ACUMED®
SPORTS MEDICINE

5885 NW Cornelius Pass Road
Hillsboro, OR 97124

BIOTRAK™ RESORBABLE FIXATION SYSTEM

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

DESCRIPTION: The ACUMED Sports Medicine resorbable fixation devices are designed to provide fixation of specific fractures, osteotomies, and arthrodeses while they heal.

INFORMATION FOR USE: The surgeon must select the type and size of implant that best meets the patient's surgical needs.

INDICATIONS: This fixation device is indicated for small bone fractures, osteotomies, and arthrodeses, cancellous fragments, and osteochondral fragments in the upper and lower extremities.

CONTRAINDICATIONS: This device is contraindicated in the presence of active or latent infection, sepsis, osteoporosis, insufficient quantity and/or quality of bone. This device is not intended for use in any indication not covered above.

WARNINGS: For safe and effective use of this implant, the surgeon must be thoroughly familiar with the implant, material, methods of application, instruments, and recommended surgical technique for this device. The device is not designed to withstand the stress of weight bearing, load bearing, and/or excessive activity. Device breakage and/or damage can occur when the implant is subjected to increased loading associated with delayed union, non-union, or incomplete healing. Improper insertion of the device during implantation can increase the possibility of loosening or migration. The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant including the possibility of the device failing due to aforementioned causes. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail. In addition, because of the thermal sensitivity of bioabsorbable materials, the device shall not be utilized if the dot in the middle of the temperature sticker has turned black. A black dot on the sensor signifies that the environmental temperature may have exceeded the softening temperature of the bioabsorbable material during storage and/or transit. Exceeding the softening temperature of the material can lead to degradation of the mechanical properties and/or warping.

PRECAUTIONS: An implant shall never be reused or resterilized. Protect implants from nicks and scratches during handling, because they can cause stress concentrations and may lead to device failure. Instruments shall be inspected for wear and/or damage prior to usage, particularly drills, taps, and drivers.

ADVERSE EFFECTS: Fracture of the implant due to excessive loading, incomplete or inadequate healing, or excessive force during insertion; Implant migration and/or loosening; Sterile inflammation as a result of a body reaction to the degradation products of the absorbable material; Pain, discomfort, or abnormal sensations due to the presence of an implant; Nerve damage resulting from surgical trauma; Bone necrosis or bone resorption.

STERILITY: This product is provided sterile. It was sterilized with a minimum of 25.0 kGy of gamma radiation. The implant must never be re-sterilized.

STORAGE INSTRUCTIONS: Store implants in a cool dry place and keep away from direct sunlight. The implant should be stored in a temperature and humidity controlled environment below 100°F. Prior to use, inspect packaging for signs of tampering or water contamination. Check the expiration date on the box to ensure that the shelf life of the product has not been exceeded. Also, please inspect the temperature sensor on the box to ensure that the center has not turned black. If the temperature of the packaging has exceeded the softening temperature of the material during its lifetime, the central dot on the temperature sensor will be black and this device must not be implanted. Use the oldest lots first because the bioabsorbable material has a finite shelf life.

CAUTION: Federal law (USA) restricts this product sale by or on the order of a physician or hospital.

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