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INSTRUCTION FOR USE – STERILE MYKNEE® PIN POSITIONER INSTRUMENTS

Use of the instrumentation requires knowledge of the anatomy, biomechanics and reconstructive surgery of the locomotive system. The instrumentation must 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 MyKnee® Pin Positioners are intact and in good working order before use, checking the correct matching with the synthetic 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® Pin Positioners and related synthetic 3D models of the patient's femur and tibia.

Indications for Use:
MyKnee® Pin Positioners are intended to be used as anatomical pin positioners 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® Pin Positioners are intended for use with the GMK® Total Knee System and its cleared indications for use. MyKnee®Pin Positioners are intended for single use only.

GENERAL

Before any surgery, the surgeon must be familiar with the 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 described by 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® Pin Positioners and the synthetic 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 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® Pin Positioners 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 pin positioner need to be properly prepared in order to ensure optimal contact between the pin positioner 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 in a subsequent surgery 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 have caused release of particles in human body. After the cuts have been performed, carefully rinse the bone with physiological solution to avoid any incidental debris remaining in the wound. Any non-functional instrument should be immediately returned to Medacta®. The type of malfunction should be reported.

SYMBOLS

Sterilized with irradiation

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

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