Medtronic
8200 Coral Sea St. NE
Minneapolis, MN 55112
www.medtronic.com

URGENT FIELD SAFETY NOTICE

Oscor Adelante® Breezeway® 10F Sheath
Sold and distributed by Medtronic as the
ARRIVE™ Braided Transseptal Sheath – Models:

990061-055	990061-070	990061-090	990061-120
990079-055	990079-070	990079-090	

RECALL

3 November, 2016

Medtronic reference: FA745

Dear Health Care Professional, Risk Manager,

Medtronic was recently notified that Oscor has initiated a product recall for certain lots of their Adelante® Breezeway® 8F & 10F sheaths due to a potential for "a fragment of the sheath inner liner to come off during the insertion of the dilator during the preparation of the sheath prior to use."

As indicated in Oscor's Product Recall letter of October 5, 2016, Oscor has received one complaint related to this issue, **which did not result in patient injury**. However, the risk for possible injury is a concern if the sheath is not properly flushed and tested with the dilator prior to use.

Medtronic sells the Oscor Adelante® Breezeway® 10F product as the ARRIVE™ Braided Transseptal Sheath (see models listed above). Our records indicate that your facility has received one or more of the units potentially affected by this issue as listed in Appendix A. As of October 27, 2016, Medtronic has forwarded the one complaint it has received to Oscor to investigate whether it is related to this issue. This complaint **did not result in patient injury**.

Medtronic is requesting that you carry out the actions below; in addition to any requested actions you may have received in the Product Recall sent by Oscor:

- Please review your inventory for impacted ARRIVE™ Braided Transseptal Sheaths as listed in Appendix A .
- Return all unused ARRIVE™ Braided Transseptal Sheaths in your inventory that match the lot numbers listed in Appendix A to Medtronic. Your Medtronic representative will assist you in the return of impacted product as necessary.

For affected product that has been used, no action is necessary and patients should continue to be managed in accordance with your standard patient management protocol.

Please share this notification with others in your organization as appropriate. If product within scope of this recall has been forwarded to another facility, please notify the facility of the issue and assist with the return of affected product.

If you have any questions, please do not hesitate to contact your Medtronic representative at <insert contact information>.

We appreciate your cooperation and apologize for the inconvenience that this issue may cause.

Sincerely,

Local /BU Manager

Appendix A: Affected ARRIVE™ Braided Transseptal Sheath Medtronic Model / Lot Numbers

Medtronic Model Number	Medtronic Lot Numbers					
990061-055	C1-08604	C1-08986	C1-09757	C1-10119	C1-12525	OR-04488
	C1-08938	C1-09756	C1-10118	C1-10147	C1-12665	OR-04633
990061-070	C1-08273	C1-08940	C1-09693	C1-09903	C1-10324	C1-11623
	C1-08340	C1-09102	C1-09742	C1-10041	C1-11439	C1-11852
	C1-08605	C1-09169	C1-09743	C1-10148	C1-11440	OR-04758
	C1-08608	C1-09170	C1-09862	C1-10185	C1-11485	OR-04759
	C1-08816	C1-09361	C1-09863	C1-10214	C1-11622	
990061-090	C1-08939	C1-08985	C1-09584	C1-10120	C1-12493	
990061-120	C1-08466	C1-09857	C1-10215	C1-11438		
990079-055	C1-08936	OR-04635				
990079-070	C1-08310	C1-08802	C1-09859	C1-10039	C1-10241	C1-11849
	C1-08364	C1-08857	C1-09860	C1-10141	C1-10242	C1-11850
	C1-08606	C1-09090	C1-09880	C1-10146	C1-11206	
	C1-08611	C1-09091	C1-09921	C1-10240	C1-11572	
990079-090	C1-08341	C1-08941	C1-09531	C1-09899	C1-10329	C1-11571
	C1-08607	C1-09173	C1-09718	C1-10040	C1-10330	OR-04757
	C1-08803	C1-09394	C1-09748	C1-10149	C1-10382	