

Buelach, 07.06.2010

Corrective Field Action Notice

Product: Elect

Dear Customer,

BIOTRONIK AG is initiating a Voluntary Corrective Field Action to remove one lot of the Elect balloon catheter.

It has been detected in house that one lot of Elect 1.5/20 has been packed with a wrong instruction for use due to an operator error. All other labelling of the product, specifically the inner and outer product labels and the compliance data card, are correct. Although the risk analysis revealed that there is no risk for the patient BIOTRONIK AG decided to remove all affected products from the market.

This Corrective Field Action does not affect any other products than the ones specified in the table below:

Designation	Reference Number	Lot Number
Elect 1.5/20	353065	01100171

BIOTRONIK AG will inform the appropriate Competent Authorities of this Voluntary Corrective Field Action.


Our records indicate that you have received affected products and we are asking for your cooperation in our efforts to complete this Field Action. Therefore, please follow the instructions outlined below.

1. Please discontinue any further use of the product lot listed, remove all the remaining units from your inventory and store them at a safe place until your BIOTRONIK sales representative will remove them from your stock.
2. Please read, complete and sign the Acknowledgement Form enclosed in this Field Action Notice, and send the completed form to your local distributor by fax or e-mail.
3. A Biotronik sales representative will visit you to remove the affected products from your stock. Please hand over the original signed Acknowledgement Form to your BIOTRONIK sales representative.
4. Please forward this notice to any health care professional of your organisation that needs to be aware of this Corrective Field Action.

We apologize for any inconvenience this Corrective Field Action may cause. We appreciate your cooperation in this matter and are committed to maintaining your confidence in the quality of our products. If you have further questions or need assistance with this Corrective Field Action, please do not hesitate to contact your local sales representative or directly BIOTRONIK, Buelach, CH, telephone number: +41 44 864 5526.

Respectfully,




Head of Regulatory Affairs