IDS Medical Systems (Singapore) Pte. Ltd.
20 Science Park Road, Teletech Park
#01-23/25, Singapore 117674
T : +65 6690 7330
F : +65 6690 7380
E : sgpidsmedicalsystems@idsmed.com
www.idsMED.com

FIELD SAFETY NOTICE

15 July 2019

<<Customer Name>>
<<Address Line 1>>
<<Address Line 2>>
<<Address Line 3>>

IDS REFERENCE:	FSCA-2019-008
MANUFACTURER REFERENCE:	#3012307300-07/08/2019-003-R
SUBJECT: Potential Occlusion of Individually Sold GRIPPER® Needles and GRIPPER® Needles Within PORT-A-CATH® Trays	
FOR THE ATTENTION OF: Chairman Medical Board (CMB), BME, Nursing and Medical staff using these devices in the various departments and the relevant Head of Departments.	
DEVICE:	Individual GRIPPER® Needles and PORT-A-CATH® Trays Containing GRIPPER® Needles
PRODUCT CODE:	Refer to [Attachment 2 Affected Part Numbers and Lots]
BATCH / SERIAL NO:	Refer to [Attachment 2 Affected Part Numbers and Lots]
PROBLEM:	Smiths Medical became aware that certain individual GRIPPER® Needles, which were manufactured between 11 June 2018 through 21 February 2019, including those that are provided in certain PORT-A-CATH® Trays, may contain an occluded or blocked needle.
ACTION TO BE TAKEN:	1. Locate and determine the number of affected products in your possession by referring to Attachment 2. 2. Complete the attached Response Form within 10 days and return it to idsMEDSGPRegulatory@idsMED.com even if you do not have any of the affected product in your possession.

We apologize for any inconvenience caused due to this notice. Meanwhile, should you require further clarification, please do not hesitate to contact:

Tina Wang @ [redacted]
Valerie Lee @ [redacted]
Wendy Sun @ [redacted]

Thank you.

With regards,
Petrina Lim
Regulatory
IDS Medical Systems (Singapore) Pte Ltd
Email: idsMEDSGPRegulatory@idsMED.com

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IDS Reference:	FSCA-2019-008
Manufacturer Reference:	#3012307300-07/08/2019-003-R
Device:	Individual GRIPPER® Needles and PORT-A-CATH® Trays Containing GRIPPER® Needles
Subject:	Potential Occlusion of Individually Sold GRIPPER® Needles and GRIPPER® Needles Within PORT-A-CATH® Trays

I acknowledge receipt of this letter dated 15 July 2019.

Customer Name:			
Department:			
Address:			
Name:		Tel:	
Designation:			
Signature:		Company Stamp:	

Check the applicable boxes below:	
	I **DO NOT** have affected medical devices remaining. All have been used or discarded.
	I **DO** have unused inventory of affected medical devices, which I will return for replacement / credit. *

Item Number	**Batch Number**	**Quantity to return**

*Please fax this acknowledgement to IDS Medical Systems at 66907380 or email to idsMEDSGPRegulatory@idsMED.com.

If there is any discrepancy in the above list, please advise us of the changes.

Thank you.