Medtronic

2019年2月4日

メドトロニック社製ペースメーカをご使用の患者様

日本メドトロニック株式会社
CRHF事業部

植込み型心臓ペースメーカ「メドトロニック Adapta DR」「メドトロニック Adapta VDD」「メドトロニック Versa DR」「メドトロニック Sensia DR」の自主回収について

弊社が製造販売いたしました植込み型心臓ペースメーカ（デュアルチャンバ型）「メドトロニック Adapta DR（アダプタ ディーアール）」「メドトロニック Adapta VDD（アダプタ ブイディーディー）」「メドトロニック Versa DR（バーサ ディーアール）」「メドトロニック Sensia DR（センシア ディーアール）」について、海外製造元より一部の製品に不具合が生じる可能性があるとの報告を受けました。不具合が発生した場合は、重篤な健康被害に至る可能性を否定できないため、医療機関、医療関係者に情報を提供し、回収を実施することといたしました。

本件の対象製品をご使用の患者様は、かかりつけ医療機関にお問い合わせ頂きますようお願い致します。

この度は、患者様ならびに患者様のご家族の皆様にご心配とご迷惑をおかけいたしますこと、深くお詫び申し上げます。

【対象製品】

植込み型心臓ペースメーカ（デュアルチャンバ型）

製品名　：（1）メドトロニック Adapta DR
（2）メドトロニック Adapta VDD
（3）メドトロニック Versa DR
（4）メドトロニック Sensia DR

製品名：メドトロニック Adapta DR

製造番号：

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製品名：メドトロニック Versa DR

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製品名：メドトロニック Sensia DR(**)
製造番号(**)：
NWL400331G, NWL416991G, NWL416996G

出荷数量(**)：1,936 個

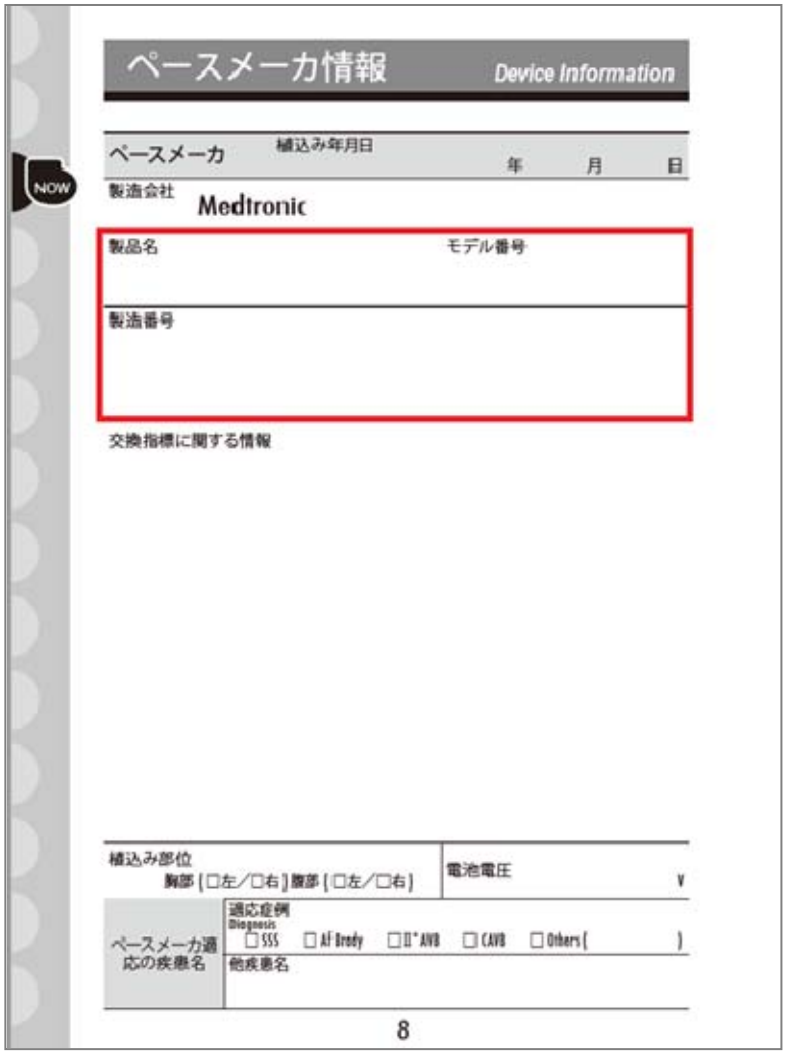
2019 年 1 月 18 日作成
2019 年 1 月 21 日訂正(*)
2019 年 2 月 4 日訂正(**)

【自主回収対象の製造番号確認方法】

自主回収対象の製造番号は、別紙の「自主回収対象の製造番号一覧」をご参照ください。

ご使用の製品名、および製造番号はお手持ちのペースメーカ手帳『ペースメーカ情報』からご確認いただけます。

ペースメーカ手帳『ペースメーカ情報』イメージ



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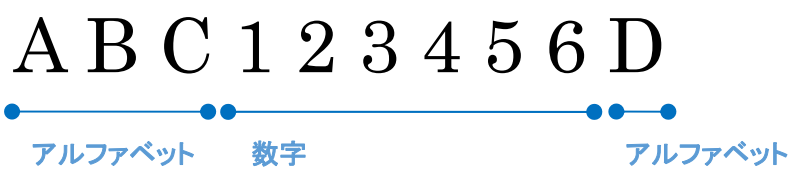

【本件に関するお問い合わせ】

本件に関する患者様のお問い合わせ窓口

本件専用のフリーダイヤル　電話番号：0120-911-381

受付時間：平日 9 時-17 時