Urgent safety information for users

Notification regarding a voluntary product recall

to

Impactor, iliac peg - MRS-TITAN Maximum

19.05.2025

Our reference	FSCA-20250502
Sender	Peter Brehm GmbH Am Mühlberg 30 91085 Weisendorf
Addressee	Medical Director Users OR-Manager Vigilance officer

Identification of the medical devices concerned

Article number	Name	LOT
54600-04	Impactor, iliac peg	530478 418882 415912 409569 408782 402707 391082

Description of the problem including the identified cause

PETER BREHM GmbH has received indications in the course of a laboratory investigation that, under very unfavourable circumstances, there is a possibility that the use of an MRS-TITAN Maximum during impacting the iliac peg (article number: 54610-30, 54610-50, 54610-70, 54610-80, 54610-90, 54610-100 /Figure 1) with the so-called "Impactor, iliac peg " (article number: 54600-04 /Figure 2), may damage the internal thread of the iliac peg.

Figure 1 : Iliac peg

Figure 2 : Impactor, iliac peg, article number: 54600-04

In individual cases, this could make connection with the "Finisher scutcher, iliac peg" (article number: 54600-06 / Figure 3) more difficult or impossible. This could make subsequent explantation of the iliac peg more difficult during a revision.

Figure 3 : Finisher scutcher, iliac peg, article number: 54600-06

This problem has not yet been observed in the field or in practical use in clinics. There have been no such customer complaints.

PETER BREHM GmbH has nevertheless decided as a precautionary measure to voluntarily recall the "Impactor, iliac peg" (article number: 54600-04 /Figure 2).

For the implantation of the iliac peg, the

"Reposition Impactor", article number 54600-03 (Figure 4)

are available with the same function.

Clinical effects

In the unlikely event that the internal thread of the iliac peg has been damaged during implantation in previous implantations, the explantation of the iliac peg becomes more difficult and, in the worst case, can lead to an increase in operating time of more than 30 minutes.

Measures to be implemented

- Check your stock immediately and exclude any further use of the affected products.
- Please return all affected products to the following address.

PETER BREHM GmbH
Reklamationsmanagement
Am Mühlberg 30
91085 Weisendorf

- Please return the enclosed reply letter to us within **15 working days** to document this safety notice, even if you do not have any of the listed products in stock. This will prevent us from unnecessarily sending you further messages on this subject.
- **In future, use the following reusable surgical instrument for impaction of the iliac peg:**

Article number	Name
54600-03	Reposition Impactor

Figure 4 : Reposition Impactor, article number: 54600-03

Disclosure of the information described here

Please ensure in your organisation that all users of the above-mentioned products and other persons to be informed are made aware of this urgent safety information. If you have supplied the products to third parties, please forward a copy of this information or inform the contact persons listed below.

Please keep this information at least until the measure has been completed.

The national competent authority has received a copy of this urgent safety information.

Contact persons

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