

**FIELD SAFETY NOTICE – FSCA****Instructions for users on how to handle the affected product.**

Alzenau, August 4, 2025

SIGNUS implant:

Item number	Batch	Date of manufacture	Item description
PSL052043	LOT 857931-BC	01.11.2024	POSEIDON ST Endplate 20x43mm 5°

Dear Sir or Madam,

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

Our documentation shows that you may have stock of the affected item. SIGNUS kindly asks you to take note of the letter and to complete and return the confirmation form at the end of the letter.

**Description of the problem:**

The above-mentioned implant batch has an incorrectly assembled connecting screw.

**Potential risk:**

Due to the incorrectly assembled connecting screw, the end plate cannot be mounted on the base body if the screw is not corrected during preparation. When the VBR is inserted, the plate will detach from the base body.

### Correction to be made by the customer:

Before using the end plate, the screw must be removed, turned around, and reinserted correctly (with the screw label facing the "end plate teeth at the top").

**The pages 4-7 contain detailed step-by-step instructions on how to carry out this simple correction.**

### Important notes:

- Only end plates with the item number PSL052043 and the LOT number 857931-BC are affected.
- All other end plates and other batches are not affected and can continue to be used as usual directly from the packaging.
- **The affected implants are fully functional and safe to use. Replacement or disposal is not necessary.**

### Measures to be taken by the customer:

1. Please remove all of the above-listed products from your stock immediately to ensure that they cannot be used without correction.
2. Please read the confirmation form, fill it out completely, sign it (page 3), and return it to us within five business days of receiving this information.
3. Please ensure that the instructions for correcting the connecting screw (pages 4-7) are enclosed with the affected product batch.
4. Please forward this information to all employees in your facility who need to be informed about this safety correction measure.
5. If the listed product has been forwarded to another facility, please contact them so that the corrective action can be implemented there or so that they can return the goods to us.
6. Alternatively, please return the affected product to us within 15 business days.
7. Please keep this information in mind until all affected products have been returned to us.
8. Please keep a copy of this letter. Please enclose a copy of this letter with the returned goods.

We apologize for any inconvenience this FSCA may cause and thank you for your cooperation and support.

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

Thank you for your support.

SIGNUS Medizintechnik GmbH

Aug. 04., 2025

Mareike Siedler  
Management & PRRC

Item number	Batch	Date of manufacture	Item description
PSL052043	LOT 857931-BC	01.11.2024	POSEIDON ST Endplate 20x43mm 5°

- ☐ We have located the affected item in our warehouse; the quantity returned is documented below. We will retain a copy of this letter for our records.
- ☐ We no longer have the affected product; the quantity returned is "0" (zero). We will keep a copy of this letter for our records.

RETURNED ITEMS (including quantity) and/or COMMENTS:

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

Name/title (please use block letters): \_\_\_\_\_

Telephone number: \_\_\_\_\_

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

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

Fax number: +49 6023 9166 131

Email address: prrc@signus.com

Postal address: SIGNUS Medizintechnik GmbH

Quality Department

Industriestraße 2

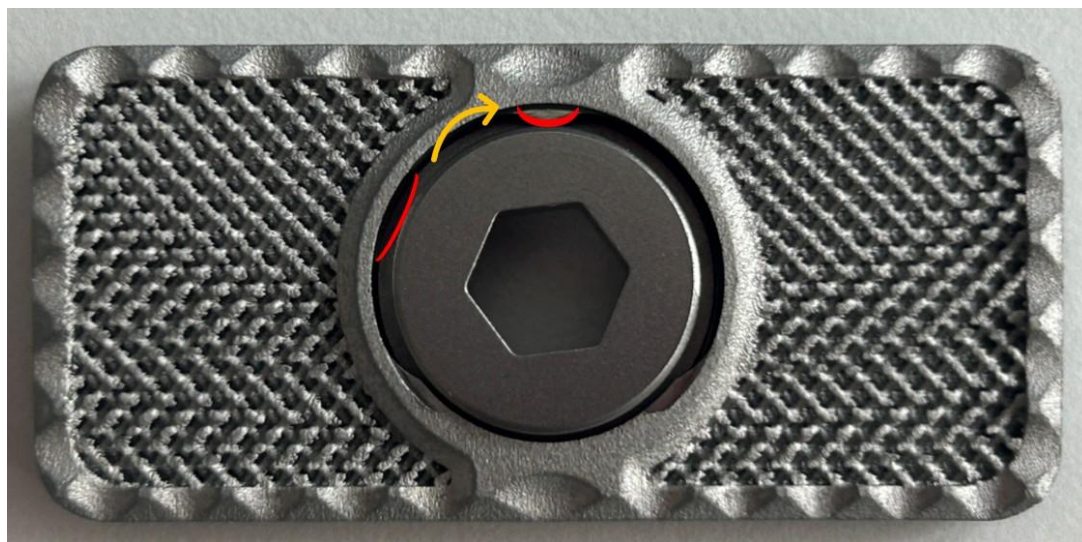
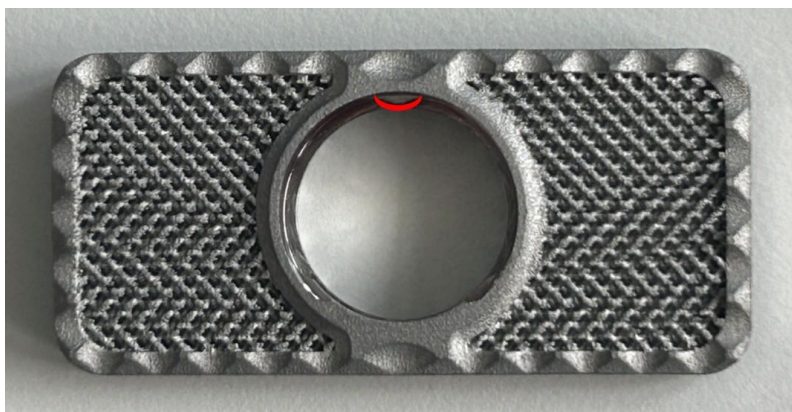
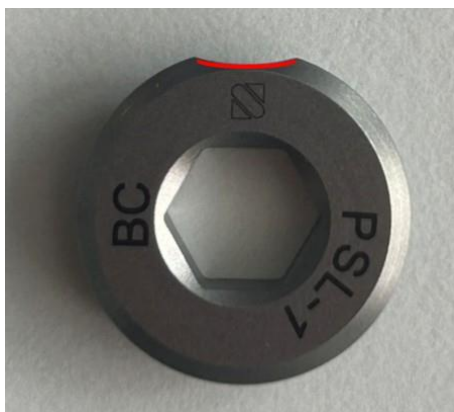
63755 Alzenau/Germany

## Instructions for correcting the connecting screw

Step-by-step instructions:

### 1. Remove the connecting screw from the endplate

Turn the connecting screw until the notch on the screw is aligned with the bulge on the plate. The connecting screw can be removed by tilting it sideways.



## 2. Align the connecting screw correctly

Turn the connecting screw so that the labeling on the screw and the teeth on the endplate are at the top.

The connecting screw must be inserted into the endplate with the labeling facing upwards.

Connecting screw at the top:



Endplate at the top:



### 3. Insert the connecting screw

The connecting screw must be aligned so that the notch on the screw is in line with the bulge on the plate.

The screw is then inserted at an angle into the endplate and turned.



BEFORE correction	AFTER correction
Endplate teeth at top and connecting screw labeling <b>at bottom/not visible</b>	Endplate teeth at top and connecting screw labeling <b>at top/visible</b>
