**Bard Limited**
Forest House, Tilgate Forest Business Park
Brighton Road, Crawley
West Sussex, RH11 9BP
England, UK.

20th January 2017

**Reference: FA2016-51**

# URGENT FIELD SAFETY NOTICE

## Multi-length ureteral stents

Dear

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* labelling for all Multi-Length Ureteral Stents listed in Attachment 1:

**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.

**Reason for Field Safety Notice (FSN):**

Bard are including the Additional Warning/Precaution to the identified list of products to ensure end users consider the presence of a knot if significant resistance is encountered during attempts at removal. The Bard Multi-Length stents are indicated to relieve obstruction in a variety of benign, malignant and post-traumatic conditions in the ureter. The IFU will be updated for all product codes listed in Attachment 1 and the Additional Warning/Precaution should be considered with all lots of previously received stock.

Our records show that your facility has purchased one or more units of the affected products. All other product codes not listed in this Field Safety Notice can continue to be used by your facility as they are safe to use and are not affected by this communication.

**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.

Please be aware that your Competent Authority is being notified of this Field Safety Notice. As part of this communication, we require that you follow the instructions below and notify Bard of your compliance with this Field Safety Notice.

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**Required actions for you and your Healthcare Facility:**

1. Pass this Notification to all those who need to be aware of it within your organisation and to any organisation where the potentially affected devices have been transferred.
2. Please make sure that the Additional Warning/Precaution (PK7644183 09/2016) is considered with the use of the product codes listed in Attachment 1.
3. If you have further distributed to your customers any of the affected products please immediately contact that location, advise them of the notification.
4. If you have any remaining inventory, include a copy of this communication with the unit(s) for future use.
5. **Product return is not required** and the units can continue to be safely used considering the content of this FSN.

**Please complete the attached Reply Effectiveness Check Form and fax to** +44(0)1293 552 428
**Alternatively this can be emailed to** Donna.Ayling@crbard.com

Note: It is extremely important that we receive this information. If you cannot fax or email the form please telephone your local Bard Customer Service Representative and report the required information verbally.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action. Should you have any questions or require assistance in this matter, please contact your local sales specialist or local Bard Customer Service Representative on +44(0)1293 606 775

Yours faithfully.
For and on behalf of C. R. Bard, Inc.

Attachment 1: List of affected product codes
Attachment 2: Stent Warnings/Precautions (PK7644183 09/2016)

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# REPLY EFFECTIVENESS CHECK FORM

By completing the below information you confirm that the Field Corrective Action Reference Number FA2016-51 has been received by your Healthcare Facility or Organisation and that it has been read and understood.

| **Please PRINT Your Contact Information and fill form out completely** | |
|---|---|
| Name | |
| Title | |
| Name of Account / Hospital | |
| Contact Phone Number | |
| Date | |
| Signature | |

**Please return completed form and any affected product ,should this be felt necessary, to:**

Donna Ayling
Bard Limited
Forest House
Tilgate Forest Business Park
Brighton Road
Crawley
West Sussex
RH11 9BP

Tel: +44(0)1293 606775
Fax: +44 (0)1293 552428
Email: Donna.Ayling@crbard.com

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## Attachment 1: List of affected product codes

| 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 |
| Silicone Figure Four Coil Stent With Guidewire, 8 Fr, 23-30 cm | 288408 |
| 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 |

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| | |
|---|---|
| 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, 288407 and 288488 are discontinued and you will not be receiving new product with the new warning/precaution.