Brief Summary Document

Overview

Product
Encore™ 26 Inflation Device – IFU 51517954

Rx Statement
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a skilled and licensed practitioner.

This device is intended to be used by, or under the supervision of, a skilled physician with experience in urological procedures requiring balloon dilatation catheters. Physicians are assisted by surgical technicians and nursing teams.

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Content

INTENDED USE/INDICATIONS FOR USE
The Encore 26 Inflation Device is recommended for use with balloon dilatation catheters to create and monitor pressure in the balloon, and to deflate the balloon.

ADVERSE EVENTS
Potential adverse events associated with procedures where the inflation devices are used may include, but are not limited to, the following:
- Abrasion
- Allergic reaction
- Discomfort
- Hemorrhage
- Infection
- Inflammation
- Injury
- Laceration
- Pain
- Perforation

Adverse events may require additional medical or surgical intervention.

There are currently no known **CONTRAINDICATIONS, WARNINGS** or **PRECAUTIONS**, associated with the use of this device.