Medical Device Quality Alert: Class II Recall of Vasofix Certo G24X19MM Yellow Batch Number 20A19G8334 and 20A21G8381

B.Braun Medical Kenya Ltd is implementing a voluntary recall of Vasofix Certo G24x19mm Yellow, batches **20A19G8334** & **20A21G8381**.

From: Pharmacy and Poisons Board

Published: 07/03/2022

Recall Reference Number: REC/2022/03

Recall Classification: Class II Recall **Recall Level:** Retail/Facility Level

Manufacturer: B. Braun Melsungen AG

Local Technical Representative: B.Braun Medical Kenya Ltd

Product name: Vasofix Certo G24x19mm Yellow

Medical device: Canula

Batch number	Expiry date
20A19G8334	01/01/2025
20A21G8381	01/01/2025

Brief description of the problem

Batches **20A19G8334** and **20A21G8381** of Vasofix Certo G24x19mm Yellow have a defect on the injection port that may result in potentially critical clinical consequences for the patient e.g blood loss, underdosing, or delay of therapy.

Action for healthcare professionals

You are advised to immediately quarantine and stop supply/ distribution or use of the impacted batches of the product. B. Braun Medical Kenya will contact you to arrange for the return of the product.

Action for patients/caregivers

No action is required for patients as this medical device is used in a healthcare facility setting.

Further Information

For stock enquiries, please contact B.Braun Medical Kenya Ltd by email at phyllis.kimani@bbraun.com or by phone at +254 723474978 and

You are advised to promptly report any cases of adverse events and suspected substandard and falsified products to the nearest healthcare facility or through the following channels:

- https://pv.pharmacyboardkenya.org/users/mpublic
- USSD code at *271#
- Email <u>pv@ppb.go.ke</u> or <u>pms@ppb.go.ke</u>
- Telephone No. 0795743049
- Mobile application: mPvERS both Android and iOS

For any further information please contact the Pharmacy and Poisons Board by email: pms@ppb.go.ke