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URGENT FIELD SAFETY NOTICE

Commercial name of the affected product:	17G Cryoablation Needle Holder FPRPR4014
FSCA-identifier:	PAF 12-02
Type of action:	Field Safety Corrective Action

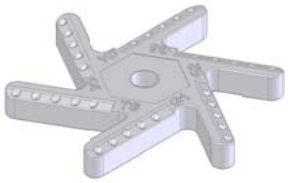
Date: April 12, 2012

Attention: <Customer Name>

DETAILS ON AFFECTED DEVICES:

This letter is a voluntary product recall for the following Galil Medical Product:

FPRPR4014 – 17G Cryoablation Needle Holder



DESCRIPTION OF THE PROBLEM:

The 17G Cryoablation Needle Holder is a star-shaped device used to hold cryoablation needles in position while conducting Needle Integrity and Functionality Testing. This recall is initiated following assessment of our Sterilization Verification procedure, including LAL testing. (LAL tests for residual bacterial components that remain after sterilization.) A portion of the Needle Holders tested did not meet our strict acceptance criteria for this test. We decided to recall this product until this issue can be resolved.

It is important to note LAL test failures were only identified for the 17G Cryoablation Needle Holder. The Needle Holders are sterile but contain an unacceptable level of bioburden. NOTE: All other Galil Medical products, including our cryoablation needles, successfully meet the acceptance criteria for this test.

To date, Galil Medical has received no complaints of patient harm resulting from use of a 17G Cryoablation Needle Holder. While the needle holder does not come in contact with a patient's body, a sterile needle will pass through the needle holder when the needle holder is in use. While a low risk, if a Needle Holder with elevated LAL levels comes in contact with human blood or cerebrospinal fluid, the patient hazard is production of fever and/or pyrogenic response.

Lots subject to this recall are identified by one of the following Lot Numbers: N7729-XXX; N7890-XXX; N7975-XXX; N8185-XXX; and N9438-XXX.

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ACTIONS TO BE TAKEN BY THE USER:

1. **Return a completed Product Recall Response Form**. Galil Medical must receive a completed Response Form from each recipient of this letter.

   Include the completed Response Form with returned product, or

   Fax a completed Response Form to 1+877-510-7757.

2. **Return all unused 17G Cryoablation Needle Holders** to Galil Medical within the next 30 days. Return product to Galil Medical, 4364 Round Lake Road West, Arden Hills, MN 55112; shipping cost is prepaid with use of the enclosed shipping label.

   - Identify inventory of the affected product
   - Complete the enclosed Product Return form
   - Package the product and completed Product Return form into a shipping box
   - Place the enclosed UPS, pre-paid label on the shipping box
   - Ship the product to Galil Medical

   Upon receipt of the returned product and review of your completed Product Return form, a credit for your purchase price of this product will be applied to your account.

3. **Use a revised needle preparation procedure** when conducting Needle Integrity and Functionality Testing. Follow the preparation procedure as described below:

   Needle Preparation for Integrity and Functionality Testing

   CAUTION. Take care to maintain sterility of each needle during testing.

   1. Fill a large basin (at least 30 cm in diameter) with sterile water or saline.
   2. Secure the needle tubing to the sterile table prior to beginning the needle testing process.
   3. Fill the basin with sterile water or saline.
   4. Place the needles, individually or in groups, in the basin such that the full length of the needle shaft is submerged in the water.
   5. Follow the test steps for Needle Integrity and Functionality Testing as described in a Galil Medical Cryoablation System User Manual.

4. **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.

CONTACT REFERENCE PERSON:

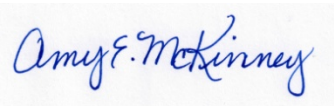
If you have any questions, please contact Galil Medical Customer Service:

USA	+1 877-639-2796
Europe	+44 (0) 1-293-459848
Israel	+972 (4) 9093200

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

Please complete and return the attached response form as soon as possible, but no later than four (4) weeks after receipt of this letter. If you have any questions, please Galil Medical Customer Service.

Sincerely,



Amy E. McKinney
Director, Regulatory Affairs
Galil Medical Inc.

Enc:
Response Form
USP Shipping Label