

SBI International	PRODUCT RECALL	FOR 05 REV OR
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NRef                      CAPA 105-2  
N°customer

Customer :

Tel  
Fax

Sujet : Product recall - ELEKTRA

Date: Decembre 16, 2010

Dear Customer,

We inform you that we are proceeding to the recall for the following items :

Part number : **930-1020 ELEKTRA bimaternal screwed cups – all lot numbers**

Reason of the recall :

We have detected cups that are potentially incompatible with the screwdriver provided for the insertion so we want to recall as a preventive action all the products 930-1020 currently on the field. Please quarantine them and identify them as "non conform".

We thank you to fill out and return by fax the attached document in order to confirm :

- ⇒ Quantities in your inventory
- ⇒ Quantities in your customer inventories
- ⇒ Date of shipment back to us (at SBI cost)

We will credit the return items and replaced according to your needs : Please place a replacement order.

Replacement solution :

You will be able to support your sales and the planned surgeries by using the screwed HA coated cup ELEKTRA part number 500.250 in replacement of the bimaternal cups on a temporary basis. We will be able to provide you with new bimaternal screwed cups 930-1020 in the next few weeks.

Risk analysis :

The non conforming cups cannot be implanted so we can assume that no non conforming products have been implanted to date.

We apologize for the inconveniences caused and remain at your disposal for any further information.

Florence LAUCK  
Quality Manager

*Contact details for further information*

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Florence LAUCK ou Maud HUMBERT  
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À Quality Managers SBI International

Téléphone + 33 (Ø)4 74 21 58 19

**Télécopie : + 33 (Ø)4 74 21 43 12**

**FAX URGENT**

Part number	Description	Lot number	Qty in your inventory	Qty in your customer inventories	Total qty
<b>930-1020</b>	Cupule bimatière vissée ELEKTRA				

Comments :

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 .....  
 .....  
 .....

Returned date : ...../...../.....

*Name and visa of the customer*