DATE

DISTRIBUTOR NAME
STREET ADDRESS
CITY, STATE, ZIP CODE, COUNTRY

DISTRIBUTOR NOTIFICATION - HARD COPY VIA FEDEX SECOND DAY WITH DELIVERY CONFIRMATION & SOFT ELECTRONIC COPY TO EMAIL@XXXX.COM WITH READ RECEIPT

RE: URGENT FIELD SAFETY NOTICE Voluntary Product Removal of Certain Lots of TB Unshrouded Bipolar Pacing Leads Recall Number: 1035166-09/07/2018-01-R

Dear Customer,

The purpose of this letter is to inform you that Oscor Inc. is voluntarily recalling certain lots of **TB Unshrouded Bipolar Pacing Leads.** Refer to "Exhibit A" attached for the list of affected lot numbers/models sold to your organization. Please pass this notification to all those who need to be aware of this within your organization. All relevant National Competent Authorities have been advised of the FSCA.

REASON FOR THE VOLUNTARY PRODUCT REMOVAL:

EVENT DESCRIPTION: During the use of some TB – Temporary Bipolar Pacing Leads, featuring the 2mm unshrouded connectors, the connector cap housing may slide and potentially expose the connection wire. In some instances, this may cause the wire to be more susceptible to loss of connectivity or breakage during movement of the cables causing interruption of the pacing system.

REASON FOR RECALL: In the last six years, a total of four serious injuries were reported to Oscor which were attributed to the above connector cap malfunction. No deaths were reported; however the risk for possible injury is a concern if the connector 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 lots in your possession.
- If you do have inventory from the lots listed on Exhibit A, immediately set aside in a manner that ensures the affected product will not be used. Check all storage, and locations as required. Quarantine all affected inventory in a secure location to avoid new shipments to your customers.
- Please pull a list of your customers (end users) impacted by the affected lot(s) and communicate these recall instructions immediately.
- Retrieve available inventory from all impacted customers (consolidate & quarantine at your location), and once all affected product has been retrieved, please proceed to return to Oscor as instructed on Exhibit A.
- Review, complete, sign and return the enclosed– Exhibit A attached to this letter, directly to Oscor Inc. at the fax number or e-mail listed on the form.

- If you do have product, please do not destroy at your location and ensure units are returned to Oscor for proper disposition. Please contact Oscor's Europe Field Safety Notice Group for a Returned Goods Authorization (RGA) number, shipment and other relevant instructions.
- You may also email FSN@oscor.com with any questions regarding any replacement arrangement as applicable.
- Confirmation that you have taken the appropriate actions to this product recall is required within ten (10) calendar days from receipt date of this email notification.

WHO TO CONTACT:

Please call Oscor Oscor's Europe Field Safety Notice Group at 0049 211 586 786-00 or email FSN@oscor.com. . Oscor Europe business hours are Monday to Friday from 8:30AM to 5:30PM GMT.

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,

Katharina Horn
Customer Relations Manager

T. 0049 211 586 786-00
F. 0049 211 586 786-86
Khorn@oscor.com

Enclosure: Exhibit A – Product Listing Affected Lots
CC: Oscor Customer File
Oscor QA TB Recall File

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EXHIBIT A

Voluntary Product Removal of Certain Lots of TB Unshrouded Bipolar Pacing Leads
Recall Number: 1035166-09/07/2018-01-R

TABLE 1: IMPACTED LOT(S) SOLD TO YOUR ORGANIZATION BY OSCOR EUROPE GMBH								
	1	2	3	4	5	6	7	8
Line	**CO #**	**Part #**	**Description**	**UM**	**Lot#**	**Ship Date**	**Qty. Sold**	**Qty. Returning**
1								
2								
Total Number of Units Sold / Returning from your Organization:								

DISTRIBUTOR INSTRUCTIONS:

1. If you have inventory from these lots at your location, please set aside in a manner that ensures that the affected product will not be used or shipped to a hospital/end user.
2. Notify your customers immediately of this recall and retrieve any inventory from their location. Ensure your customer(s) set aside affected inventory in a manner that assures the affected product will not be used and returned to you (to be returned to Oscor).
3. Confirm the total number of units from the lot(s) referenced in the above Table 1 and complete quantity returning to Oscor. Even if the quantity is at 0 (zero), please complete the form in its entirety and return via e-mail at FSN@oscor.com or via Fax at 0049 211 586 786-86.
4. Upon receipt of the completed form (Exhibit A), if inventory is available to be returned, Oscor's Europe Field Safety Notice Group will issue a Returned Goods Authorization (RGA) number with shipping instructions for units being returned.
5. You may also e-mail FSN@oscor.com with any questions regarding any replacement arrangements 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 FSN@oscor.com or via Fax at 0049 211 586 786-86. Should you have any questions please contact our Oscor's Europe Field Safety Notice Group at 0049 211 586 786-00. Thank you for your support and we do apologize for any inconvenience caused.

END OF DOCUMENT