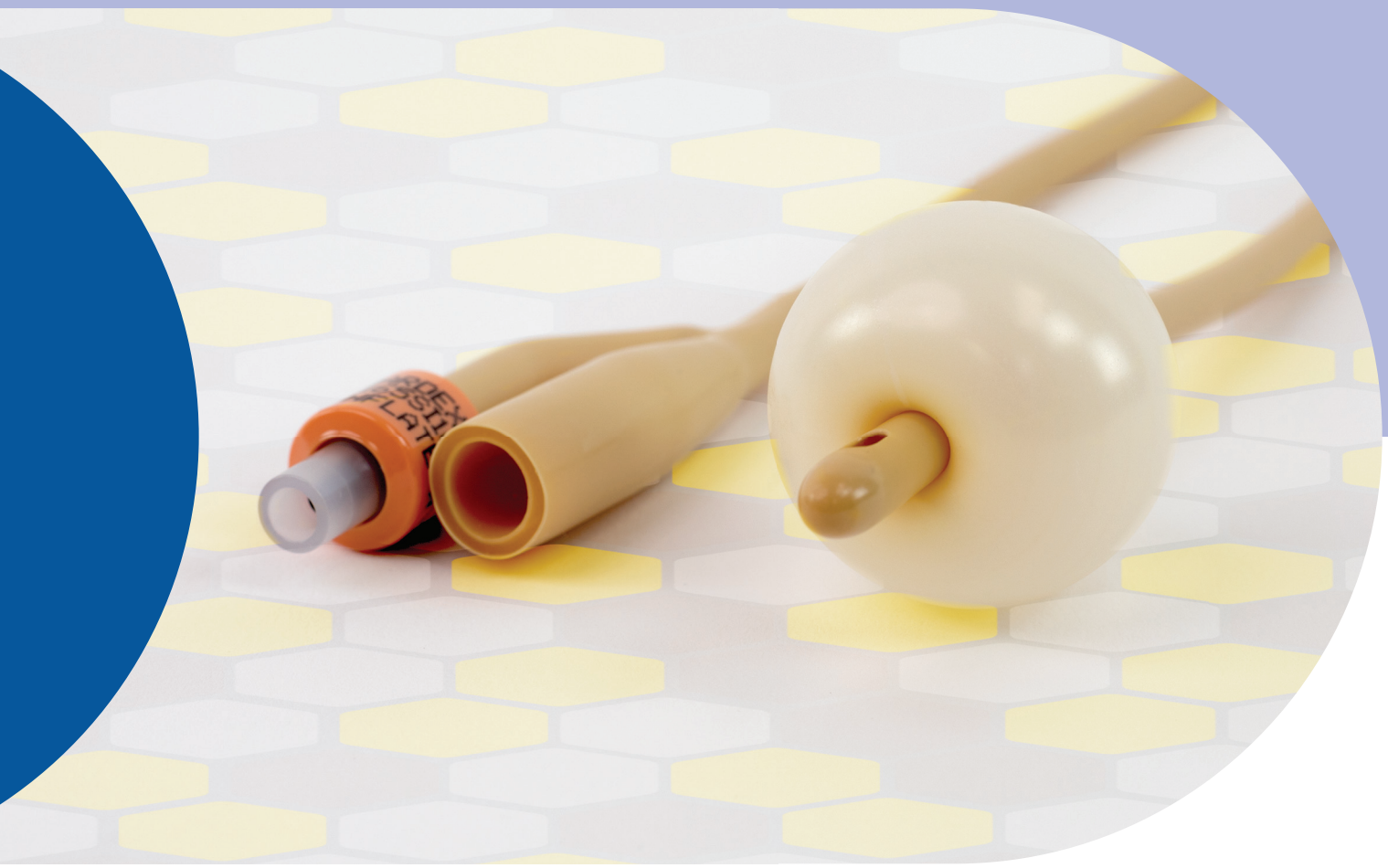


Bardex™ I.C. Foley Catheter

with the Bactiguard® Coating

Lower the occurrence of CAUTI
Provide a surface that resists encrustation+
Reduce adherence of UTI pathogens

+based on pre-clinical testing on adhesion of Proteus mirabilis, an important contributor for encrustation of Foley catheters

BD

The challenge

3x

higher mortality rates in the ICU

12.1

day increased length of stay outside of the ICU

14.9

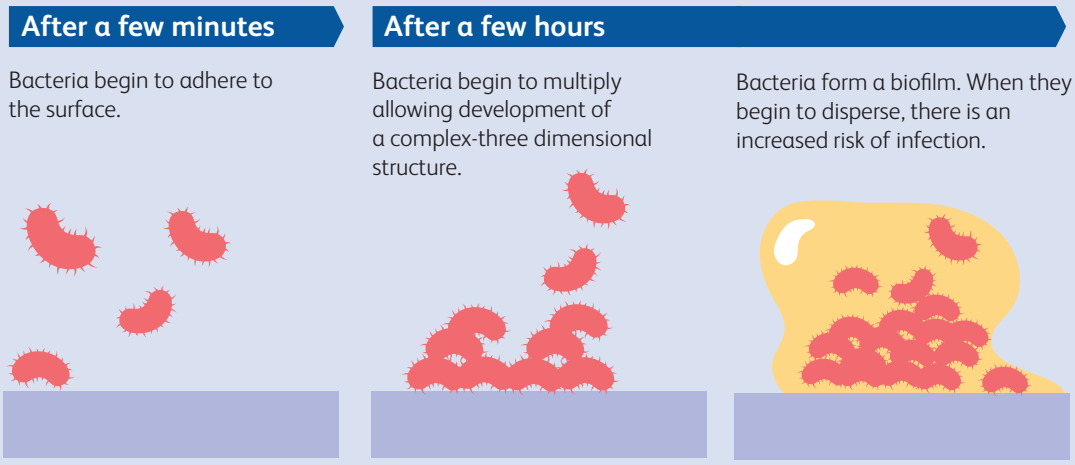
day increased length of stay in the ICU

CMS first implemented CAUTI reporting requirements in acute care hospitals in 2012.[1] Since then, changes to the definition of CAUTI have resulted in lower numbers of reportable infections.[2]

The presence of these infections may not be part of conventional reporting methods, but that doesn't mean they are not occurring. A large, retrospective real-world analysis demonstrated that for every CAUTI, there are 7 non-CAUTI hospital onset UTIs (HOUTIs).[3]

Positive urine cultures are a major contributor to hospital onset bacteremia and fungemia (HOB), which is defined as a bloodstream infection that is diagnosed on or after day 4 of a patient's hospital admission.[4]

HOBs have mortality rates that are 3x higher in patients with an ICU encounter, have a higher risk of readmission, and a significantly longer length of stay, 12.1 days without an ICU stay and 14.9 days with an ICU stay.[4]



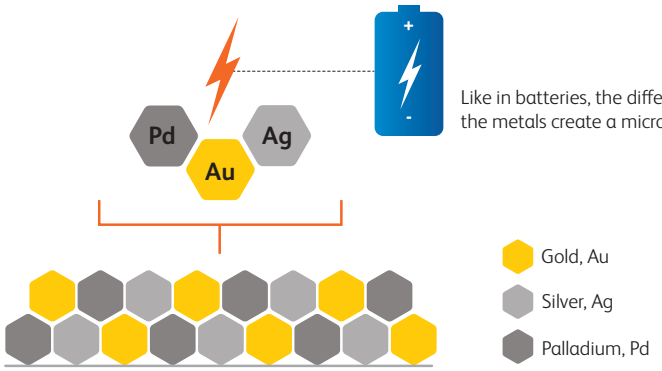
Catheter associated urinary tract infection (CAUTI)

CAUTI occurs when germs, usually bacteria, enter the urinary tract through a Foley catheter and cause an infection. Catheters are susceptible to the accumulation of bacteria, which can lead to biofilm formation on the surface. Microbes in biofilms are more resistant to antibiotics due to the extracellular polymeric substance that protects the cells.

The solution

Galvanic effect

The Bactiguard®* Coating on the Bardex™ Infection Control (I.C.) Catheter is based on a very thin noble metal alloy coating, consisting of gold, silver and palladium. When in contact with fluids, the noble metals create a galvanic effect.



Reduction of microbial adhesion

The galvanic effect creates a micro current that reduces microbial adhesion to the catheter material, which decreases the risk for biofilm formation leading to infection.

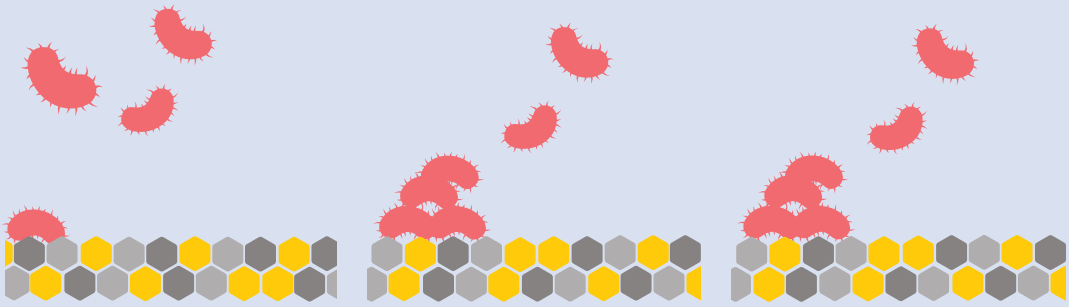
After a few minutes

Bacteria begin to adhere to the surface.

After a few hours

Less bacteria adhere to the Bactiguard® Coated surface compared to an uncoated surface, which reduces the risk for biofilm formation leading to infection.

After a few days

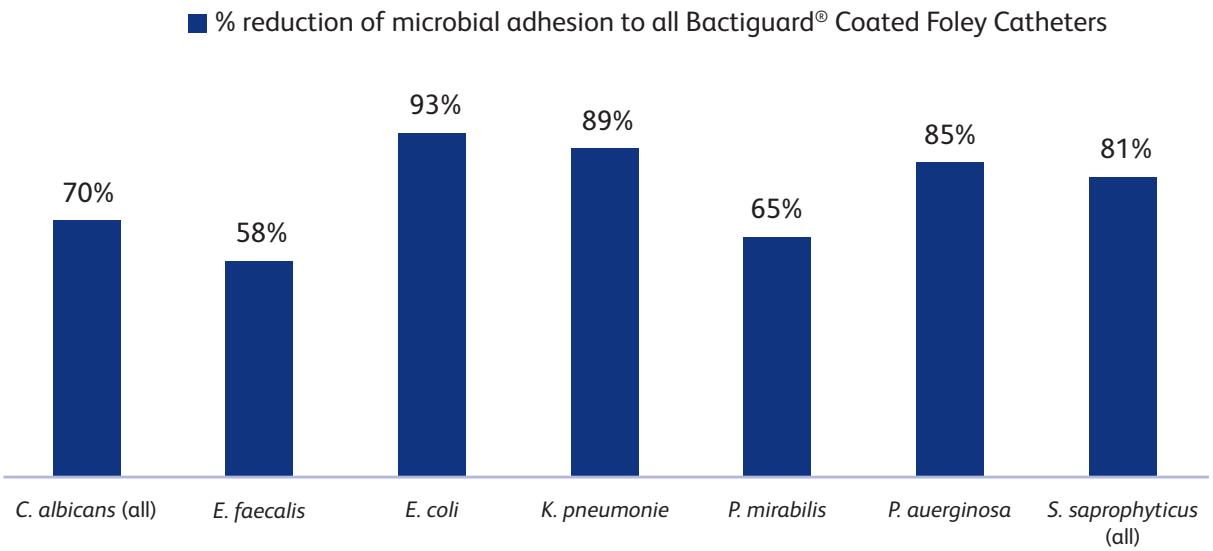


Bactiguard® Coating on the Bardex™ Infection Control (I.C.) Catheter

The solution

In vitro test

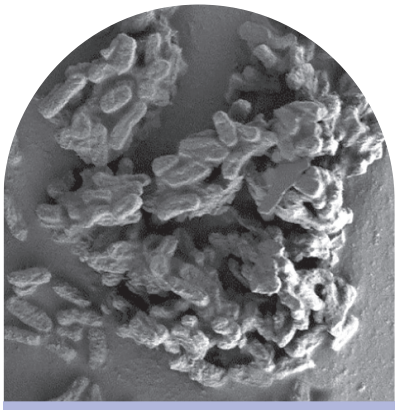
The reduction of microbial adhesion and colonization to device surfaces has been verified for clinically relevant microbial strains using an in vitro test. It evaluates the adhesion of gram-positive and gram-negative bacteria to device surfaces.[6]



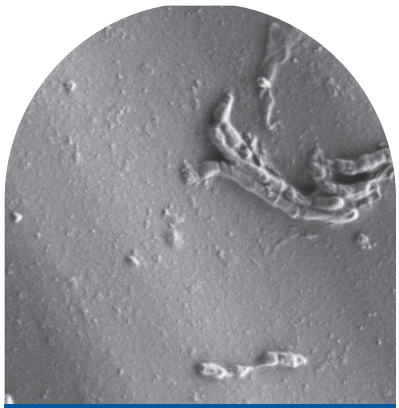
Summary of ll microbial reduction to Bactiguard® Coated Foley Catheters

Scanning electron microscopy

The reduction of microbial colonization has been observed by scanning electron microscopy (SEM). The pictures show the colonization of *E. Coli* on an uncoated surface versus on a Bactiguard® Coated surface. Less bacteria colonize the Bactiguard® Coated surface.



E. Coli colonization on uncoated surface



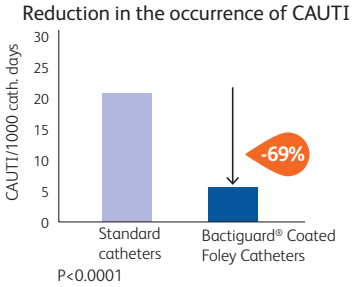
E. Coli colonization on Bactiguard® Coated surface

The evidence

The efficacy of Bactiguard® Coated Foley Catheters has been evaluated in more than 20 studies published in peer reviewed journals. The studies below comply with the latest CAUTI definition, measuring only symptomatic infections for patients catheterized longer than 2 days.

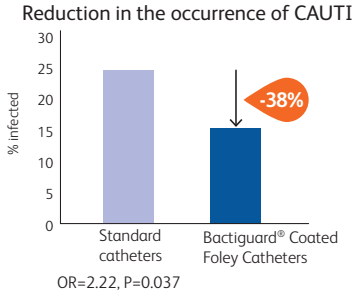
Randomized multicenter study, India – 2021

Kai-Larsen et al conducted a multicenter study with 1000 urology, general surgery and intensive care patients, catheterized for more than 2 days. There was a reduction in the occurrence of CAUTI by 69% in the group with a Bactiguard® Coated Foley Catheter, compared with the standard catheter group. CAUTI / 1000 catheter days; 6.5 vs. 20.8.[6]



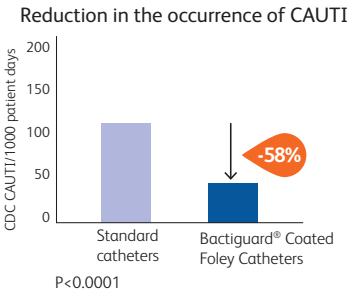
Cardiac surgery patients, Spain – 2015

Hidalgo Fabrellas et al performed a randomized study on 116 post-op cardiology patients in Spain with a 4 day mean catheterization time, and found a 38% reduction in the occurrence of CAUTI. The use of Bactiguard® Coated Foley Catheters was shown to be cost effective.[9]



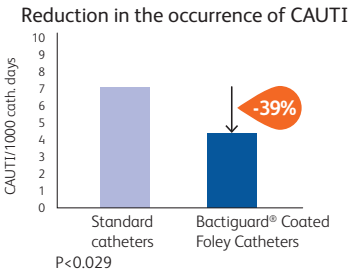
Multicenter study, USA – 2014

Lederer et al conducted a multicenter surveillance study in the USA, including 853 patients at 7 hospitals, catheterized for an average of 8 days. The Bactiguard® Coated Bardex™ I.C. Foley Catheter reduced the occurrence of CAUTI by 58% after it's introduction.[7]



Burn unit patients, USA – 2002

Newton et al studied the effect of Bactiguard® Coated Bardex™ I.C. Foley Catheters on 1,757 patients in a burn unit in Georgia. Results demonstrated a 39% reduction in the occurrence of CAUTI per 1,000 catheter days with Bactiguard® Coated Bardex™ I.C. Foley Catheters.[8]



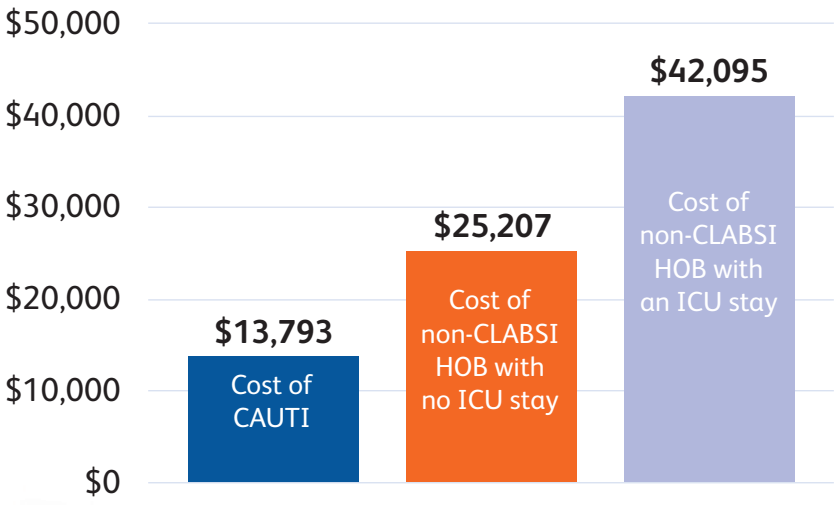
The cost savings

Health economic benefits

According to a report prepared for the Agency for Healthcare Research and Quality, the estimated cost for a CAUTI is $13,793.[10] The Bactiguard® Coating has been found to reduce the risk of CAUTI by 32 to 71.2% compared with standard catheters.[6, 7,11,12,13]

A number of studies have estimated a net economic benefit when utilizing the Bactiguard® Coated Foley catheter.[11,12,13] Similarly, a decision model that contemplated the reduction in symptomatic UTI and bacteremia estimated a cost savings with silver alloy-coated catheters compared to standard catheters.[14]

In addition, urinary pathogens are likely the primary source of 12.7% of non-CLABSI hospital-onset bacteremia and fungemia (HOB).[4] Non-CLABSI HOB contributes an additional $25,207 incremental cost in patients without an ICU stay and substantially more in patients with an ICU stay.[4]



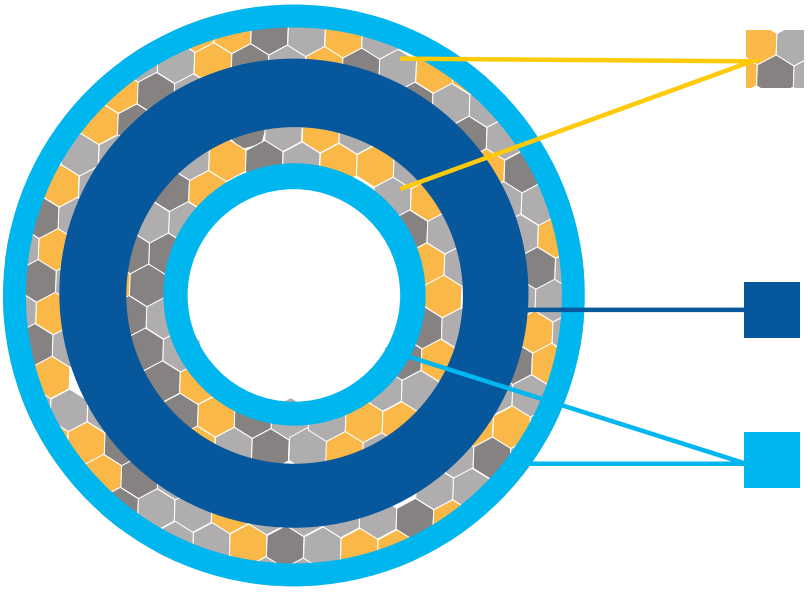
The product

Bardex™ I.C. Foley Catheters

The Bardex™ I.C. Anti-Infective Foley Catheter has a coating that combines the Bactiguard® Coating with Bard® Hydrogel.

The Bardex™ I.C. Catheter solution is unique and is applied to the inner lumen and outer surface of the catheter to ensure coverage of all surfaces.

Bardex™ I.C. Foley Catheters are approved for transurethral and suprapubic use for up to 28 days. The Bactiguard® Coating requires no special procedures for handling, use or disposal.



Bactiguard® Coating
On both the inside and the outside of the catheter

Catheter material
Core material in latex

Hydrogel coating
Reduces friction

Latex order information

Non-Specialty Latex IC Catheters	
Catalog No.	Description
0165SI08	Bardex™ I.C. 8 Fr. Foley Catheter
0165SI10	Bardex™ I.C. 10 Fr. Foley Catheter
0165SI12	Bardex™ I.C. 12 Fr. Foley Catheter
0165SI14	Bardex™ I.C. 14 Fr. Foley Catheter
0165SI16	Bardex™ I.C. 16 Fr. Foley Catheter
0165SI18	Bardex™ I.C. 18 Fr. Foley Catheter
0165SI20	Bardex™ I.C. 20 Fr. Foley Catheter
0165SI22	Bardex™ I.C. 22 Fr. Foley Catheter
0165SI24	Bardex™ I.C. 24 Fr. Foley Catheter
0165SI26	Bardex™ I.C. 26 Fr. Foley Catheter
0165SI28	Bardex™ I.C. 28 Fr. Foley Catheter
0165SI30	Bardex™ I.C. 30 Fr. Foley Catheter
0166SI14	Bardex™ I.C. 14 Fr. Foley Catheter with a 30cc balloon
0166SI16	Bardex™ I.C. 16 Fr. Foley Catheter with a 30cc balloon
0166SI18	Bardex™ I.C. 18 Fr. Foley Catheter with a 30cc balloon
0166SI20	Bardex™ I.C. 20 Fr. Foley Catheter with a 30cc balloon
0166SI22	Bardex™ I.C. 22 Fr. Foley Catheter with a 30cc balloon
0166SI24	Bardex™ I.C. 24 Fr. Foley Catheter with a 30cc balloon
0166SI26	Bardex™ I.C. 26 Fr. Foley Catheter with a 30cc balloon
0166SI28	Bardex™ I.C. 28 Fr. Foley Catheter with a 30cc balloon
0166SI30	Bardex™ I.C. 30 Fr. Foley Catheter with a 30cc balloon
0168SI12	Bardex™ I.C. 12 Fr. Coudé Foley Catheter - Carson Model
0168SI14	Bardex™ I.C. 14 Fr. Coudé Foley Catheter - Carson Model
0168SI16	Bardex™ I.C. 16 Fr. Coudé Foley Catheter - Carson Model
0168SI18	Bardex™ I.C. 18 Fr. Coudé Foley Catheter - Carson Model
0168SI20	Bardex™ I.C. 20 Fr. Coudé Foley Catheter - Carson Model
0168SI22	Bardex™ I.C. 22 Fr. Coudé Foley Catheter - Carson Model
0168SI24	Bardex™ I.C. 24 Fr. Coudé Foley Catheter - Carson Model
129414	Bardex™ I.C. 14 Fr. 3-Way Monoplug Temperature Sensing Foley Catheter
129414M	Bardex™ I.C. 14 Fr. 3-Way Molex Temperature Sensing Foley Catheter
129416	Bardex™ I.C. 16 Fr. 3-Way Monoplug Temperature Sensing Foley Catheter
129416M	Bardex™ I.C. 16 Fr. 3-Way Molex Temperature Sensing Foley Catheter
129418	Bardex™ I.C. 18 Fr. 3-Way Monoplug Temperature Sensing Foley Catheter
129418M	Bardex™ I.C. 18 Fr. 3-Way Molex Temperature Sensing Foley Catheter

Specialty Latex IC Catheters	
Catalog No.	Description
0167SI16	Bardex™ I.C. 16 Fr. 3-way Foley Catheter with a 30cc balloon
0167SI18	Bardex™ I.C. 18 Fr. 3-way Foley Catheter with a 30cc balloon
0167SI20	Bardex™ I.C. 20 Fr. 3-way Foley Catheter with a 30cc balloon
0167SI22	Bardex™ I.C. 22 Fr. 3-way Foley Catheter with a 30cc balloon
0167SI24	Bardex™ I.C. 24 Fr. 3-way Foley Catheter with a 30cc balloon
0167SI26	Bardex™ I.C. 26 Fr. 3-way Foley Catheter with a 30cc balloon

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2. FAQs: NHSN CAUTI Definition & Rebaseline - Centers for Disease Control, Centers for Disease Control, www.cdc.gov/nhsn/pdfs/rebaseline/faq-cauti-rebaseline.pdf. Accessed 26 Dec. 2023.
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14. Saint S, Veenstra DL, Sullivan SD, Chenoweth C, Fendrick AM. The potential clinical and economic benefits of silver alloy urinary catheters in preventing urinary tract infection. Arch Intern Med. 2000;160(17):2670-2675.

Foley catheters are intended for use in the drainage and/or collection and/or measurement of urine. Cautions: Latex Foley catheters contain natural rubber latex which may cause allergic reactions.

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

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.

Not all products, services, claims or features of products may be available or valid in your local area. Please check with your local BD Representative.

This is intended for Health Care Professionals only.

Please consult product label and insert for any indications, contraindications, hazards, warnings, cautions and directions for use.

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