Market Withdrawal

May, 16 2025

Product Field Action #: 3954415

Product Name: Demayo Leg Wrap

Identification of the Affected Product:

Table 1

Catalog Number	Product Description	GTIN	Lot Number
110550	Demayo Leg Wrap	00696588000916	I25028005 I25007001 I24326002 I25028004 I24330001 I25002001

Dear Customer,
Cc: Chairman Medical Board and relevant Head of Departments

Stryker is releasing this customer letter on behalf of the Legal Manufacturer, Innovative Medical Products (IMP), who has issued a voluntary, lot number specific Market Withdrawal for the Demayo Leg Wrap. The Demayo Leg Wrap is manufactured by IMP and distributed by Stryker. The intent of this letter is to list all known risks potentially associated with the use of the product.

Issue:

It was discovered that specific lots of the Demayo Leg Wrap may have brown spots in the foam pad surface. The visual/cosmetic defect was found to be nylon (polyamide) particulates that may turn brown upon reaction with ethylene oxide during the sterilization process.

Potential Risks:

Analysis concluded that the polyamide is a commonly used material in medical devices and has established biocompatibility.

Identification of the cosmetic defect in the foam pad surface may cause minimal extended surgical time to obtain a new leg wrap that does not contain brown spots. The minimal extended surgical time would pose no adverse health consequences to the patient.

Use of the leg wrap that contains a cosmetic defect would result in no clinical harm due to the following risk mitigations:

a. The device's distal location relative to the surgical wound site.
b. The application of a cohesive wrap that effectively separates the device from the knee joint wound.
c. The standard protocol for total knee arthroplasty, which includes wound irrigation and cleansing.

Actions Needed:

Our records indicate that you may have received the affected product listed in Table 1. On behalf of the Legal Manufacturer, IMP, it is Stryker's responsibility as the distributor to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions.

1. Please inform users of this Market Withdrawal and forward this notice to all individuals who need to be made aware within and outside of your organization.
2. Immediately check all stock areas and/or operating room storage to determine if the device from the affected product table is at your facility.
3. Discontinue use of and discard the recalled device identified in the affected product table.
4. Please **contact your Local Sales Office or your Stryker Sales Representative directly for product replacement, returns and inventory questions.**

Please keep Stryker informed of any adverse events associated with this product by emailing:

asean.pms@stryker.com.

We regret any inconvenience this action may cause. If you have any questions or concerns after reviewing this letter, please contact Stryker Sales Representative. For questions pertaining to the recall, email

asean.pms@stryker.com.

Sincerely,

ChiaNee Lim

Electronically signed by: ChiaNee Lim
Reason: I approve this document
Date: May 16, 2025 15:49 GMT+8

Chia Nee Lim
Senior QA Specialist, ASEAN