

Urgent Field Safety Notice

Pre-Loaded Barricaid® Delivery Tool

Type of action: (Field Safety Notice– Corrective Action)

Date: 6 January 2015

Attention: All Authorized Intrinsic Therapeutics Medical Professionals.

Details of affected devices:

Type of device and model names: Pre-Loaded Barricaid Delivery Tool which is assembled with the Barricaid Prosthesis Catalogue no. series: BAR-D8-XX x 14 / FG Ref. No. series: 273XX15-EU (Refer to the Model names below in Table 1).

Device description: The Pre-Loaded Barricaid Delivery System Tool is a single use/disposable sub component of the Barricaid Prosthesis finished good device (Ref Nos. 273XX15-EU in Tables 1 and 2). The Barricaid Prosthesis (implant) is pre-loaded on the delivery tool and is utilized during the implantation procedure. The Barricaid Prosthesis and the Barricaid Delivery System Tool are packaged as a single assembly and are provided sterile.

Catalogue no.	FG Ref. No.	Description
BAR-D8-8x14	2730815-EU	Barricaid Prosthesis: 8mm wide Mesh
BAR-D8-10x14	2731015-EU	Barricaid Prosthesis: 10mm wide Mesh
BAR-D8-12x14	2731215-EU	Barricaid Prosthesis: 12mm wide Mesh

Table 1: Available sizes of Barricaid Prosthesis which are implanted using the Pre-Loaded Barricaid Delivery Tool

Intrinsic Therapeutics Inc. is issuing this Field Safety Notice/ Corrective Action for specific lots of the Pre-Loaded Barricaid Delivery Tool that were not manufactured according to specification. The affected Lots of Pre-Loaded Barricaid Delivery Tools are listed in Table 2 below.

Catalogue no.	FG Ref. No.	Lot / Batch No.	Mfr. Date (YY-M-DD)	Exp. Date (YY-M-DD)	Catalogue no.	FG Ref. No.	Lot / Batch No.	Mfr. Date (YY-M-DD)	Exp. Date (YY-M-DD)
BAR-D8-8x14	2730815-EU	01061401	13-Jan-14	17-Feb-17	BAR-D8-12x14	2731215-EU	04111305	19-Apr-13	24-May-16
BAR-D8-10x14	2731015-EU	01061402	13-Jan-14	17-Feb-17	BAR-D8-8x14	2730815-EU	05121401	19-May-14	23-Jun-17
BAR-D8-10x14	2731015-EU	01061403	13-Jan-14	17-Feb-17	BAR-D8-10x14	2731015-EU	05121402	19-May-14	23-Jun-17
BAR-D8-12x14	2731215-EU	02281402	17-Mar-14	21-Apr-17	BAR-D8-8x14	2730815-EU	05141302	20-May-13	24-Jun-16
BAR-D8-8x14	2730815-EU	03141401	24-Mar-14	28-Apr-17	BAR-D8-8x14	2730815-EU	05141303	20-May-13	24-Jun-16
BAR-D8-8x14	2730815-EU	02081301	15-Feb-13	22-Mar-16	BAR-D8-12x14	2731215-EU	05141307	20-May-13	24-Jun-16
BAR-D8-8x14	2730815-EU	02081302	15-Feb-13	22-Mar-16	BAR-D8-10x14	2731015-EU	05141308	20-May-13	24-Jun-16
BAR-D8-8x14	2730815-EU	02081303	15-Feb-13	22-Mar-16	BAR-D8-8x14	2730815-EU	06071305	17-Jun-13	22-Jul-16
BAR-D8-10x14	2731015-EU	02081304	15-Feb-13	22-Mar-16	BAR-D8-12x14	2731215-EU	06071307	17-Jun-13	22-Jul-16
BAR-D8-10x14	2731015-EU	02081305	15-Feb-13	22-Mar-16	BAR-D8-12x14	2731215-EU	06071308	17-Jun-13	22-Jul-16
BAR-D8-12x14	2731215-EU	02081306	15-Feb-13	22-Mar-16	BAR-D8-8x14	2730815-EU	06071309	17-Jun-13	22-Jul-16
BAR-D8-8x14	2730815-EU	03131301	25-Mar-13	29-Apr-16	BAR-D8-10x14	2731015-EU	06071310	17-Jun-13	22-Jul-16
BAR-D8-8x14	2730815-EU	03131302	25-Mar-13	29-Apr-16	BAR-D8-10x14	2731015-EU	07191302	2-Aug-13	6-Sep-16
BAR-D8-8x14	2730815-EU	03131303	25-Mar-13	29-Apr-16	BAR-D8-8x14	2730815-EU	09121301	23-Sep-13	28-Oct-16
BAR-D8-10x14	2731015-EU	03131304	25-Mar-13	29-Apr-16	BAR-D8-8x14	2730815-EU	09121302	23-Sep-13	28-Oct-16
BAR-D8-10x14	2731015-EU	03131305	25-Mar-13	29-Apr-16	BAR-D8-10x14	2731015-EU	09121303	23-Sep-13	28-Oct-16
BAR-D8-12x14	2731215-EU	03131306	25-Mar-13	29-Apr-16	BAR-D8-10x14	2731015-EU	09121304	23-Sep-13	28-Oct-16
BAR-D8-12x14	2731215-EU	03131307	25-Mar-13	29-Apr-16	BAR-D8-12x14	2731215-EU	09121305	23-Sep-13	28-Oct-16
BAR-D8-12x14	2731215-EU	03131308	25-Mar-13	29-Apr-16	BAR-D8-12x14	2731215-EU	09121306	23-Sep-13	28-Oct-16
BAR-D8-10x14	2731015-EU	04111303	19-Apr-13	24-May-16	BAR-D8-10x14	2731015-EU	11061301	18-Nov-13	23-Dec-16
BAR-D8-12x14	2731215-EU	04111304	19-Apr-13	24-May-16					

Table 2: Finished Goods devices and lot numbers affected.

Description of the Problem: The Pusher Assembly component of the affected Pre-Loaded Barricaid Delivery Tool has the potential to fracture and separate into two parts during impaction (i.e., the distal end of the Pusher Assembly becomes separated from the proximal end of the Pusher Assembly). Five such reports have been received by the manufacturer, that results in a rate of ~1% of surgeries performed. Appropriate implant placement has not been impacted, and no reports of patient harm have been received.

If the Pusher Assembly separates during implantation of the Barricaid Prosthesis, there is the potential for the Pusher Alignment Pin and / or distal end of the Pusher Assembly to become exposed or detached, possibly extending the surgery in order to remove the components. Although the Pusher Alignment Pin should be easily visible to the surgeon, there is the potential for the Pusher Alignment Pin to become detached from the Pusher Assembly and left in the patient if not observed during surgery, which could result in a foreign body reaction.

The Pusher Assemblies manufactured during a specific period between January 2013 and June 2014 were not made to Intrinsic Therapeutics' specifications due to a manufacturing process error. This issue has since been corrected on all other (and future) Preloaded Barricaid Delivery Tools. Only the lots listed above in Table 2 are affected.

Field Safety Notice/ Corrective Actions: Please check Table 2 on page 1 and 2 of this Field Safety Notice as a matter of urgency. Affected Pre-Loaded Barricaid Delivery Tools (i.e., those with Lot/Batch numbers included in Table 2) should be quarantined and returned to Intrinsic Therapeutics to be exchanged for unaffected devices. To do this, complete the "Request for exchange of affected devices" section at the bottom of Attachment A on page 4 of this FSN and send it back to Intrinsic Therapeutics Inc., noting the finished goods Ref. number(s), Lot/Batch number(s) and total number of affected devices being returned for exchange.

Transmission of this Field Safety Notice: This notice shall be passed on to all those who need to be aware within your organization(s) or to any organization(s) where these products may have been transferred. To confirm receipt of this FSN please complete and return Attachment A on page 4 of this FSN.

We sincerely apologize for any inconvenience this issue may have caused to your organisation.

For any enquiries about this Field Safety Notice or the Pre-loaded Barricaid Delivery Tool please contact your local authorized distributor or representative.

If you need any further information or support concerning this issue, please contact one of the following:

CONTACT (PRODUCT EXCHANGE):

DAVID B. JOHNSON | Director of Quality
Intrinsic Therapeutics Inc.
30 Commerce Way, Woburn, MA 01801, USA
Office: +1 (781) 932-0222 x117
Fax: +1 (781) 932-0252
Email: djohnson@in-thera.com

CONTACT (REGULATORY INQUIRIES):

EUROPEAN AUTHORIZED REPRESENTATIVE
Gerhard Frömel
MPS Medical Product Service GmbH
Borngasse 20
35619 Braunfels
Germany
Phone: +49 (0) 6442 962073
Fax: +49 (0) 6442 962074
Email: g.froemel@mps-gmbh.eu

The undersigned confirms that the appropriate Regulatory Agencies have been notified.

Sincerely,

MARY MCNAMARA-CULLINANE | Senior Director of Regulatory Affairs

Intrinsic Therapeutics Inc.
30 Commerce Way, Woburn, MA 01801, USA
Office: +1 (781) 932-0222 x120 | Fax: +1 (781) 932-0252
Email: mmcnamara@in-thera.com

ATTACHMENT A:

Completing this attachment shall serve as your organization’s acknowledgment of receipt of the Field Safety Notice related to the Pusher Assembly component within the affected Pre-Loaded Barricaid Delivery Tools.

REQUEST FOR EXCHANGE OF AFFECTED DEVICES:

Affected Pre-Loaded Barricaid Delivery Tools (i.e., those with Lot/Batch numbers included in Table 2) should be quarantined and returned to Intrinsic Therapeutics to be exchanged for unaffected devices (Please check the appropriate box below).

NO, our organization has no affected product in stock which shall be returned to Intrinsic Therapeutics. (Please complete **Section 1** below).

YES, our organization has affected product in stock (which has been quarantined) which shall be returned to Intrinsic Therapeutics and exchanged for unaffected devices (Please complete **Section 1 and Section 2** below).

Please fill in the information below accordingly and return immediately to Intrinsic Therapeutics Inc. via one of the following methods:

Post: 30 Commerce Way, Woburn, MA 01801, USA | **Email:** djohnson@in-thera.com | **Fax:** +1 (781) 932-0252

SECTION 1: ORGANIZATION INFORMATION

Print Name:	
Signature:	
Organization:	
Address:	
City:	
Country:	
Telephone:	
Email:	

SECTION 2: REQUEST FOR EXCHANGE OF AFFECTED DEVICES

Finished Goods Ref. No.	Lot / Batch No. & - Serial No.	No. of affected devices being returned for exchange identified with the Lot / Batch No.
<i>Example: 2730815-EU</i>	<i>01061401-01 thru 01061401-10</i>	<i>10</i>