OPTIVU™ SHOULDER SCAPULAR ANCHOR PINS - PACKAGE INSERT

STERILE R

℞ Only

IMPORTANT INFORMATION

Before using an MR Surgical product, the intended user should review and understand the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., the applicable User Manual, product literature, written Surgical Technique). MR Surgical is not liable for complications arising from the use of the device outside of its indicated uses, surgical technique or judgment, product selection and similar matters outside the control of MR Surgical.

DESCRIPTION

The OptiVu™ Shoulder Scapular Anchor Pins are disposable, single-use devices which are provided sterile to the end-user for the purpose of providing fixation of the MR Surgical OptiVu Shoulder Scapular Anchor via drilling into the coracoid bone.

TRAINING

The Scapular Anchor Pins are surgical assistance tools. They should only be used by authorized surgeons, trained in the use of the device by MR Surgical or other personnel authorized by MR Surgical.

INTENDED USE

The Scapular Anchor Pins are components of a three-dimensional tracking system to be used in conjunction with anatomy reference anchors and tracking markers to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, and to position instrumentation relative to those axes by displaying their locations.

INDICATIONS FOR USE

The Scapular Anchor Pins are indicated for stereotaxic guidance during orthopedic surgical procedures performed in an operating room. The patient population has the same characteristics as those suitable for the compatible MR Surgical Navigation System. Note that the clinical benefit or performance is determined based on the MR Surgical OptiVu Shoulder Navigation System used in conjunction with the Scapular Anchor Pins. For more information about indications for use, refer to the associated system User Manual and/or Surgical Technique.

CONTRAINDICATIONS

Contraindications are included in the Surgical Technique and/or User Manual of the compatible MR OptiVu Shoulder Surgical Navigation System.

PRECAUTIONS AND WARNINGS ⚠

The following are general precautions related to the use of MR Surgical products, including the Scapular Anchor Pins:

- Universal Precautions should be observed by all healthcare professionals working with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.
- Personal protective equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices, and equipment. PPE includes gown, mask, goggles or face shield, and shoe covers.
- Do not stack instruments or place heavy instruments on top of delicate devices.
- Precautions should be taken to prevent injuries caused by sharp instruments, pins, or screws when handling these devices after surgical procedures.
- MR Surgical instruments should not be used to perform surgery in applications other than those specified in the User Manual.
- Reuse of a single-use device that has come into contact with blood, bone, tissue, or other body fluids may lead to patient or user injury. Associated risks include but are not limited to mechanical failure and transmission of infectious agents.
- Devices which are provided sterile cannot be re-sterilized if the packaging or sterile barrier is damaged as indicated by the symbol on the package label.
- If applicable, if during surgery this instrument and/or those attached to it experience significant interference (ex. in a manner affecting their being secured to bone), instrument should be re-secured and bone registration should be repeated.
- Pins removed from their original packaging cannot be re-sterilized and must be disposed of after surgery, even if they were not used.
- Minimize excess heat buildup due to friction between metallic components and adjacent surfaces, whether bone or other metallic components. Excess heat buildup in instruments in contact with bone may cause heat necrosis and lead to early failure of the component.
- Use caution in positioning the pins to avoid injuring veins, arteries, and other patient anatomy. Avoid areas which may interfere with other instruments or implant components. If the pin is not properly secured into the bone, its performance may be compromised during insertion and removal.
- During the surgery, verify that the pin is properly secured into the surgical drill during installation and removal.

Other specific precautions are included in the Surgical Technique and/or User Manual of the compatible MR Surgical OptiVu Shoulder Navigation System.

BEFORE EVERY SURGERY

Protective packaging must be checked for possible damage when opening the package before use, as this could impair the sterility of the devices. The expiry date for the sterility of the product should also be verified. If the package has been compromised or if the product is expired, dispose of the box and use another one. The user must verify that the components used with the systems are in good condition prior to the surgery. The instruments shall be inspected for excessive bending or other damage such as excessive wear or deterioration prior to use to ensure that they are in good working order. Bends in the instruments may affect system accuracy. If the components are not in good working condition, the system should not be used, and technical support should be contacted. Verify whether the pins' diameter and length are compatible with the surgical drill using the information provided on the packaging labels.

ADVERSE EFFECTS

Possible complications associated with the use of the Scapular Anchor Pins may include, but are not limited to, the following: misplacement of the implants potentially leading to dislocation, impingement or limb length discrepancy. The occurrence of one of these complications may affect patient safety.

STERILITY

The Scapular Anchor Pins are provided sterile via gamma radiation. The Scapular Anchor Pins are intended for single-use applications only. Possible risks associated with reuse of a single-use device include, but are not limited to, patient or user injury, mechanical failure, and transmission of infection agents. Do not re-sterilize the Scapular Anchor Pins.

STORAGE AND HANDLING

The Scapular Anchor Pins are supplied in their original packaging, which ensures that each instrument is kept in a way that they are not damaged and that their functionality and sterility are preserved during transportation. In order to maintain their performance, the Scapular Anchor Pins must be kept in their packaging until the surgery and in an environment where the temperature does not exceed the limits specified on package labeling. The Scapular Anchor Pins are provided sterile and are single-use devices as indicated on the label.

DISPOSAL INFORMATION

After use, the instrument is a potential biohazard, since it may be contaminated with blood or other body fluids, bone or tissue. Handle and dispose of product in accordance with accepted medical practice and with applicable local, state and national laws and regulations.

ADVERSE EVENTS/COMPLAINT HANDLING

The user and/or patient should report any suspected serious incident or serious safety issue related to the device by informing the manufacturer and the competent authority of the member state in which the serious incident has occurred.

CUSTOMER SERVICE INFORMATION

Manufactured By:

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