OptiVu™ TRACKER - 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™ Trackers are disposable, single-use three-dimensional tracking subcomponents which are affixed to given surgical instruments to allow the ability to track and display the intra-operative positions of the instruments and patient anatomy to the user. They are available in different configurations which correspond to a variety of surgical instruments.

TRAINING

The OptiVu Trackers 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 OptiVu Trackers are components of a three-dimensional tracking system to be used in conjunction with surgical instruments and 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 OptiVu Trackers are indicated supporting 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 Reference 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 OptiVu Trackers:

- Devices removed from their original packaging are not re-sterilizable and must be disposed of after surgery even if they were not used.
- Malfunction or breakage of the OptiVu Trackers may lead to serious outcomes including, but not limited to: infection, surgical delays, poor joint mechanics, adverse tissue reaction, discomfort.

In case of malfunction or breakage, dispose of the product and use another set of OptiVu Tracker. Other specific precautions are included in the Surgical Technique and/or User Manual of the compatible MR Surgical OptiVu 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. Ensure the Trackers are securely assembled to the intended instruments.

RESTRICTIONS FOR USE

OptiVu Trackers should be used only with intended components, instruments, and surgical navigation systems as indicated or supplied by MR Surgical. The use of tracking devices other than those intended by MR Surgical may lead to inaccuracies.

ADVERSE EFFECTS

Possible complications associated with the use of OptiVu Trackers 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

OptiVu Trackers are provided sterile via gamma radiation. OptiVu Trackers 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 OptiVu Trackers. Polycarbonate components may show eventual crazing or cracking due to steam boiler chemicals and lubricants.

STORAGE AND HANDLING

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

TECHNICAL INFORMATION

OptiVu Trackers should only be assembled once to their dedicated instrument. The trackers should be attached to the dedicated instrument by applying hand pressure to the center of the attachment posts. All three tracker posts should be firmly seated on the metal attachment studs, with an audible click for each post indicating that the tracker is fully seated (Figure 1).

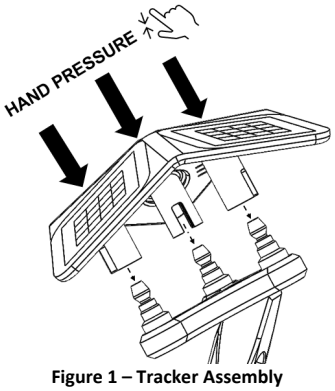

Figure 1 – Tracker Assembly

The indicator number and associated instrument name information directly marked on the reverse side of the trackers should align with indicator number and instrument name marked on the reusable instrument to which the tracker is attached (Figure 2).

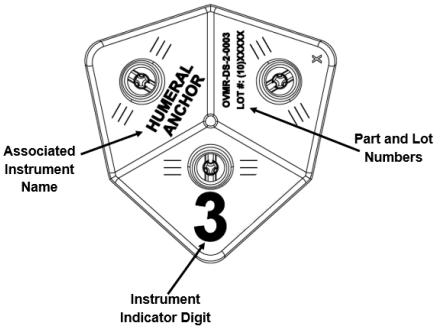

Figure 2 – Tracker Marking Example

The user shall ensure that the OptiVu Trackers remain clean throughout the surgery. If they become soiled during use, use a dry gauze to gently wipe the faces clean. Minimize handling of the OptiVu Trackers to prevent damage or malposition. Disassemble the trackers by hand and follow instructions for disposal.

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

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