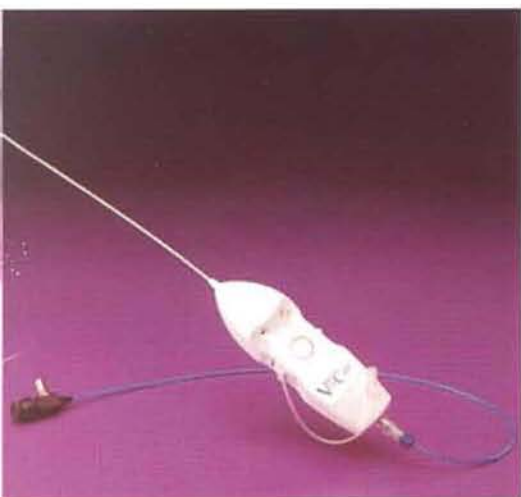




A BIOMET COMPANY



Spinal Endoscopy

VUECATH[®]
System

WHAT IS SPINAL ENDOSCOPY?

Spinal endoscopy is a procedure for directly observing the inside of the spinal canal. The spinal canal is located inside the spinal column. In it are found the spinal cord, spinal nerves, and their respective coverings. Spinal endoscopy allows the physician to inspect these structures for evidence of inflammation, scarring, compression, or other abnormalities. Injection of medicines through the endoscopic catheter can be used to treat some causes of spinal pain. The procedure is performed in an outpatient hospital or clinic setting. A very thin fiberoptic endoscope, about the diameter of a pencil lead, is placed into the spinal canal using a steerable catheter. The extremely small size of the endoscope and catheter allows reliable information about the spine to be obtained with minimal risk and discomfort.

WHAT ARE THE MOST COMMON REASONS FOR PERFORMING SPINAL ENDOSCOPY?

- Treatment of back or leg pain caused by inflammation or compression of a spinal nerve due to a disc injury, postoperative scarring, or narrowing of the spinal canal.
- Diagnosis of scarring or inflammation around a spinal nerve when other tests are inconclusive.
- Other conditions where the physician has a need to directly observe the inside of the spinal canal or inject medications into the spine under direct vision.

^{EBI} VUECATH[®] System

A minimally invasive system to directly visualize
the lumbar space when treating patients with
chronic low back pain.




HOW IS SPINAL ENDOSCOPY PERFORMED?

The procedure is performed in an outpatient setting. A local anesthetic is used. Intravenous sedation may be added if necessary. A soft, steerable catheter less than 2.5mm in diameter is inserted into the lowest part of the spine near the tailbone. This catheter contains passages for the insertion of the fiberoptic endoscope and for injection of irrigation fluid and medications. The images of the spinal canal are displayed on a video monitor. Permanent images can be

VUECATH[®]
System





made if needed. The procedure typically lasts 15 to 30 minutes. The procedure is typically not painful, although patients may experience feelings of pressure in the back or legs and occasional tingling sensations.

Patients are usually ready to go home within 30 minutes after the procedure. Post-procedure side effects may include minor headache and soreness or drainage at the insertion site. A severe spinal headache is possible but very rare. Patients should not drive or perform any strenuous activity for the first 12 hours after the procedure. Usual activities can be resumed the following day.

Major complications are very rare but may require immediate treatment. High fever, severe headache, or progressive weakness or numbness in the legs should be reported promptly to your physician.

The physician performing the procedure will tell the patient to rest for about a day after the procedure. It is not good to drive a motor vehicle, operate machinery or make important decisions for about a day after the procedure. After that the patient can usually resume a normal life style. The physician may prescribe drugs for post-operative pain. He or she will tell you not to take alcohol with these pain-killing drugs, as the combination could be very dangerous. If after the first day the patient has fever, vomiting, headaches or persistent pain at the site in the back where the devices were inserted, he or she should report these to the doctor.

Indications for Use:

When used with a fiberoptic endoscope, the EBI[®] VueCath[®] Spinal Endoscopic System can be used in the lumbar and sacral spine for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications.

In addition, the system may be used by physicians for the illumination and visualization of tissues of the epidural space in the lumbar and sacral spine for the purpose of assisting in the diagnosis of disease utilizing a caudal approach via the sacral hiatus.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

EBI, as the manufacturer of this device, does not practice medicine and does not recommend this or any surgical technique for use on a specific patient. The physician who performs this procedure is responsible for determining and utilizing the appropriate technique for each individual patient. EBI is not responsible for selection of the appropriate technique to be utilized for an individual patient.

Please refer to the package inserts accompanying the VueCath System components for full prescribing information including contraindications, warnings, precautions, and possible adverse effects.

This product and its method for use are covered under one or more of the following U.S. patents: Des. 343,678; Des. 349,340; 5,342,299; 5,399,164; 5,423,311; 5,437,636; 5,531,687; 5,624,397; 6,010,493; 6,464,682; 6,470,209. Other U.S. and foreign patent rights pending and/or issued.

Distributed by:

Independent Medical Associates

IMA
Independent Medical Associates

11733 66th Street North
Suite 113
Largo, FL 33773

Phone: 888-548-4462
Fax: 888-548-1462
E-Mail: Info@I-MA.com

 **EBI**
A BIOMET COMPANY

EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054
www.ebimedical.com
1-800-526-2579