Bard Singapore Pte Ltd
No 1 Coleman Street #06-07
The Adelphi
Singapore 179803
Tel: (65) 6580 5988
Fax: (65) 6337 3588
Co Reg No. 199901639R

13 October 2016

URGENT NOTIFICATION: Mislabeled SafetStep® Huber Needle Length in Pouches

Dear Customer:

This letter is to inform you that Bard Access Systems recently became aware that one specific lot of SafeStep Huber Needle Set may contain a needle that differs from the length and gage described on the label for some of the units within the lots, per table below:

Item Code	Description	Lot #	Reason
LH-0029YN	SafeStep® Huber Needle Set 22 Gauge x 3/4"	ASZKS07**6**	May contain a 1" x 22 gage needle

Bard advises users of this product to confirm that the length of the needle matches that which is described on the packaging prior to use.

In addition, if the product identified above has been further distributed to the clinic, please inform them of this notification. Please be advised that this notification does not impact any consumed product or patients having used these devices.

The product can be used with the understanding that adjustments to the depth of insertion may be required. Should you feel it necessary to return the unused product that may be discrepant as outlined in this letter, please contact your Bard Sales Representative.

We sincerely regret any inconvenience this may cause to you or your facility.

Sincerely,

[redacted]

Mary Kennell
Director of Regulatory Affairs & Quality, Australia, New Zealand and South East Asia

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CUSTOMER ACKNOWLEDGEMENT FORM

MEDICAL DEVICE NOTIFICATION

Item Code	Description
LH-0029YN	SafeStep® Huber Needle Set 22 Gauge x 3/4"

PLEASE SCAN BACK TO: Complaints.Singapore@crbard.com

Please fill out and return this customer acknowledgement form confirming receipt of this notification as soon as possible and either hand it to your Bard Sales Representative, scan a copy to Complaints.Singapore@crbard.com or fax it to 6337 3588.

I have read and understood the attached medical device notification.

Signature: _____ Date: _____

Print Contact Name:		**Company Stamp:**	
Name of Facility:			
Contact Phone:		**Fax:**	