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2021 年 2 月 18 日

メドトロニック社製 胸部ステントグラフトをご使用の患者様

日本メドトロニック株式会社
カーディアックサージェリー&アオルティック

Valiant Navion 胸部ステントグラフトシステム の自主回収に関して

この度、日本メドトロニック株式会社は、大動脈の治療に用いられる大動脈用ステントグラフト「Valiant Navion 胸部ステントグラフトシステム」（以下、当該製品）の自主回収を実施することといたしました。大動脈用ステントグラフトは、人工血管（グラフト）にステントと呼ばれる針金状の金網を縫い合わせたものであり、脆弱な大動脈を補強するための植え込み型医療機器です。調査の結果、患者様に植え込まれた一部の当該製品にタイプ IIIb エンドリーク*が発生する可能性が否定できないことが判明いたしました。

関係する医療機関を通じて本件に関する情報を提供させていただきますので、今後の診療に関しましては医療機関からの指示に従っていただきますよう、お願い申し上げます。弊社は、患者様の安全を第一に考え、今後も情報を共有していく所存です

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。

*タイプⅢb エンドリークとは、ステントグラフトのファブリックの破損などで瘤内に血液が流れ込むもの（参考資料：2020 年改訂版 大動脈瘤・大動脈解離診療ガイドライン）

【対象製品】

一般的名称：大動脈用ステントグラフト

販　売　名：Valiant Navion 胸部ステントグラフト

製 造 番 号：別紙参照

出 荷 時 期：2019 年 10 月以降

製 品 情 報：https://www.medtronic.com/jp-ja/about/news/pressrelease/2019-10-31.html

【本件についてのお問合せ先】

本件専用のフリーダイヤル　電話番号：0120-283-916　受付時間：平日 10 時-17 時

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別紙

【2021 年 2 月 22 日更新】

対象モデル番号／シリアル番号に誤りがあったため、下記の通り訂正いたします。なお、総数量および出荷時期に変更はございません。謹んでお詫びし、訂正いたします。

変更箇所

- 対象モデル番号／シリアル番号 VNMC2525C180TJ／V29552755 を追加
- 対象モデル番号／シリアル番号 VNMC3428C207TJ／V29873749 の重複分を削除

対象モデル番号／シリアル番号：

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