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NON STERILE MYSPINE® INSTRUMENTS

CAUTION

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

All Medacta MySpine Instruments are supplied in single-use packages.

SYMBOLS

	Do not reuse
	Do not resterilize
	Caution, read the accompanying documents
	Consult instructions for use
	Do not expose to sunlight
	Store in a dry place
	Do not use if package is damaged
	Use by
	Lot number
	Reference number
	Non-sterile
	Manufacturer

ENGLISH

NON STERILE MYSPINE® INSTRUMENTS - INSTRUCTIONS FOR USE

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 vertebra 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.

1. APPLICATION FIELD

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

2. INDICATIONS FOR USE

MySpine Standard

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 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 Standard is intended for use with M.U.S.T Pedicle Screw System and its cleared indications for use.
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 intra-operatively per the surgical plan. MySpine Screw placement guides are intended for single use only.

MySpine Low Profile

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 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 Low Profile is intended to be used with any 510(k) cleared, legally marketed, pedicle screw spinal system (for its approved indications for use) and its respective compatible components for non-cervical open, posterior spinal fixation procedures intended for fusion. MySpine Low Profile is 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 intra-operatively per the surgical plan. MySpine Screw placement guides are intended for single use only.
Please see below for compatibility requirements between the MySpine guides and the 510(k) cleared pedicle screw system intended to be used.

3. COMPATIBILITY REQUIREMENTS/INFORMATION (applicable for MySpine Low Profile only)

Please see the following compatibility requirements between the MySpine guides and the 510(k) cleared pedicle screw system intended to be used:

- Refer to the used pedicle screw spinal system labelling for information such as contraindications, warnings, precautions, and instructions for use.
- The surgical planning software provides indications about the M.U.S.T. Pedicle Screw System placement. If a different pedicle screw spinal system is used, it is the surgeon's responsibility to verify the corresponding implant size (diameter and length) and its compatibility.
- The selected MySpine drill based guide diameter represents the nominal value of the corresponding drill bit to be used during the surgery, it is the surgeon's responsibility to verify the corresponding drill diameter and its compatibility.

- The MySpine K-wire based guides are designed for the M.U.S.T. Pedicle Screw System instrumentation, which provides 1.5 mm K-wires. If a different pedicle screw spinal system is used, it is the surgeon's responsibility to verify the corresponding K-wire diameter and its compatibility.

4. CONTRAINDICATIONS

Contraindications in using MySpine instrumentation are the same as in situations when a spinal fusion with pedicle screws are contraindicated. The 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.

5. 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 used only for its intended purpose as indicated in the surgical techniques. The use of some motor-driven instruments (drill bits, taps, etc.) may cause a temperature rise between these instruments and bone. It is advisable to sprinkle these instruments with physiological saline during use. Under no circumstances should an item of instrumentation be implanted.

6. DESCRIPTION

The instrumentation is made from materials appropriate for the manufacture of surgical instruments. These materials are not intended to stay in permanent contact with the patient. The instrumentation is supplied non sterile and it is intended to be single use. The instrumentation manufactured by Medacta International meets the mechanical and functional characteristics of the operative technique, and these instructions. Before surgery, the user should refer to the surgical technique and other labeling or contact the representative of the company for more details on how to use the instrumentation.

7. STORAGE AND HANDLING

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 and bended parts. The devices can be sterilized in an autoclave and stored in containers conforming to current standards:

- Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture.
- Care must be taken in handling of wrapped cases to prevent damage to the sterile barrier.

8. CLEANING AND STERILIZATION

It is the responsibility of health care institutions to clean (decontaminate and wash) and sterilize the instrumentation before use in accordance with approved methods:

- Remove any documents and cushioning foam from the container before sterilization.
- Follow the instructions and warnings issued by the supplier for any cleaning and disinfection agents and equipment used.
- Do not exceed 140°C [284°F] during processing steps.
- Detergents with a pH range between 6.0 and 8.0 should be used. Detergents with a pH outside of this range can have an adverse effect or be damaging to the instruments and instrument cases. Detergents should be used at the concentration level recommended by the detergent manufacturer.
- Do not use wire brushes, scouring pads or objects that may damage the instrumentation.
- Scratches or dents can result in breakage.
- For automated cleaning with our Medacta instruments, place heavier instruments and instruments with cutting edges on the bottom of containers.
- Do not place heavy instruments on top of MySpine devices.

For detailed instructions please refer to the document "Recommendations for cleaning, decontamination and sterilization of Medacta International orthopaedic devices" (reference 75.09.050US) available at www.medacta.com or request directly from your Medacta representative. The Health Care Institution is responsible for cleaning and sterilization of MySpine instruments before their use.

9. WARNING

Check the expiration date prior to use. Using the MySpine Pedicle Screw Placement Guides after the expiration date will not guarantee the optimum bone match between the modeled guide and the patient which could lead to unpredictable outcomes of pedicle screw placement and the spine fixation. The surgeon should confirm that the CT imaging accurately represents the patient's anatomy at the time of surgery and should not use the MySpine guides if significant changes to the patient's anatomy have occurred since the acquisition of the CT images. The expiration date is set for skeletally mature patients 6 months post CT scan and 3 months post CT scan for skeletally immature patients. Since each vertebra has a specific MySpine Pedicle Screw Placement Guide created for it, care should be taken to ensure the correct guide is being used. The contact points between each vertebra and the corresponding screw placement guides need to be properly prepared in order to ensure optimal contact between the guide and the bone surface.

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. All pedicle screw spinal system components and accessories are to be used, after removal of the MySpine Guide, as directed by the pedicle screw spinal system's instructions for use and surgical technique. 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.

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