INSERT FOR HEALTHCARE PROVIDERS AND CAREGIVERS

Enforcement Discretion of UroShield During the COVID-19 Outbreak

September 17, 2020

Coronavirus Disease 2019 (COVID-19)

This Healthcare Provider Insert informs you of the significant known and potential risks and benefits of the UroShield during the COVID-19 pandemic. The UroShield is under Enforcement Discretion to aid in the reduction of catheter-associated urinary tract infection (CAUTI) incidence in patients requiring long-term (≥ 14 days) indwelling catheterization

The UroShield is not intended for use for suprapubic or other types of catheterization other than catheterization through the urethra with a Foley catheter. The UroShield is compatible with urinary catheters of the following sizes: 12, 14, 16, 18, 20 and 22 French Gauge (Fr). The UroShield Actuator should be replaced at the time of catheter replacement.

What do I need to know about COVID-19?
Current information on COVID-19 infection for healthcare providers, including case definitions and information about clinical signs and symptoms and/or epidemiological criteria, is available on the CDC website listed below.

What is the UroShield?
The UroShield device is a single-patient, extracorporeal accessory to indwelling urinary catheters consisting of a disposable Actuator and a reusable Driver. After the Foley catheter is placed in the patient, the disposable Actuator is clipped on the extracorporeal part of the catheter and then connected to the reusable Driver through the Actuator's cable connector and Driver's cable socket connection. When the Driver is turned on, the Actuator creates surface acoustic waves that propagate on the catheter surface. The surface acoustic waves reduce bacterial adhesion on the catheter surface.

What are the known and potential benefits and risks 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.
- Reducing the incidence 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

When used in appropriately selected patients in accordance with the Instructions for Use, the known and potential benefits of the UroShield outweigh the known and potential risks.

Report Adverse events to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

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How can I learn more?

CDC websites:
General: https://www.cdc.gov/COVID19
People at Higher-Risk for COVID-19:
https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html

FDA websites:
General: www.fda.gov/novelcoronavirus

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