



Field Safety Notice

Notification regarding a voluntary product recall

Reference R-20210711-2/ R-20210711-3

Affected Products

Article Number	Description	
42300-836-1	Valgus Platte	
42300-837-1	Valgus Platte	
42300-838-1	Valgus Platte	
42300-839-1	Valgus Platte	
42300-651-1	Valgus Platte 5° left	
42300-652-1	Valgus Platte 6° left	
42300-653-1	Valgus Platte 7° left	
42300-654-1	Valgus Platte 8° left	
42300-655-1	Valgus Platte 9° left	
42300-656-1	Valgus Platte 5° right	
42300-657-1	Valgus Platte 6° right	
42300-658-1	Valgus Platte 7° right	
42300-659-1	Valgus Platte 8° right	
42300-660-1	Valgus Platte 9° right	

Description of the Situation

Due to a customer feedback it became aware that a weld seam was insufficiently executed during the manufacture of the affected valgus plates. After multiple intended uses, the stability of the welded holder on the femoral site, is not always guaranteed and can become loose and thus may protrude.

This can lead to sticking of the flexion gauge when it is inserted into the valgus plate during instrumentation. In the worst case, the flexion gauge cannot be inserted into the valgus plate.



Fig. 1: valgus plate with welding seam



Fig. 2: Insertion of flexion gauge in the valgus plate



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Clinical Effects

In case of sticking of the valgus plate with the flexion gauge, the operating time is extended by < 30 minutes, if it is possible to switch to a different valgus angle. If it is not possible to switch to another angle, the surgery must be canceled.

Measures to be taken

- Please ensure that within your organization all users of the above-mentioned products and all other persons to be informed, are made aware of this field safety notice.
- Please check your stock immediately and ensure that the affected products are no longer used.
- Please return all affected products address stated in the following. You will immediately receive a replacement free of charge.

PETER BREHM GmbH
Complaint Management
Am Mühlberg 30
91085 Weisendorf
Germany

- Please return the enclosed fax reply for documenting this safety notice to us within 5 working days, even if you do not have any of the listed products in stock. This will prevent us from sending you unnecessary further messages regarding this issue.
- If you have any questions regarding the field safety notice, measures to be taken or possible replacement products, please contact your sales representative.

Contact Persons

Customer Service International: +49 9135 – 7103 – 669

Head of Product Development

Person Responsible for Regulatory Compliance