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Biomet Microfixation OnPoint™ Scope and Instruments

ATTENTION OPERATING SURGEON

DESCRIPTION

The Biomet Microfixation OnPoint Scope and Instruments consist 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.

MATERIALS

Micro-endoscope:

Stainless Steel
Glass

Instruments:

Stainless Steel

USP Class VI Silicone

Lexan® or Radel®

Medical grade epoxy

®Lexan is a trademark of SABIC Innovative Plastics IP BV

®RADEL IS A REG. TM OF AMOCO POLYMERS, INC.

INDICATIONS FOR USE

This system is indicated to be used by a trained physician to provide illumination and visualization of an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures. Examples of surgical use include but are not limited to procedures on the knee, shoulder, ankle, elbow, wrist, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and the cervix.

CONTRAINDICATIONS

Active infection

WARNINGS

1. The Biomet Microfixation™ OnPoint 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 Microfixation OnPoint disposable micro-endoscope is to be used by a trained physician for viewing and illumination in diagnostic and operative arthroscopic procedures (which may include the temporomandibular joint [TMJ]), endoscopic examination and in any interior cavity of the 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 stopcock on the cannula, with or without the used of the cannula plug.

STERILITY

The Biomet Microfixation 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 (available separately) 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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Manufactured for:

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