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STERILE MYSPINE® MC AND DRILL PILOT INSTRUMENTS

CAUTION

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

All Medacta MySpine Sterile Instruments are supplied in single-use packages. The sterilization method is indicated on the label.

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
	Sterilized by irradiation
	Manufacturer

ENGLISH

STERILE MYSPINE® MC AND DRILL PILOT 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 MC and Drill Pilot Guides are intact and in good working order before use, checking the correct matching with the 3D vertebra models provided with the guides. No undesirable side effects are known if these instructions for use are respected.

1. APPLICATION FIELD

This document is applicable for all MySpine MC and Drill Pilot Guides and related 3D models of the patient's vertebra(e).

2. INDICATIONS FOR USE

MySpine 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 Drill Pilot is intended as a thoracic and lumbar posterior pedicle targeting guides for patients requiring spinal fusion between the levels of T1 to L5. The device is intended for perforating a guiding hole to assist in the positioning of pedicle screws in the vertebral body. MySpine MC is intended as a lumbar and sacral posterior pedicle targeting guide for patients requiring spinal fusion between the levels of L1 to S1. The device is provided with two options:

• Drill based
• K-wire based

MySpine MC drill based are intended for perforating a guiding hole to assist in the positioning of pedicle screws in the vertebral body. MySpine MC K-wire based are intended for the placement of K-wires to assist in the positioning of pedicle screws in the vertebral body. The use of the guides involves a surgical planning software, with which the surgeon preoperatively plans the surgical placement of the implants based upon the radiological images of the patients' anatomical landmarks and the selected surgical equipment. 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 MC and Drill Pilot guides are intended for single use only.

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

3. COMPATIBILITY REQUIREMENTS/INFORMATION

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 labeling 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 MC and Drill Pilot 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 product literature and surgical 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, K-wires, 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 sterile and it is intended to be single use. The instrumentation manufactured by Medacta International meets the mechanical and functional necessities of the surgical 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 prior to use: holes, pins and bended parts. The packages should be stored in a cool, dry place, away from light. Handle with care.

8. PACKAGING

The MySpine guides and the 3D models are supplied sterile, in single use individual packages. The sterilization method is indicated on the label. The expiration date and package integrity must be checked to ensure the sterility of the contents has not been compromised. If the package is damaged, do no use the component. Do not re- sterilize.

9. WARNING

Check the expiration date prior to use. Using the MySpine MC and Drill Pilot 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 MC and Drill Pilot 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 surgical steps, the surgeon must verify and confirm that the MySpine MC and Drill Pilot 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. 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. MySpine instruments are meant for 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 into the human body. Any non-functional instruments should be immediately returned to Medacta. The type of malfunction should also be reported.

ENGLISH

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