

Scopis GmbH • Heinrich-Heine-Platz 10 • 10179 Berlin

Dear customer

Scopis GmbH, now a part of Stryker
Heinrich-Heine-Platz 10
10179 Berlin

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safety officer for medical devices

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30.08.2018

Urgent Medical Device Recall Notification

Product Recall Mayfield tracker

concerns users of Scopis products

The purpose of this notification is to advise you as a user of the Scopis product Mayfield tracker, that Scopis GmbH is voluntarily recalling the following Mayfield tracker lots:

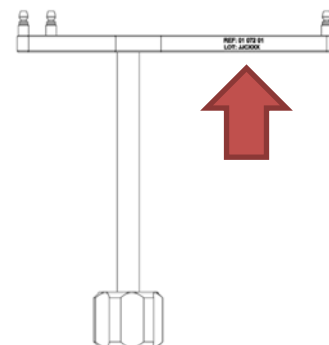
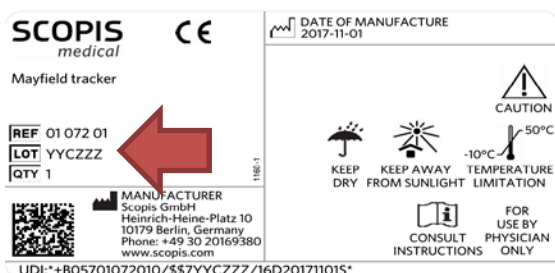
Scopis Mayfield catalogue number	Product name	Affected lots
01 028 01	Mayfield tracker	01 028 01-S05 01 072 01-S05
01 072 01	Mayfield tracker	01 072 01-S05 160101 17C101

You can find the lot number either

On the packaging label

or

lateral at the longest arm of the tracker



Reason for Recall:

There is a potential for navigation inaccuracy when changing the unsterile Mayfield tracker to the sterile Mayfield tracker after registration.

Other registration methods as described in the instruction for use are not affected.

Risk to Health:

If an undetected navigation inaccuracy occurred, there is a remote risk the inaccuracy could lead to a harm causing permanent impairment.

To reduce the risk to health please ensure to always follow the warning in the instruction for use „Scopis Navigation Systems“ (chapter 6.3.5 page 88): “If a non-sterile Image-to-Patient Registration has been conducted, where the Patient tracker was exchanged for a sterile one for the intervention, it is necessary to repeat the testing / verification of the Image-to-Patient Registration after the exchange.”

Testing / verification of the Image-to-Patient Registration is important to ensure that a possible navigation inaccuracy due to the tracker exchange is noticed.

Actions to be taken by you:

1. Check all areas for affected products. Quarantine of any affected Mayfield trackers.
2. Fill in page 4 of this letter and send it per mail to your distributor and/or to gm@scopis.com or per fax to +49 (0) 30 201 6 38 20.
3. As soon as we have the confirmation back (see point 2) we will provide you with the necessary information to return the affected products.
4. Scopis will send you new Mayfield tracker as soon as possible.

Note: new Mayfield trackers are expected to be available in October 2018 for replacement.

Passing on of the outlined information:

Please make sure that all users of the product and other people who must be informed receive this notification. In case you have passed the product on to third parties, please forward a copy of this notification or inform the contact person listed below.

Please keep this notification at least until the measure has finished. The German competent authority BfArM has received a copy of this notification.

Contact person:

Andreas Reutter, Scopis GmbH, Heinrich-Heine-Platz 10, 10179 Berlin

Tel.: +49 30 201 69 38 0

Fax: +49 30 201 69 38 20

Mail: qm@scopis.com

We apologize for any inconvenience this action may cause your facility.

Yours sincerely

Andreas Reutter

Safety Officer for Medical Devices

Confirmation

Scopis GmbH
 Andreas Reutter
 Heinrich-Heine-Platz 10
 10179 Berlin

Tel.: +49 30 201 69 38 0
 Fax.: +49 30 201 69 38 20
 Mail: qm@scopis.com
 www.scopis.com

Name of company	
Contact person	
Email Address	

We hereby confirm that we received and understand the recall notification of following Mayfield trackers:

Scopis catalogue number	Product name	Affected lots
01 028 01	Mayfield tracker	01 028 01-S05 01 072 01-S05
01 072 01	Mayfield tracker	01 072 01-S05 160101 17C101

Following affected products are on hand:

Scopis catalogue number	Product name	Affected lots	Quantity on hand
01 028 01	Mayfield tracker	01 028 01-S05	
01 028 01	Mayfield tracker	01 072 01-S05	
01 072 01	Mayfield tracker	01 072 01-S05	
01 072 01	Mayfield tracker	160101	
01 072 01	Mayfield tracker	17C101	

Company stamp

Date, Signature