Rev 1: June 2019
FSN Ref: FSN-F183-01 FSCA Ref: FSCA-F183-01

Date: 13 June 2019

Urgent Field Safety Notice (FSN)
Barricaid® Prosthesis

Dear Health Care Practitioner,

The purpose of this letter is to inform you of a corrective action that Intrinsic Therapeutics is introducing in relation to the Barricaid Prosthesis. Our records indicate that you have used the medical device with patient(s).

We are providing you important information regarding an issue with the implant card that may have been provided with the product. Please review this information carefully with relevant members of your staff.

The action has also been reported to the relevant regulatory authorities in your country.

If you need further information or support concerning the issue, please contact us at FSCA@in-thera.com.

Intrinsic Therapeutics apologizes for any inconvenience caused by this issue.

Kind regards,

David Johnson
Vice President of Quality and Compliance

1 Information on Affected Device

1.1 Device Type & Commercial name

Barricaid® Prosthesis

1.2 Primary clinical purpose of device(s)*

The Barricaid prosthesis is intended as an adjunct to a lumbar discectomy procedure as a means to maintain the relative position of nucleus within the disc space, thereby reducing the risk of a recurrent herniation.

1.3 Lots affected

All lots supplied after May 11, 2011 are affected. See attached list for the affected products supplied to your hospital.

2 Reason for Field Safety Corrective Action (FSCA)*

2.1 Description of the product problem

Patients that had the Barricaid® Prosthesis implanted in Germany, Switzerland and Austria after May 11, 2011 received an implant card that states that, "*The implant is….safe for use with….magnetic resonance imaging.*" (No other countries are affected by this FSN.) This card indicates that the implant is safe for use with Magnetic Resonance Imaging (MRI), however the effect of MRI has not been determined outside of the tested range. Specifically the appropriate language should be as follows:

> *"Non-clinical testing demonstrated that the Intrinsic Therapeutics Barricaid device is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:*
>
> - *Static magnetic field of 1.5-Tesla and 3-Tesla, only*
> - *Maximum spatial gradient magnetic field of 3000 Gauss/cm or less*
> - *Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system*
>
> *Under the scan conditions defined, the Intrinsic Therapeutics Device is expected to produce a maximum temperature rise of 1.6˚C after 15-minutes of continuous scanning."*

2.2 Hazard giving rise to the FSCA*

The residual risk to the patient is considered low, given that it is not typical to be scanned outside the parameters tested. In the case that such scanning was to occur the clinical risk of implant movement or over-heating is considered limited, however not tested. There might be a potential residual risk related to the use outside the tested parameters: Magnetic field interactions and heating potentially pose a risk to a patient with a metallic implant.

2.3 Probability of problem arising

Based on the assessment it can be concluded that the level of occurrence is limited, however that the severity of the risk cannot be determined. Therefore there is a residual risk to the patient that needs to be communicated.

3 Type of Action to be taken

It is imperative that you perform the following actions:

- Discard any implant cards still in your possession.
- Contact all patients who may have received an implant card since May 11, 2011. These implant cards contain the information that the implant is safe for use with magnetic resonance imaging.
- Provide those patients the following materials (supplied by Intrinsic Therapeutics):
  - Updated implant card with appropriate MR compatibility information.
  - Sticker with appropriate MR compatibility information (to be placed by the patient on their existing implant card if they still have it, since that card contains the original lot and serial information of their implant).

Intrinsic Therapeutics does not require extra follow-up of patients or review of patients' previous results.

Complete and return the reply form to: FSCA@in-thera.com as soon as the action is completed

Customer Reply Form

1. Field Safety Notice (FSN) information			
FSN Reference number	FSCA-F183-01	FSN Date	TBD
Device name	Barricaid® Prosthesis		
Product Code(s)	BAR-D8-8X14, BAR-D8-10X14, BAR-D8-12X14		

2. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation **ALL ITEMS MUST BE CHECKED – PLEASE SEE CONTACT INFORMATION BELOW IF YOU HAVE ANY QUERIES.**			
☐	I confirm receipt of the Field Safety Notice and that I have read and understood its content.	Customer to complete or enter N/A	
☐	All actions requested by the FSN have been completed.	Customer to complete or enter N/A	
☐	I have destroyed affected implant cards.	Qty:	
		date	
		N/A (no implant cards available)	Comments:
Print Name*		Customer print name here	
Signature*		Customer sign here	
Date*			

4. Return acknowledgement to sender	
Email	FSCA@in-thera.com
Postal Address	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	Pre-filled by manufacturer/sender/requester

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

TEMPLATE PATIENT LETTER

[HOSPITAL LETTERHEAD]

DATE

Dear patient,

We are writing to you in association with the Barricaid Prosthesis that was implanted at our hospital. When you were discharged, you may have been given an implant card that contained inaccurate MR compatibility information. We are sending you the enclosed card and sticker that contain the accurate information.

The original implant card stated, “The implant is….safe for use with….magnetic resonance imaging.” This card indicates that the implant is safe for use with Magnetic Resonance Imaging (MRI), however the effect of MRI has not been determined outside of the tested range. Specifically the appropriate language is:

> Non-clinical testing demonstrated that the Intrinsic Therapeutics Barricaid device is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:
>
> - Static magnetic field of 1.5-Tesla and 3-Tesla, only
> - Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
> - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system
>
> Under the scan conditions defined, the Intrinsic Therapeutics Device is expected to produce a maximum temperature rise of 1.6˚C after 15-minutes of continuous scanning.

If you undergo an MRI scan outside these parameters, there is some possibility that your implant could heat up or move slightly which could cause you some pain and/or discomfort.

If you have your original implant card (which includes the device lot and serial number), please place the enclosed sticker over the prior instructions. If you do not have your original implant card, please retain the enclosed implant card instead.

Please be in touch with me if you have any questions or concerns.