Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 220 **dated** 29/11/2022 **Regarding NCMDR Field Safety Corrective Action of V. Mueller Bipolar Forceps from (mfr: Becton Dickinson & Co. (BD)).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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Circular No. 220/ 2022

5 -05-1444 H
29 -11-2022

Field Safety Corrective Action of V. Mueller Bipolar Forceps from Becton Dickinson & Co. (BD).

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17325
Product	V. Mueller Bipolar Forceps.
Description	Bipolar Forceps.
Manufacturer	Becton Dickinson & Co. (BD).
The affected products	REF: See "Table 1" in the attached FSN. Lot Numbers: All lot numbers.
Reason	The Instructions For Use (IFU) provided by BD is missing certain content that is contained in the manufacturer's IFU. This missing content is related to the interface with the device power supply, as well as cleaning and maintenance instructions.
Action	1. Replace your current IFU for the products listed in Table 1 with the updated IFU provided with this notification. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
Directorate General of Pharmaceutical Affairs & Drug Control

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BD Switzerland Sàrl
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www.BD.com

7th November 2022

PRODUCT NOTIFICATION – SUR-22-4498

V. Mueller™ Bipolar Forceps

REF: See Table 1 **Lot Numbers:** All lot numbers

Type of Action: Advisory

Dear Customer,

BD is issuing an advisory product notification for all lot numbers of **V. Mueller™ Bipolar Forceps**. According to our distribution records your organisation may have received the impacted product in Table 1. Product was distributed between December 2011 and January 2022.

Product Code (REF)	Product Name	Lot Number	UDI
F-1305	V. Mueller™ SCOVILLE-GREENWOOD BAYONET IRRIGATING BIPOLAR FORCEPS INSULATED, 1.5MM TIP OVERALL LENGTH 7-3/4" (195MM)	All Lots	10885403040856
F-5125	V. Mueller™ TITANIUM BAYONET BIPOLAR FORCEPS, STRAIGHT, FINE 0.5MM TIP OVERALL LENGTH 8-3/4" (225MM	All Lots	10885403041211
F-5126	V. Mueller™ TITANIUM BAYONET BIPOLAR FORCEPS, 1.0MM TIP, STRAIGHT MEDIUM OVERALL LENGTH 8-3/4" (225MM)	All Lots	10885403041228
F-1000	V. Mueller™ CUSHING BAYONET BIPOLAR INSULATED FORCEPS, 0.7MM TIP OVERALL LENGTH 7-1/2" (190MM)	All Lots	10885403040702
F-3015	V. Mueller™ ADSON BIPOLAR FORCEPS 1.0MM TIP, INSULATED OVERALL LENGTH 4-3/4" (120MM)	All Lots	10885403040979
F-1035	V. Mueller™ HARDY-STYLE BAYONET BIPOLAR FORCEPS, 0.5MM TIP, INSULATED OVERALL LENGTH 8-1/2" (215MM)	All Lots	10885403040740
F-5022	V. Mueller™ TITANIUM ROUND HANDLE BAYONET BIPOLAR FORCEPS 1.5MM TIP OVERALL LENGTH 10-1/2" (265MM)	All Lots	10885403041075
F-5018	V. Mueller™ TITANIUM ROUND HANDLE BAYONET BIPOLAR FORCEPS,1.0MM TIP OVERALL LENGTH 10-1/2" (265MM)	All Lots	10885403041068
F-5016	V. Mueller™ TITANIUM ROUND HANDLE BAYONET BIPOLAR FORCEPS 0.7MM TIP OVERALL LENGTH 10-1/2" (265MM)	All Lots	10885403041051
F-5067	V. Mueller™ ROUND HANDLE BAYONET BIPOLAR FORCEPS 0.7MM TIP OVERALL LENGTH 10-1/2" (265MM)	All Lots	10885403041167

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F-5002	V. Mueller™ TITANIUM ROUND HANDLE BAYONET BIPOLAR FORCEPS, 1.0MM TIP OVERALL LENGTH 8-1/2" (215MM)	All Lots	10885403040986
F-5073	V. Mueller™ ROUND HANDLE BAYONET BIPOLAR FORCEPS 1.5MM TIP OVERALL LENGTH 10-1/2" (265MM)	All Lots	10885403041198
F-5127	V. Mueller™ TITANIUM BAYONET BIPOLAR FORCEPS, 0.5MM TIP, ANGLED-UP FINE OVERALL LENGTH 8-3/4" (225MM)	All Lots	10885403041235
F-2002	V. Mueller™ CUSHING BIPOLAR FORCEPS 1.5MM TIP, INSULATED OVERALL LENGTH 7" (180MM)	All Lots	10885403040900

Table 1: Impacted product

This advisory is limited to the product codes listed in Table 1. No other product codes are affected.

Description of the Problem

BD has identified that the Instructions For Use (IFU) provided by BD is missing certain content that is contained in the manufacturer's IFU. This missing content is related to the interface with the device power supply, as well as cleaning and maintenance instructions. Refer to the attached updated **V. Mueller™ Bipolar Forceps** IFU.

The potential consequences of inappropriate power supply to the **V. Mueller™ Bipolar Forceps** device include the inability to effectively induce hemostasis, on one extreme, or electrical burn injuries, on the other. Either of these complications could adversely affect the efficient and safe delivery of care to patients.

The potential consequences of inappropriate cleaning, maintenance, and storage of the **V. Mueller™ Bipolar Forceps** device include contamination of sterile operative fields leading to infection, abscess formation, sepsis and, at an extreme, septic shock.

To date there has been no adverse events related to this issue.

There is no requirement for customers to return any V. Mueller™ Bipolar Forceps to BD. These products can continue to be used in accordance with the guidance in this notification.

Actions taken by BD:

BD will implement appropriate corrective actions to prevent recurrence and is providing, with this notification, the **V. Mueller™ Bipolar Forceps** IFU which contains the missing content.

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Customer Actions:

- Replace your current IFU for the products listed in Table 1 with the updated IFU provided with this notification.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 30th November 2022**.
- Circulate this notification to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- If you experience any issues with the **V. Mueller™ Bipolar Forceps**, please report as a complaint as per your normal process.

Distributor Actions:

- Review the information in **Table 1** and determine if **V. Mueller™ Bipolar Forceps** in your possession are impacted.
- Replace the current IFU with the updated IFU provided with this product notification.
- Identify the facilities where you have distributed affected product and notify them immediately of this notification. Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **30th November 2022**.
- Complete and return the Customer Response Form following completion of your reconciliation activities.

	End User with Inventory	**End User with ZERO inventory**	**Where to send completed form**
Purchased **directly** from BD	Complete the form in its entirety and ensure that all recommended actions have been implemented as required	Complete the form in its entirety and retain a copy of this notification for your records	EMEAFieldAction@bd.com
Purchased from a **distributor/3rd party**	Complete the form in its entirety	Complete the form in its entirety and retain a copy of this notification for your records	Return the form to your distributor/3rd party

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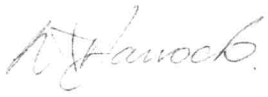
Contact Reference Person

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,



Lorna Darrock
Associate Director, Post Market Quality
EMEA Quality