



Medtronic

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, please contact your local Medtronic representative **Ameesa- +966 2 653 0306** who 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,

Amer Sidani
Business Manager Coronary & RDN – MENA



Medtronic

URGENT MEDICAL DEVICE RECALL

Medtronic Interventional Wires and ATTAIN HYBRID® Guide Wires

Model and Lot Numbers

CRDM information underlined and **Coronary** information in **bold**.

Medtronic Model Numbers:

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

Affected Lot Numbers:

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