

رسالة سلامة
Safety Communication

To: Healthcare Provider

إلى: مقدمي الرعاية الصحية

Title	The introducer dilator included within Datascope/Getinge IAB insertion kits fracturing at the hub	العنوان
Medical Device Description	Datascope Sensation/Sensation Plus/MEGA/Linear IAB CATHETERS, Packaged Insertion Kits, & Reinforced Introducer Sets	اسم ووصف الجهاز/المستلزم الطبي
Medical Device Products Identifier	Distributed Affected Lot Number: All	الأرقام للجهاز/المستلزم الطبي
	Manufacturing Dates: IAB Kits: Since May 9 th , 2020 Packaged Insertion Kits & Reinforced Introducer sets: Since May 31st 2018	
	Distribution Dates: IAB Kits: Since May 9 th ,2020 Packaged Insertion Kits & Reinforced Introducer sets: Since May 31st 2018	
Manufacturer	Getinge	اسم المصنع
Authorized Representative	Al-Jeel Medical & Trading Co. LTD	الممثل المعتمد
Medical Devices Marketing Authorization (MDMA)	GHTF-2018-0563	إذن التسويق
Potential /Associated risks	The introducer dilator included within Datascope/Getinge IAB insertion kits fracturing at the hub when attempting to remove the introducer dilator from the sheath, leaving the introducer dilator body housed within the sheath. This issue may impact patient safety when performing a sheathed IAB catheter insertion.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	<ul style="list-style-type: none"> - DO NOT USE the sheath or introducer dilator included in identified Datascope/GETINGE IAB insertion kits to perform a sheathed insertion. - Further, do not use the provided Datascope/GETINGE sheath with an alternative dilator as the Datascope/GETINGE sheath is designed to perform safely only with the accompanying introducer dilator. • Please follow the “Four options for Customers” and “WARNINGS” as mentioned in the FSN letter in the attached Safety Alert: Safety Alert 	التوصيات
For Reporting	  	للإبلاغ