



GRAVITY™ SUTURE ANCHOR SYSTEMS

153202-1

The following languages are included in this packet:

English (en)
Español (es)

Deutsch (de)
Italiano (it)

Nederlands (nl)
Português (pt)

Français (fr)
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For additional languages, visit our website www.wright.com. Then click on the **Prescribing Use** option.

For additional information and translations please contact the manufacturer or local distributor.



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*The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.

Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION
GRAVITY™ SUTURE ANCHOR SYSTEM
(153202-1)

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I. DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by

	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
	Authorized EC Representative in the European Community
	Sterilized using ethylene oxide
	Sterilized using radiation
	Sterilized using gas plasma

STERILE A	Sterilized using aseptic processing techniques
R ONLY	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
PEEK	Poly(ether-ether ketone)

II. GENERAL PRODUCT INFORMATION

Through the advancement of internal fixation hardware, the surgeon has been provided a means of correcting deformity and reducing pain for many patients. While the implants used are largely successful in attaining these goals, it must be recognized that they are manufactured from metal and polymeric materials and no implant can be expected to withstand the activity levels and loads as would normal, healthy bone after fusion occurs. The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection.

Surgeons must be familiar with the applicable operative technique and instructions for use for each product. This package insert and the immediate package label contain essential warnings, precautions, and contraindications for each surgery. Additionally, the surgical technique should be referenced for detailed information about implant selection, relevant product details, proposed surgical instructions, and/or assembly use. The surgeon should contact Wright for the proposed product-specific surgical technique.

In using fusion implants, the surgeon should be aware of the following:

- **The correct selection and sizing of the implant is extremely important.** Selection of the proper size, shape, and design of the implant increases the potential for success. The implants require careful seating and adequate bone support. Proper implant selection must consider design, fixation, patient weight, age, bone quality, size, activity level, preoperative level of health, and also the surgeon's experience and familiarity with the device. Implant longevity and stability may be affected by these variables. Surgeons should inform the patients about these factors.
- **In selecting patients for surgery, the following factors can be critical to the eventual success of the procedure:**
 1. **Patient's occupation or activity.** If the patient is involved in an occupation or activity which includes substantial lifting or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The implant will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.

2. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
3. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

A. PATIENT SELECTION

Use of internal fixation hardware requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bone stock to receive implant
- Availability of post-operative therapy
- Cooperative patient

B. INDICATIONS

The GRAVITY Suture Anchor Systems are indicated for use:

- In the repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a slap lesion, acromioclavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction;
- In the repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or ulnar or radial collateral ligament tear/separation;

- In the repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament;
- In the repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tenodesis;
- In the repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments, medial stabilization tendons/ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments, Tendon Transfers, tendon reattachments, and ligament reconstructions of the midfoot, forefoot, and hindfoot procedures associated with flatfoot reconstruction, hindfoot deformity, midfoot reconstruction, lateral/medial ankle reconstruction or instability, Hallux Valgus or Varus, and MTP instability including:
 - Achilles reattachment/reconstruction
 - Flexor Digitorum Longus Transfer
 - Flexor Hallucis Longus Transfer
 - Extensor Hallucis Longus Transfer
 - Brostrom Procedures
 - Peroneal Tendon Relocation
 - Capsule Repair
 - Deltoid reconstruction / reattachment
 - Plantar Plate Repair
 - Spring Ligament Repair

C. CONTRAINDICATIONS

No product specific contraindications.

D. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Bone resorption or over-production
- Allergic reaction(s) to implant material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

E. PRECAUTIONS

Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant.

It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

IF EXCESSIVE LOADING CANNOT BE PREVENTED, AN IMPLANT SHOULD NOT BE USED.

The main goal of surgery with this implant is to establish soft tissue to bone union. Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant.

Abnormal force loading and subsequent wear may be caused by:

- Uncorrected instability
- Improperly sized implant
- Inadequate soft tissue support
- Implant malposition
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or overactivity

Proper fixation at the time of surgery is critical to the success of the procedure. Bone stock must be adequate to support the device.

Some preventative measures to consider to minimize the potential for complications:

- Follow guidelines for indications and contraindications provided above
- Identify prior pathology
- Stabilize collapse deformities
- Bone graft pre-existing cysts
- Use a properly sized implant
- Avoid K-wires and sutures through the implant

Avoid flanging implant surfaces to minimize the potential for early fatigue failure.

If complications develop, possible corrective procedures include:

- Implant removal

- Synovectomy
- Bone grafting of cysts
- Replacement of the implant
- Removal of the implant with fusion of the joint

Recommendations Regarding Device Fragments

- Use medical devices in accordance with their labeled indications and Wright Medical Technology's instructions for use, especially during insertion and removal.
- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with Wright Medical Technology's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - a. The material composition of the fragment (if known);
 - b. The size of the fragment (if known);
 - c. The location of the fragment;
 - d. The potential mechanisms for injury, e.g., migration, infection;
 - e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Clinical results depend on surgeon and technique, pre-operative and post-operative care, the implant, patient pathology and daily activity. It is important that surgeons obtain appropriate informed consent and discuss the potential for complications with each patient prior to surgery. This may include a review of alternative, non-implant procedures such as soft tissue reconstruction or arthrodesis.

Concerning Magnetic Resonance Environments

There are inherent risks associated with the use of implants in the MR environment; including component migration, heat induction, and signal interference or distortion near the component(s). Heat induction of implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants.

These implants have not been evaluated for safety and compatibility in the MR environment. These implants have not been tested for heating, migration, or image artifact in the MR environment. The safety of this in the MR environment is unknown. Scanning a patient who has the device may result in patient injury.

F. HANDLING AND STERILIZATION

IMPLANTS

The implants described in this package insert are provided sterile. Implants in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. If the inner package integrity has been compromised, contact the manufacturer for further instructions. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

This product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

G. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

III. SPECIFIC PRODUCT INFORMATION

A. GRAVITY TITANIUM SUTURE ANCHOR SYSTEM

DESCRIPTION

The GRAVITY Titanium Suture Anchor System features sterile, single-use devices for use in soft tissue reattachment procedures. The implants are available in a range of sizes and feature threaded titanium anchors loaded with ultra-high molecular weight polyethylene (UHMWPE) suture.

B. GRAVITY PEEK-OPTIMA™ SUTURE ANCHOR SYSTEM

DESCRIPTION

The GRAVITY PEEK-OPTIMA™ Suture Anchor System features sterile, single-use devices for use in soft tissue reattachment procedures. The implants are available in a range of sizes and feature threaded PEEK-OPTIMA™ anchors loaded with ultra-high molecular weight polyethylene (UHMWPE) suture.

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