

## Das Problem FIELD SAFETY NOTICE – FSCA

### Instructions for users on how to handle the affected product

Alzenau, January 23, 2026

SIGNUS Instrument:

Item number	Batch	Date of manufacture	Item description
AC0017-H	976466	24.07.2024	DIPLOMAT Screwdriver, set screw
	976468	10.09.2024	
AC0018-H	976469	23.07.2024	DIPLOMAT MIS Screwdriver, set screw
	976470	23.07.2024	
	984370	09.07.2025	
AC0057-H	976464	24.07.2024	DIPLOMAT Screwdriver, set screw, reduction
	976465	24.07.2024	
	984389	08.07.2025	

Dear Sir or Madam,

SIGNUS Medizintechnik GmbH would like to inform you about a field safety notice for the above-mentioned SIGNUS instruments.

Our documentation shows that you may have stock of the affected instruments in your warehouse. SIGNUS kindly requests that you take note of this letter and follow the instructions.

#### Description of the problem:

In the case of individual set screwdrivers from the batches listed above, it is possible that set screws are difficult to insert or cannot be inserted properly due to a fitting problem.

#### Potential risk:

If the set screw is not picked up correctly, this can lead to the connection between the set screwdriver and the set screw coming loose before the required torque has been applied to secure the set screw. If

the torque is not applied, in the worst case this can lead to the set screw loosening and the rod coming loose. Sufficient torque is applied when the torque limiter triggers.

### **Probability of occurrence**

The probability of occurrence is very low. Only the batches listed are affected. Only a few set screwdrivers within these batches are affected. The fit problem only occurs under certain combinations of set screwdriver and set screw.

### **Measures to be taken by the customer:**

Please carry out the following measures:

1. A set screwdriver (AC0017 or AC0017-A or AC0017-B) will be sent to you with this letter. Please sterilize it separately and keep it ready for surgeries. If there are any problems with the set screwdriver on the instrument tray, the additional screwdriver can be used for final tightening of the set screw. After the surgery, it is essential to be ensured that the set screwdriver is sterilized separately.
2. Please check the fit on the set screw before insertion. The set screw can be inserted securely even if the fit is not perfect. If necessary, the additional set screwdriver must be used for final tightening.
3. When using non-sterile implants on an implant tray, it is possible to check the fit of all set screws before surgery.
4. Please read the confirmation form (page 4), fill it out, sign it and return it to us within five working days of receiving this information.
5. Please forward this information to all employees in your facility who need to be informed about this problem.
6. Please keep this information in mind until all affected set screwdrivers have been replaced and you are asked to send back the additional screwdriver.

We apologize for any inconvenience and extra work this FSCA may cause and thank you for your cooperation and support. We are working hard to find a solution as soon as possible. Addressing this matter is currently our top priority.

If you have any questions, please contact your sales representative.

Thank you for your support.

SIGNUS Medizintechnik GmbH

Mareike Siedler  
Managing Director & PRRC

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- We have taken note of this letter. We will keep a copy of this letter for our records.
- We have localized affected instruments in our warehouse and informed all users.
- We have received an additional set screwdriver and keep it on hand for any surgeries. Item number: \_\_\_\_\_

Clinic: \_\_\_\_\_

Name/Degree (in block letters): \_\_\_\_\_

Phone number: \_\_\_\_\_

Signature and date: \_\_\_\_\_

Comments: \_\_\_\_\_

Please return this confirmation form to one of the following addresses:

Fax-number: +49 6023 9166 131

E-Mail address: prrc@signus.com

Postal address: SIGNUS Medizintechnik GmbH

Abteilung Qualität

Industriestraße 2

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