system and to avoid damaging the fiber through mechanical stress*."

3. § Handling and storage conditions: "*The transport and the handling of medical laser probes require an enhanced care. Laser probes can be damaged by stresses, impacts or high-grade torsions. Such damages impact the functionality and/or appropriate operation/treatment."*

4. For Ringlight fibers Point 9, « *Pay special attention to the integrity of the distal end and cleanliness of the SMA connector. If the distally fixed glass cap should be damaged or broken, dispose the fiber. After connection to the nonsterile ENDOTHERME 1470nm, the aiming beam must be visible as a radially red emitted ring. If this not the case, the product must not be used."*
   For Ringlight_SB fibers Point 1 § Presentation of the probe, "*Using sterile gloves, unpack the probe and check it visually. Under no circumstances should the fiber come into contact with non-sterile parts. Ensure that the SMA connector is clean, and that the optical face of the connector does not come into contact with any other part before connection. Take care to ensure the integrity of the distal end. If the protective glass cap attached to the distal end of the fiber is damaged or broken, do not use the fiber."*

Consequently, the use of surgical instruments (such as Kocher forceps) during the laser procedure can fracture the silica body of Ringlight fibers.

Risks for the patient:

Fracture of the silica body of Ringlight fibers can lead to laser transmission failure and local heating of the sheath, until it separates into two parts, leaving part of the fiber in the patient's vein.

Risk prevention:

The risks associated with possible breakages are well known. The prevention of these risks is ensured in particular by:

1. Recommended use in the current instructions for use of Ringlight fibers and Ringlight_SB fibers

After the procedure, the Ringlight fiber must be inspected for damages in particular at the distal silica cap. In the unlikely event of the fiber tip breaking off and remaining inside the body (or if this is considered possible), respective clinical measures are to be taken.

2. "Back Reflection" safety system installed on Endotherme 1470 and LumeSeal laser devices compatible with Ringlight fibers range enables:

   ✓ Permanently detect laser power drift (generator emission level), without having to wait for annual maintenance,
   ✓ Permanently detect a potential anomaly in laser transmission through the fiber, or a variation in the signal emitted at the end of the fiber (obstruction).

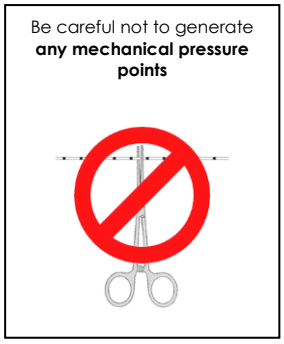
Measures implemented by LSO Medical:

In order to further reduce the risk of fiber breakage and to reinforce point 10 and 7 of the instructions for use version J-en and B-en mentioned above, the instructions for use (IFU) will now contain an additional warning note mentioning:

New point 11 of IM EMB 62 version K-en dated 05/01/2024 of Ringlight fibers and point 8 of IM EMB 72 version C-en dated 04/01/2024 of Ringlight fibers SnakeBack:

Do not generate a mechanical pressure point (e.g. when holding the fiber with a Kocher-type clamp). This mechanical pressure point could fracture the fiber, resulting in faulty laser transmission and local heating of the sheath.

As well as a new warning § Handling and storage conditions:



In agreement with the Agence Nationale de Sécurité du Médicament et des Produits de Santé, and as a precautionary measure, we ask you to:

- Acknowledge receipt of this document by returning the "reply coupon - information certificate" below.
- To inform users and those to whom you have distributed the products of this safety information.

We are at your disposal for any information concerning this document and you can contact the LSO MEDICAL Medical Device Vigilance Manager on +33 3 20 67 90 00.

Rest assured that our priority is to guarantee a high level of safety and quality. LSO Medical apologizes for any inconvenience caused.

Yours sincerely

Medical Device Vigilance Manager
Anne-Sophie DECARPIGNY

In all cases: To be returned by e-mail to Fsn202401@lsomedical.com

REPLY COUPON – INFORMATION CERTIFICATE

FSN202401

Customer name:

- "I confirm receipt of the FSN202401 dated 14/06/2024, having read it and understood its contents".
- "I acknowledge that I have informed the persons concerned".

Date :

Name : **Position :**

Signature : **Stamp :**

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

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