

Urgent Field Safety Notice FSN#01-09

February 27, 2009

Commercial name of affected product:

Item-No.

Product

0065000

Galileo Blood Grouping Instrument

Field Safety Notice FSN#01-09 regarding Field Safety Corrective Action "FSCA#01-09 Problem with Monitor Tables on the GalileoTM"

To the attention of Distributors and affiliates

We have been made aware that some monitor tables for the Galileo cabinet may not be welded correctly. If the monitor table is hit hard, the welding at the foot of the monitor may break and the table may fall off.

The affected monitor tables will be replaced by Immucor. The monitor tables replaced can either be disposed on your site or returned to Immucor. In either case please send a written confirmation to my attention after implementation of the Field Safety Corrective Action.



Urgent Field Safety Notice FSN#01-09

Confirmation of implementation of the "Field Safety Corrective Action" FSCA#01-09

Also, please sign and return a copy of this letter by facsimile (0049 6074 842099) to Alfred Wörsching after implementation of the "Field Safety Corrective Action" including disposal or return of the defective Monitor Tables.

I confirm that our facility has implemented the Field Safety Corrective Action FSCA#01-09 regarding "Problem with Monitor Tables on the Galileo TM "
Name:
Position:
Facility/Institution:



Urgent Field Safety Notice FSN#01-09

Also, please sign and return a copy of this letter by facsimile (0049 6074 842099) to Alfred Wörsching to acknowledge receipt of this notification.

Please contact International Technical Support +49 6074 8420-50 or via email: tech.support.int@immucor.com if you need further information.

We regret the inconvenience this has caused you and your customers.

Thank you in advance for your help.

Sincerely,

Dr.

Manager RA/QA Germany

I verify that our facility was made aware of the	
Field Safety Notice FSN#01-09 regarding	
"FSCA#01-09 Problem with Monitor Tables on the Galileo™"	
Name:	
Position:	
Facility/Institution:	