<insert date>

Re: URGENT FIELD SAFETY NOTICE for Baylis Medical ProTrack™ Microcatheter Lots CIFA131113 CIFA100614, CIFB100714, CIFA241014, CIFA161013, CIFA271113, CIFA311213, CIFA210214, CIFA070314, CIFA270314, CIFA070514, CIFA210514, CIFA240614, CIFA100714, CIFA180814, CIFA080914, CIFA221014, CIFA050115, CIFA210115 and CIFA060215

Type of Action: REMOVAL

Baylis Medical Company is voluntarily recalling 20 lots of ProTrack™ Microcatheter due to the possibility, however remote, that the catheter may have circumferential cracks along its length. The following lots are subject to this voluntary recall:

Part Number: **CIC35-145**
Lot Number
CIFA131113
CIFA100614
CIFB100714
CIFA241014

Part Number: **CIC38-145**	
Lot Number	Lot Number
CIFA161013	CIFA240614
CIFA271113	CIFA100714
CIFA311213	CIFA180814
CIFA210214	CIFA080914
CIFA070314	CIFA221014
CIFA270314	CIFA050115
CIFA070514	CIFA210115
CIFA210514	CIFA060215

If the cracks are present on the device, they are likely to be detected by a physician upon removal of the catheter from the packaging. The cracks may result in leakage of fluids along the catheter. There have been no adverse event reports related to this discovery.

No other ProTrack™ Microcatheter or other Baylis Medical devices are affected by this recall. The recall is limited to CIC35-145 and CIC38-145 Lots CIFA131113, CIFA100614, CIFB100714, CIFA241014, CIFA161013, CIFA271113, CIFA311213, CIFA210214, CIFA070314, CIFA270314, CIFA070514, CIFA210514, CIFA240614, CIFA100714, CIFA180814, CIFA080914, CIFA221014, CIFA050115, CIFA210115 and CIFA060215. All other lots of ProTrack™ Microcatheter remain safe to use.

Please immediately examine your inventory and quarantine any ProTrack™ Microcatheter lots noted in this letter that you may maintain in inventory and complete the attached response form. Your assistance is appreciated.

Baylis Medical Company Inc.
2645 Matheson Blvd. East, Mississauga ON Canada L4W 5S4 / Tel.: (905) 602-4875 / Fax: (905) 602-5671
www.baylismedical.com

Our records show that you have received this product from Baylis Medical Company. Please see the instructions below.

<table>
<tr><td>Affected Products</td><td>Baylis Medical the ProTrack™ Microcatheter

<table>
<tr><th>Part Number</th><th>Lot Number(s)</th></tr>
<tr><td>CIC35-145</td><td>CIFA131113</td></tr>
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</table>
</td></tr>
<tr><td>Safety Instructions</td><td>1. Immediately segregate all affected product in your inventory in a manner that ensures it will not be used.
2. Complete the attached acknowledgement form and include with it a list of customers impacted by this field safety notice and fax it back to ATTN: Quality Department (905) 602-5671.
3. A Baylis Medical Representative will contact you once your acknowledgment form has been received and will provide you with a RMA # for return of product.
4. Return all product clearly labeled with the RMA# to:
Attn: Quality Department
RMA#
2645 Matheson Blvd. East
Mississauga, ON L4W 5S4
CANADA</td></tr>
<tr><td>Product Correction</td><td>For every ProTrack™ Microcatheter, you will be supplied with a ProTrack™ Microcatheter at no charge.</td></tr>
<tr><td>Contact Information</td><td>Amy Lefler, Senior Quality Engineer
alefler@baylismedical.com +1 (905) 602-4875 ext. 223</td></tr>
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Please be advised that the FDA and applicable National Competent Authorities have been notified of this safety notice. The Authorized European Representative for Baylis Medical is:

Quality First International
20 Eversley Road, Bexhill-on-Sea, East Sussex
TN40 1HE, United Kingdom
Telephone: +44 208 221 2361
Telefax: +44 208 221 1912

Please contact us immediately if you have any questions.

Regards,

Laura Conquergood

Director of Operations
Baylis Medical Company