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URGENT FIELD SAFETY NOTICE

Commercial name of the affected product:	FPRPR3508, IceRod 1.5 PLUS 90° Cryoablation Needle
FSCA-identifier:	PAF 15-02
Type of action:	Field Safety Corrective Action

Date: October 6, 2015

Attention: Mr. Christian Sem

DETAILS ON AFFECTED DEVICES:

This letter is a voluntary field corrective action for the following Galil Medical Product:

FPRPR3508 IceRod 1.5 PLUS 90° Cryoablation Needle

DESCRIPTION OF THE PROBLEM:

Galil Medical received a customer complaint in which a FPRPR 3508 IceRod 1.5 PLUS 90° Cryoablation Needle was mislabelled. The top box label with the part number FPRPR3193 IceRod 1.5 MRI Cryoablation Needle was mislabelled. The label on the side of the box and all internal labelling and documentation are correct.

Investigation of this situation determined the root cause of this incident to be due to assembler error. Investigation also identified the possibility for additional lots needles to be mislabelled. This could present the potential for a patient safety issue in a situation where a user intended to use an MRI needle, but pulled a box containing a non-MRI compatible needle. Galil has received no reports of this type of situation occurring or any reports of patient injury related to this type of event.

Lots subject to this recall are identified by one of the following Lot Numbers: B6430-XXX; B6431-XXX; B6432-XXX; B6433-XXX; B6434-XXX; B6435-XXX; B6436-XXX; and B6437-XXX. There are a total of 78 individual needle kits worldwide that are covered under this recall.

ACTIONS TO BE TAKEN BY THE USER:

1. **Return a completed Product Recall Response Form**. Galil Medical has attached a Product Action Response form listing the lot numbers of potentially affected needles shipped to you.
    a. For each of these needles, compare the top box label with the side box label to ensure the FPRPRxxxx product number matches.
    b. IF the product numbers do not match, note that on the Product Action Response form and quarantine the product. Galil Medical will supply you with a corrected label for you to apply to this product. Please see item 3, Galil Medical Corrective Action, below.
    c. If the product numbers do match, the product is safe to use.

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d. For any product no longer in your inventory, please identify the disposition of that product.

Fax a completed Response Form to 1+651-287-5097 or email the completed form to regulatory@galilmedical.com no later than **Wednesday, October 14, 2015.**

2. Forward and Communicate Recall Notice

Forward and communicate this Recall Notice and instructions to individuals in your organization and/or to other organizations affected by this action.

Transmission of this Field Safety Notice:

This notice needs to be passed on all to those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

3. Galil Medical Corrective Action:

Upon receipt of your completed Product Action Response Form, Galil Medical will immediately ship you replacement top box labels containing the correct part number. Please apply the replacement label over the incorrect top box label.

To reiterate, the needles in the box, FPRPR3508 IceRod 1.5 PLUS 90º Cryoablation Needles are safe for use in a non-MRI suite.

CONTACT REFERENCE PERSON:

If you have any questions, please contact Galil Medical Customer Service at +972 (4) 909 3200.

The undersigned confirms that this notice is being reported to the appropriate Competent Authorities and is conducted in accordance with their guidance.

Again, please complete and return the attached response form no later than Wednesday, **October 14, 2015**. If you have any questions, please Galil Medical Customer Service or your local Galil Medical representative.

Sincerely,

Amy E. McKinney

Amy E. McKinney
Vice President, Global Regulatory Affairs & Quality
Galil Medical Ltd.

Enc: Response Form