Use of the instrumentation requires knowledge of the anatomy and pathology, biomechanics and surgical corrections of the spine. The instrumentation can be used only by a qualified surgeon who practices with an awareness of current advances in science and surgical techniques. The user should ensure that the MySpine Pedicle Screw Placement Guides are intact and in good working order before use, checking the correct matching with the plastic 3D vertebral models provided with the guides. The user should also take all necessary precautions to avoid any incidents (gloves, protective glasses...).

No undesirable side effects are known if these instructions for use are respected.

**APPLICATION FIELD**

This document is applicable for all MySpine Pedicle Screw Placement Guides and related plastic 3D models of the patient's vertebra(e).

**Indications for Use**

MySpine is intended as a thoracic and lumbar posterior pedicle targeting guide for patients requiring spinal fusion between the levels of T1 to L5. MySpine Pedicle Screw Placement Guides are intended to be used as anatomical perforating guides specific for a single patient anatomy to assist intraoperatively in the positioning of pedicle screws in the vertebral body. MySpine is intended for use with M.U.S.T Pedicle Screw System and its cleaned indications for use.

MySpine Low Profile screw placement guides are intended for the placement of K-wires to assist in the positioning of pedicle screws.

Use of the guides involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of patient radiological images with identifiable placement anatomical landmarks and surgical equipment components. These components include patient-specific guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intraoperatively per the surgical plan.

MySpine Pedicle screw placement guides are intended for single use only.

**CONTRAINDICATIONS**

Contraindications in using MySpine instrumentation are the same as in situations when a spinal fusion with pedicle screws are contraindicated. Please refer to the M.U.S.T. Pedicle Screw System and its cleaned indications for use.

MySpine screw placement guides are made of Polyamide-PA 12; it is strictly the surgeon’s responsibility to verify that the patient is not allergic to this material.

**GENERAL**

Before any surgery, the surgeon must be familiar with the sales product literature and operative technique and must carefully read these instructions for use. The instrumentation should be stored and handled with care. MySpine surgical instruments can be damaged by inadequate handling: visually inspect the instrument and check for damage: holes, pins, bent parts.

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It is the user's responsibility to follow the preparation procedure in order to ensure the accuracy of the system. At all times during the Awl, Pedicle Probe and actual screw placement, the surgeon must verify and confirm that the MySpine Pedicle Screw Placement Guides are positioned correctly on the vertebra. In the case of any doubts or signs of instability between guide and bone, the screw insertion trajectory should be verified by fluoroscopy. In case of standard guides usage, this may be done after the insertion of the two awls or probes into the pedicles. When using Low Profile guides the check may be done after the insertion of the two K-wires or cannulated awls.

Sterilization is the responsibility of operating theatre personnel. To know about the specific conditions of use and loading, it is essential to refer to the written instructions provided by the manufacturer of the sterilizer as well as the internal procedures of the health care institution. MySpine instruments are meant to be single patient use. Reutilizing them on other patients or even on the same patient would lead to unpredictable pedicle screws placement.

Visually inspect the guides after use in order to verify they did not experience any mechanical damage which may cause release of particles in human body.

Any non-functional instruments should be immediately returned to Medacta. The type of malfunction should also be reported.

**SYMBOLS**

- ![Non-sterile](image)
- ![Consult instructions for use](image)
- ![Caution, read the accompanying documents](image)
- ![Manufacturer](image)
- ![Reference number](image)
- ![Lot number](image)
- ![Serial number](image)
- ![Do not reuse](image)
- ![Date of manufacture](image)
- ![Do not expose to sunlight](image)
- ![Store in a dry place](image)
- ![Do not resterilize](image)
- ![Do not use if packaging is damaged](image)
- ![Use by](image)

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