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MYSPINE® STERILE S2-ALAR/ALAR-ILIAC AND S2-SI PEDICLE-SACRO ILIAC 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	Lot number
REF	Reference number
STERILE R	Sterilized by irradiation
	Manufacturer

ENGLISH

MYSPINE® S2-ALAR/ALAR-ILIAC AND S2-SI PEDICLE-SACRO ILIAC INSTRUMENTS - INSTRUCTIONS FOR USE

1. GENERAL

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 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.

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 the bone. It is advisable to sprinkle these instruments with physiological saline during use. Under no circumstances should an item of instrumentation be implanted.

2. PRODUCT DESCRIPTION

The instrumentation is made from materials appropriate for the manufacture of surgical instruments. These materials are not intended to be in permanent contact with the patient. The instrumentation is supplied sterile and it is intended for 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.

3. INTENDED USE

The MySpine Screw Placement Guides are intended to be used as anatomical perforating guides specific to a single patient's anatomy to assist intraoperatively in the positioning of pedicle and sacro-iliac screws in spinal fixation surgery.

4. INDICATIONS

MySpine S2-Alar/Alar-Iliac and MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides are intended to be used with any 510(k) cleared, legally marketed, pedicle screw system (for its approved indications for use) and its respective compatible components for non-cervical open, posterior spinal fixation procedures intended for fusion. The SI trajectory of the MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guide is only intended to be used with M.U.S.T. SI Headless Screw System and its cleared indications for use. MySpine S2-Alar/Alar-Iliac and MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides (hereinafter referred to as "MySpine guides") are intended to be used as anatomical perforating guides, specific to a patient's anatomy, to assist intraoperatively in the preparation of the screw trajectory in S1, S2 and in the Ilium. The guides are created using a surgical planning software which pre-operatively plans the positions of the components based upon radiological images of the patients' anatomical landmarks and the selected surgical equipment. The MySpine guides are intended for single use only.
Please see below the compatibility requirements between the MySpine guides and the 510(k) cleared pedicle screw system intended to be used.

5. COMPATIBILITY REQUIREMENTS AND 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 labeling of the pedicle screw system to be used 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. If different pedicle system is used, it is the surgeon's responsibility to verify the corresponding implant size (diameter and length) and its compatibility.
- The selected diameter of the MySpine drill-based guide 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.

6. CONTRAINDICATIONS

Contraindications in using the MySpine instrumentation are the same as contraindications for spinal fusion with pedicle and/or sacro-iliac screw. The MySpine 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.

7. WARNINGS

Check the expiration date prior to use. Using the MySpine 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 screw placement and 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 at 6 months post-CT scan for skeletally mature patients and at 3 months post-CT scan for skeletally immature patients. Since a specific MySpine Guide has been created for each vertebra, care should be taken to ensure that 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 to ensure the accuracy of the system. At all times during the surgical steps, the surgeon must verify and confirm that the MySpine Guides are positioned correctly on the vertebra. In case of doubt or signs of instability between guide and bone, the screw insertion trajectory should be verified by fluoroscopy. Since the MySpine instruments are meant to be used for a single patient, 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.

8. HANDLING

The instrumentation should be handled with care. The MySpine surgical instruments can be damaged by inadequate handling: visually inspect the instrument and check for damage prior to use: holes, pins, bent parts.

9. PACKAGING

The MySpine guides and the plastic 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.

10. STORAGE

The packages must be stored in a cool, dry place, not exposed to sunlight.

11. FURTHER INFORMATION

The recommended instructions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact Medacta.

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This document is intended for the US market.