

医療機器回収の概要

(クラス II)

1. 一般名及び販売名

一般の名称：手動式除細動器
販売名：ハートスタート MRx
型式番号：M3535A, M3536A

2. 対象ロット、数量及び出荷時期

製造番号：

US00533860, US00533873, US00533874, US00533875, US00533876, US00533877, US00533878, US00533879,
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対象台数 : 1225 台

出荷時期 : 平成 21 年 4 月から平成 25 年 5 月

3. 製造販売業者等名称

製造販売業者の名称 : 株式会社フィリップスエレクトロニクスジャパン
製造販売業者の所在地 : 東京都港区港南 2-13-37 フィリップスビル
許可の種類 : 第一種医療機器製造販売業
許可番号 : 13B1X00221
輸入先製造業者名 : フィリップスメディカルシステムズ
(アメリカ合衆国)

4. 回収理由

海外において、当該製品（MRx:M3535A）を同期モード（同期カルディオバージョン）で除細動を試みたときに非同期ショックをしてしまったために心室細動が誘発されたとの事例が海外製造元に報告されました。海外製造元で調査したところ、同期モードにするために取扱説明書の手順とは違い同期ボタンを押しながら同時に除細動選択ノブでエネルギーを設定した場合、通常はショックボタンを押し続けてR波後のタイミングで除細動ショック（同期ショック）をするところが、ショックボタンを押すと同時に除細動ショック（非同期ショック）をする可能性があることが判明しました。そのため、海外製造元から、ソフトウェアの修正を行うとの連絡を受けました。弊社においても自主回収としてソフトウェアの修正を行うことといたしました。

5. 危惧される具体的な健康被害

同期モードで当該事象が発生した場合、ショックボタンを押すと、意図しない除細動ショックが行われ心室細動が誘発される可能性があります。

しかしながら、通常通りに取扱説明書の記載手順に沿って同期モードの設定操作を行えば本事象が発生することはありません。

そのため重篤な健康被害が発生する可能性はないと考えております。

現在まで、国内において本件に起因すると思われる事象および健康被害発生への報告は受けておりません。

6. 回収開始年月日

平成 25 年 9 月 9 日

7. 効能・効果又は用途等

本品は、体外又は体内の電極を介して電気パルスショックを供給することによって心室細動が発現した心臓の除細動を行うことを目的として使用する。

本品には、心電図（ECG）モニタが備わっており、心電図の監視と除細動放電の両方に機能する粘着性の除細動電極（パッド）を介して患者に装着し、電気パルスショックを供給すべき時点を操作者に知らせる半自動（AED）モードと、心電図の解析と電気パルスショックを操作者が手動で行う手動モードがある。

8. その他

当該対象製品を納入した医療機関等は、すべて把握しておりますので、連絡の上、ソフトウェアの修正作業を実施いたします。

9. 担当者及び連絡先

担当者 : 小野 英夫、熊谷 昌彦
連絡先 : 株式会社フィリップスエレクトロニクスジャパン
薬事・品質保証本部
電話番号 : 0120-802-337
FAX 番号 : 03-3740-5206