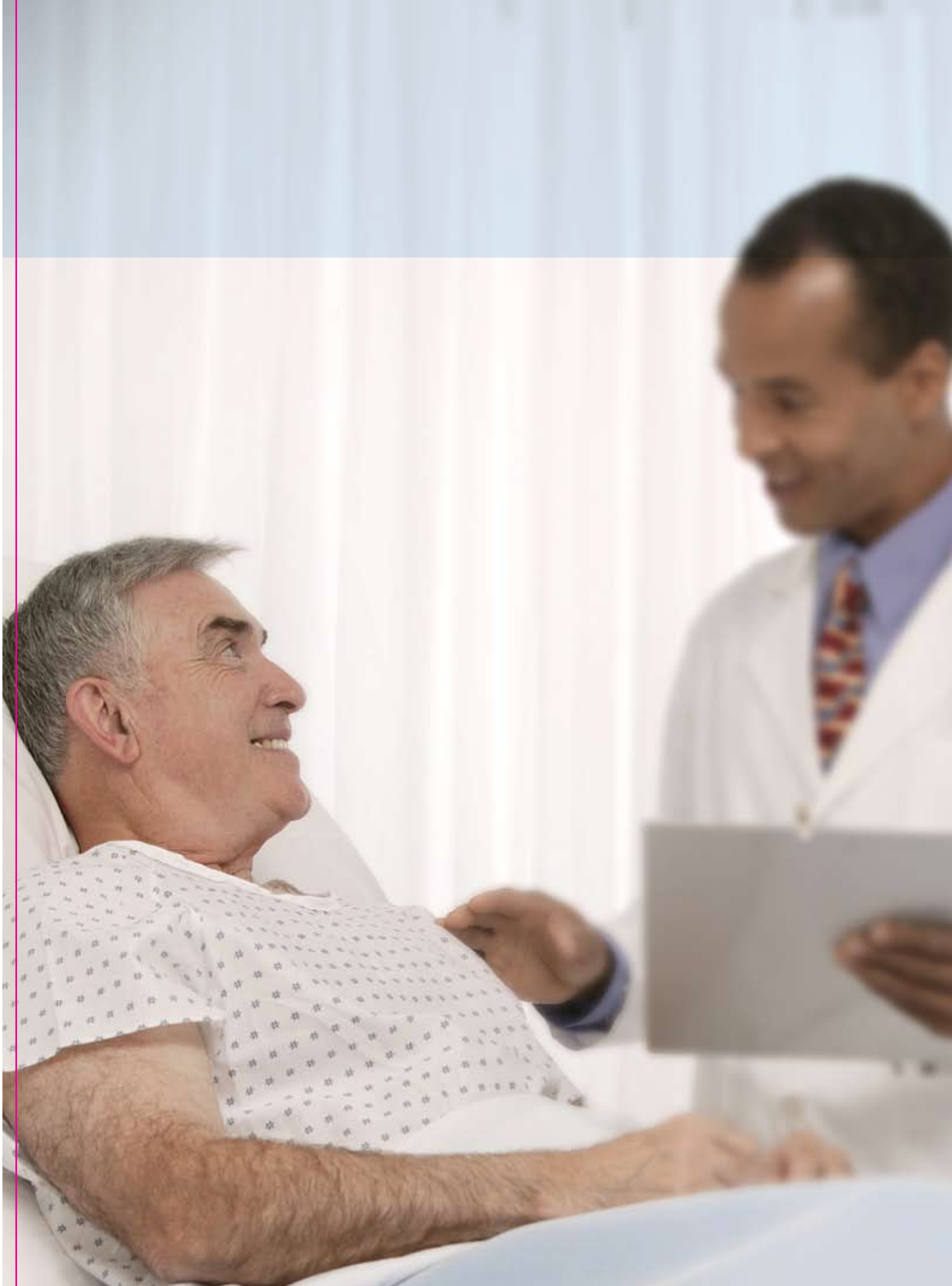
Dover™ Urology Products

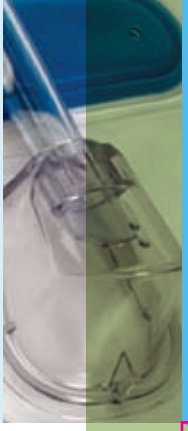
Urological Innovations in Silicone

COVIDIEN

Dover™

The mission of Dover™ urology products is to create and deliver innovative healthcare solutions. With 1 in 4 patients catheterized in the US, it is vital that your urology products are of the highest quality, with superb function, and provide lasting improvements to patients lives. Dover™ urology products embody these requirements due to collaboration with medical professionals to provide a Best-in-Class offering. Our goal is to deliver value to healthcare professionals for the purposes of improving patients lives.





Dover™ Urology Products

Catheterization complications extend beyond the Foley catheter. All components, including the Foley, drain bag, and prepping components, contribute to patient care and their final outcomes. You care about the well-being of your patients and, therefore, you must question the entire system.

Dover™ urology products are the answer

By focusing on each aspect of the system, Dover™ urology products offer a Best-In-Class Product that reduces catheter-associated complications and improves overall collection system flow. Dover™ urology products has set out to produce the best possible outcomes, provide efficient and safe practices, while improving patients lives.

Material Selection

The Foley materials you select will have a direct impact on patient safety from the moment they are put into use. Selecting latex-free materials can reduce complications associated with catheterization.

Dover™ urology products offer a premium solution, featuring the latest innovations in material and construction. Dover™ 100% silicone catheters reduce encrustation, lower the incidence of urethral irritation, and eliminate latex allergy concerns.

Comparing Latex to 100% Silicone

LATEX

Latex-based Foley catheters provide an increased risk to patients.

LATEX IS:

Cytotoxic

- Body rejects latex by exhibiting foreign body response (irritation) due to its toxic properties

Organic

- Organic protein rich material containing chemicals as a result of the manufacturing process
- Proteins act as a food source for bacteria

Porous

- Absorbs moisture causing catheter expansion

Allergy Promoting

- Latex material is known to cause various levels of allergic reactions (type I-IV)

Adherent

- Encourages encrustation

HYPERSENSITIVITY

Latex, when used in direct patient contact, can be a significant source of irritation.

"The ideal materials should be biologically inert, chemically stable in urine without any release of toxic contaminants and resistant to encrustation."

Pariente FL, Bordenave L, Jacob F, Bareille R, Baquey C, Le Guillou M. "Cytotoxicity Assessment of Latex Urinary Catheters on Cultured Human Urothelial Cells." European Urology (2000) 38(5):640-643, ©S. Karger AG, Basel. Used with permission.

*The FDA requires a warning label on all products containing latex due to the inherently cytotoxic nature of this substance.

100% SILICONE

100% Silicone Foley catheters reduce catheter-associated complications compared to Latex Foley catheters. Silicone material offers optimal performance while eliminating latex concerns.

SILICONE IS:

Biocompatible

- Non-reactive to human tissue

Inorganic

- Contains no extractable chemicals
- Protein-Free

Non-Porous

- Will not absorb body fluids and eliminates "Foley catheter expansion"

Non-Toxic

- Free of latex allergens and non-reactive Human Urethral Cells

Non-Adherent

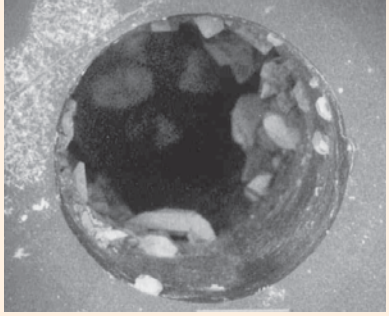
- Repels urine, blood, salts & organic materials
- Reduces encrustation which minimizes the likelihood of occlusion

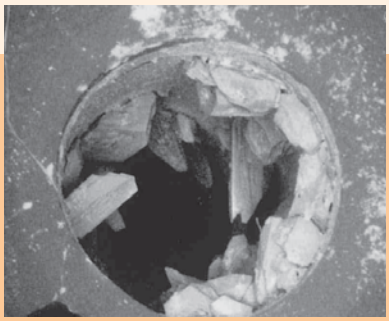
A true broad-spectrum

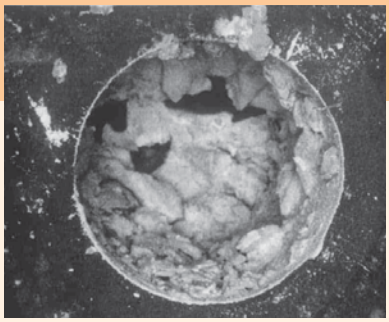
solution

Patients with indwelling Foley catheters are prone to many complications. Stricture, Encrustation, Bladder Lesions, and Hypersensitivity are some of the likely complications facing your patients.

By simply choosing Dover™ urology products, the probability of a complication is drastically reduced. As one of the largest manufacturers of 100% Silicone Foley catheters, Covidien's line of Dover™ urology products provides an unmatched broad-spectrum solution to reduce catheter-associated complications.







Cross-sections of BARDEX IC Catheter. Source: Sabbuba N, Stickler D.

Encrustation

Encrustation is a significant cause of catheter failure.

"The silicone-based Dover catheters took a statistically significant longer time to block [occlude] than did latex-based BARDEX catheters."*

Sabbuba N, Stickler D. "Report of Encrustation Performance of Foley Catheters in a Laboratory Model of the Catheterized Bladder" Cardiff School of Biosciences (December 2002). Used with permission.

Type of Catheter	Mean Time to Blockage in Hours
Bardex*† Lubricath*†	30.5 hours
Bardex*† IC	29.8 hours
Dover Silicone	53.7 hours
Dover Silver	51.7 hours

Average mean time to block ± 1 SD. Statistically significant in vitro study.

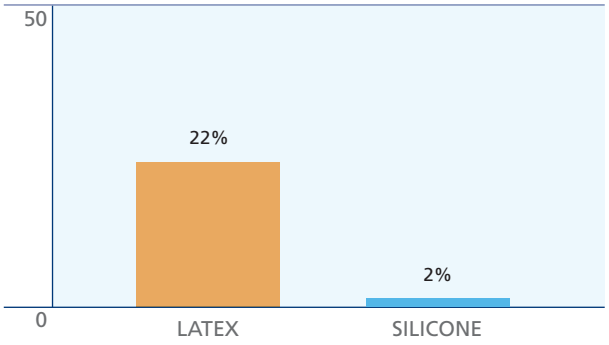
Urethritis

Urethritis is a major source of patient discomfort and contributes to a breakdown in tissue integrity.

"Of those with latex catheters 22% developed urethritis, compared with 2% of those in the silicone catheter group. This difference is statistically significant (P<0.01)."

Nacey JN, Tulloch AGS, Ferguson AF. "Catheter-induced Urethritis: A Comparison Between Latex and Silicone Catheters in a Prospective Clinical Trial." British Journal of Urology (1985) 57:325-328. Used with permission.

Incidence of Urethritis

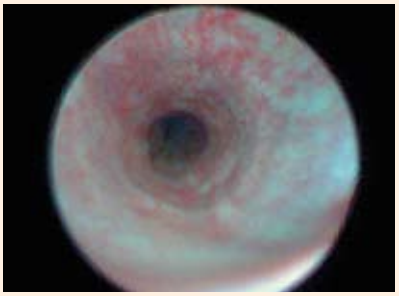


Peer-reviewed, published, clinical in vivo study Source: Nacey JN, Tulloch AGS, Ferguson AF.

"Decreased inflammatory response, reduced urethral discharge, and lower risk of ascending urinary tract infections have also been reported as advantages of silicone catheters compared to latex catheters.

Gonzalgo M, Walsh PC. "Balloon Cuffing and Management of the Entrapped Foley Catheter." Urology (2003) 61:825-827. Used with permission.

Urethral stricture



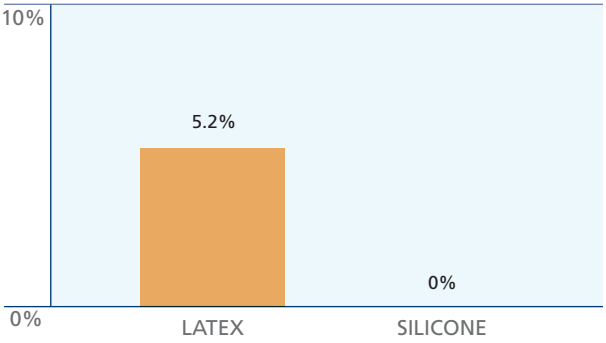
Normal urethra

Stricture

Stricture reduces the ability of a patient to void which may lead to bladder distention, kidney failure and other major complications.

"Thus the overall incidence of urethral stricture in the group with latex catheters was 5.2% when followed up for between 15 and 24 months compared with 0% in those with silicone catheters followed up for between 12 and 28 months."

Incidence of Stricture



"On the basis of our two series, we suggest that silicone catheters be used routinely for short-term catheterization in men undergoing bypass surgery."

Ferrie BG, Groome J, Sethia B, Kirk D. "Comparison of Silicone and Latex Catheters in the Development of Urethral Stricture after Cardiac Surgery." British Journal of Urology (1986) 58:549-550. Used with permission.

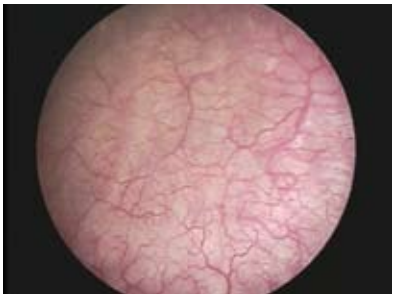
Peer-reviewed, published, clinical in vivo study. Source: Ferrie BG, Groome J, Sethia B, Kirk D.

Bladder Lesions

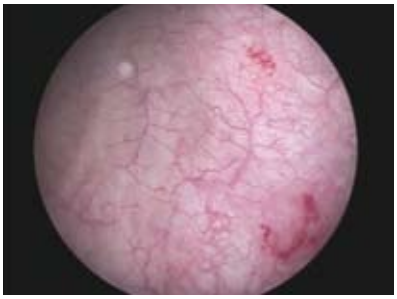
Pressure-induced bladder distention and catheter-associated suction lesions are both inherent complications of catheterization in non-vented closed systems.

"Top-vented catheter valve tubing will produce a clinically and statistically significant difference in suction lesions of the bladder versus traditional non-vented catheter drainage tubing."

Grocela JA, MD, MPH. "A Prospective, Randomized, Blinded Comparison of Top-Vented Catheter Valve vs. Non-Vented Catheter Valve Suction Damage to the Bladder in a Convenience Sample of Woman Undergoing Urethral Support Surgery" Presented at New England Section of the American Urological Association, September 26th 2008. Used with permission.

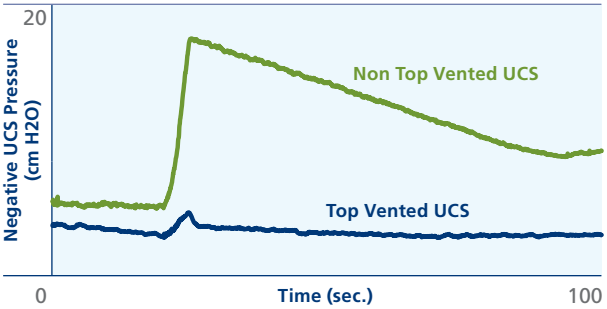


Pre catheterization



Post catheterization

Suction Comparison of Vented and Non Vented Urine Collection Systems



Increased suction may cause bladder lesions.

** Source data on file (meter and bag average)*

It's not just how it's made – It's how

it works

Proven construction and materials matter. Proven performance matters even more. When you select the market leading Dover™ 100% silicone catheters, you have chosen products that are fabricated from materials that out-perform latex. The result? The extrusion molding process, combined with the unique properties of silicone, provide larger internal lumens, greater resistance to shaft collapse and improved flow. Dover™ urology products work better because they are made better.

Construction

For unparalleled patient comfort and consistent clinical performance, today's silicone provides larger internal lumens, stronger catheter walls, better flow rates and true French sizes — all in a biocompatible material.

"A desirable property of silicone catheters compared to latex catheters is improved durability."

"Silicone catheters may be better suited to patients who have undergone urologic procedures that may require vigorous irrigation or aspiration of clots."

"The silicone shaft tubing is less prone to collapse during manipulation compared to latex tubing."

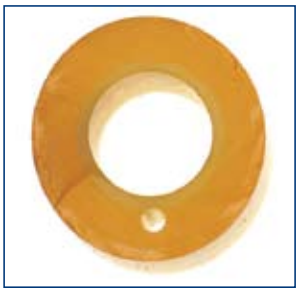
Gonzalgo M, Walsh PC. "Balloon Cuffing and Management of the Entrapped Foley Catheter." Urology (2003) 61:825-827. Used with permission.

Dover™ 100% Silicone Catheter © Covidien

Bardex™ Lubricath Catheter © Covidien

Improved Flow

Cross-section of Dover™ Silicone Catheter © Covidien

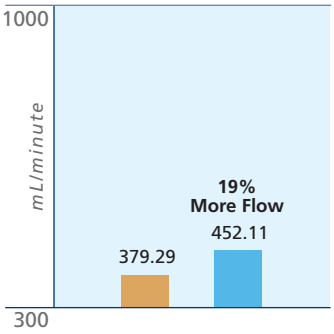


Cross-section of Bardex™ Lubricath* Catheter © Covidien*

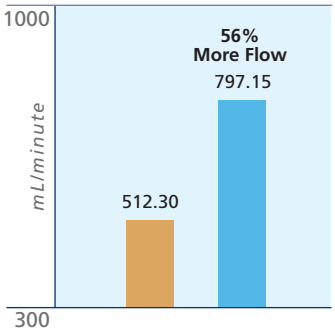
Bardex™* Latex Catheter

Dover™ 100% Silicone Catheter

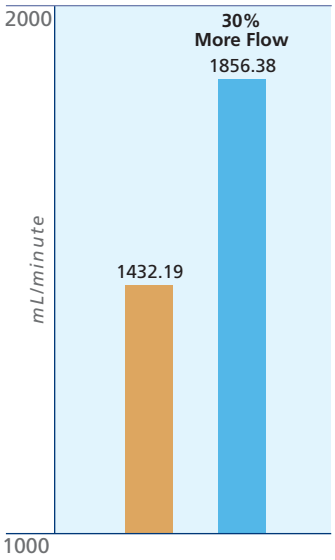
16Fr, 5cc 2 Way Foley



18Fr, 5cc 2 Way Foley

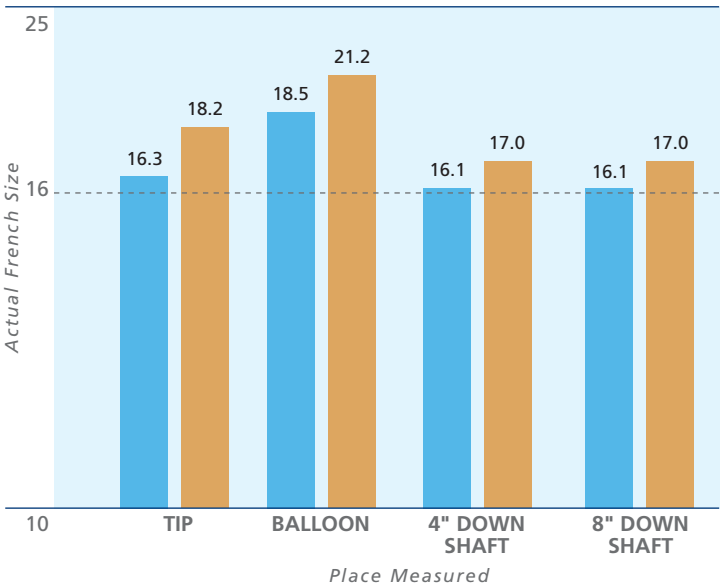


24Fr, 30cc 2 Way Foley



Source: Data on file ASTM-F623-99*

True French Sizes (16FR)



*Source: Data on file**

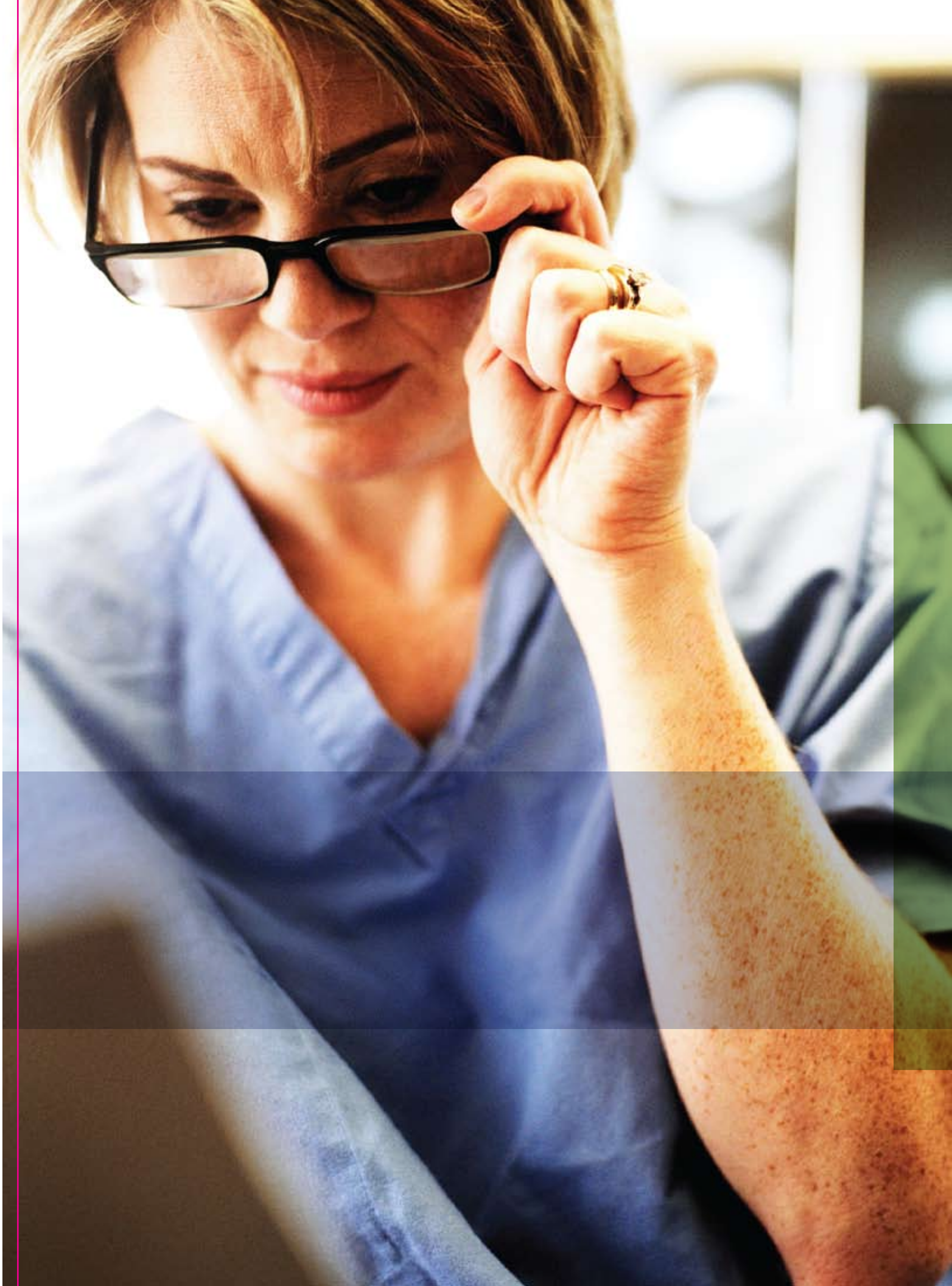
Catheter O.D. Comparison: Dover™ 16Fr vs. Bardex™* 16Fr

Dover™ silicone offers superior extrusion manufacturing processes to provide consistent and accurate catheter sizing. Compared to Bard™* Latex, Dover™ silicone is more than 2X more accurate.

- 16 Fr Dover Silicone tolerances are +/- 2.5 Fr
- 16 Fr Bardex™* Lubricath™* tolerances are +/- 5.2 Fr

Dover™ Silicone 16 F

Bardex™* Latex 16 F



Dover™ silver 100% silicone Foley catheters represent the very latest in catheter technology. Its phospate silver ion technology, coupled with a hydrogel coating on both the internal and external surfaces, slowly releases ionic silver particles. This technology is engineered to release higher concentrations of silver ions during the first five days and provide consistent elution over time.

Best in class

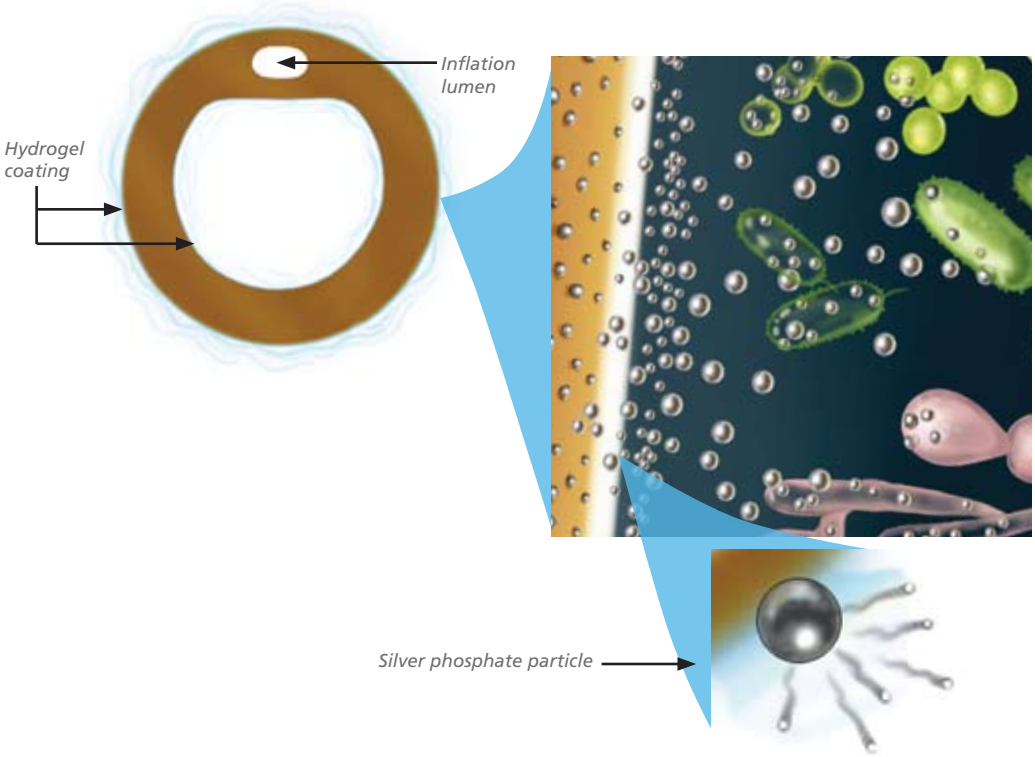
silver

elution performance

Programmable Release Technology

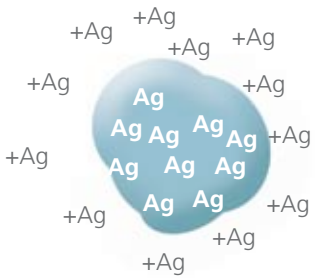
Not all silver technology is created equal. Phosphate silver ion technology, coupled with a hydrogel coating on both internal and external catheter surfaces, slowly releases ionic silver particles from the Dover 100% silicone platform.

Magnified View of Hydrogel Silver Elution Process

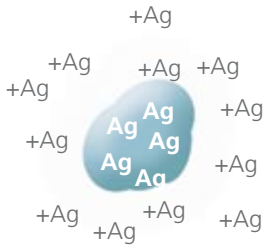


Suspended within the catheter hydrogel coating lies a completely efficient ionic silver elution technology.

Silver Phosphate particle with silver ions in suspension (non-active)



As the water-soluble phosphate dissolves, ionic silver becomes active.

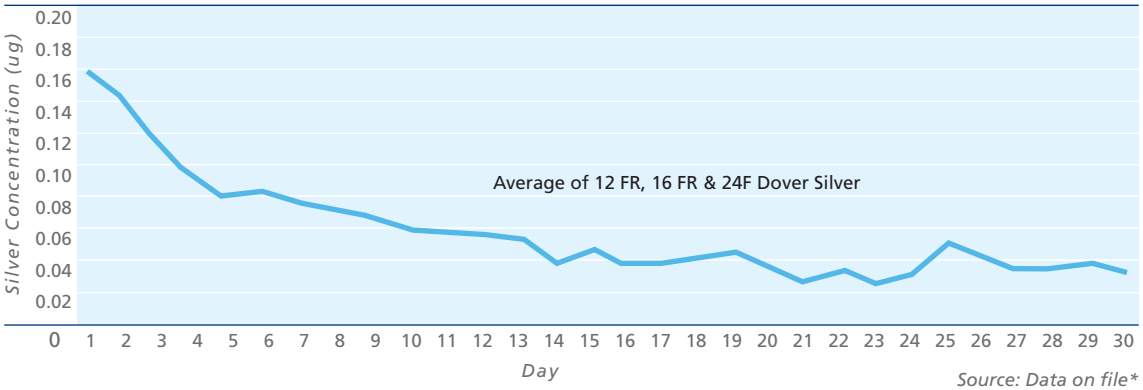


Dissolve rates are engineered to maximize the release of active silver ions over time.

Silver Coating on a Premium Silicone Platform

The Dover™ silver catheters release higher concentrations of silver ions during the first five days and provide consistent elution over time. Coupled with a "slicker" hydrogel coating on inert silicone material, the silver is truly "available".

Silver Elution Profile Psuedo Urine

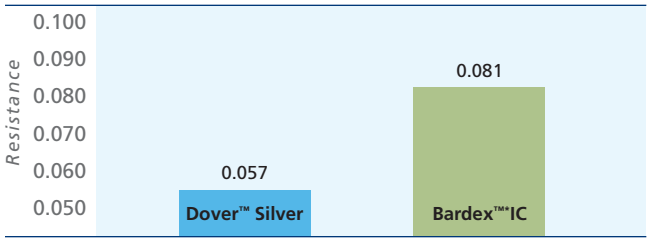


*Source: Data on file**

Hydrogel Coating

As compared to the Bardex™* IC Catheter, the Dover™ silver hydrogel coating reduces friction, limiting urethral irritation.

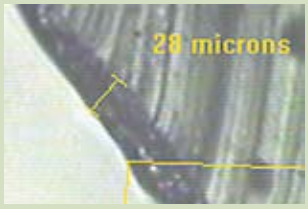
Hydrogel Coated Catheter Friction Test



Source: Data on file

Compared to the Bardex™* IC, the Dover Silver coating is 3.5x thicker.

Bardex™ IC Catheter*



Dover™ Silver Catheter

A urine collection system requires constant flow to ensure the bladder empties properly and remains free of positive and negative pressures that act on the urinary tract. Eliminating these pressures by using a vented system will minimize complications such as bladder distention and bladder lesions. A vented system will optimize flow performance, minimizing caregiver time and improving patient comfort and safety.

Dover™ urology products' total system approach addresses all aspects of urine collection to optimize flow and improve patient safety in an ergonomic design.

Optimized

flow performance

Minimized complications

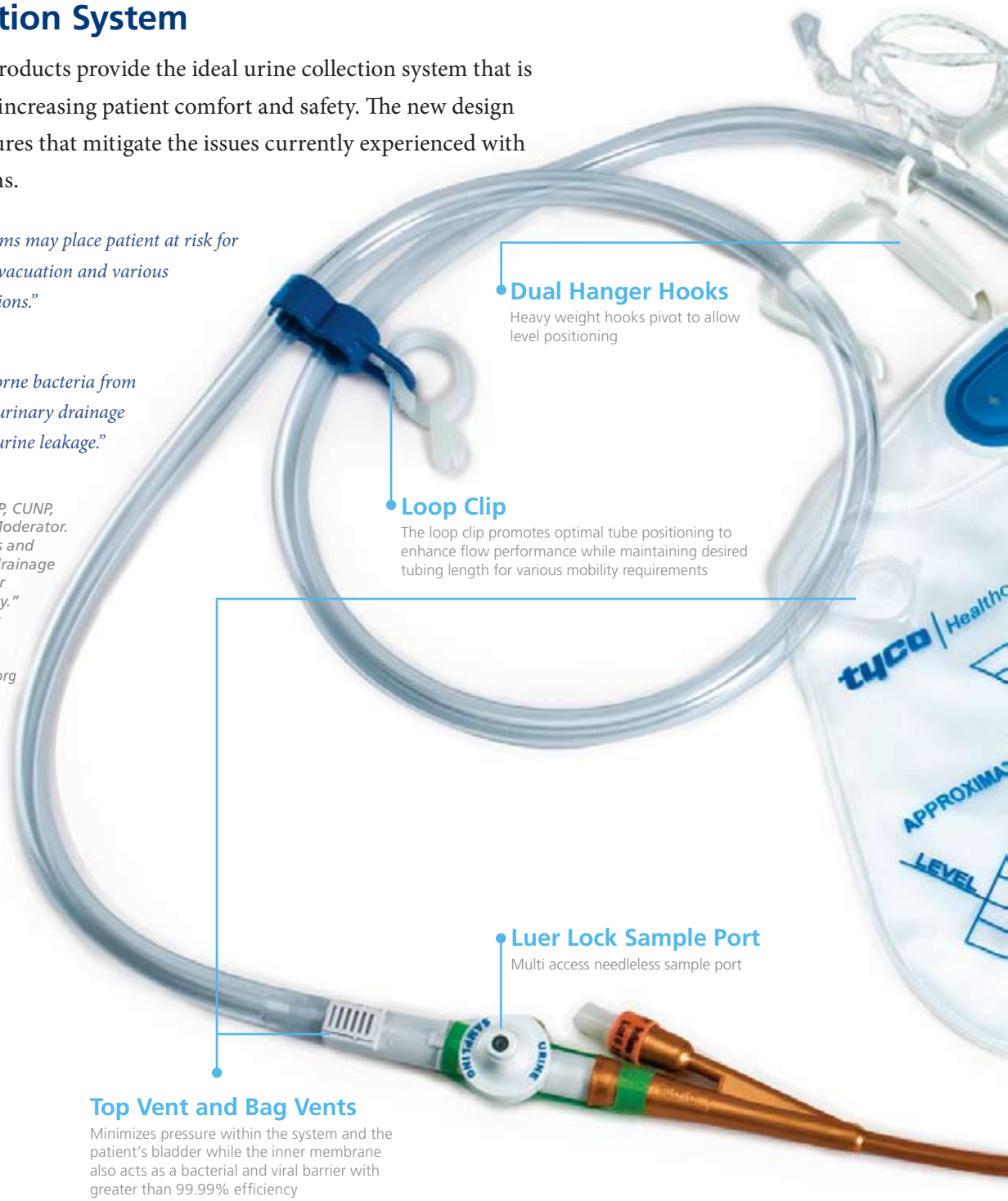
The Collection System

Dover™ urology products provide the ideal urine collection system that is easy to use while increasing patient comfort and safety. The new design incorporates features that mitigate the issues currently experienced with traditional systems.

"Dynamic flow problems may place patient at risk for incomplete bladder evacuation and various inflammatory conditions."

"A filter prevents airborne bacteria from gaining access to the urinary drainage system and prevents urine leakage."

Gray, M., (PhD, FPN, PNP, CUNP, CCCN, FAANP, FAAN). Moderator. "Symposium: Consensus and controversy in urinary drainage systems: Implications for improving patient safety." Safe Practices in Patient Care Vol.4, No 1; 1-8. Accessed October 2008 http://www.safe-practices.org



Dual Hanger Hooks

Heavy weight hooks pivot to allow level positioning

Loop Clip

The loop clip promotes optimal tube positioning to enhance flow performance while maintaining desired tubing length for various mobility requirements

Luer Lock Sample Port

Multi access needleless sample port

Top Vent and Bag Vents

Minimizes pressure within the system and the patient's bladder while the inner membrane also acts as a bacterial and viral barrier with greater than 99.99% efficiency

Anti-Reflux Device

Lower point of entry to further assist the gravity fed downward flow dynamic

Urine Meter Face Plate Needleless Sample Port

Self sealing luer lock sample port, compatible with OSHA's recommendation for needleless sampling reduces the likelihood of system contamination by maintaining a closed system

Drain Spout

45 degree pedestal ensures device remains vertical during operation, offers one-handed operation reduces in exposure to fluids while maintaining a truly closed system

Flow

Vented System
Loop Clip
Lowered Point of Entry
Anti Reflux Device

Safety

Needleless Luer Lock Sampling
Vented System
Loop Clip
Anti Reflux Device
Drain Spout
True Closed System
Latex Free

Ease of Use

Needleless Luer Lock Sampling
Loop Clip
Hanger Hooks
Drain Spout

All cited reference articles used with permission.
Copies of cited articles available on request.
*Data available on request
™* trademark of C. R. Bard, Inc.

H6424 8M 04/09

COVIDIEN

15 Hampshire Street
Mansfield, MA
02048

1-800-962-9888
508-261-8000

www.covidien.com