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Urgent Field Safety Notice

Amphirion® Deep Percutaneous Transluminal Angioplasty (PTA) Balloon Dilation Catheter
Affected Model and Lot Numbers Noted in Appendix A

Recall

October 2015

Medtronic reference: FA684

Dear Risk Manager or Health Care Professional:

The purpose of this letter is to advise you that Medtronic is conducting a voluntary Urgent Medical Device Recall of select lots of the Amphirion® Deep PTA Balloon Dilation Catheter. This recall has been initiated due to a potential breach of the pouch seal for the product manufactured in these select lots. A complete list of all models and lots affected by this recall is provided in Appendix A of this communication. According to Medtronic's records, you have received one or more of the potentially affected catheters. This issue does not affect any other Medtronic products or implantable devices.

It is important to note that, through 15 October 2015, Medtronic has received no customer complaints or reports of adverse patient events regarding improperly sealed pouches. The potential for a breach in the pouch enclosing the sterilized product was discovered during internal packaging testing, which involves exposure to extreme use conditions.

Despite the lack of field complaints associated with this issue, Medtronic is taking precautions to execute this recall as a pouch seal breach could potentially result in compromised sterility of the product**. Patients who have received treatment with an Amphirion® Deep PTA Balloon Dilation Catheter affected by this recall should continue to be monitored in accordance with your standard practice.**

Our records indicate that your facility has received one or more of the affected units as defined by model and lot numbers indicated below. Medtronic is asking that you take the following actions if not already completed:

- Immediately quarantine and remove all potentially affected products that remain in your inventory.
- Return all affected product in your inventory to Medtronic. Your Medtronic Sales Representative will assist with the return and credit of affected product.

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.

The Competent authority of your country has been notified of this action.

For questions related to this communication, please contact your Medtronic representative. Medtronic is committed to ensuring its products meet the highest quality standards. We appreciate your cooperation and apologize for any inconvenience this issue may cause.

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland

Amphirion® Deep Percutaneous Transluminal Angioplasty (PTA) Balloon Dilation Catheter
Appendix A: Affected Model and Lot Numbers

Affected Amphirion Deep PTA Balloon Dilation Catheter Models (OUS):

AMD015020002	AMD020120152	AMD025150152	AMD030150152	AMD040120002	AMD335210002
AMD015020151	AMD020150002	AMD030040002	AMD035040152	AMD040120152	AMD335210152
AMD015020152	AMD020150152	AMD030040152	AMD035120002	AMD040150002	AMD354210002
AMD020040002	AMD025040152	AMD030080002	AMD035150002	AMD040150152	AMD354210152
AMD020040152	AMD025080152	AMD030080152	AMD035150152	AMD225210002	
AMD020080002	AMD025120002	AMD030120002	AMD040040152	AMD225210152	
AMD020080152	AMD025120152	AMD030120152	AMD040080002	AMD253210002	
AMD020120002	AMD025150002	AMD030150002	AMD040080152	AMD253210152	

Affected Amphirion Deep PTA Balloon Dilation Catheter Lots (OUS):

209406892	209436627	209471309	209532768	209551998	209633607	209664057	209759610	209760087
209406894	209436628	209471310	209532769	209553420	209633608	209664058	209759612	209760092
209425763	209470464	209471311	209532770	209553421	209633610	209722475	209759614	209793539
209425766	209470465	209471312	209532771	209553422	209633611	209722478	209759615	209794020
209425767	209470466	209471313	209532772	209553423	209633612	209722479	209759616	209794024
209425768	209470467	209471314	209532773	209553424	209633613	209722660	209759617	209821555
209425769	209470468	209471315	209532774	209553426	209633614	209722661	209759618	209821662
209425770	209470469	209507754	209532775	209553427	209633615	209722662	209759619	209821663
209425771	209470470	209507755	209532776	209553428	209633616	209722663	209760060	209821666
209425773	209470471	209507756	209532777	209553429	209633617	209722664	209760061	209821677
209425778	209470472	209507757	209532778	209601495	209633618	209722665	209760062	209855562
209425802	209470473	209507758	209532779	209601496	209633619	209722666	209760063	209855566
209425805	209470474	209509780	209532780	209601499	209633620	209722667	209760064	209882402
209425806	209470475	209509781	209532781	209601620	209633621	209722668	209760066	209882406
209425807	209470476	209509782	209532782	209601621	209633622	209722670	209760068	209900845
209436574	209470477	209509783	209532783	209601625	209633623	209722671	209760069	209900847
209436575	209470478	209509784	209532784	209601628	209633624	209722673	209760070	209900848
209436576	209470479	209509785	209532785	209601629	209633625	209722674	209760073	209900850
209436577	209471300	209509786	209532786	209601630	209633627	209722675	209760076	209900856
209436578	209471301	209530579	209532787	209601631	209633629	209722677	209760077	209900859

209436620	209471302	209532760	209532788	209601633	209664048	209722678	209760078	209917247
209436621	209471303	209532762	209532789	209633600	209664049	209722679	209760079	209917249
209436622	209471304	209532763	209532790	209633601	209664050	209722680	209760081	
209436623	209471305	209532764	209532791	209633602	209664051	209722681	209760082	
209436624	209471306	209532765	209551995	209633603	209664053	209722682	209760083	
209436625	209471307	209532766	209551996	209633604	209664055	209722683	209760084	
209436626	209471308	209532767	209551997	209633606	209664056	209722685	209760085	