

平成 21 年 5 月 19 日

報道関係者各位

日本メドトロニック株式会社

植込み型心臓ペースメーカー Kappa600、Kappa700、Sigma シリーズ
の自主改修について
(クラス I)

1. 改修の概要

植込み型心臓ペースメーカー メドトロニック Kappa 及び Sigma シリーズの一部の製品で、ある特定のワイヤの離脱が通常よりも高い割合で発生していることが確認されたため自主改修いたします。尚、このワイヤは電気回路と電池やコネクタなどの他の部品をつなぐものです。

Kappa 及び Sigma シリーズは発売以来、日本国内において約 9 万個が使用され、全世界では 170 万個以上が使用されています。今回の改修の対象になるものはこのうちの一部で、現在も使用されている 5,970 個 (使用中止が確認できていないものも含む) です。

なお、今回の改修の対象となるものは、全世界では 36,900 個程度と推定されます。

2. 改修する事業者

- (1) 名 称：日本メドトロニック株式会社
代表取締役社長 島田 隆
- (2) 所在地：東京都港区東新橋二丁目 14 番 1 号 コモディオ汐留
- (3) 業事法に基づく事業の業態：第一種医療機器製造販売業
(許可番号 13B1X00261)

3. 改修する医療機器の概要

販売名	承認番号	承認年月日
メドトロニック Kappa DR600	21100BZY00158000	平成 11 年 3 月 8 日
メドトロニック Kappa SR700	21100BZY00157000	
メドトロニック Kappa DR700	21100BZY00159000	
メドトロニック Kappa VDD700	21100BZY00160000	
メドトロニック Sigma D	21200BZY00438000	平成 12 年 7 月 13 日
メドトロニック Sigma DR	21200BZY00437000	
メドトロニック Sigma S	21200BZY00436000	
メドトロニック Sigma SR	21200BZY00435000	
メドトロニック Sigma VDD	21200BZY00434000	

(1) 用途等：心筋に長時間連続して電気刺激を与え、心臓のリズムを補正することを目的として機能する植込み型心臓ペースメーカー。

(2) 輸入先製造元：Medtronic Inc.: 米国

4. 改修の対象

- (1) シリアル番号：別紙のとおり
- (2) 出荷時期：平成 13 年 1 月 12 日から平成 17 年 7 月 29 日
- (3) 出荷数：10,373 個 改修対象数：5,970 個

販売名	出荷時期	出荷数	改修数 (使用数)
メドトロニック Kappa DR600	平成 13 年 3 月 14 日から 平成 14 年 4 月 1 日	30	16
メドトロニック Kappa SR700	平成 13 年 1 月 12 日から 平成 15 年 6 月 17 日	4,230	3,140
メドトロニック Kappa DR700	平成 13 年 1 月 17 日から 平成 14 年 12 月 24 日	3,946	1,413
メドトロニック Kappa VDD700	平成 13 年 1 月 22 日から 平成 14 年 4 月 16 日	1,203	538
メドトロニック Sigma D	平成 16 年 11 月 4 日	1	1
メドトロニック Sigma DR	平成 14 年 3 月 7 日から 平成 17 年 7 月 12 日	395	352
メドトロニック Sigma S	平成 16 年 6 月 28 日から 平成 16 年 9 月 1 日	3	3
メドトロニック Sigma SR	平成 14 年 3 月 7 日から 平成 17 年 7 月 1 日	425	380
メドトロニック Sigma VDD	平成 14 年 4 月 2 日から 平成 17 年 7 月 29 日	140	127

- (4) 医療施設数：1,334 施設
- (5) 改修開始日：平成 21 年 5 月 19 日（情報提供開始）

なお、今回の改修対象製品は、平成 13 年 1 月から平成 17 年 9 月の間に植え込まれています。

5. 改修に至った理由、原因等

今回のワイヤ離脱には 2 種類の異なる原因が特定されています。第一の原因は、ワイヤの接合部分の表面メッキ処理の問題で、主として平成 12 年 11 月から平成 14 年 11 月の間に製造された製品の一部です。第二の原因は、製造工程上で部品を洗浄するために使用した洗浄剤に起因しています。以下に不具合数を記します。

原因	製品	国内			全世界		
		不具合数	植込み総数	不良率	不具合数	植込み総数	不良率
表面メッキ処理	Kappa	45	9,408	0.47%	285	58,281	0.49%
	Sigma	6	226	2.65%	131	14,918	0.88%
洗浄剤	Sigma	5	737	0.68%	225	40,595	0.55%

尚、上記の原因に対する改善策は既にとられており、今回の改修対象製品群以外への影響はありません。さらに、Kappa600、700、Sigmaシリーズの製品は、国内では平成 18 年 5 月には後継の新製品に切替わっており、現在は販売されていません。また、現在販売中の機種には、新しいワイヤ接続方法が使われています。

6. 危惧される具体的な健康被害

この事象により、間歇的または完全なペースング不全が発生し、失神やめまいの原因となる場合があります。また、ペースメーカー依存度の高い患者様においては、ペースング不全により、稀に死亡や重篤な健康被害の原因になる可能性があります。日本国内においては、ワイヤ離脱が合計 56 例 (Kappa 45 例、Sigma 11 例) 報告されていますが、死亡例はありません。海外では本件との関連が完全に否定できない死亡例が 2 例報告されています。

7. 改修方法

当該製品は平成 18 年 5 月に販売を終了しており、市場から回収を行う製品はありません。既に患者様が使用されている製品につきましては、医療機関に対し推奨する患者様へのフォローアップ方法を情報提供します。

- 失神やめまいの症状があれば、すぐ受診するよう患者様に注意喚起する。
- 対象製品群の製品が植込まれ、ペースメーカー依存度が高い患者様の場合、交換を検討する。
- 対象製品群の製品が植込まれ、ペースメーカー依存度が低い患者様の場合、通常のフォローアップを継続する。

8. その他

納入した医療機関及び患者様はすべて弊社が把握しておりますので、速やかに情報提供を行います。

9. 本件に関するお問い合わせ先

連絡先: 日本メドトロニック株式会社
東京都港区東新橋二丁目 14 番 1 号 コモディオ汐留

(報道関係者向け) 電話: 03-6430-7618 (直通)
ファックス: 03-6430-7050
担当者: 永野 玲子
清水 真治

(本件お客様窓口) 電話: 0120-911-381 (直通)
土日祝祭日除く

対象製品のシリアル番号について

メドトロニック Kappa DR 600

PHF621000S PHF621028S PHF621030S PHF621032S PHF621049S PHF621102S
PHF621103S PHF621104S PHF621105S PHF621106S PHF621107S PHF621116S
PHF621127S PHF621134S PHH620230S PHG620016S

メドトロニック Kappa SR 700

PHT144569H PHT145905H PHT147455H PHT147996H PHT148609H PHT148765H
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