

*Object:* Urgent Field Safety Corrective Action  
**Recall of TactiCath Quartz® Catheters**

*Details of Device:* TactiCath Quartz Catheter  
ENDOSENSE codes: PN-004 065 / PN-004 075

*Endosense Reference:* FSCA-1212

December 11<sup>th</sup>, 2012

Dear Sir or Madam,

Endosense is committed to continuously strive for further development and permanent delivery of products of highest quality. For this reason we constantly undertake major efforts to increase our standards of design and production.

With the start of our new TactiCath Quartz product line, Endosense installed additional sample testing with improved test coverage which allowed us recently to identify a higher than expected variability in strength of the catheter's distal part. Despite very high safety margins, we cannot rule out that catheters exist which may be outside of its design specifications. The statistical probability for a product failure is extremely low. However, considering the potential risk to the patient, we have decided to recall all existing and unused TactiCath Quartz catheters.

As a consequence, we kindly ask you to quarantine and not to use the TactiCath Quartz catheters which are in your lab stock. Endosense will replace these products with new catheters which underwent additional systematic testing. Your local representative will contact you to organize the replacement.

It is important to underline that this is a voluntary and preventive action initiated by Endosense and that no related adverse event has been reported.

The applicable Competent Authorities have been notified accordingly. 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.

After almost 3 years of commercialization, Endosense products have been used in more than 2,500 procedures across Europe, Australia and the US with no patient related safety issues linked to the quality of our products.

We appreciate your 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,



*VP Quality Assurance, Clinical & Regulatory Affairs*