

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 56 dated 27/3/2023 Regarding NCMDR FSN of Atlas Gold PTA Dilatation Catheter from (mfr: BD Switzerland Sarl).

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





Circular No. 56/2023


05-09-1444 H

27-03-2023

نتقدم بثقة  
Moving Forward  
with Confidence

رؤية عمان  
2040  
Oman Vision

### Field Safety Notice of Atlas Gold PTA Dilatation Catheter from BD Switzerland Sarl.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=18459">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=18459</a>
Product	Atlas Gold PTA Dilatation Catheter.
Description	Dilatation Catheter.
Manufacturer	BD Switzerland Sarl.
Local agent	Intamedica Company LLC.
The affected products	Refer to "Table 1: Impacted product " in the attached FSN.
Reason	The Data Matrix code on the outer carton (secondary packaging) displays an incorrect expiration date when scanned. The printed human readable and barcode expiration date displayed on the same outer carton (secondary packaging) is correctly labelled.
Action	1. For any impacted product ensure that the printed expiry date in the human readable or barcodes are referred to and not the carton Data Matrix code. 2. Contact the local agent for remedial action.
Product Image	
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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan AlRubaic

Director General







16 February 2023

**PRODUCT NOTIFICATION – PI-23-4619**

**Atlas™ Gold PTA Dilatation Catheter**

**REF: See Table 1 Lot Numbers: See Table 1**

**Type of Action: Advisory**

Dear Customer,

BD is issuing this product notification for specific lots of **Atlas Gold PTA Dilatation Catheter**. According to our distribution records your organisation may have received the impacted product in Table 1. Product was distributed between April 2022 and June 2022.

<b>Product Code (REF)</b>	<b>Lot Number</b>	<b>Expiry Date (DD/MM/YYYY)</b>
ATG120142	93QG0134	22/03/2024
ATG120144	93QG0048	08/03/2024
ATG120182	93PG0167	25/02/2024
ATG120184	93PG0147	24/02/2024
ATG120204	93PG0090	25/02/2024
	93PG0149	25/02/2024
	93QG0019	04/03/2024
	93QG0020	04/03/2024

**Table 1: Impacted product**

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

**Description of the Problem**

Based on customer feedback, BD has identified that the Data Matrix code on the outer carton (secondary packaging) displays an **incorrect** expiration date when scanned. The printed human readable and barcode expiration date displayed on the same outer carton (secondary packaging) is **correctly labelled** (refer to Figure 1), as is the human readable and barcode expiration date printed on the inner pouch.



BD Switzerland Sàrl  
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 Route de Crassier 17  
 1262 Eysins – Switzerland  
 Tél: +41 21 556 30 Fax:  
 +41 21 556 30 99  
 www.BD.com

	<b>BALLOON DIAMETER</b>	<b>18mm</b>	REF Catalogue Number <b>ATG120184</b>
	<b>BALLOON LENGTH</b>	<b>40mm</b>	
<b>SL</b>	<b>SHAFT LENGTH</b>	<b>120cm</b>	LOT Lot Number <b>93PG0147</b>
	<b>RECOMMENDED GUIDEWIRE</b>	<b>.035"</b>	Use By <b>2024-02-24</b>
	<b>RECOMMENDED INTRODUCER</b>	<b>8F</b>	
<b>NP</b>	<b>NOMINAL PRESSURE</b>	<b>6atm</b> <small>1atm = 101.3kPa</small>	 <small>(01)00801741060885</small>  <small>(17)246224(10)93PG0147</small>
<b>RBP</b>	<b>RATED BURST PRESSURE</b>	<b>16atm</b> <small>1atm = 101.3kPa</small>	

**18mm 40mm 120cm 8F .035"**

ATG120184  
 93PG0147  
 2024-02-24  
(01)00801741060885(17)246224(10)93PG0147

**Figure 1:** Representative label for example purposes. **Data Matrix code** circled in red on the outer carton displays an incorrect expiration date when scanned.

The **printed expiry dates** circled in green displays the correct expiration date.

**Potential Risk**

BD has determined that this situation is not likely to cause adverse health consequences as end users are likely to refer to the correct human readable and barcoded expiration date printed on the carton and unit packaging.

**There is no requirement for customers to return any Atlas™ Gold PTA Dilatation Catheter to BD. These products can continue to be used in accordance with the guidance in this notice.**

**Actions taken by BD:**

BD has identified the root cause and is implementing corrective actions to prevent recurrence of this issue.



**Customer Actions:**

- Review the information in **Table 1** to determine if the **Atlas™ Gold PTA Dilatation Catheter** in your possession are impacted.
  - For any impacted product ensure that the printed expiry date in the human readable or barcodes are referred to and **not** the carton Data Matrix code.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 14<sup>th</sup> March 2023.**
- Circulate this notification to all those who need to be aware within your organisation or to any organisation where the potentially affected product has been transferred.
- If you experience any issues with the **Atlas™ Gold PTA Dilatation Catheter**, please report as a complaint as per your normal process.

**Distributor Actions:**

- Review the information in **Table 1** and determine if the **Atlas™ Gold PTA Dilatation Catheter** in your possession are impacted.
  - For any impacted product ensure that the printed expiry date in the human readable or barcodes are referred to and **not** the carton Data Matrix code
- 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 **14<sup>th</sup> March 2023.**
- Complete and return the Customer Response Form following completion of your reconciliation activities.

	<b>End User with Inventory</b>	<b>End User with ZERO inventory</b>	<b>Where to send completed form</b>
Purchased <b>directly</b> 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	<a href="mailto:Ahmed.Shebah@bd.com">Ahmed.Shebah@bd.com</a>
Purchased from a <b>distributor/3<sup>rd</sup> party</b>	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	Return the form to your distributor/3 <sup>rd</sup> party



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**Contact Reference Person**

If you have any questions about this, please contact your local BD representative or the local BD office by e-mail [Ahmed.Shebah@bd.com](mailto:Ahmed.Shebah@bd.com)

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,

A handwritten signature in cursive script, appearing to read "L. Darrock".

Lorna Darrock  
Associate Director, Post Market Quality  
EMEA Quality





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## Customer Response Form - PI-23-4619

### Atlas™ Gold PTA Dilatation Catheter

REF: See Table 1 Lot Numbers: See Table 1

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Return to [Ahmed.Shebah@bd.com](mailto:Ahmed.Shebah@bd.com) as soon as possible or **no later than the 14<sup>th</sup> March 2023**.

**By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

<b>Account/Organisation Name:</b>	
<b>Department (if applicable):</b>	
<b>Address:</b>	
<b>Postcode:</b>	<b>City:</b>
<b>Contact Name:</b>	
<b>Job Title:</b>	
<b>Contact Telephone Number:</b>	<b>Contact E-mail Address:</b>
<b>Name of your supplier for this product (if not direct from BD)*</b>	
<b>Signature:</b>	<b>Date:</b>

*This form must be returned to BD before this action can be considered closed for your account.*

*\*If you were forwarded this Product Notification via a distributor/3<sup>rd</sup> party, please return your completed form to that organisation for reconciliation purposes.*