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MySpine MC and Drill Pilot Instruments

CAUTION
Federal law (USA) restricts this device to sale distribution and use by or on the order of a physician.

ENGLISH **Instructions for use - MySpine MC and Drill Pilot Instruments**

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.

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

Indications for Use
MySpine is intended for use with M.U.S.T Pedicle Screw System and its cleared indications for use.
MySpine Drill Pilot is intended as a thoracic and lumbar posterior pedicle targeting guide 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.

Use of the guides involves a 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 MC and Drill Pilot 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. surgical technique for a comprehensive discussion of the contraindications.

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.

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.

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 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.

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.

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.

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.

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.

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 into the human body.

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

SYMBOLS

Non-sterile


Consult instructions for use


Caution, read the accompanying documents


Manufacturer

Reference number

Lot number

Serial number


Do not reuse


Date of manufacture


Do not expose to sunlight


Store in a dry place

Do not resterilize


Do not use if packaging is damaged


Use by

Last Update: September 2017

Distributed by Medacta USA, 3973 Delp Street, Memphis, TN 38118