

*Object:* FIELD SAFETY NOTICE – Advice to all TactiCath users

*Details of Device:*

TactiCath Catheter  
(All serial numbers)

BIOTRONIK code: 375401  
ENDOSENSE code: PN-003 065

*Endosense Reference:* FSCA-1107

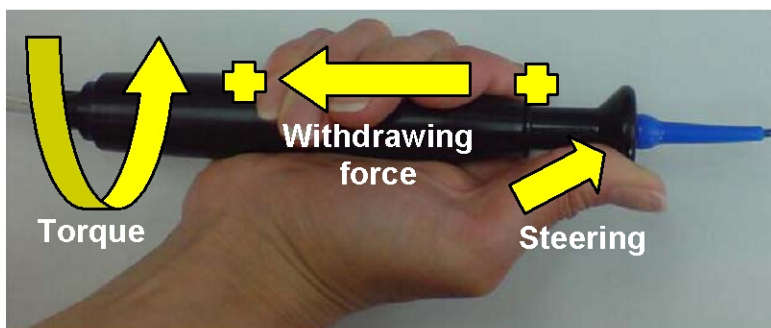
July, 2011

Dear Sir or Madam,

ENDOSENSE continuously strives to further develop and permanently deliver the highest quality products.

We have recently identified the possibility that the handling of the catheter in combination with a sheath under excessive mechanical stress (described below) might affect the performance of its irrigation line. The purpose of this communication is to help you to minimize the likelihood of this occurrence. It is important to underline that this is a preventive advice and that no adverse event on the use of TactiCath has been reported.

When a partially or totally steered catheter is engaged in a sheath, and drawn back while a strong torque is manually applied to the catheter handle (illustrated below), the internal components of the catheter can be exposed to an excessive stress. This can lead to a partial or total collapse of the irrigation line and thus obstruct the irrigation flow towards the catheter tip. As a result the temperature at the tip of the catheter may rise and the control algorithm of the ablation generator may limit or stop the energy delivery to the patient if programmed appropriately. Additionally, certain irrigation pumps may stop and alert the user by displaying a high pressure alarm.



In order to ensure full performance of the irrigation line during an ablation procedure, we recommend following these instructions when using the catheter in combination with a sheath:

- Avoid applying simultaneous high torque and tensile stress (pulling) to the catheter while the catheter tip is engaged in the sheath in a curved position.
- Release the steering (*make the catheter straight*) when pulling back the catheter into the sheath.

As already mentioned in the catheter's Instructions for Use, we also recommend checking irrigation flow and tip temperature during any ablation.

In addition, we would like to re-emphasize the importance to set the upper limit of the catheter tip temperature on the ablation generator in accordance with its User Manual.

The applicable National Competent Authorities have been advised of this Field Safety Notice.

We hope to have been of assistance with this information. If you have any further questions or concerns, please do not hesitate to contact us.

With best regards,



VP Quality Assurance, Clinical & Regulatory Affairs  
Endosense