

الممثل المعتمد

Date: 25 April 2022

Reference Number: SG-2204-389-H

**Medical Devices Sector** 

**National Center for Medical Devices Reporting** 

**Authorized Representative** 

## رسالة سلامة **Safety Communication**

To: Healthcare providers		إلى: مقدمي الرعاية الصحية		
Title:	Risk of air embolism	المعنوان:		
Medical Device Description	BD Plastipak 50mL Syringe with Luer- Lok Tip	اسم ووصف الجهاز/المستلزم الطبي:		
Manufacturer:	Becton Dickinson & Co. (BD)	اسم المصنع:		

Becton Dickinson B.V.

Medical Devices Marketing Authorization (MDMA)	GHTF-2020-0178	إذن التسويق:
Potential /Associated Risks	A potential for air ingress into the syringe when the barrel is damaged and the syringe is used in an infusion pump.	المخاطر المحتملة /المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	<ul> <li>Follow Good Clinical Practice regarding the inspection of medical devices for damage, integrity and function before, during, and after use. Devices found with damage should not be used.</li> <li>If you identify syringe damage, report as a complaint as per your normal process.</li> <li>Notify all users about this safety communication</li> </ul>	التوصيات



## الهيئة العامة للضذاء والدواء Saudi Food & Drug Authority

	AR name:	Becton Dickinson BV Saudi Limited Company		
Authorized Representative Details:	Assigned Contact Person:	Nawaf Mansour Alsalmi	معلومات الممثل المعتمد:	
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Related Links		<u>Here</u>	روابط ذات صلة	

**For Reporting:** 







للإبلاغ: