

Urgent Field Safety Notice**Field safety corrective action****concerning
OCT-Camera 211 01 A1 and 211 01 A3**

01.10.2020

Sender

HAAG-STREIT SURGICAL GmbH & Co. KG
Rosengarten 10
22880 Wedel

Receiver

Doctors and clinical personnel,
Distributors of HAAG-STREIT SURGICAL GmbH & Co. KG

Dear Sir or Madam,

The HAAG-STREIT SURGICAL GmbH & Co. KG has initiated a Field Safety Corrective Action concerning the the OCT camera of the versions listed below. Our records show that one or more of the floor stands listed below were supplied to you.

Identification of affected medical devices

The OCT-Camera „iOCT“, in the versions REF 211 01 A1 and 211 01 A3

Product	Reference no.	Serial no.
OCT-Kamera	211 01 A1	0005, 0008, 0011, 0022, 0023, 0026
OCT-Kamera	211 01 A3	0153, 0154, 0157, 0159, 0160, 0165, 0166, 0168, 0170, 0171, 0172, 0174, 0176, 0177, 0178, 0179, 0180, 0182, 0183

Description of the problem

The OCT camera, as an accessory for surgical microscopes, enables optical coherence tomography (OCT) during microsurgical procedures on the patient's eye. To generate the OCT image, the tissue (e.g. the retina) is scanned with the light of a laser diode. The light beam is moved via a mirror.

If the movement of the mirror fails due to a technical error, the laser diode is automatically switched off and no damage to the eye can occur. If this automatic deactivation fails to function in the event of a second error, the stationary laser beam could cause permanent damage to the retina of the patient's eye.

Cause

The OCT camera is equipped with an automatic laser beam shut-off to protect the patient's eye. As a result of a malfunction, the OCT unit might not recognize whether the laser beam is safely switched off as described.

Possible risk

There is a risk of permanent damage to the retina of the patient's eye caused by the light energy of the static laser beam.

The risk exists exclusively during operations on the posterior segment of the patient's eye.

This safety information is a preventive action to prevent possible patient harm. There are no reports of injuries.

What actions are to be taken?

Should one or more continuous straight lines be displayed on the screen of the OCT camera during an operation on the posterior segment of the patient's eye (see picture), the described risk possibly exists.



OCT image in case of error

Actions:

1. switch off the OCT camera immediately (menu OCT -> Switch off).

The OCT camera is not permitted to be used any more. Please contact your responsible country representative.

2. Perform the software update of the OCT camera. You will receive the new software version via your local representative, who will correct the error.
3. Please fill out and return the enclosed response form as soon as the software update has been performed.

Transmission of the information

Please ensure that all users of the products mentioned are aware of and receive this urgent safety information. If you have passed the products to third parties, please forward a copy of this information and inform the below mentioned contact person.

Contact Details

The replacement of the component will be organized through your local distributor. They will contact the service personnel for updating the software. For questions concerning this procedure, please contact: J. Adler

Phone: +49 (0)4103 709 234, Fax: +49 (0)4103 709-355,

Email: vigilance-surgical@haag-streit.com

Please keep this information until the action has been closed accordingly.

We apologize for any inconvenience caused by this safety action and thank you in advance for your support in ensuring timely processing.

Yours Sincerely,

HAAG-STREIT SURGICAL GmbH & Co. KG

Response / confirmation form
Urgent Field Safety Notice

Field safety corrective action

concerning
OCT-Camera 211 01 A1 and 211 01 A3

We hereby confirm that:

The software version to correct the error has been installed on subsequent units.

REF / Serial number of the OCT-Camera: REF: _____ SN: _____

Name of facility: _____

Address: _____

Additions to address: _____

City: _____ ZIP Code: _____

Country: _____

Contact details: _____

Local Distributor: _____

Name of Employee: _____
(in printed letters)

Date and Signature: _____

Please return this form completed and signed via e-mail to:
vigilance-surgical@haag-streit.com or by fax to + 49 (0) 4103 709 355