



Mymedic Innovation Sdn Bhd

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URGENT – Field Safety Notice

To all users of the Catheter Foley 2 Way Balloon

Re: Catheter Foley 2 Way Balloon with potential for water in the catheter balloon not being able to be removed and catheter balloon not being able to deflate

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients/user when using the Catheter Foley 2 Way Balloon of the Mymedic Urology Care Devices that can be identified by our product code which is LPC30816 for batch LPC816-2306.

When does this malfunction occur and what are the potential risks?

This Field Safety Notice is issued to address reported complaints related to Catheter Foley 2 Way Balloon Size 16FG:5cc – 10cc. User have reported to have difficulties to remove water from the catheter and deflating the catheter balloon during urine bag change procedure. Based on findings, user had used MyMedic Innovation Foley catheter for a Suprapubic Catheterization (SPC) procedure, whereas the catheter was specifically designed for Urethral Catheterization. Misusing the product beyond its intended use can lead to product failure and pose serious risks to patients' safety.

What steps can the user take to avoid the potential risk of this issue?

User can refer to the directions and precautions printed on the individual pouch to ensure user is aware of correct usage and to prevent any misuse of the product. To prevent any balloon-related issues, it is essential for user to perform inflation and deflation test of the balloon with air prior to use and to ensure the balloon is inflated with sterile water only to guarantee the retention of the catheter. Additionally, the Instruction For Use (IFU) for the Foley Catheter 2-Way Balloon can be accessed by scanning the QR code on the individual pouch, which provides further information required before, during, and after the procedure using the Foley catheter. For any inquiries regarding the use of the Foley Catheter 2-Way Balloon, the user can directly contact the manufacturer.

How will the issue finally be resolved?

Mymedic Innovation has prepared a modification to the labeling on the individual pouch of Foley Catheter 2-Way Balloon. First, the intended use of the Foley catheter is clearly highlighted on the pouch to prevent misuse. Second, additional precautions and directions have been included, emphasizing the importance of inflating and deflating the balloon slowly during the procedure to minimize the risk of failure. Third, the Instructions for Use (IFU) for the MMI Foley Catheter have been updated with more informative guidelines to enhance user understanding and ensure safe and proper usage.

We would like to remind user to carefully read information stated on the individual pouch label and Information for Use (IFU) for the relevant information. User can easily access the full Instruction For Use (IFU) of the Catheter Foley 2 Way Balloon by scanning QR code printed on the individual pouch of the Foley

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,



Mohamad Farkhan Bin Damri
Director
Mymedic Innovation Sdn Bhd

Contact person of this notification:

Department : Customer Care
Telephone : 03-3191 4868 (ext 106)
Fax : 03-3181 7868
E-mail : customer care@mymedic.com.my

Acknowledgement of receipt

I hereby confirm as the owner / responsible operator of the Catheter Foley 2 Way Balloon with the lot number LPC816-2306 that I received the following document:

Field Safety Notice

Catheter Foley 2 Way Balloon with potential Catheter Foley 2 Way Balloon with potential for the balloon not being able to deflate

Place : _____

Date : _____

Name : _____

Signature : _____

Company stamp: