

Bard Singapore Pte Ltd

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



URGENT: Notification – Incorrect Gauge Size labeling of Per-Q-Cath® Products

21 June 2015

Dear Valued Customer,

This is to inform you of an incorrect lumen gauge size labeling involving Per-Q-Cath line of products. The list of affected products is shown in Table 1 at the end of this letter.

Bard Access Systems (BAS) identifies catheter size in two ways on this product, for customer convenience: French size and gauge size. During an internal labeling review, we became aware that the product gauge size (Ga) is incorrect on certain Per-Q-Cath products. The product gauge (Ga) size is provided in two locations: on the label and in some cases on the catheter hub.

The indication of incorrect gauge size on the label and product does not impact device use, as the device itself was manufactured consistently with the specifications. Please note that not all products bear the product gauge (Ga) size on the hub of the catheter. This information is summarized in Table 2. A representative label sample and catheter hub is shown in Figures 1a and 1b, respectively. **The corresponding French size is not affected and is correct for these products.**

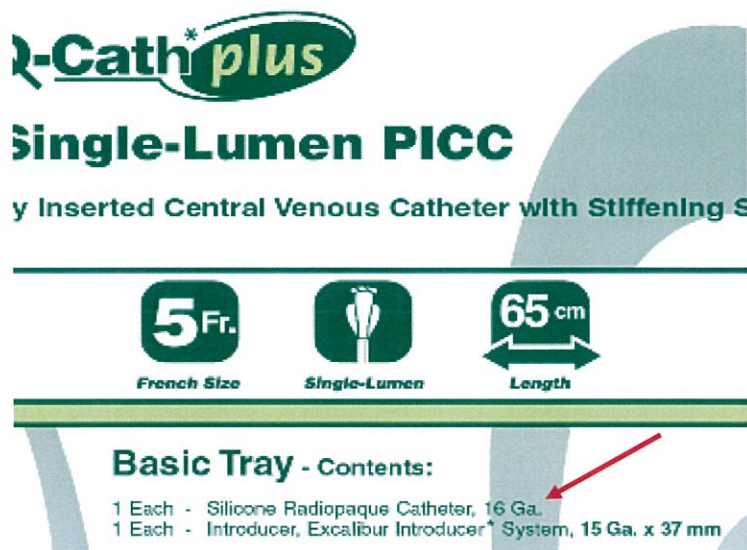


Fig. 1a. On the label (representative 5Fr SL)



Fig. 1b. On the product (catheter hub)

Our records indicate you have purchased some units of the affected catheter kit(s), and we want to ensure that you are notified of this issue.

This situation does not represent a public health hazard. No complaints or injuries have been reported as a result of this incorrect gauge size, and the Health Hazard associated with this issue has been determined to be negligible. The cause of this issue has been corrected and all future lots will be manufactured with unit labels indicating correct gauge size.

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We do not foresee a return of any units for this issue, as the product functions as intended and is manufactured according to design specifications with the correct French size designation. However, if the unit does not meet your needs, we will provide you with replacement units.

We sincerely regret any inconvenience this may cause to you or your facility. Please direct any questions to our RA/QA Manager, Kathleen Leong at kathleen.leong@crbard.com

Sincerely yours,



Mark Wallwork
Vice President & General Manager, Asia

Table 1.0 Affected Codes

S. No.	Product Code	Product Size (Fr.)	Description
1	4133105	3Fr SL	Per-Q-Cath®, 3 Fr. Single-Lumen PICC with Stiffening Stylet Wire
2	4133135	3Fr SL	Per-Q-Cath® 3 Fr. Single-Lumen Midline Catheter with Stiffening Stylet Wire
3	4133110	3Fr SL	Per-Q-Cath® 3 Fr Single-Lumen PICC Catheter Intermediate Tray with Stiffening Stylet, and Excalibur® Introducer
4	4133115	3Fr SL	Per-Q-Cath® 3 Fr Single-Lumen PICC Catheter with Safety Introducer and Stiffening Stylet
5	4134115	4 Fr. SL	Per-Q-Cath® 4 Fr Single-Lumen PICC Catheter, with Excalibur® Introducer and Stiffening Stylet
6	4134105	4 Fr. SL	Per-Q-Cath® 4 Fr Single-Lumen PICC Catheter with Stiffening Stylet Wire
7	4135105	5 Fr. SL	Per-Q-Cath®, 5 Fr. Single-Lumen PICC with Stiffening Stylet Wire
8	4244202	4 Fr. DL	Per-Q-Cath® 4.0 French Dual Lumen Midline Catheter, Intermediate Tray with Safety Introducer
9	4235115	5 Fr. DL	Per-Q-Cath® 5 Fr Dual-Lumen PICC Catheter, with Safety Excalibur® Introducer and Stiffening Stylet
10	4245202	5 Fr. DL	Per-Q-Cath® 5 Fr Dual-Lumen Midline Catheter, Intermediate Tray with Safety Introducer

Table 2.0 Product Size & Gauge Labeling

Product Size (Fr.)	Actual Correct Gauge	Gauge on Label	Gauge on Product
3 Fr. SL	21	20	Not indicated
4 Fr. SL	20	18	Not indicated
5 Fr. SL	19	16	Not indicated
4 Fr. DL	21/24	20/23	20/23
5 Fr. DL	20/20	19/19	19/19