URGENT FIELD SAFETY NOTICE/ PRODUCT RECALL

HARD COPY VIA FEDEX SECOND DAY WITH DELIVERY CONFIRMATION &
SOFT ELECTRONIC COPY TO KHORN@OSCOR.COM WITH READ RECEIPT

July 3, 2017

OSCOR EUROPE GMBH
KATHARINA HORN
FRITZ-VOMFELDE-STRAßE 6
DUSSELDORF, 40547, GERMANY

RE: URGENT FIELD SAFETY NOTICE Voluntary Product Removal of Certain Lots of ATAR™ Extension Cables
Recall Number: 1035166-06/01/2017-01-R

Dear Customer,

The purpose of this letter is to inform you that Oscor Inc. is voluntarily recalling certain lots of ***ATAR™ Extension Cables.*** Refer to "Exhibit A" attached for the list of affected lot numbers/models sold to your organization. The FDA has been notified and is aware Oscor Inc. is voluntarily taking this action.

REASON FOR THE VOLUNTARY PRODUCT REMOVAL:
During the use of some ATAR™ extension cables, the cable was separating from the connector at the proximal end. The analysis of the returned devices revealed that the connector and wire separation was attributed to a fracture of the conductor cable likely caused by extensive use. This event resulted in cable malfunction, causing interruption of the pacing system. Oscor received a total of 66 complaints related to that failure mode, of which 5 resulted in patient injuries. No deaths were reported; however the risk for possible injury is a concern if the cable separates during use.

WARNING:
For pacing dependent patients, an interruption of pacing system could result in serious injury or death if not detected. Continuous monitoring is required.

WHAT TO DO:
- Immediately check your inventory against the list provided with this letter listed on Exhibit A to confirm that you do or do not have units from these lot(s) in your possession.
- Identify and set aside any unit from the identified lot(s) in a manner that ensures the affected product will not be used. Check all storage and quarantine in a secure location to avoid new shipments to your customers.
- Please pull a list of the hospitals (end users) impacted by the affected lot(s) and communicate these recall instructions immediately.
- Retrieve inventory from all impacted customers to be returned to Oscor as instructed on Exhibit A.
- Review, complete, sign and return the enclosed Acknowledgement Form – Exhibit A attached to this letter, directly to Oscor Inc. at the fax number or e-mail on the form for immediate replacement (as applicable).

WHO TO CALL:

Please call Oscor Inc. Customer Service Department at 727-937-2511 or e-mail RGA@Oscor.com. Oscor hours of operation are Monday to Friday from 8:30AM to 5:30PM Eastern Time.

Should you experience any adverse reactions or quality problems with the use of this product it may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax at 1-800-FDA-0178; by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787; or on the MedWatch website at www.FDA.GOV/MedWatch

We apologize for the inconvenience this has caused you, and will use or best efforts to correct this situation as soon as possible. Thank you.

Sincerely,

Mary Wheeler

Mary Wheeler
Customer Relations Manager
Oscor Inc.

Enclosure: Exhibit A – Product Listing Affected Lots
CC: Oscor Customer File
Oscor Regulatory Department
Oscor Quality Group

July 3, 2017

OSCOR EUROPE GMBH
KATHARINA HORN
FRITZ-VOMFELDE-STRAßE 6
DUSSELDORF, 40547, GERMANY

EXHIBIT A

Voluntary Product Removal of Certain Lots of ATAR™ Extension Cables
Recall Number: 1035166-06/01/2017-01-R

ATAR™ REUSABLE EXTENSION CABLES: (Unit of Measure = EA)

TABLE 1: IMPACTED LOT(S) SOLD TO YOUR ORGANIZATION BY OSCOR INC.							
	1	2	3	4	5	6	7
Line #	**CO #**	**Oscor Part #**	**Description**	**Lot #**	**Ship Date**	**Qty/Lot (UM EA)**	**Qty of Units in Customer Inventory**
1	CO-021215-010	4B-81-530Z-G	ATAR-A, DARK BLUE REUSABLE	D2-02824	2/26/2015	5	
2	CO-021215-010	4B-81-530Z-X	ATAR-MDT2 REUSABLE	D2-02582	2/26/2015	5	
3	CO-021215-010	4B-81-530Z-H	ATAR-V, WHITE REUSABLE	D2-02764	2/26/2015	5	
4	CO-021215-010	4B-81-531Z-S	ATAR-V2 REUSABLE	D2-02787	2/26/2015	5	

TABLE 2: INVENTORY RECONCILIATION FOR INVENTORY RETURNIING TO OSCOR INC.							
	1	2	3	4	5	6	7
Line #	**Model #**	**Lot #**	**Qty in Inventory**	**Qty Sold By Distributor**	**Units Used By End User**	**Total Units Returned From Customer**	**Total Units Returning to Oscor Per Lot**
1	4B-81-530Z-G	D2-02824					
2	4B-81-530Z-X	D2-02582					
3	4B-81-530Z-H	D2-02764					
4	4B-81-531Z-S	D2-02787					

ATAR™ DISPOSABLE EXTENSION CABLES: (Unit of Measure = Box of 5)

TABLE 1: IMPACTED LOT(S) SOLD TO YOUR ORGANIZATION BY OSCOR INC.							
	1	2	3	4	5	6	7
Line #	**CO #**	**Oscor Part #**	**Description**	**Lot #**	**Ship Date**	**Qty Of Cables**	**Qty of Units in Customer Inventory**
1	CO-060614-007	4B-81-530Z-A	ATAR D-A, DARK BLUE DISPOSABLE	D2-02535	06/17/14	50	
2	CO-060614-007	4B-81-530Z-B	ATAR D-V, WHITE DISPOSABLE	D2-02536	06/17/14	50	
3	CO-021215-010	4B-81-530Z-D	ATAR D-MDT DISPOSABLE	D2-02766	02/26/15	25	
4	CO-031716-025	4B-81-530Z-W	ATAR D-R NP DISPOSABLE	B4-13018	03/23/16	10	
5	CO-021215-010	4B-81-530Z-Z	ATAR D-MDT2	D2-02582	02/26/15	25	
6	CO-021215-010	4B-81-531Z-J	ATAR D-V2	D2-02737	02/26/15	25	
7	CO-122815-004	4B-81-531Z-J	ATAR D-V2	D2-02755	01/11/16	15	
8	CO-011917-010	4B-81-531Z-J	ATAR D-V2	D2-04281	03/14/17	15	
9	CO-011917-010	4B-81-531Z-J	ATAR D-V2	D2-04282	03/14/17	5	

TABLE 2: INVENTORY RECONCILIATION FOR INVENTORY RETURNIING TO OSCOR INC.							
	1	2	3	4	5	6	7
Line #	**Model #**	**Lot #**	**Qty in Inventory**	**Qty Sold By Distributor**	**Units Used By End User**	**Total Units Returned From Customer**	**Total Units Returning to Oscor Per Lot**
1	4B-81-530Z-A	D2-02535					
2	4B-81-530Z-B	D2-02536					
3	4B-81-530Z-D	D2-02766					
4	4B-81-530Z-W	B4-13018					
5	4B-81-530Z-Z	D2-02582					
6	4B-81-531Z-J	D2-02737					
7	4B-81-531Z-J	D2-02755					
8	4B-81-531Z-J	D2-04281					
9	4B-81-531Z-J	D2-04282					

DISTRIBUTOR INSTRUCTIONS:

1. If you have inventory from these lots at your location, please set aside in a manner that ensures the affected product will not be used or shipped to a hospital/end user.
2. Please notify your customers immediately of this recall and retrieve any inventory from their location. Please ensure your customer(s) set aside affected inventory in a manner that ensures the affected product will not be used and returned to you (to be returned to Oscor).
3. Please confirm the number of units which are in your inventory from the lot(s) referenced on Table 1 above (complete Column 7). Even if the quantity is at 0 (zero), please complete the form in its entirety and return via e-mail at RGA@Oscor.com or via Fax at 727-934-9835.
4. Upon receipt of the above completed form (Exhibit A), Oscor's Customer Service Team will review and provide a Returned Goods Authorization (RGA) number with shipping instructions for units being returned. You may also e-mail RGA@Oscor.com with any questions or additional information required.
5. Oscor's Customer Service Team will provide you with a confirmation of the replacement units as applicable.

Please provide the name and title of the person responsible at your organization for managing this recall request:

NAME:	**TITLE:**
SIGNATURE:	**DATE:**
PHONE #:	**E-MAIL:**

Please return the ***completed*** form via e-mail to RGA@Oscor.com or via Fax at 727-934-9835. Should you have any questions please contact our Customer Service Team at 727-937-2511. Thank you for your support and we do apologize for any inconvenience caused.

END OF DOCUMENT