

## **Occluder Occlusion Balloon Catheter Prescriptive Information**

**Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

**Caution:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

### **Warning**

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

### **Intended Use/Indications for Use**

The Occlusion Balloon Catheters are indicated for use for temporary ureteral occlusion and applications including, renal opacification, dislodgment of calculi and preventative calculi migration.

Any use for procedures other than those indicated in instructions is not recommended.

### **Contraindications**

- None known

### **Warnings**

See the product label for recommended shelf life. As with all latex rubber, the latex used in the balloon suffers deterioration over time. Storage beyond the expiration date listed on the package may cause the balloon to deteriorate.

### **Precautions**

**Caution:** This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

- As with other balloon catheters, the likelihood of infection increases with prolonged insertion. It is recommended that the maximum insertion time be kept under 24 hours.
- Care should be exercised in both introducing and removing balloons to avoid adding undue stress, which might rupture a balloon catheter.
- Carefully read all instructions prior to using this device.

**Caution:** A thorough understanding of the technical principles, clinical applications and risks associated with occlusion procedures is necessary before using this product.

### **Adverse Events**

The complications that may result from an occlusion balloon procedure include:

- Ureteral perforation
- Ureteral spasm
- Hemorrhage
- Hematoma
- Hypotension
- Pain and tenderness
- Arrhythmias
- Infection
- Allergic reaction to contrast medium

- Pyrogenic reaction

**Caution:** Bleed catheter of all air before use in ureteral system.

**Caution:** Prior to introduction, test the balloon to determine the amount of fluid necessary to inflate the balloon to the desired inflation diameter. Refer to Inflation Tables below for recommended inflation volume. Failure to do so may result in balloon or ureteral rupture.

**Caution:** When inflating the balloon, always inflate slowly. Fluoroscopic monitoring of the balloon during inflation is recommended. If loss of pressure from the balloon occurs during inflation or if balloon ruptures, immediately discontinue the procedure. Deflate the balloon, do not reinflate and remove carefully.

**Caution:** Do not use a high pressure injector. Maximum distal lumen pressure is 250 psi (17 atm/bar; 1723 kPa).

**Caution:** The larger the syringe diameter, the greater the suction that is applied.

**Caution:** If resistance is encountered when removing a guidewire through a catheter or when removing a catheter through the scope, stop and remove them as a complete unit to prevent damage to the guidewire, catheter, or ureter.