

# B|BRAUN

B. Braun Melsungen AG  
Division Aesculap

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D-12359 Berlin

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Your reference	Our reference	Tel. +49-30-68 98 97-	Fax +49-30-68 98 97-	Date
	HH-QM	57	30	June 14, 2005

## Product removal Intradyn Tear-Away

Dear customer,

B. Braun Melsungen AG as medical product manufacturer is committed to assuring the safety and effectiveness of our products for both health care professionals and patients.

We have elected to initiate a product removal of **Intradyn Tear-Away Introducer Sheaths** which is being performed with the knowledge of the United States Food and Drug Administration (FDA). Further distribution or use of the product should be discontinued immediately.

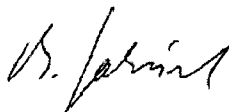
Recently, we have had reports on a small number of our **Intradyn Tear-Away Introducer Sheaths** with cracked hubs/handles and/or improper peeling of the sheath during use.

The attached list indicate the products and lot numbers which you have received.

Within the next days our local B. Braun representative will contact you for taking back the goods and discussing further actions. For returned goods we will give you a credit note.

We apologize for any inconvenience this may have caused and we appreciate your patience.

Yours sincerely,



Vors. d. Aufsichtsrats:  
Justus Mische

Vorstand:  
Dr. h.c. Ludwig Georg Braun  
(Vorsitzender)  
Prof. Dr. Dr. h.c. Michael Ungethüm  
(stellv. Vorsitzender)

Dr. rer. nat. Wolfgang Feller  
Klaus Hofer  
Dr. rer. nat. Meinrad Lugan  
Harald Niemann

Sitz der Gesellschaft: Melsungen  
Reg. Gericht: Amtsgericht Fritzlar  
-Registerabteilung Melsungen-  
Caroll H. Neubauer

HRB 11 000

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Coroflex Blue Safety Notice

Bernhard Gabriel  
Director of Quality Management

Dr. Michael Boxberger  
Director Clinical Marketing

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