


Medtronic
Medtronic, Inc.

8200 Coral Sea Street NE

Mounds View, MN 55112

www.medtronic.com
URGENT FIELD SAFETY NOTICE
**Medtronic Interventional Wires and Attain Hybrid® Guidewires
Model and Lot Numbers: See Attached List
Recall**

October 21, 2013

Medtronic Reference: FA594

Dear Healthcare Professional (Hospital Administrator, OR Manager, and Risk Manager)

Medtronic has identified the potential for an issue with a specific subset of lot numbers of the Medtronic Interventional Wires and ATTAIN HYBRID® Guidewires where the PTFE (polytetrafluoroethylene) coating could delaminate and detach from the Guidewire. As a result, we are recalling the Guidewires from specific lots as noted in the attached list. This issue affects a subset of the following Medtronic Guidewires manufactured from mid April 2013:

Cougar® NITINOL WORKHORSE GUIDEWIRE	COUGAR® Steerable Guidewire
Zinger® STAINLESS STEEL WORKHORSE GUIDEWIRE	ZINGER® Steerable Guidewire
Thunder®EXTRA-SUPPORT GUIDEWIRE	THUNDER® Steerable Guidewire
ProVia® CROSSING GUIDEWIRE	ATTAIN HYBRID® Guide Wire

Delamination and detachment of the PTFE coating may lead to embolic occlusion and thrombosis in coronary, cerebral, peripheral or pulmonary vasculature. Vascular thrombosis and/or occlusion have the potential to result in irreversible damage or injury to vital organs including myocardial infarction or stroke.

Through October 15, 2013, Medtronic has received a total of four (4) complaints related to this issue. Medtronic has received no reports of patient deaths as a result of this issue.

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.

Our records show that your facility has received one or more of these Guidewires, as shown in the attachment to this notification. Consequently, Medtronic requests you immediately take the following actions:

Consequently, Medtronic requests you immediately take the following actions:

1. Remove and quarantine all potentially affected Guidewires that remain in your inventory.
2. Return the potentially affected Guidewires to Medtronic. Your local Medtronic representative will assist you with this device return. If replacement product is needed, your Medtronic representative can assist you with identifying suitable replacement product.

Medtronic has taken the necessary steps to prevent any future shipment of the potentially affected product. Regulatory agencies will be notified about this recall as applicable.

Please share this notification with others in your organization as appropriate. If any Guidewires within the scope of this recall have been forwarded to another facility, please notify that facility accordingly and facilitate the retrieval of the affected product.

We apologize for the inconvenience this may cause you; please be assured that patient safety and product quality remain our primary concern. Should you have any questions, please contact your Medtronic representative.

Sincerely,


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URGENT MEDICAL DEVICE RECALL
Medtronic Interventional Wires and ATTAIN HYBRID® Guide Wires
Model and Lot Numbers

October 21, 2013

Medtronic Model Numbers:

15PROV300HS	CGRLS300HS	CGRXT300J	LVCXT190S	THNDR190J	ZNGRMS180S
3PROV180HS	CGRLS300S	CGRXT300S	LVTNDR190S	THNDR190S	ZNGRS180HJ
3PROV180SS	CGRXT190HJ	GWR419478	LVZRLS180J	THNDR300J	ZNGRS180HS
3PROV300HS	CGRXT190HS	GWR419488	LVZRLS180S	THNDR300S	ZNGRS180S
3PROV300SS	CGRXT190J	GWR419688	LVZRMS180J	ZNGRLS180HJ	
CGRLS190HJ	CGRXT190S	LVCLS190J	LVZRMS180S	ZNGRLS180HS	
CGRLS190HS	CGRXT300HJ	LVCLS190S	LVZRXT180J	ZNGRMS180HJ	
CGRLS190S	CGRXT300HS	LVCXT190J	LVZRXT180S	ZNGRMS180HS	

Affected Lot Numbers:

6752371	G13A00108	G13A00874	G13A01354	G13A01639	GV846
6752383	G13A00109	G13A00910	G13A01355	G13A01640	GV847
6752385	G13A00110	G13A00911	G13A01400	G13A01641	GV848
6759937	G13A00112	G13A00920	G13A01401	G13A01650	GV849
6759939	G13A00113	G13A00921	G13A01409	G13A01651	GV851
6759941	G13A00114	G13A00931	G13A01410	GT414	GV852
6769772	G13A00116	G13A00936	G13A01411	GU543	GV854
6781453	G13A00117	G13A00937	G13A01446	GV117	GV875
6781454	G13A00118	G13A00939	G13A01447	GV118	GV876
6781455	G13A00123	G13A00940	G13A01449	GV121	GV919
6808160	G13A00130	G13A00971	G13A01450	GV259	GW405
6808161	G13A00692	G13A00972	G13A01452	GV260	GW406
6808164	G13A00713	G13A00973	G13A01477	GV261	GW407
6808165	G13A00715	G13A00974	G13A01478	GV276	GW508
6808166	G13A00716	G13A00975	G13A01569	GV287	GW509
6808167	G13A00734	G13A00976	G13A01584	GV381	GW510
6831243	G13A00735	G13A00977	G13A01600	GV382	GW547
6840866	G13A00788	G13A00978	G13A01601	GV827	GW594
6840878	G13A00792	G13A00979	G13A01604	GV829	GW675
6840879	G13A00794	G13A00980	G13A01605	GV830	GW683
6866694	G13A00803	G13A00981	G13A01606	GV831	GW687
6866696	G13A00804	G13A00982	G13A01607	GV832	GW688
6866697	G13A00805	G13A01016	G13A01608	GV835	GW690
6873688	G13A00809	G13A01017	G13A01609	GV836	GW695
6873692	G13A00810	G13A01270	G13A01620	GV837	GW706
6873694	G13A00811	G13A01271	G13A01621	GV838	GW710
G13A00104	G13A00814	G13A01300	G13A01622	GV839	GW745
G13A00105	G13A00815	G13A01324	G13A01623	GV840	GW746
G13A00106	G13A00843	G13A01330	G13A01624	GV844	GW758
G13A00107	G13A00870	G13A01352	G13A01638	GV845	GW761
					GW768