



# Precautionary Statement (21362001)

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**Biomet Sports Medicine, Inc.**  
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**21362001**  
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## **Biomet Sports Medicine™ InnerVue™ Diagnostic Scope System**

### **ATTENTION OPERATING SURGEON**

#### **DESCRIPTION**

The Biomet Sports Medicine™ InnerVue™ Diagnostic Scope System consists of a fiber-optic based micro-endoscope, cannula, trocar, blunt obturator, and cannula plug. All of these items are disposable, and for single-use only. The micro-endoscope is made to couple with a non-disposable system handpiece that contains a light source and camera, which is available separately.

The scope is also available as a stand-alone item.

#### **MATERIALS**

Stainless Steel  
Glass  
Medical grade epoxy  
Lexan or Radel

#### **INDICATIONS FOR USE**

The InnerVue™ Diagnostic Scope System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening. Examples of generic surgical use include the visualization of joints within the body. These joints can include joints located in the torso/trunk, upper/lower extremities, and the temporomandibular joint.

#### **CONTRAINDICATIONS**

Active infection is a contraindication for use of this device.

#### **WARNINGS**

1. The Biomet Sports Medicine™ InnerVue™ Diagnostic Scope System instruments are provided sterile.
2. Inspect the system instruments for any evidence of damage prior to use. Pay particular attention for scratches on optical surfaces. Scratches can interfere with image quality.
3. Use caution to treat this system as you would any fine optical device.
4. Single-use only. DO NOT REUSE.

#### **POSSIBLE ADVERSE EFFECTS**

1. Infection following the procedure.
2. Introduction of foreign materials can result in an inflammatory response or allergic reaction.

3. Wound dehiscence.
4. Nerve damage.
5. Damage to tissue and/or bone near or around micro-endoscope when inserted into a surgical or natural opening.

### **INSTRUCTIONS FOR USE**

The Biomet Sports Medicine™ InnerVue™ disposable micro-endoscope is to be used by a trained physician for viewing and illumination in diagnostic and operative arthroscopic procedures (which may include, but is not limited to, the temporomandibular joint [TMJ]), endoscopic examination, and in any interior cavity of human body through either a surgical or natural opening. The micro-endoscope can be passed through a surgical or natural opening. The cannula with trocar or obturator is placed into the surgical or natural opening. Once the cannula has been placed, the trocar or obturator is removed. The cannula is then used as an insertion tube for the micro-endoscope. Fluid may be introduced or removed from the cavity through the port on the cannula, with or without the use of the cannula plug.

### **STERILITY**

The Biomet Sports Medicine™ InnerVue™ Diagnostic Scope System instruments are sterilized by exposure to Ethylene Oxide (ETO) gas. These instruments are for one-time, single patient use only. Do not use any instrument from an opened or damaged package. Do not resterilize. Do not use past expiration date.

**DO NOT STEAM AUTOCLAVE** the disposable micro-endoscope as it will be irreparably damaged.

### **Cleaning of the handpiece**

The handpiece can be cleaned and disinfected with cleaning agents meant for the cleaning of electrical equipment. Follow manufacturer instructions. **DO NOT** use cleaning agents that are not compatible with plastics. **DO NOT** allow excessive moisture or liquids to come in direct contact with the handpiece.

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

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