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Manufactured by:

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INSTRUCTIONS FOR USE - MYKNEE® INSTRUMENTS

Use of the instrumentation requires knowledge of the anatomy, biomechanics and reconstructive surgery of the locomotive system. The instrumentation can be used only by a qualified surgeon who practises with an awareness of current advances in science and surgical techniques. Before use, ensure that the MyKnee® Cutting Blocks are intact and in good working order, by visually inspecting the blocks. If 3D bone models are available, verify the Cutting Blocks fitting. 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.

APPLICATION FIELD

This document is applicable for all MyKnee® Cutting Blocks and related plastic 3D models of the patient's femur and tibia.

Indications for Use:

MyKnee® Cutting Blocks are intended to be used as anatomical cutting blocks specific for a single patient anatomy, to assist in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting.

MyKnee® Cutting Blocks are intended for use with GMK® Total Knee System and its cleared indications for use. MyKnee® Cutting Blocks are intended for single use only.

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 operative techniques. The use of some motor-driven instruments (bits, reamers, drills, 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.

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 labelling 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. MyKnee® orthopaedic surgical instruments can be damaged by inadequate handling: visually inspect the instrument and check for damage: slots, holes, 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 of 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 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 MyKnee® 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 to your Medacta® representative. The Health Care Institution is responsible for cleaning and sterilization of MyKnee® instruments before their use.

WARNING

Check the expiration date prior to use. Using the MyKnee® cutting blocks after the expiration date will not guarantee the optimum bone match between the model and the patient which could lead to unpredictable outcomes of the total knee replacement. The contact points between femur or tibia and the corresponding cutting block need to be properly prepared in order to ensure optimal contact between the cutting block and the bone surface. It is the user's responsibility to follow the preparation procedure in order to ensure the accuracy of the system. 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 to the internal procedures of the health care institution. MyKnee® instruments are meant to be single patient use. Reutilizing them on other patients or even on the same patient would lead to unpredictable total knee replacement outcomes. Visually inspect the blocks after use in order to verify they did not experience any mechanical damage which may cause release of particles in human body. After the cuts have been performed, carefully wash the bone with physiological solution to avoid any incidental debris remain into the wound.

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

SYMBOLS



Non-sterile



Do not reuse



Consult instructions for use



Date of manufacture



Caution, read the accompanying documents



Do not expose to sunlight



Manufacturer



Store in a dry place



Reference number



Do not resterilize



Lot number



Do not use if packaging is damaged



Serial number

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