

# INSERT FOR PATIENTS

## Enforcement Discretion of UroShield During the COVID-19 Outbreak

September 17, 2020

Coronavirus  
Disease 2019  
(COVID-19)

You are being given this Patient Insert because you are diagnosed with COVID-19 or you are at high-risk for COVID-19, and you have an indwelling urinary catheter. While you are in a healthcare environment (i.e., a hospital, temporary hospital, or nursing home), your healthcare provider or caregiver will use the UroShield for the reduction of catheter-associated urinary tract infections (CAUTI).

This Patient Insert contains information to help you understand the risks and benefits of using the UroShield to prevent CAUTI during the COVID-19 epidemic.

After reading this Insert, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

---

**For the most up to date information on COVID-19, please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**

<https://www.cdc.gov/COVID19>

---

### What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat, or new loss of taste or smell.

### What is the UroShield?

The UroShield device is a single-patient, external accessory to indwelling urinary catheters consisting of a disposable Actuator and a reusable Driver. After the Foley catheter is placed, the disposable Actuator is clipped on the part of the catheter that is outside your body and then connected to the reusable Driver. When

the Driver is turned on, the Actuator creates surface acoustic waves that cause small vibrations on the catheter surface. The surface acoustic waves make it more difficult for bacteria to stick to the catheter surface.

### Why will UroShield be used on me?

UroShield is being used on you because you are at risk for developing a CAUTI because you have an indwelling urinary catheter and because you either have been diagnosed with COVID-19 or at a higher-risk for COVID-19. Patients at higher-risk of COVID-19 are defined by the Center for Disease Control and Prevention (CDC) to include the following: people 65 years and older; people who live in a nursing home or long-term care facility; and/or people of all ages with underlying medical conditions, particularly if not well controlled, including people with: chronic lung disease or moderate to severe asthma, serious heart conditions, immunocompromise, severe obesity (body mass index [BMI] of 40 or higher), diabetes, chronic kidney disease undergoing dialysis, or liver disease. Please see the CDC Webpage for more information about your risk profile for COVID-19 based on your other health conditions:

<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html>

Uninfected, well-functioning indwelling catheters are routinely changed every 28 days. CAUTI requires treatment and replacement of the infected catheter, which often requires you to go into a hospital. Therefore, CAUTI increases interactions between healthcare providers, caregivers, and patients.

Reducing the risk of CAUTI reduces the frequency of catheter changes associated with CAUTI, and reduces your chances of needing to go into the hospital. Therefore, reducing the risk of CAUTI may prevent SARS-COV-2 exposure between you, your healthcare providers, and your caregivers.

### What are the known and potential risks and benefits of the UroShield?

Known and potential benefits of the UroShield include:

- Decreased risk of CAUTI, and related complications, hospitalization, sepsis, and death in patients with or at high risk of COVID-19, who require long-term indwelling catheterization.

---

**How can I learn more?** The most up-to-date information on COVID-19 is available at the CDC General Webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

# INSERT FOR PATIENTS

## Enforcement Discretion of UroShield During the COVID-19 Outbreak

September 17, 2020

Coronavirus  
Disease 2019  
(COVID-19)

- Reducing the risk of CAUTI, may prevent exposure to SARS-CoV-2 by minimizing interactions between healthcare providers, caregivers, and patients.

Known and potential risks of the UroShield include:

- Induced inflammatory response of the urethral tissue due to vibration.
- Penile tumescence in catheterized male patients causing discomfort and pain.

The UroShield has been designed to minimize the risk of CAUTI. However, should CAUTI occur, it may present the following risks to patients:

- Death
- Sepsis
- Prolonged Hospitalization
- Increased Hospitalization
- Increased Levels/Expense of Care

Your doctor will determine if you are an appropriate patient for UroShield. FDA has concluded that the known and potential benefits from the use of the UroShield outweigh its potential risks for use during the COVID-19 outbreak.

---

**You have the option to refuse this product. If you choose to decline use of this device, you should discuss any alternative options with your healthcare provider.**

---

### How is the UroShield used?

The UroShield is connected to your indwelling catheter after the catheter is in place. The UroShield is compatible with urinary catheters of the following sizes: 12, 14, 16, 18, 20 and 22 French (Fr). The UroShield Actuator should be replaced at the time of catheter replacement.

### When should the UroShield device NOT be used?

The UroShield is not intended for use for suprapubic or other types of catheterization other than catheterization through the urethra with a Foley catheter.

### Is the UroShield FDA-approved or cleared?

No. The UroShield is not approved or cleared by the FDA. FDA has agreed to exercise Enforcement Discretion for the use of the UroShield to aid in the reduction of catheter-associated urinary tract infection (CAUTI) incidence in patients requiring long-term ( $\geq 14$  days) indwelling catheterization for the duration of the COVID-19 epidemic.

---

**How can I learn more?** The most up-to-date information on COVID-19 is available at the CDC General Webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.