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

14 October 2016

URGENT: MEDICAL DEVICE NOTIFICATION

Dear Customer:

This letter is to inform you of an additional *Warning/Precaution for* multi-length ureteral stents. You can expect to see the following added statement included in the *Warning/Precaution* labeling for all multi-length ureteral stents that you purchase in the future.

Additional Warning/Precaution: Multi-length Ureteral Stents: Formation of knots in multi-length ureteral stents may occur. This may result in injury to the ureter during removal and/or the need for additional surgical intervention. The presence of a knot should be considered if significant resistance is encounter during attempts at removal.

Our records show that your facility has purchased at least one unit of sale for one or more of the product codes identified in Attachment 1: Product Codes Impacted.

Reason for Notification:
The Food and Drug Administration has requested manufacturers of multi-length ureteral stents to add a statement in the *Warnings/Precautions* section of product labeling, requesting end users to consider the presence of a knot if significant resistance is encountered during attempts at removal.

Bard has agreed with FDA to add a warning/precaution to the device labeling to inform users of this additional consideration during removal of the medical device.

Clinical Risk Statement:

Bard has completed an internal Health Hazard Evaluation and concluded that there is the potential for a moderate severity of harm to a patient should the medical professional fail to consider the formation of a knot if significant resistance is encountered during attempts at removal.

Action required:

- Examine your inventory and identify any product subject to this notification. If you have any remaining inventory, include a copy of this communication with the unit(s) for future use.
- If you may have further distributed or transferred this product, please identify the respective user and notify them at once of this communication. Your notification to these users may be enhanced by including a copy of this product communication letter.

This notification should be carried out to the user level.

This product notification is being made with the knowledge of the Food and Drug administration.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action.

Sincerely,

[redacted]

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

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Attachment 1: Product Codes Impacted

Product Name	Product Code
Flouro-4™ Silicone Coil Ureteral Stent With Guidewire (Multilength) 5 Fr, 23-30 cm	277405
Flouro-4™ Silicone Coil Ureteral Stent With Guidewire (Multilength) 6 Fr, 23-30 cm	277406
Flouro-4™ Silicone Coil Ureteral Stent With Guidewire (Multilength) 7 Fr, 23-30 cm	277407
Flouro-4™ Silicone Coil Ureteral Stent With Guidewire (Multilength) 8 Fr, 23-30 cm	277408
Silicone Figure Four Coil Stent With Guidewire, 5 Fr, 23-30 cm	288405
Silicone Figure Four Coil Stent With Guidewire, 6 Fr, 23-30 cm	288406
Silicone Figure Four Coil Stent With Guidewire, 7 Fr, 23-30 cm	288407
Inlay® Multilength Ureteral Stent With Nitinol Guidewire, 4.7 Fr X 22-32 cm	776400
Inlay® Multilength Ureteral Stent With Nitinol Guidewire, 6 Fr X 22-32 cm	776600
Inlay® Multilength Ureteral Stent With Nitinol Guidewire, 7 Fr X 22-32 cm	776700
Inlay® Multilength Ureteral Stent With Nitinol Guidewire, 8 Fr X 22-32 cm	776800
Inlay® Versafit® Multilength Ureteral Stent With Hydro-Glide® Guidewire 4.7 Fr, 22-32cm	777400
Inlay® Versafit® Multilength Ureteral Stent With Hydro-Glide® Guidewire 6 Fr, 22-32 cm	777600
Inlay® Versafit® Multilength Ureteral Stent With Hydro-Glide® Guidewire 7 Fr, 22-32 cm	777700
Inlay® Versafit® Multilength Ureteral Stent With Hydro-Glide® Guidewire 8 Fr, 22-32 cm	777800
Inlay® Versafit® Multilength Ureteral Stent Without Guidewire 4.7 Fr, 22-32cm	778400
Inlay® Versafit® Multilength Ureteral Stent Without Guidewire 6 Fr, 22-32cm	778600
Inlay® Versafit® Multilength Ureteral Stent Without Guidewire 7 Fr, 22-32cm	778700
Inlay® Versafit® Multilength Ureteral Stent Without Guidewire 8 Fr, 22-32cm	778800
Inlay Optima® Multilength Ureteral Stent With Nitinol Guidewire, 4.7 Fr X 22-32 cm	786400
Inlay Optima® Multilength Ureteral Stent With Nitinol Guidewire, 6 Fr X 22-32 cm	786600
Inlay Optima® Multilength Ureteral Stent With Nitinol Guidewire, 7 Fr X 22-32 cm	786700
Inlay Optima® Multilength Ureteral Stent With Nitinol Guidewire, 8 Fr X 22-32 cm	786800
Inlay Optima® Multilength Ureteral Stent With Hydro-Glide® Guidewire, 4.7 Fr, 22-32 cm	787400
Inlay Optima® Multilength Ureteral Stent With Hydro-Glide® Guidewire, 6 Fr, 22-32 cm	787600
Inlay Optima® Multilength Ureteral Stent With Hydro-Glide® Guidewire, 7 Fr, 22-32 cm	787700
Inlay Optima® Multilength Ureteral Stent With Hydro-Glide® Guidewire, 8 Fr, 22-32 cm	787800
Inlay Optima® Multilength Ureteral Stent Without Guidewire, 4.7 Fr, 22-32 cm	788400
Inlay Optima® Multilength Ureteral Stent Without Guidewire, 6 Fr, 22-32 cm	788600
Inlay Optima® Multilength Ureteral Stent Without Guidewire, 7 Fr, 22-32 cm	788700
Inlay Optima® Multilength Ureteral Stent Without Guidewire, 8 Fr, 22-32 cm	788800

**** Product codes 288405, 288406 and 288407 are discontinued and you will not be receiving new product with the new warning/precaution.***

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CUSTOMER ACKNOWLEDGEMENT FORM

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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:**	