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INSTRUCTIONS FOR USE - STERILE 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. The user should ensure that the MyKnee® Cutting Blocks are intact and in good working order before use, checking the correct matching with the plastic 3D 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.

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 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.

PACKAGING

The MyKnee cutting 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 not use the component. Do not resterilize.

STORAGE AND HANDLING

The packages should be stored in a cool, dry place, away from light. Handle with care.

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. 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



Sterilized with irradiation



Do not reuse



Non-sterile



Date of manufacture



Consult instructions for use



Do not expose to sunlight



Caution, read the accompanying documents



Store in a dry place



Manufacturer



Do not resterilize



Reference number



Do not use if packaging is damaged



Lot number



Use by



Serial number

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