URGENT FIELD SAFETY NOTICE
NRG TRANSSEPTAL NEEDLE

Type of Action: Return of Device to Supplier

17 October 2016

Attention Valued Customer:

Baylis Medical Company is voluntarily recalling selected lots of the NRG Transseptal Needle due to a possible defect in the sterile packaging (Tyvek side) of the product. The defect may affect the sterility of the product.

Baylis Medical Company has identified the defect through internal investigation. It is possible that the defect can be identified by a user through visual inspection of the product packaging prior to use. However, in the case that a packaging defect is not identified and the product is used in a patient, there may be a remote risk of infection.

While no adverse event or patient injury has been reported due to any packaging defect, Baylis Medical Company has made the decision to conduct a voluntary recall of the lots mentioned below.

We are notifying you of this recall as our records indicate that you have been supplied with one or more of the affected lots of the **NRG Transseptal Needle**.

The specific lots affected are detailed at the end of this letter. All other lots of the **NRG Transseptal Needle** remain safe to use. No other Baylis Medical Company devices are affected by this recall.

Please **immediately** complete the following actions:

1. Examine your inventory for affected product and lot numbers.
2. Quarantine any lots noted in this letter.
3. Complete the attached Acknowledgement Form and return the form to Baylis Medical Company via one of the following methods:
    a. Email at recalls@baylismedical.com
    b. FAX to (905) 602-5671 ATTN: Quality Department

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

Returning the Acknowledgement form indicates that you have completed a review of your inventory. We will contact you within two (2) business days with a Return Merchandise Authorisation (RMA) Number and information on how to obtain replacement product for any product to be returned for exchange. To help Baylis Medical Company facilitate your product exchange, please write the RMA number on the outside of your return package(s).

Our Customer Service Department is available for all questions regarding this notice, at 1-800-276-4416, ext.185 or by email at recalls@baylismedical.com. We appreciate your cooperation and sincerely apologise for any inconvenience caused by this recall.

Please be advised that the relevant National Competent Authorities have been advised of this safety notice. The European Authorised Representative for Baylis Medical Company 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

Sincerely,

Ellen Harfield
Quality Manager

Baylis Medical Company Inc.
2645 Matheson Blvd. East, Mississauga ON Canada L4W 5S4 / Tel.: (905) 602-4875 / Fax: (905) 602-5671
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Affected Lots of NRG Transseptal Needle

Please see attached

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URGENT FIELD SAFETY CORRECTIVE ACTION

NRG Transseptal Needle

ACKNOWLEDGEMENT FORM

Site Name			
Site Contact			
Site Address			
Contact Email			
Contact Phone		Contact Fax	

Site Acknowledgement (One box must be checked)

☐ This site **does not have any** of the affected lots of NRG Transseptal Needle.

☐ This site has _____ pieces of the affected lots of NRG Transseptal Needle (complete appended tables)

By completing this acknowledgement form stating that you have no product, you attest that you have no unused product in your inventory.

By returning product, you attest that you have returned all unused product in your inventory.

Name	Signature	Date

Form Instructions:

1. Please complete this form electronically, or print clearly.
2. Please return completed forms to Baylis Medical Company either by
    a. Email recalls@baylismedical.com
    b. Fax to ATTN: Quality Department at (905) 602-5671
3. If you have product to return, a Return Merchandise Authorisation Number (RMA) will be provided to you via email or fax.
4. Once you receive the RMA Number, please send product with a copy of this form to:

    Attn: Quality Department
    RMA#
    c/o Baylis Medical Company
    2775 Matheson Blvd. East
    Mississauga, ON L4W 4P7
    CANADA

Please contact our Customer Service Department for all questions regarding this notice, at 1-800-276-4416, ext.185 or by email at recalls@baylismedical.com. We appreciate your cooperation and sincerely apologise for any inconvenience caused by this action.

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APPENDIX B

List of EU Affected Lots

Model Number	Lot Number	Date of Manufacture	Date of Expiry
NRG-56-32-C0	NGFC041115	13-Nov-2015	31-Oct-2018
NRG-56-32-C0	NGFH211215	21-Jan-2016	31-Dec-2018
NRG-71-C0	NGFA071015	16-Oct-2015	30-Sep-2018
NRG-71-C0	NGFF081015	21-Oct-2015	30-Sep-2018
NRG-71-C1	NGFB111115	23-Nov-2015	31-Oct-2018
NRG-71-C1	NGFD081015	22-Oct-2015	30-Sep-2018
NRG-71-C1	NGFD151015	22-Oct-2015	30-Sep-2018
NRG-98-C0	NGFD111115	24-Nov-2015	31-Oct-2018
NRG-E-HF-71-C0	NGFA020316	17-Mar-2016	28-Feb-2019
NRG-E-HF-71-C0	NGFC071015	21-Oct-2015	30-Sep-2018
NRG-E-HF-71-C0	NGFC210316	05-Apr-2016	28-Feb-2019
NRG-E-HF-71-C0	NGFF040416	20-Apr-2016	28-Mar-2019
NRG-E-HF-71-C0	NGFF070316	29-Mar-2016	28-Feb-2019
NRG-E-HF-71-C1	NGFI290416	20-May-2016	28-Apr-2019
NRG-E-HF-98-C0	NGFC151015	29-Oct-2015	30-Sep-2018
NRG-E-HF-98-C0	NGFI110416	22-Apr-2016	28-Mar-2019
NRG-E-HF-98-C1	NGFE180416	02-May-2016	28-Mar-2019
NRG-E-HF-98-C1	NGFG151015	30-Oct-2015	30-Sep-2018
NRG-HF-71-C0	NGFB071015	20-Oct-2015	30-Sep-2018
NRG-HF-71-C1	NGFE041115	16-Nov-2015	31-Oct-2018
NRG-HF-71-C1	NGFE211215	11-Jan-2016	30-Nov-2018
NRG-HF-71-C1	NGFF210316	05-Apr-2016	28-Feb-2019

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