

Dear Customer

Field Safety Corrective Action Notice Ref R001_13

We at Greiner Bio-One pride ourselves in the quality of our products and are committed to ensuring their safety in use. During our process of market surveillance we have become aware of an occasional problem affecting some of the products within the range of Safety Blood Collection Sets

The problem relates to the luer connector incorporated into some of these products where, on rare occasions, a small crack has been identified in the connector.

The result of such a crack could lead to minor leakage of blood or infusion fluid during use or under filling of evacuated blood collection tubes/blood culture bottles.

As already stated, only a very small number of devices have shown this problem however as a precautionary measure we would ask that you immediately isolate any of the potentially affected products, which are listed on the enclosed form, which our records show were delivered to you.

We would therefore request that you:-

- a) Confirm receipt of this "Safety Corrective Action Notice" by return e-mail to noel.ennett@gbo.com

And

- b) Advise us as soon as possible, by completing the enclosed form and returning to us by fax/e-mail, of the quantity of any potentially affected product that you have isolated in order that we can arrange for its return to us and subsequent replacement

We apologise for any inconvenience this may cause and thank you for your immediate attention in this matter. Should you have any questions relating to this "Safety Corrective Action Notice" please do not hesitate to contact us.

Yours faithfully



Noel Ennett
Operations Director

Item Number	Description	Lot Number
450081	Safety Blood Col.Set+LA 21Gx19cm SP	12H23
450081	Safety Blood Col.Set+LA 21Gx19cm SP	12H24
450081	Safety Blood Col.Set+LA 21Gx19cm SP	12I17
450081	Safety Blood Col.Set+LA 21Gx19cm SP	12I26
450081	Safety Blood Col.Set+LA 21Gx19cm SP	12H30
450082	Safety Blood Col.Set+LA 23Gx19cm SP	12H21
450082	Safety Blood Col.Set+LA 23Gx19cm SP	12H22
450082	Safety Blood Col.Set+LA 23Gx19cm SP	12H30
450083	Safety Blood Col.Set+LA 21Gx10cm SP	12I16
450084	Safety Blood Col.Set+LA 23Gx10cm SP	12H29
450086	Safety Blood Col.Set+Holder 23Gx19cm SP	12H28
450086	Safety Blood Col.Set+Holder 23Gx19cm SP	12H25
450086	Safety Blood Col.Set+Holder 23Gx19cm SP	12H27
450086	Safety Blood Col.Set+Holder 23Gx19cm SP	12I26
450086	Safety Blood Col.Set+Holder 23Gx19cm SP	12I24
450086	Safety Blood Col.Set+Holder 23Gx19cm SP	12I25
450092	Safety Blood Collection Set 23Gx19cm SP	12H23
450095	Safety Blood Col.Set+LA 21Gx30cm SP	12H19
450095	Safety Blood Col.Set+LA 21Gx30cm SP	12I22
450099	Safety Blood Col.Set+LA 25Gx30cm SP	12H26
450182	Safety Blood Coll.Set+BCH 21Gx19cm	12H21
450182	Safety Blood Coll.Set+BCH 21Gx19cm	12H30
450184	Safety Blood Coll.Set+BCH 21Gx30cm	12H22
450184	Safety Blood Coll.Set+BCH 21Gx30cm	12H23
450185	Safety Blood Coll.Set+BCH 23Gx30cm	12H24
450185	Safety Blood Coll.Set+BCH 23Gx30cm	12H23
450185	Safety Blood Coll.Set+BCH 23Gx30cm	12I20

RETURN to:

Greiner Bio-One GmbH
Bad Haller Straße 32
4550 Kremsmünster
Tel: +43 7583 6791
Fax: +43 7583 6318
Email: tracey.forrester@gbo.com
Attn.: Tracey Forrester



Confirmation

We,

Name of company:

Address of company:

Herewith confirm to Greiner Bio-One GmbH, that we have acknowledged the information regarding

FSCA Ref:

R001_13

We have already informed our customers who have received the concerned products of the Field Safety Corrective Action and its related risks.

Details:

Number of customers informed

Quantities currently in our stock

Item No.	LOT No.	Quantity

Name (please PRINT):

Position in company:

Signature:

Date:

Company stamp to be placed here:

Attention:

This confirmation has to be returned to the above contact by 8th April 2013. Once Greiner Bio-One has received this confirmation regarding quantities remaining at your premises, further instructions will be provided. Buyer is aware of the fact that seller is obliged to trace back each individual item to the customer and/or end user according to seller's Good Manufacturing Practice (GMP).