

INSTRUCTIONS FOR USE Marquise MIS Channel

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALES BY OR ON THE ORDER OF A PHYSICIAN.

Indications:

The Marquise® MIS Channels are indicated for minimally invasive access to an area of the spine. The Marquise® MIS Channels and accessories are designed to assist the surgeon in maintaining minimally invasive exposure to allow performance of spine surgical procedures.

Contraindications:

The Marquise® MIS Channels and accessories have no known contraindications. The instruments should not be inserted into body cavities or natural body openings.

There are no known risks associated with use of the instruments aside from normal risks of surgery. The instruments should not be used non-sterile or in the presence of an infectious disease process.

Directions For Use:

A surgical procedure brochure or manual for the Marquise® MIS Channel System should be reviewed prior to use. The insertion probe is used to separate muscle and has depth markings to allow selection of the appropriate length Marquise® MIS Channel. The Marquise® MIS Channel is inserted over the insertion probe to an appropriate depth and the Channel is attached to a stable table-mounted arm. The insertion probe is removed to expose the surgical site and position is confirmed with fluoroscopy. Once visualization is obtained through the Marquise® MIS Channel, the surgeon can complete the planned surgical procedure.

Potential Adverse Effects:

Risks possibly associated with the use of the Marquise® MIS Channels and accessories are similar to those associated with any surgery to the planned area. The most frequently stated risks are blood loss, neurological damage, damage to the surrounding soft tissue, and infection. Each of these risks is associated with the risks of conventional surgical intervention. Additional risks associated with the use of the Marquise® MIS Channel System, other than those described for spinal surgery in general, include instrument malfunction, such as breakage and fragmentation. In the event of breakage, fragments should be removed, as this instrument should not be implanted.

Additional risks are attendant to surgery and the use of anesthesia, etc., and are not directly related to the use of the Marquise® MIS Channel System. These include, but are not limited to, pneumonia, phlebitis, embolism, wound infection, blood loss with or without anemia.

Warnings and Precautions:

Surgery may not be successful. In the event of technical complications, the surgical technique can be converted to an open procedure and the surgery completed.

The surgeon should have knowledge of alternative surgical techniques and should realize that patient selection and compliance will affect the results.

Additional considerations:

1. The Marquise® MIS Channel is a single-use, sterile instrument. Do not attempt to re-sterilize.
2. The Marquise® MIS Channel should be securely attached to a stable table-mounted arm to avoid unexpected movement of the instrument during use.

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Cleaning Procedure:

The Marquise® MIS Channels are single-use disposable instruments. Do not attempt to clean or re-sterilize the Channels after use.



Sterilization:

STERILE

The Marquise® MIS Channels are supplied sterile and non-reusable. Sterile product will be clearly labeled as such on the package label. Before opening, verify that the Tyvek® pouch packaging is intact and undamaged. The sterility of the product can only be assured if the packaging is intact and undamaged. Do not use Channels if there is any sign of damage to the Tyvek® pouches. Before use, verify that the sterilization indicator is a dark orange or red color. Do not use Channels if sterilization indicator is any color other than dark orange or red.

Product Complaints:

Any Health Care Professional (e.g., customer or user of this system), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Spinal Elements, Inc. Further, if this system ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, Spinal Elements should be notified immediately. If any Spinal Elements product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, Spinal Elements should be notified immediately by telephone, fax, or written correspondence. When filing a complaint, please provide the component(s) name and reference number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from Spinal Elements is requested.

Further Information:

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