

Smith & Nephew
Orthopaedics GmbH
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www.smith-nephew.com

 We are **smith&nephew**

Smith & Nephew Orthopaedics GmbH • Postfach 64 • 78501 Tuttlingen

Name and address of hospital/medical practice

04. February 2010

Urgent Field Safety Notice

Labeling Update-SpineCath & Acutherm Catheters & Introducer Needles

Dear Dr. (name),

As an important customer to Smith & Nephew, we would like to inform you of a labeling update to our Instructions for Use regarding the SpineCath and Acutherm catheters. As you are aware from the current product's label, it is important not to attempt to reposition the catheter if resistance is felt during the procedure or to withdraw or maneuver a kinked catheter as "damage to the catheter may result".

Such damage may include shearing of the catheter's tip, which may result in a fragment of the catheter being left in the patient. The incidence of this failure mode with the SpineCath and Acutherm product lines is very low (i.e. 0.20%)ⁱ and below the published rate for this category of products (1.13%)ⁱⁱ. Further, there have been no known reported cases of this risk being associated with any patient morbidityⁱⁱⁱ.

We take patient safety seriously and are committed to providing complete and accurate information regarding the safe usage of our products. Despite a low occurrence rate, we wanted to provide additional information surrounding this risk. As such, the following will be added to the "Warnings" section of our Instructions for Use:

"Withdrawing a damaged or kinked catheter through the introducer needle may result in the end of the catheter being sheared off and left in the patient. If resistance is felt when withdrawing the catheter through the introducer needle, carefully remove the catheter and introducer needle together as a unit and return to Smith & Nephew for evaluation."

Sitz der Gesellschaft / Registered Office
Tuttlingen

Bankverbindungen / Bank Details

Deutsche Bank (BLZ 253 700 75) 2 187 870
Dresdner Bank (BLZ 643 800 11) 2 718 832

Handelsregister / Commercial Register
Stuttgart, HRB 450226

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Geschäftsführer / Managing Director
Dieter Schulz

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02622541001

USt-Id-Nr. / VAT-RPT-No.

DE 232032632



ISO 13485:2003
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Best Regards,

Smith & Nephew GmbH


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Regulatory Affairs & Quality Assistant

¹ Based on sales versus reported tip breakages from 2005 to present.

² Eckel, T., Ortiz, A., "Intradiscal Electrothermal Therapy in the Treatment of Discogenic Low Back Pain", Techniques in Vascular and Interventional Radiology, Vol. 5, No. 4 (December), 2002; pp 217-222.

³ Bama, et al., "Intradiscal Electrothermal Therapy", emedicine Clinical Procedures, <http://emedicine.medscape.com/article/1145641-print>.

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