

«Hospital\_Name»

«Users\_Name» - «Department»

«Customer\_Address»

«Zip\_Code» «City»

«Country\_name»

<Reference: 92611185-FA>

19 November 2020

## **Cover letter for Distributors - Product Advisory IceFORCE™, IcePearl™, IceRod™, IceSphere™, IceSeed™, IceEDGE™ Cryoablation Needles and Prostate Cryoablation Kits**

Dear «Users\_Name»,

Boston Scientific (BSC) is initiating a Product Advisory for the IceFORCE™, IcePearl™, IceRod™, IceSphere™, IceSeed™, IceEDGE™ Cryoablation Needles and Prostate Cryoablation Kits on behalf of Galil Medical Ltd., the legal manufacturer of the products. Please find more information in the attached Field Safety Notice.

### **You are kindly requested to follow the below instructions:**

- 1- Please read this notice and the instructions attached to this Cover letter
- 2- **Please complete the attached Acknowledgement Form even if you do not have any affected product.**
- 3- **When completed, please return the Acknowledgement Form to Boston Scientific office** for the attention of «Customer\_Service\_Fax\_Number» on or before **18 December 2020**.
- 4- **Please notify all your customers that have received affected product of this notification.** To effectively manage this notification, your accounts are to communicate directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this notification to their own customers.

Although Boston Scientific is not physically recalling any product, your Competent Authority is being notified of this Field Safety Notice, unless per local regulation, this task is to be performed by you as a Distributor.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



Marie Pierre Barlanga  
Quality Department  
Boston Scientific International S.A.

Attachments: - Distributor's Acknowledgement Form  
- Field Safety Notice

Please complete the form & Send it to:  
«Customer\_Service\_Fax\_Number»

«Sold\_to» - «Hospital\_Name» - «City» - «Country\_name»

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**Distributor's Acknowledgement Form – Product Advisory  
IceFORCE™, IcePearl™, IceRod™, IceSphere™, IceSeed™, IceEDGE™  
Cryoablation Needles and Prostate Cryoablation Kits**

92611185-FA

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**I acknowledge receipt of the Boston Scientific Field Safety**

**Notice dated 19 November 2020 for the**

**IceFORCE™, IcePearl™, IceRod™, IceSphere™, IceSeed™,  
IceEDGE™ Cryoablation Needles and Prostate Cryoablation Kits**

**and will disseminate this information to our customers.**

NAME\* \_\_\_\_\_ TITLE \_\_\_\_\_

Telephone \_\_\_\_\_ Email \_\_\_\_\_

Distributor' SIGNATURE\* \_\_\_\_\_ DATE\* \_\_\_\_\_

\* Required field

dd/mm/yyyy



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**Reference: 92611185-FA**

19 November 2020

**Urgent Field Safety Notice - Product Advisory**  
**IceFORCE™, IcePearl™, IceRod™, IceSphere™, IceSeed™, IceEDGE™**  
**Cryoablation Needles and Prostate Cryoablation Kits**

Dear «Users\_Name»,

Boston Scientific is voluntarily issuing a Product Advisory for the IceFORCE™, IcePearl™, IceRod™, IceSphere™, IceSeed™, IceEDGE™ Cryoablation Needles and Prostate Cryoablation Kits on behalf of Galil Medical Ltd., the legal manufacturer of the products. This advisory is being communicated in response to recent complaints of gas leaks from the needle shaft that determined some users of these devices are not adhering to the preparation technique described within the products' Instructions for Use (IFU), which ensures needle integrity of the entire needle shaft. This advisory is intended to reinforce existing instructions within the IFU directing users to fully submerge the entire needle shaft in sterile water or saline prior to the patient being anesthetized to identify a possible defective needle, therefore reducing the likelihood of patient harm from a gas shaft leak during the procedure.

If testing is properly performed prior to use a gas leak can be detected and the device can be exchanged prior to patient exposure with no adverse health consequences. The most serious potential injury would be due to incomplete integrity and functionality testing creating the risk of gas entry inside the body with the potential of life-threatening gas embolism. While the most severe outcome has not been reported, there have been two complaints of patient harm that required medical intervention to remove gas from chest cavities.

**Technique as described within the IFU**

Below is an excerpt taken from the IFU, to reiterate the proper technique. When the device is prepared and tested as per instructions in the IFU, a shaft leak would be clearly identifiable to the user and the device would be exchanged for another.

## Section 5:

- **BEFORE THE PATIENT IS ANESTHETIZED**, Needle Integrity and Functionality Tests on each cryoablation needle and thermal sensor must be completed successfully.
- A defective cryoablation needle with a gas leak can cause a gas embolism in the patient. Such needle must never be used and should be returned to Boston Scientific for evaluation.

## Section 9.1 Needle Preparation

1. Using aseptic technique, carefully remove the cryoablation needle from the package and place in a sterile work area.
2. Prepare a large basin (at least 30 cm in diameter) containing sterile water or saline to conduct the needle testing.

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

- Secure the needle tubing to the sterile table prior to beginning the needle testing process.
- Fill the basin halfway with sterile water or saline.
- Place the needles, individually or in groups, in the basin such that the **full length of the needle** is submerged in the sterile water or saline.

Our records indicate that your facility received some of the concerned product. The **Attachment 1 below provides a complete list of all affected products**, including Product Description, Material Number (UPN), GTIN number, and Lot/Batch numbers and expiry date. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice.**

**NO product is being recalled and you are NOT required to return product to Boston Scientific.**

## **INSTRUCTIONS:**

- 1- Please read this notice and the instructions attached to this letter.
- 2- **Please complete the attached Acknowledgement Form even if you do not have any affected product.**
- 3- **When completed, please return the Acknowledgement Form to your Boston Scientific office** for the attention of «**Customer\_Service\_Fax\_Number**» on or before **18 December 2020.**
- 4- Please pass on this notice to any healthcare professional from your organization that need to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Although Boston Scientific is not physically recalling any product, your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



Marie Pierre Barlanga  
Quality Department  
Boston Scientific International S.A.

Attachment: Acknowledgement Form

## **Attachment 1 : Affected Product Listing**

<b>UPN</b>	<b>UPN Description</b>	<b>GTIN</b>	<b>Lot/Batch</b>	<b>Expiration Dates</b>
FPRPR3602	IceFORCE™ 2.1 CX 90° Cryoablation Needle	07290104831003	All	All
FPRPR3604	IceFORCE™ 2.1 CX Cryoablation Needle	07290104831027	All	All
FPRPR3618	IceFORCE™ 2.1 CX L 90° Cryoablation Needle	07290104831089	All	All
FPRPR3601	IcePearl™ 2.1 CX 90° Cryoablation Needle	07290104830990	All	All
FPRPR3603	IcePearl™ 2.1 CX Cryoablation Needle	07290104831010	All	All
FPRPR3617	IcePearl™ 2.1 CX L 90° Cryoablation Needle	07290104831072	All	All
FPRPR3533	IceRod™ 1.5 CX 90° Cryoablation Needle	07290104830587	All	All
FPRPR3573	IceSphere™ 1.5 CX 90° Cryoablation Needle	07290104831133	All	All
FPRPR4009	IceRod™ 1.5 i-Thaw™ Cryoablation Needle	07290104830204	All	All
FPRPR3508	IceRod™ 1.5 PLUS 90° Cryoablation Needle	07290104830563	All	All
FPRPR3510	IceRod™ 1.5 PLUS Cryoablation Needle	07290104830570	All	All
FPRPR3204	IceRod™ 1.5 90° Cryoablation Needle	07290104830242	All	All
FPRPR3203	IceRod™ 1.5 Cryoablation Needle	07290104830198	All	All
FPRPR3560	IceSphere™ 1.5 90° Cryoablation Needle	07290104830945	All	All
FPRPR3558	IceSphere™ 1.5 Cryoablation Needle	07290104830938	All	All
FPRPR3561	IceSphere™ 1.5 S 90° Cryoablation Needle	07290104830556	All	All
FPRPR3260	IceSphere™ 1.5 90° Cryoablation Needle	07290104830259	All	All
FPRPR3258	IceSphere™ 1.5 Cryoablation Needle	07290104830211	All	All
FPRPR3202	IceSeed™ 1.5 90° Cryoablation Needle	07290104830235	All	All
FPRPR3201	IceSeed™ 1.5 Cryoablation Needle	07290104830181	All	All
FPRPR3506	IceEDGE™ 2.4 90° Cryoablation Needle	07290104830594	All	All
FPRPR3195	IceRod™ 1.5 MRI 90° Cryoablation Needle	07290104830297	All	All
FPRPR3193	IceRod™ 1.5 MRI Cryoablation Needle	07290104830273	All	All
FPRPR3194	IceSeed™ 1.5 MRI 90° Cryoablation Needle	07290104830280	All	All
FPRPR3192	IceSeed™ 1.5 MRI Cryoablation Needle	07290104830266	All	All
FPRPR3605	IceFORCE™ 2.1 CX Prostate Cryoablation Kit	07290104831034	All	All
FPRPR3606	IcePearl™ 2.1 CX Prostate Cryoablation Kit	07290104831041	All	All
FPRPR3607	Three IceFORCE™ 2.1 CX Prostate Cryoablation Kit	07290104831058	All	All
FPRPR3608	Three IcePearl™ 2.1 CX Prostate Cryoablation Kit	07290104831065	All	All
FPRPR3572	IceRod™ i-Thaw™ Prostate Cryoablation Kit	07290104830983	All	All
FPRPR3008	IceSeed™ Prostate Cryoablation Kit	07290104830068	All	All
FPRPR3070	IceRod™ Prostate Cryoablation Kit	07290104830082	All	All
FPRPR3570	Five IceSphere™ Prostate Cryoablation Kit	07290104830969	All	All
FPRPR3571	Five IceRod™ i-Thaw™ Prostate Cryoablation Kit	07290104830976	All	All
FPRPR4070	IceRod™ i-Thaw™ Prostate Cryoablation Kit	07290104830105	All	All
FPRPR4518	IceSeed™ Prostate Cryoablation Kit	07290104830075	All	All
FPRPR4570	IceRod™ He-Thaw Prostate Cryoablation Kit	07290104830099	All	All