



## Urgent Safety Information

*Recall*

*concerning*

Art. No. 730211-33, electrode insert, grasping forceps, fenestrated (for BISON bipolar clamp)

Sutter Medizintechnik GmbH  
Tullastr. 87  
79108 Freiburg/Germany

01.12.2014

Distributor:

Identification of the medical devices affected:

Art. No. 730211-33, electrode insert, grasping forceps, fenestrated (for BISON bipolar clamp)

LOT: 1K12

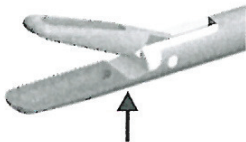
LOT: 1L01

LOT: 1L03

LOT: 2L03

LOT: 1L08

LOT: 2L08



Description of problem:

Due to the mix-up of raw materials during mechanical manufacturing, one invasive component (see illustration) of the above-listed electrode inserts was manufactured with the wrong material. The mechanical quality of the material used is poorer than the material of the proper original parts. As a result, in very rare and unfavorable instances, an unexpected break in the material may occur. This in turn could affect the functioning of the electrode insert and lead to a loss of the component.

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**Which measures have to be taken by the recipient of this letter?**

Please verify if the electrode inserts concerned have been used or put on stock by you. The LOT number is printed on the anterior (distal) part of the electrode insert's black tube insulation and on the product packaging.

Please note: Only the LOT numbers above are affected.

Please discontinue the use of the above-listed electrode inserts immediately.

Please return the above-listed electrode inserts to us. You will receive replacements free of charge.

There is no risk to the safety of patients who have already been treated with one of the above electrode inserts.

**Passing on the information described in this letter**

Please ensure that all users of the above-mentioned products and other affected persons receive this **urgent safety information**. If you have passed on products to third persons, please pass on a copy of this letter to them, or inform the contact person listed below accordingly.

Please keep this information on file until the action required has been concluded.

Please use the enclosed form to let us know if you will return the goods or if you have already rejected and disposed of them.

The German Federal Institute for Drugs and Medical Products has received a copy of this **urgent safety information**.

**Contact person:**

Reinhard Dichmann  
Manager Customer Service  
+49-(0)761-51551-25

Sutter Medizintechnik GmbH



Company Safety Officer



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LOT: 1K12  
LOT: 1L01  
LOT: 1L03  
LOT: 2L03  
LOT: 1L08  
LOT: 2L08

We have received the urgent safety information and

Are returning the electrode inserts affected (to be replaced).

Have already rejected and disposed of the electrode inserts affected.

Date:

Signature: