ReFlow Medical

To: Risk Management Director or Material Management (please forward this letter to all potential users of the product – e.g. interventional radiologists, angiologists)

URGENT FIELD SAFETY NOTICE- VOLUNTARY MEDICAL DEVICE RECALL- WINGMAN 35 CROSSING CATHETER

Dear customer:

We would like to inform you that ReFlow Medical has initiated a voluntary recall of the Wingman 35 Crossing Catheter.
The Wingman 35 Crossing Catheter may be prone to tip detachment.

We are aware of two complaints received regarding the tip failure. There have been no reports of injury or death associated with the tip failures.

If a catheter tip detaches from the Wingman 35 Crossing Catheter, it can cause injuries to blood vessel walls, thrombotic events, foreign body embolization, heart attacks and death.

The following reference numbers are affected by the recall:

Reference	Lot#	Expiration date
Wingman 35 Crossing Catheter, 60cm		
WGM35065CE	1508074R	8/7/2016
WGM35065CE	1509154	9/15/2016
WGM35065CE	1510054	10/5/2016
WGM35065CE	1602164R	2/17/2017
WGM35065CE	1604194	4/19/2017
Wingman 35 Crossing Catheter, 90cm		
WGM35090CE	1505144R1	5/14/2016
WGM35090CE	1505144R2	5/14/2016
WGM35090CE	1505144R3	5/14/2016
WGM35090CE	1508264	8/27/2016
WGM35090CE	1601044R	1/4/2017
WGM35090CE	1603024R	3/2/2017
WGM35090CE	1603024R2	3/2/2017
WGM35090CE	1603214R	3/24/2017
WGM35090CE	1605194R2	5/2019

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Wingman 35 Crossing Catheter, 135cm		
WGM35135CE	1505061R	5/6/2016
WGM35135CE	1505264	5/26/2016
WGM35135CE	1506104R	6/10/2016
WGM35135CE	1508204	8/20/2016
WGM35135CE	1508205R	8/20/2016
WGM35135CE	1602174R	3/1/2017
WGM35135CE	1611114	11/2019

This is OK if the Lot 1505144R3 if staying on the table – 20 or 21 lots

The reference number and lot number are printed on the label of the primary and secondary packaging. Our records show that you have received some of the affected products.

Which actions have to be taken by users?
Please be aware that only the products listed on the answer letter are affected by this voluntary recall. Please read the following instructions and carry out the described actions.

1. Please remove all affected products from your inventory and store them in a secure separate location. There products must not come into clinical use. Mark the product as "Recalled Product- RECALL 2017-001".
2. Please forward this letter to all staff members in your organization that need to be aware of this information letter and the initiated recall.
3. Please transfer this notice to other organizations on which this action has an impact
4. Please fill in the answer letter indicating the quantity of products that have already been used and the quantity of products that are being returned as well as your contact details.
5. Please return the completed and signed answer letter to your German distributor:

   Dr. George Landsberg, CEO. Ab medica Deutschland GmbH & Co KG
   Willstätterstrasse 13. 40549 Düsseldorf. Germany
   Tel.: +49 (0) 211 585 881-0 Fax: +49 (0) 211 585 881-11
   Email: glandsberg@abmedica.org
   or to :
   ReFlow Medical by fax (1+ 760.290.3216), email (quality@reflowmedical.com) or mail (1003 Calle Sombra, San Clemente, CA 92673, USA) **within 5 calendar days, even if you are not going to return any product.**
6. If you have any additional questions regarding return of the products, credit note, replacement or shipping, please contact your distributor (see above) or our customer services at +1.949.275.0098
7. Please only return affected products listed in the answer letter to ReFlow Medical
8. Please maintain awareness of this notice until all required actions within your organization have been completed.

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The return of the answer letter, and any answer letters from other parties where the device has been distributed, is crucial for ReFlow Medical to complete this FSCA. Your cooperation in this matter is greatly appreciated.

We apologize for any inconvenience this has caused and thank you for your understanding.

Informing the authorities
Your Competent Authority was informed about this incident and has received a copy of this Field Safety Notice.

Sincerely.

[redacted]
ReFlow Medical, Inc.

ReFlow Medical

Please respond within 5 calendar days
Via FAX: +49 (0) 211 585 881-
Email: glandsberg@abmedica.org
Or mail: Dr. George Landsberg, CEO. Ab medica Deutschland GmbH & Co KG
Willstätterstrasse 13. 40549 Düsseldorf. Germany
or
Via FAX: 1+ 760.290.3216
Email: quality@reflowmedical.com
Or mail: ReFlow Medical Inc., 1003 Calle Sombra, San Clemente, CA 92673

URGENT FIELD SAFETY NOTICE VOLUNTARY MEDICAL DEVICE RECALL
WINGMAN 35 CROSSING CATHETER

Answer Letter

Customer:

Delivered products:
Please fill out legibly the last two columns and complete your contact information

Reference Number	Article Description	Lot Number	Delivered quantity	Used quantity	Quantity to be returned
(to be completed by distributor)	(to be completed by distributor)	(to be completed by distributor)	(to be completed by distributor)		

Contract person	
Phone number	
Date	
Signature	

If you have any additional questions regarding the return of the products, credit note, replacement or transport please contact your German distributor (see above) or ReFlow Medical Customer Service at: 1+ 949.275-0098 or irizk@reflowmedical.com
Thank you in advance for your prompt response.