Non sterile MySpine S2-alar/alar-iliac 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
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 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.

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.

2. PRODUCT 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.

3. INTENDED USE

MySpine Screw Placement Guides are intended to be used as anatomical perforating guides specific to a single patient’s anatomy to assist intra-operatively in the positioning of pedicle screws in spinal fixation surgery.

4. INDICATIONS

MySpine S2-Alar/Alar-Iliac is intended for use with M.U.S.T. Pedicle Screw System and its cleared indications for use. MySpine S2-Alar/Alar-Iliac guides (referred to from this point on as, MySpine guides) are intended to be used as anatomical perforating guides, specific to a patient’s anatomy, to assist intra-operatively 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 surgical equipment selected.

MySpine guides are intended for single use only.

5. CONTRAINDICATIONS

Contraindications in using MySpine instrumentation are the same as in situations when a spinal fusion with pedicle screws is contraindicated. Please refer to the M.U.S.T. surgical technique for a comprehensive list of the contraindications. 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.

6. 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 pedicle screw placement and the spine fixation. Since each vertebra has a specific MySpine 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 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.

Since 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.

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

7. HANDLING

The instrumentation should be 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, bent 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.

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.

8. STORAGE

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

9. FURTHER INFORMATION

Recommended directions 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.