ENDOSENSE

Object: FIELD SAFETY NOTICE
Update concerning certain serial numbers of the TactiCath® Catheters

Details of Device: TactiCath Catheter
BIOTRONIK code: 375401 / 378979
ENDOSENSE code: PN-003 065 / PN-003 165

Endosense Reference: FSCA-1108 – *Update of FSCA-1107*

05 September, 2011

Dear Sir or Madam,

In a Field Safety Notice issued in July 2011, we informed you about the possibility that the handling of the TactiCath catheter under excessive mechanical stress could affect the performance of its irrigation line. Thanks to your support in conduction of the Field Safety Notice we were able to further investigate catheters under complaint which were returned to us for analysis. Excessive testing and investigation of our production records enabled us to identify two lots of irrigation tubes which contributed to elevated likelihood of impaired irrigation performance. Catheters produced with other tubing lots were verified to ensure proper irrigation functionality.

After careful consideration, we have decided to voluntarily and preventively recall the potentially affected catheters produced with the suspicious irrigation tube lots, and to replace them with catheters that will fulfill our standards and the highest level of quality.

As a consequence, we kindly ask you to quarantine any catheter with the following serial numbers: 3360, 3366, 3367, 3374 through 4559, and 4568. Your local representative will contact you to organize the replacement of these catheters. No new action is required for TactiCath catheters which fall outside of the serial numbers mentioned above.

It is important to underline that this is a voluntary and preventive action initiated by ENDOSENSE and that no adverse event related to an impaired irrigation performance has been reported.

The applicable Competent Authorities have been notified of the Field Safety Corrective Action. This Field Safety Notice must be passed on to all physicians within your organization (or any organization to where the affected devices have been transferred) who need to be aware of this product recall.

We appreciate your continuous cooperation with this matter and apologize for the inconvenience that it may cause. If you have any further questions or concerns, please do not hesitate to contact us or your local representative.

With best regards,

[redacted]

VP Quality Assurance, Clinical & Regulatory Affairs

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