

Bard® Flip-Flo™ Catheter Valve – Instructions for Use

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Instructions for Use

Description: The Flip-Flo™ Catheter Valve is a device that can be added to a catheter that is placed in the urethra or in suprapubic region. The valve is placed on the end of the catheter and can be manually opened and closed to release urine. For adult patients only.

Indication for Use: For use with an indwelling catheter.

Intended Use: The Flip-Flo™ Catheter Valve is intended to facilitate urine drainage and/or collection. For urological use only.

Intended Users: Qualified Healthcare Professionals, Caregiver, Patient/User.

Contraindications:

- Reduced bladder capacity
- Cognitive impairment
- No bladder sensation
- Insufficient manual dexterity to operate the Flip-Flo™ Catheter Valve

Warnings: This product should not be used without assessment of bladder function by an appropriate medical professional.

This is a single use device. Do not re-sterilize any portion of this device. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.

Leave Flip-Flo™ Catheter Valve in open position to allow continuous urine drainage overnight. It is recommended that the Flip-Flo™ Catheter Valve is changed every 5-7 days. Simply disconnect the valve from the catheter and discard.

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practices and applicable local, state and federal laws and regulations.

If you have any clinical concerns with the use of this device for your condition, please contact your healthcare professional.

Users and/or patients within the European Union, should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. Users outside of the European report any serious incident that has occurred in relation to the device to the manufacturer and the regulatory authority of the country in which the user and/or patient is established.

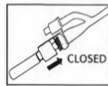
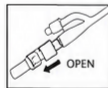
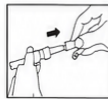
Precaution: Do not use device if package is opened or damaged.

Instructions for Use:

Warning: This product should not be used without assessment of bladder function by an appropriate medical professional.

Instructions:

- Wash hands thoroughly before and after operating Flip-Flo™ valve.
- Attach Flip-Flo™ valve to catheter ensuring that you do not touch either the catheter end or the valve connector.
- Empty bladder as frequently as advised by your doctor or nurse.
- To open the Flip-Flo™ valve, push lever down.
- Allow urine to drain into toilet or an appropriate receptacle.
- To close the Flip-Flo™ valve, pull lever up.
- A night drainage bag may be attached to the flexible connector to allow continuous urine drainage overnight.



Warning: Leave Flip-Flo™ valve in open position.

It is recommended that the Flip-Flo™ valve is changed every 5-7 days. Simply disconnect the valve from the catheter and discard. Attach a new valve following the above instructions.

For U.S. patents that may apply, see bd.com/patents.

The BD English symbols glossary is located at bd.com/en-us/symbols-glossary.

Symbol	Title	Standard Ref. No.	Explanatory Text
Symbols Derived from Standard: ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.			
	Manufacturer	5.1.1	Indicates the medical device manufacturer.
	Authorized Representative in the European Community	5.1.2	Indicates the authorized representative in the European Community.
	Date of manufacture	5.1.3	Indicates the date when the medical device was manufactured.
	Use by	5.1.4	Indicates the date after which the medical device is not to be used.
	Lot number	5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.

Symbols Derived from Standard: ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.

Symbol	Title	Standard Ref. No.	Explanatory Text
	Sterilized using ethylene oxide	5.2.3	Indicates a medical device that has been sterilized using Ethylene Oxide.
	Do not re-sterilize	5.2.6	Indicates a medical device that is not to be re-sterilized.
	Do not use if package is damaged and consult instructions for use	5.2.8	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	Single sterile barrier system	5.2.11	Indicates a single sterile barrier system.
	Single use	5.4.2	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Consult instructions for use or consult electronic instructions for use	5.4.3	Indicates the need for the user to consult the instructions for use.
	Caution	5.4.4	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Medical device	5.7.7	Indicates the item is a medical device.
	Unique device identifier	5.7.10	Indicates a carrier that contains unique device identifier information.

Symbols Derived from Standard: ISO 7000 – Graphical symbols for use on equipment.

Symbol	Title	Standard Ref. No.	Explanatory Text
	Packaging unit	2794	To indicate the number of pieces in the package.
	Open here	3079	To identify the location where the package can be opened and to indicate the method of opening it.

Symbols Derived from Standard: ISO 20417:2021 – Medical devices – Information to be supplied by the manufacturer.

	Authorized Representative for Switzerland	N/A	Indicates the authorized representative for Switzerland.
	Authorized Representative for the United Kingdom	N/A	Indicates the authorized representative for the United Kingdom.
Other			
	Not Made with Natural Rubber Latex	N/A	To indicate the device is Not Made with Natural Rubber Latex.

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C. R. Bard, Inc.
8195 Industrial Boulevard
Covington, GA 30014 USA +1.844.823.5433 bd.com



Becton Dickinson Ireland Ltd.
Donore Road, Drogheda, Co. Louth, A92 YW26
Ireland

BD Switzerland Sàrl
Route de Crassier 17, Business Park Terre-Bonne
Batiment A4, 1262 Eysins, Switzerland

Becton, Dickinson UK LTD
1030 Eskdale Road, Winnersh Triangle
Wokingham, Berkshire, England, RG41 5TS



Australian Sponsor:
Becton Dickinson Pty Ltd, T/A Bard Australia Pty Ltd
66 Waterloo Road, Macquarie Park, NSW, 2113
Australia

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