ANCHORLOK® SOFT TISSUE ANCHOR SYSTEM

115314-6

The following languages are included in this packet:

English (en)
Español (es)
Türkçe (tk)
Deutsch (de)
Italiano (it)
Nederlands (nl)
Português (pt)
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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.**

℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL
ANCHORLOK® SOFT TISSUE ANCHOR SYSTEM
(115314-6)

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
LOT	Batch code
REF	Catalog number
2	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
EC REP	Authorized EC Representative in the European Community
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using radiation
STERILE GAS	Sterilized using gas plasma
STERILE A	Sterilized using aseptic processing techniques
℞ ONLY	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	Do not use if packaging is ripped or damaged.
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)

OUTLINE:

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   C. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS
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I. 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

See Section II for specific product information.

B. CONTRAINDICATIONS

Absolute contraindications include:

- Overt infection;
- Distant foci of infections;
- Rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
- Skeletally immature patients;
- Inadequate neuromuscular status (e.g. prior paralysis, fusion and/or inadequate muscle strength), poor bone stock, or poor skin coverage;
- Pathological conditions of the bone (such as cystic changes or severe osteopenia) or comminuted bone which would compromise secure fixation;
- Pathological conditions of the soft tissues to be attached which would impair secure fixation;
- Physical conditions which would eliminate or reduce adequate support or retard healing such as reduced blood supply to the site;

- Conditions which may interfere with healing or decrease the likelihood of proper postoperative care such as senility, mental illness, or alcoholism;
- Attachment of artificial ligaments or other implants.

The following conditions may impair the success of the implant and should be considered carefully by the medical professional prior to implantation. These relative contraindications include but are not limited to:

- Physical conditions tending to adversely affect stable fixation such as systemic/metabolic disorders or medical treatments leading to progressive deterioration of bone (e.g., cortisone therapies, immunosuppressive therapies), a history of general or local infectious disease, or an allergy to the implant materials.
- Conditions which, singularly or concurrently, tend to impose severe loading at the fixation site such as obesity, heavy labor, active sports, young age, history of falls, drug/alcohol abuse, or mental conditions.

See Section II for specific product information.

C. 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

See Section II for specific product information.

D. PRECAUTIONS

- Excessive physical activity and trauma affecting the fixation site may result in premature failure by loosening the anchor. Unreasonable stresses on the fixation site and inappropriate activities should be avoided.
- The surgeon should be thoroughly familiar with the surgical protocol for this implant prior to use.
- Proper handling of anchors is mandatory. Damage or alterations to the anchors may produce stresses and cause defects which could become the focal point for an anchor failure.
- An anchor should never be reused. Even though the anchor appears undamaged, it may be fatigued from previous stresses and may have developed microscopic imperfections which could lead to failure.
- Under most conditions, the ANCHORLOK® is self-tapping. In cases where the clinician encounters unusually hard bone, predrilling an appropriate pilot hole may be necessary.

Recommendations Regarding Device Fragments

- Use medical devices in accordance with their labeled indications and Wright'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

The devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. The devices described in this package insert have not been tested for heating or migration in the MR environment.

See Section II for specific product information.

E. HANDLING AND STERILIZATION

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.

See Section II for specific product information.

F. STORAGE CONDITIONS

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

See Section II for specific product information.

II. SPECIFIC PRODUCT INFORMATION

A. ANCHORLOK® Soft Tissue Anchor System

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Description

The ANCHORLOK® Soft Tissue Anchor System is a single-use, sterile device intended to provide a means for firmly securing soft tissue to bone.

Indications

The ANCHORLOK® Soft Tissue Anchor System is 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.

CAUTION

Federal Law (U.S.A.) restricts this device to sale, distribution, and use by or on the order of a physician.