COATED LATEX FOLEY CATHETERS

BARD®

COATED LATEX FOLEY CATHETERS

A superior catheter material engineered for performance.

MADE WITH BARD COATED LATEX

Trusted Performance Built In

UROLOGY

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MADE WITH BARD COATED LATEX

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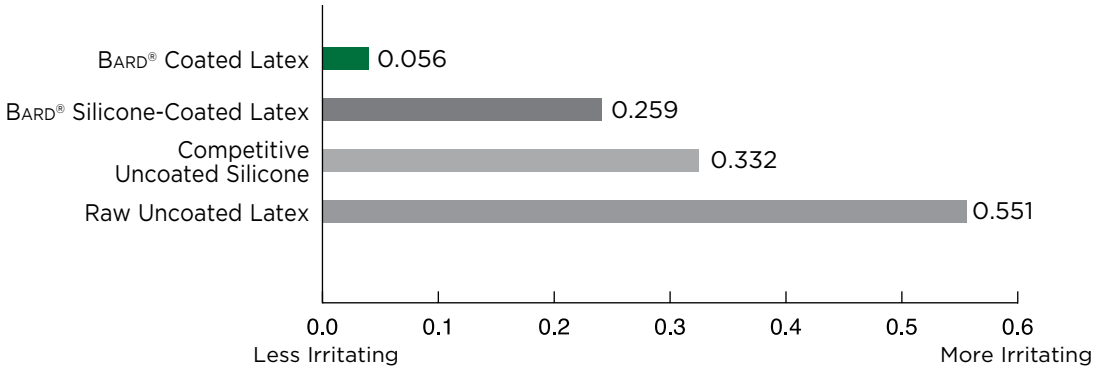
Bard Coated Latex:

Reduce the Risk of Urethral Irritation and Infection

The exclusive BARD® hydrogel coating is proven to reduce friction, a major cause of irritation.

- **Less irritation of delicate urethral tissue means less risk of infection.**



Per 24-hour hydration testing: The coefficient of friction (COF) measures the ease with which two surfaces slide against each other. A lower COF indicates less resistance, while a higher COF indicates more resistance, more friction and greater irritation.

Exclusive Bard® Hydrogel Coating Enhances Patient Safety

In a proprietary process, the exclusive hydrogel coating penetrates the inner latex substrate to create a lubricious barrier that enhances patient safety, and remains intact throughout the course of use.

Insertion:

- Allows atraumatic insertion for enhanced patient comfort

Indwelling:

- Absorbs mucosal fluid to form a "cushion" between the catheter surface and delicate urethral tissue, thereby reducing friction and irritation that can lead to infection[1]
- Provides a lubricious surface that resists encrustation of urine salts

Removal:

- BARD® hydrogel coating maintains its integrity throughout the course of use, resulting in less trauma upon removal

BARD® Coated Latex Foley catheters prevent bacterial adherence and encrustation.

- **No encrustation means less trauma to urethral tissue upon removal.**

Comparative Analysis of Bacterial Adherence to Catheters

	Outside Surface (in Serum)		Inside Surface (in Urine)	
Bacteria	**Silicone**	**Bard Coated Latex**	**Silicone**	**Bard Coated Latex**
E. coli	1.3 ±0.5	0.0	91.5 ±4.4	0.0
Pseudomonas f.	7.3 ±0.9	0.0	0.0	0.0
S. aureus	5.9 ±1.9	0.0	68.4 ±3.8	0.0
Klebsiella	1.9 ±1.0	0.0	25.9 ±3.3	0.0
S. epidermidis	0.0	0.0	185.1 ±9.1	0.0
Proteus m.	6.7 ±1.2	0.0	21.1 ±2.5	0.0
Serratia	65.1 ±3.5	0.0	79.2 ±4.4	0.0
Proteus m. (G114)	135.7 ±4.8	0.0	14.1 ±2.6	0.0

Adapted from Roberts, JA, Kaack, MB, Fussell, EN. Adherence to Urethral Catheters by Bacteria Causing Nosocomial Infections. *Urology*. 1993; 41(4): 338-342.

Trusted Performance Built In

A Superior Catheter Material Engineered for Performance

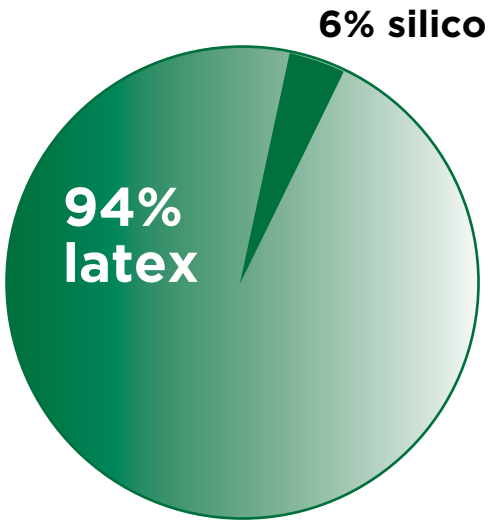
For more than 70 years, BARD® has delivered on its commitment to develop the highest quality Foley catheters. One of the most important contributions BARD® has made to improving Foley catheters has been in the material itself. From the Teflon® coating introduced in the 1960s to the exclusive BARD® hydrogel coating of today, there have been successive innovations, each aimed at reducing the risk of infection and raising the standard of performance.

BARD® Coated Latex Foley catheters maximize the best properties of latex to produce consistent high quality performance clinicians can rely on to:

- enhance patient safety
- reduce friction and irritation that can lead to infection
- ensure catheter strength, integrity and reliable performance

There's good reason why over 90% of the Foley catheters in trays chosen by clinicians are latex. Compared to silicone, BARD® Coated Latex Foley catheters are less irritating, more lubricious, more reliable, and significantly stronger. Clinicians can feel confident when they see "Made with BARD® Coated Latex." It's a sign of performance and safety, backed by a history of innovation and quality.

Percentage of Foley catheters in trays by material[2]



U.S. Foley catheter market reflects the overwhelming choice of clinicians – latex.

A History of Innovation and Quality

2000s BARD® introduces BARDEX® I.C. COMPLETE CARE® System by adding antimicrobial agents to the drainage tubing, collection bag, and outlet tube in order to provide complete protection to help reduce catheter-associated urinary tract infections (CAUTIs).

1990s Bard introduces the BARDEX® I.C. latex anti-infective Foley catheter with Bacti-Guard®* silver alloy and hydrogel coating significantly reducing CAUTIs and also the LUBRI-SIL® I.C. silicone Foley catheter.

1980s Bard introduces LUBRICATH® hydrogel-coated latex for greater lubricity and added benefit of reduced bacterial adherence.

1970s Bard introduces a 100% silicone catheter because some urologists asked for a less pliable catheter for traction during procedures.

1960s Bard introduces Teflon®-coated latex Foley catheter.

1950s Bard produces first sterile-packaged Foley catheters.

1940s Bard begins distribution of the first American Woven Catheter.

1930s Davol Rubber Co., in partnership with C. R. Bard Inc., mass produces Foley catheters.

1920s C. R. Bard, Inc. is formally incorporated. Dr. Frederick Foley invents rubber latex Foley catheter.

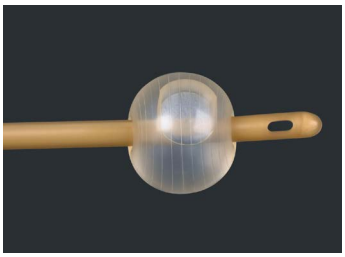
Trusted Performance Built In

Choose Proven Catheter Strength, Integrity and Performance

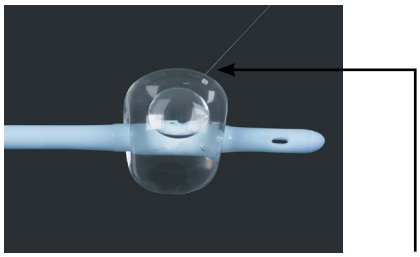
BARD® Coated Latex Foley catheters consistently outperform silicone.†

Prevent premature deflation and unexpected dislodgement

Per ASTM F623 (American Society for Testing and Materials) simulated use test:



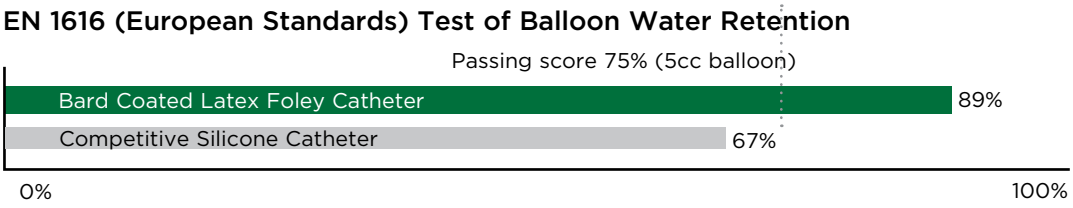
Zero pinholes mean less risk of balloon collapse with Bard Coated Latex Foley catheters.



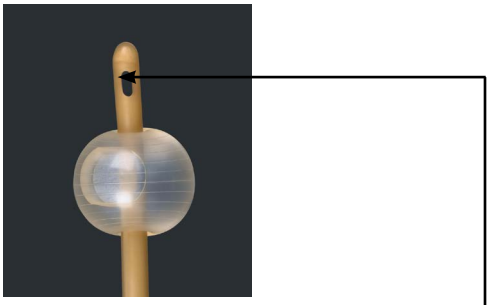
Competitive silicone Foley catheters tested formed pinholes up to 50% of the time.

BARD® Coated Latex Foley catheters demonstrate superior balloon water retention to keep the catheter optimally positioned within the bladder.

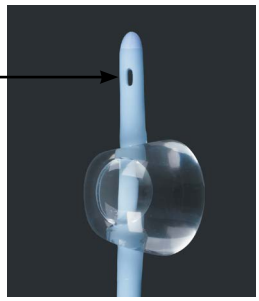
EN 1616 (European Standards) Test of Balloon Water Retention



Ensure optimal seating within the bladder neck, minimizing leakage



BARD® Coated Latex Foley catheter balloons retain their shape (measured as 54/46 concentricity).



Note the irregular shape of a competitive silicone Foley catheter (measured as 68/32 concentricity).

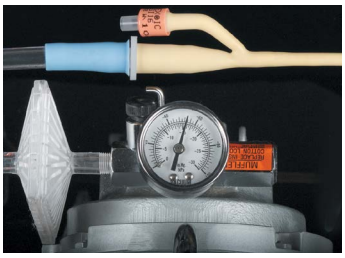
Reduce clotting and maximize urine flow

BARD® Coated Latex Foley catheter eyeholes are 91% larger than tested competitive silicone Foley catheters.

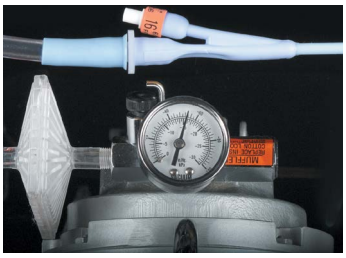
Reduce the risk of failure in traction

- Because the Bard® Coated Latex Foley catheter balloon is dipped, it cannot be pulled off. Tested competitive 16 French silicone Foley catheter balloons pull off with only 6.8 lbs of force. This no pull off feature also reduces the risk of balloon fragments remaining in the bladder.

Reduce the risk of funnel collapse during aspiration of clots or mucous



The Bard® Coated Latex Foley catheter funnel resists kinking and urine flow obstruction. Funnel strength is greater than -23 in. Hg.

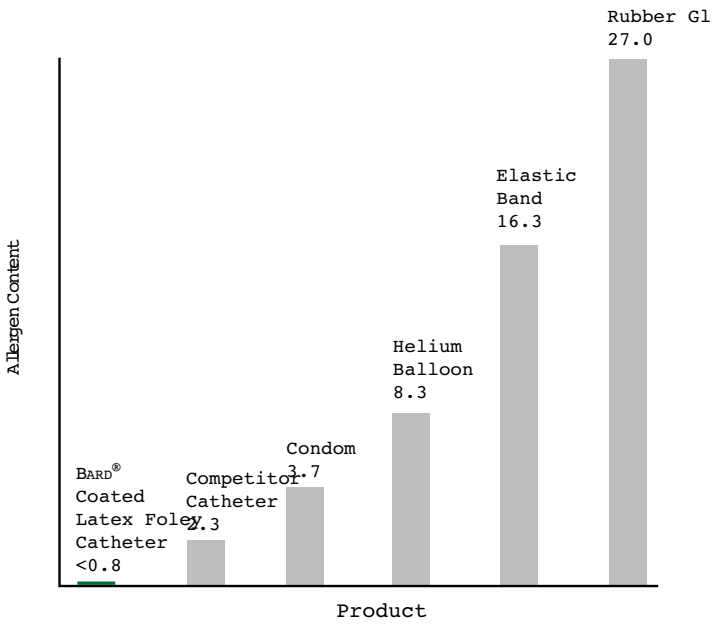


Tested competitive silicone Foley catheters cannot match Bard's funnel durability, collapsing with only -15 in. Hg.

Rely on the Refined Process

Bard is a global manufacturer of the highest quality latex urological products, and has the only U.S. manufacturing facility dedicated to the production of latex Foley catheters. For the last 70 years, there have been no confirmed allergic reactions to Bard Coated Latex Foley catheters.

The ability of a product to cause an allergic reaction is directly related to the amount of allergens present. Bard's manufacturing practices incorporate an extensive leaching process that removes the maximum amount of allergens in latex.



Latex Allergen Content Test Results (RAST Inhibition)[2]

Three samples per product were tested by RAST Inhibition. Of the samples tested, the Bard catheter had the lowest amount of allergen content, as well as demonstrating the most consistent results among the three samples tested (each Bard sample was shown to have less than 0.8 µg/g allergen content).

† Data on file.

What you should know about latex allergies and Bard® Coated Latex Foley catheters

- The latex sensitivity risk in the general population has been estimated at less than 1% with some as little as 0.12%.[3]
- Bard® Coated Latex has the lowest allergen levels in the industry – less than 0.8 µg/g.[2]
- In the last 70 years, there have been no confirmed allergic reactions to Bard® Coated Latex Foley catheters.

MADE WITH BARD COATED LATEX
Trusted Performance Built In

Sterile: Contents of inner wrap are sterile unless package has been opened or damaged.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Single Use Only.
Do not re-sterilize.
For urological use only.

Warning: On catheter, do not use ointments or lubricants having a petrolatum base. They will damage the catheter and may cause balloon to burst.

Warning: 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.

Visually inspect the product for any imperfections or surface deterioration prior to use. If package is opened or if any imperfection or surface deterioration is observed, do not use.

The Sign of Performance and Safety

Feature	Benefit
Superior Strength	Guards against premature deflation or collapse
	Maintains balloon integrity
	Resists tears and collapse during clot aspiration
	Resists rupture
Exclusive Bard Hydrogel Coating	Reduces the risk of infection
	Resists encrustation
	Allows smooth, atraumatic insertion and removal for enhanced patient comfort
Extensive Leaching Process	Enhances patient safety (no confirmed allergic reactions to date)

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www.bardmedical.com

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1. Daifuko R, Stamm W. Bacterial Adherence to Bladder Uroepithelial Cells in Catheter-Associated Urinary Tract Infection. NEJM 1986; 314: 1208-13.

2. Data on file. Bard Medical Division.

3. Liss GM, Sussman GL. Latex sensitization: occupational versus general population prevalence rates. *Am.J.Ind.Med.* 1999; 35: 196-200.

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, cautions and directions for use.

* The Foley catheters included in the Bardex I.C. System contain Bacti-Guard silver alloy coating, which is licensed from Adhesive Technology (International) Licensing, B.V.

 1007-23 R09/10 TLX P12/10 2.5M