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Field Safety Notice

Name of Project:	UNO2
Project Number: (if available, e.g. from SAP)	N/A
Name of Product: (if available)	OPMI LUMERA 300

Document is signed in the electronic document management system (DMS). The table below is obsolete.

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Change History

The document change history is recorded in the electronic document management system (DMS). The table below is obsolete.

Version Number	Changed Section	Description of Change	Reason for Change
01	N/A	Initiation	Initiation



Carl Zeiss Suzhou Co., Ltd.

To whom it may concern

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Our Ref. : FSCA -SHS-2023-001

Date: 2023-08-10

FIELD SAFETY NOTICE

FSCA- SHS-2023-001, OPMI LUMERA 300, inspect (repair if needed) the suspension arm

Dear Customer,

You are using our OPMI LUMERA 300 and we thank you for your loyalty and trust in our products.

At ZEISS, the quality and safety of all our products is our highest priority. Unfortunately, with this letter, we must inform you, that we detected a possible screw missing on devices of the above-mentioned OPMI LUMERA 300 and that we will therefore perform a Field Safety Corrective Action. In the following, we will give you a precise description of the situation and provide clear guidance on how to avoid any inconveniences for your patients.

Problem description

In certain devices there is a probability of specific screw missing during assembly. This screw is used to prevent one internal thread cap rotating which ensure the connection between suspension arm and the suspended components. The identified defect may lead to a potential risk.

In consequence, we, Carl Zeiss Suzhou Co., Ltd., have decided to take field safety corrective action on all OPMI LUMERA 300 that may potentially have the problem, to inform customers and prevent harm to patients.

Hazard involved:

Carl Zeiss Suzhou Co., Ltd. has not received any reports about injuries, or any other adverse effects associated with the described failure. The specific screw missing from suspension

arm may cause the suspended components fall from the suspension arm, it may lead to a potential injury to the person under the suspended components.

Affected products

Our traceability records indicate that you have received the attached affected product(s).

Actions to be taken:

Kindly fill in the "Acknowledgement and Receipt Form" which is attached to this letter. Return the "Acknowledgement and Receipt Form" to the email address indicated on the form.

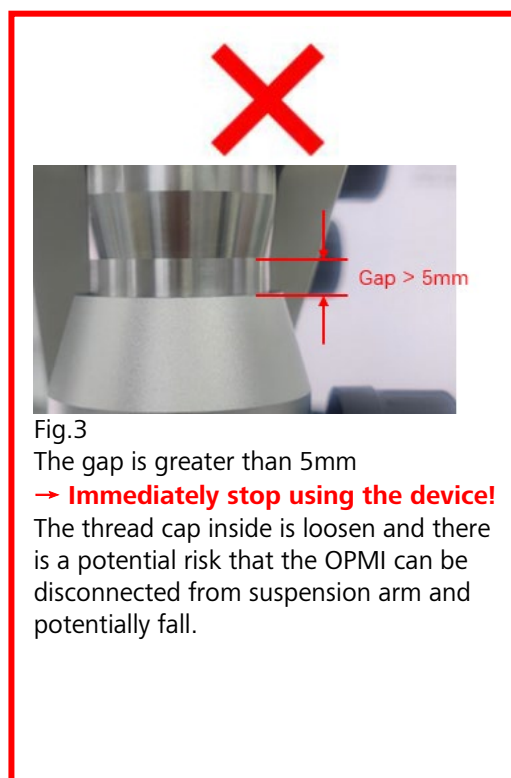
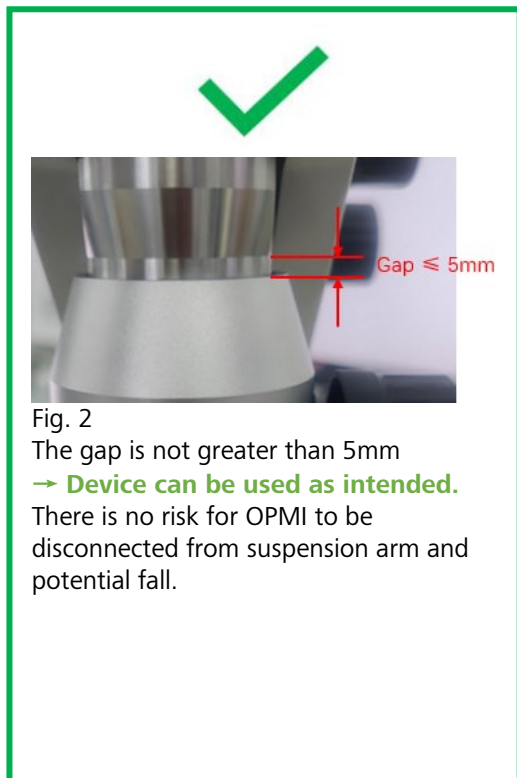
Urgent and important mandatory action to be taken by user:

The gap shown in Fig 1 indicates the fasten status of thread cap (not visible) which carries all load of suspension arm. If this gap is not in its nominal value, there is a risk of OPMI falls from suspension arm.

Before each use of OPMI LUMERA 300, please perform the following mandatory inspection:

- Measure the gap shown in Fig. 1
If the gap is greater than 5mm, **please Immediately stop using the device!**
In this case the OPMI LUMERA 300 can no longer be used.





We are planning to inspect (repair if needed) of the suspension arm immediately. Our service staff will contact you to arrange an appointment for inspection (repair if needed) of the suspension arm. Please do not hesitate to contact your local ZEISS organization in case of any concern or question.

We thank you for your careful attention, your consequent verifications, and your continuous support. We apologize for any inconvenience this situation might cause. If you have any questions, please do not hesitate to get in touch with us.

Best regards

Carl Zeiss Suzhou Co., Ltd.