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| **PATIENT REIMBURSEMENT GUIDE FOR VALIANT-NAVION™ THORACIC STENT GRAFT SYSTEM 病人報銷指引****SAFE-N Program** |

As a patient with the Valiant Navion™ Thoracic Stent Graft System, which was used to repair your aorta, we understand you may have questions about expenses surrounding your care and treatment as a result of the Valiant Navion recall. A “recall” means that the manufacturer has asked physicians to stop using the device with new patients; it does not mean that patients have been asked to have the device removed.

作為曾經植入“美敦力” 范倫特納威昂胸主動脈支架的患者，我們理解由於“美敦力” 范倫特納威昂胸主動脈支架召回，您可能會對有關您的護理和治療的費用有疑問。「召回」是代表製造商通知醫師停止讓新病患使用此醫材，不代表要求病患移除體內的醫材。

As you may be aware from previous communication from your physician, on February 17, 2021, Medtronic instructed physicians to immediately stop using the Valiant Navion device **in new patients** because Medtronic discovered that some patients with the device developed a leak between the stent graft and the aorta. These leaks are generally treatable and can usually be detected with Computed Tomography (“CT”) imaging. The earlier a leak is detected, the sooner it may be treated. If left untreated, leaks can potentially lead to internal bleeding. For this reason, regular imaging is an important part of follow-up for all patients implanted with a Medtronic Valiant Navion Thoracic Stent Graft.

如同您從醫師處獲得之訊息，美敦力已於 2021 年 2 月 17 日宣布通知醫師立即停止讓新病患使用“美敦力” 范倫特納威昂胸主動脈支架，因為公司發現部分使用此醫材病患的主動脈覆膜支架和主動脈之間發生滲漏。這些滲漏通常可以被治療，且可以使用電腦斷層掃描（Computed Tomography，CT）進行偵測。越早偵測到滲漏，就能越快獲得治療。若未治療，則滲漏可能會造成內出血，基於此原因，定期電腦斷層掃描是所有植入“美敦力” 范倫特納威昂胸主動脈支架之病患，進行後續追蹤時非常重要的部分。

Medtronic has developed a program to provide assistance to physicians and their patients in light of the recall. The SAFE-N (Safety Assessment for Everyone-Navion) Program has several components, including imaging and data collection, physician resources, and patient support. Medtronic is committed to working with physicians and their patients to reduce financial barriers to recommended follow-up by helping to address any unreimbursed recall-related medical expenses. Under this program, you may be eligible for reimbursement of out-of-pocket medical and incidental expenses for additional imaging\* and medical treatment that is directly related to the Valiant Navion recall. Requests for reimbursement will be processed by Syntactx/NAMSA, a third-party vendor retained by Medtronic for this purpose.

因此，針對召回行動，美敦力制定了一項計劃以支援醫生及其患者。SAFE-N（全民安全評估-Navion）計劃有幾個組成部分，包括成像和數據收集、醫生資源和患者支援。美敦力致力於與醫生及其患者合作，協助解決任何未報銷的召回相關醫療費用。根據此計劃，您可能有資格獲得與“美敦力” 范倫特納威昂胸主動脈支架召回直接相關的額外成像\*和醫療的自付費用的報銷。美敦力提供有限保固以提供此支援。報銷申請將由美敦力為此目的聘請的第三方供應商Syntactx/NAMSA處理。

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| **Out-of-pocket expenses related to additional imaging\* and medical treatment associated directly with the Valiant Navion recall are eligible for reimbursement.****與"范倫特納威昂胸主動脈支架"召回直接相關的額外成像\*和醫療相關的自付費用有資格獲得報銷。****DO NOT DELAY IMAGING OR****TREATMENT切勿延遲影像學檢查****治療** | **TO SEEK REIMBURSEMENT FOR TREATMENT費用報銷申請*** **Have your physician or other providers submit your medical bills to insurance as usual.**

**讓您的醫生或其他提供者像往常一樣將您的醫療帳單提交給保險。*** **Contact the helpline if there are expenses that remain your responsibility.如有剩餘的自付費用，請聯繫熱線**

**TAIWAN SAFE-N****Reimbursement Helpline:****台灣 SAFE-N 服務熱線****+886 80 149 1551** |

**IMPORTANT重要事項**

**WHAT EXPENSES MAY BE ELIGIBLE FOR REIMBURSEMENT UNDER THE SAFE-N PROGRAM?
根據SAFE-N計劃，哪些費用可能有資格獲得報銷？**

Medtronic has contacted your physician to update an earlier recommendation for annual imaging. Medtronic now recommends that you seek routine CT imaging with contrast by your surgeon or doctor **every 6 months** instead of annually – or as frequently as your physician deems appropriate in his or her medical judgment.Of course, your doctor may have individualized patient recommendations about whether or when you need imaging, or what type of imaging, and Medtronic defers to your doctor in those considerations. Please contact your doctor to speak about what this new recommendation may mean for you and your ongoing care.

美敦力已聯繫您的醫生，以更新之前的年度成像檢查建議。美敦力現在建議您每6個月或者您的醫生認為適當的醫療判斷的頻率由外科醫生或醫生進行常規電腦斷層掃描，而不是每年一次。您的醫生可能會對您是否或何時需要成像或哪種類型的成像有個人化的患者建議，美敦力在這些考慮方面尊重您的醫生專業意見。請聯繫您的醫生，談談這項新建議以及術後追蹤和護理。

Each patient’s imaging and medical treatment may be different based on treatment recommendations from their medical providers and other factors. Generally, out-of-pocket expenses for treatment related to the Valiant Navion recall may be reimbursed if (1) they are unreimbursed by insurance due to co-pays, coinsurance, or deductibles; (2) coverage has been denied by applicable insurance; or (3) the patient is uninsured. Where these criteria are met, reimbursement may be available for:

根據醫療服務提供者的治療建議和其他因素，每位患者的成像和醫療治療可能會有所不同。一般來說，如果（1）由於共同支付，共同保險或免賠額而未被保險報銷;（2）被適用的保險拒絕承保的;或（3）患者沒有保險，與范倫特納威昂胸主動脈支架召回相關的治療自付費用可以報銷。

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| * Additional physician visits\*額外的醫生就診
* Additional CT/MR imaging with or without contrast\* 附加 CT/MR 成像，帶或不帶造影劑\*
* Additional Chest X-rays\*額外胸腔X光檢查
* Procedures to reinforce the Navion graft加強范倫特納威昂胸主動脈支架的手術
* Corrective surgery矯正手術
* Hospital and anesthesiology services

住院和麻醉服務 * Inpatient hospital or rehab expenses related to reintervention與再干預相關的住院或康復費用
 | * Outpatient clinical expenses related to additional imaging and medical treatment 與額外影像學和醫療相關的門診費用
* Reasonable expenses related to additional imaging and medical treatment (e.g., parking, meals, hotel, time off work, and other reasonable travel expenses)與額外成像和醫療相關的合理費用（例如，停車、膳食、酒店、休假和其他合理的差旅費用）
* Additional limitations may apply; reimbursements are subject to review and approval可能適用其他限制;報銷須經審查和批准
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\* Lifelong, regular follow-up, including at least annual follow-up is part of routine care for Navion patients. The SAFE-N Program covers updated recommendations for additional follow up and imaging every 6 months or as frequently as deemed appropriate by your physician’s medical judgment,. Uninsured patients also may be eligible for reimbursement of unreimbursed medical expenses for routine, annual imaging.
終身定期隨訪，包括至少每年隨訪是 Navion 患者常規護理的一部分。 SAFE-N計劃涵蓋了每6個月或醫生的醫學判斷認為適當的頻率的額外隨訪和成像的更新建議。 未投保的患者也可能有資格獲得常規年度影像學檢查的未報銷醫療費用的報銷。

**REQUESTING REIMBURSEMENT FOR OUT-OF-POCKET EXPENSES RELATED TO IMAGING AND TREATMENT
要求報銷與影像學和治療相關的自付費用**

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| **IMMEDIATE ACTIONS立即行動** | **NEXT STEPS後續步驟** |
| **Submit Expenses to Insurance向保險提交費用**Expenses related to your medical care and treatment should be covered by **your health insurance.與您的醫療護理和治療相關的費用應由您的健康保險承保。**Please have your physician and other providers submit all imaging and medical treatment expenses related to the Valiant Navion recall to your health insurance, as you would for any other medical expense. This includes insurance provided through your current or former employer; your spouse’s insurance; National Health Insurance, if applicable. Retain all Explanation of Benefit statements (EOB statements) relating to your additional imaging and medical treatment, as well as other invoices from your providers. EOB submission will be required for processing reimbursement claims.請讓您的醫生和其他醫療機構將與Valiant Navion召回相關的所有成像和醫療費用提交到您的健康保險中，就像您支付任何其他醫療費用一樣。這包括通過您現任或前任僱主提供的保險;您配偶的保險;國民健康保險（如適用）。保留與您的額外成像和醫療相關的所有福利說明（EOB聲明），以及您的供應商的其他發票。處理報銷申請或將需要提交EOB。 | **Contact Syntactx for More Information聯繫Syntactx以獲取更多資訊**If – **after you have requested reimbursement from your health insurance** – you still have eligible out-of-pocket expenses that are not covered, contact Syntactx at **+886 80-149-1551** or email SAFE-N-Reimburse@syntactx.com to request information or to complete an intake form. You may also visit [NavionSafety.syntactx.com](file:///C%3A%5CUsers%5Cabyard%5CDesktop%5CNavionSafety.syntactx.com)/twn for more information.Syntactx is a confidential, third-party medical services company supporting patients and caregivers seeking assistance in processing requests for reimbursement of out-of-pocket medical and incidental expenses related to the Valiant Navion recall.如果您在從健康保險中申請報銷后，您仍然有符合條件的自付費用，但未涵蓋，請致電**+886 80-149-1551**與Syntactx聯繫，或發送電子郵件 SAFE-N-Reimburse@syntactx.com 以請求資訊或填寫相關表格。您也可以存取 NavionSafety.syntactx.com/twn 瞭解更多資訊。 |

**SUBMITTING A CLAIM THROUGH SYNTACTX
通過SYNTACTX提交索賠**

**STEP 1 步驟1**

**Schedule Your Follow Up Imaging or Care:** It is important you do not delay care due to concerns about financial barriers. Please work with your healthcare providers to schedule and obtain the care they believe is appropriate based on your individual medical circumstances. Once you do, please maintain copies of any documents provided by your doctors or insurers for your Valiant Navion-related care.

**安排您的追蹤成像或護理：**重要的是，您不要因為擔心財務障礙而延遲護理。請與您的醫療保健提供者合作，根據您的個人醫療情況安排並獲得他們認為合適的護理。請保留您的醫生或保險公司為您的Valiant Navion相關護理提供的任何檔的副本。

*Certain arrangements regarding payment may be needed before receiving care if you have a co-pay, deductible, or co-insurance, or if your insurance requires pre-approval. Medtronic has Syntactx available to help you. Please contact the Taiwan SAFE-N reimbursement helpline: +886 80 149 1551 or email:* SAFE-N-Reimburse@syntactx.com*.*

*如果您有共同支付，免賠額或共同保險，或者如果您的保險需要預先批准，則在接受護理之前可能需要有關付款的某些安排。美敦力有Syntactx為您提供説明。 請聯繫臺灣 SAFE-N 報銷熱線：+886 80 149 1551 或發送電子郵件至：SAFE-N-Reimburse@syntactx.com*

**STEP 2 步驟2**

**Submit Your Bills to Medicare or Insurance:** Have your healthcare providers submit your medical expenses to your insurance as they typically would. Please maintain a copy of any Explanation of Benefits “EOB” or other documents you receive from your insurer, as well as a copy of any bills received from your providers. Note that you may receive bills from more than one healthcare provider for any imaging or reintervention.

**將您的帳單提交給醫療保險或保險：**如同一般正常程序, 您的醫療保健提供者通常會將您的醫療費用提交給您的保險。請保留您從保險公司收到的任何福利解釋"EOB"或其他文件的副本，以及從您的供應商處收到的任何帳單的副本。您可能會收到來自多個醫療保健提供者的任何成像或重新干預的帳單。

**STEP 3 步驟3**

**Complete Claim Forms:** If you have unreimbursed expenses related to your care, i.e., expenses for which you, the patient, remain responsible, please complete the necessary claim forms. To submit a reimbursement request for a claim, please retain copies of all paperwork submitted, including:

**填寫索賠表格：**如果您有與您的護理相關的未報銷費用，即您（患者）仍然負責的費用，請填寫必要的索賠表。要提交索賠報銷申請，請保留所有提交的文書工作的副本，包括：

* Out-of-Pocket Medical Expense and/or Incidental Expense Reimbursement Claim Form(s).
自付醫療費用和/或雜費報銷報銷表
* EOB documentation noting applicable deductibles, co-pays, co-insurance, and denied coverage. (if applied)
EOB檔，註明適用的免賠額，共同支付，共同保險和拒絕承保。 （如適用）
* Where the requested incidental expenses exceed $500, receipts and detailed documentation for all out-of-pocket expenses related to reasonable incidental expenses associated with seeking additional imaging and medical treatment.
如果要求的雜費超過500美元，則提供與尋求額外影像和醫療相關的合理雜費相關的所有自付費用的收據和詳細檔。

**Uninsured Patients:** Uninsured patients must also complete and sign an Uninsured Status Verification Form.

無保險患者：無保險患者還必須填寫並簽署無保險身份驗證表。

**STEP 4 步驟4**

**Submit Your Claim Forms to Syntactx:** Within 90 days of the imaging, reintervention, or treatment date, e-mail your completed warranty claim form to:

將您的索賠表提交給Syntactx：在成像、重新干預或治療日期后的 90 天內，將填妥的保修索賠表通過電子郵件發送至：

SAFE-N-Reimburse@syntactx.com

Mailing and facsimile are also available at:

**或郵寄和傳真至：**

**Syntactx**

**RE: SAFE-N Project**

**4 World Trade Center**

**150 Greenwich Street, 44th Floor**

**New York, New York, 10007**

**Fax: 1 (800) 342-1401**

After reviewing your submitted reimbursement form, Syntactx will send you an email message updating you on your reimbursement status. Please expect between 45-60 days to verify and process payment requests once all required forms have been submitted.

在審核您提交的報銷表格后，Syntactx將向您發送一封電子郵件，更新您的報銷狀態。提交所有必需的表格后，請預計在45-60天內驗證和處理付款請求。

**ADDITIONAL QUESTIONS 其他問題**

Individuals with questions about this process or needing assistance are encouraged to contact:
對此過程有疑問或需要幫助，請聯繫：

Taiwan SAFE-N reimbursement helpline　臺灣SAFE-N報銷熱線：

 +886 80 149 1551

Email　電郵:
SAFE-N-Reimburse@syntactx.com

You may also visit　您也可以瀏覽

 [NavionSafety.syntactx.com](file:///C%3A%5CUsers%5Cabyard%5CDesktop%5CNavionSafety.syntactx.com)/twn

**FOR MORE INFORMATION　了解更多詳細資訊**

Contact your health insurance provider for questions about coverage for your imaging and treatment.
請聯繫您的健康保險提供者，瞭解有關您的成像和治療範圍的問題。

*This SAFE-N Program is limited to its express terms and does not constitute a representation, judgment, admission, or assumption of liability by Medtronic with respect to imaging, reintervention, and/or utilized thoracic stent graft systems. No action taken by Medtronic in connection with the Voluntary Product Recall, including this SAFE-N Program, shall be construed as an admission of any fault or liability whatsoever to the patient, doctor, health care professional, or to any third party. Medtronic makes no representation with respect to any potential impact of reimbursements on a patient’s eligibility to participate in a Health Savings Account or other tax-favored health plan; please consult with a tax advisor as necessary. All rights reserved.
本SAFE-N計劃僅限於其明確條款，不構成美敦力對成像、再干預和/或使用胸支架移植系統的陳述、判斷、承認或責任承擔。 美敦力在自願產品召回（包括本 SAFE-N 計劃）方面採取的任何行動均不得解釋為承認患者、醫生、醫療保健專業人員或任何第三方的任何過錯或責任。美敦力對報銷對患者參與健康儲蓄帳戶或其他稅收優惠健康計劃的資格的任何潛在影響不作任何陳述;如有必要，請諮詢稅務顧問。保留所有權利。*