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 precautions, 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 the patient's occupation or activity.

- **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.

- **Skin foreign body sensitivity, where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.**

II. 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 musculoskeletal 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 neurovascular 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 condition of the soft tissues to be attached which would impair secure fixation
  - Physical conditions which would eliminate or reduce adequate support or retard healing

Do not use if packaging is ripped or damaged.

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### Symbols and Abbreviations

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
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<tbody>
<tr>
<td>SOT</td>
<td>Batch code</td>
</tr>
<tr>
<td>Catalog number</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Do not re-use</td>
</tr>
<tr>
<td>Caution, consult accompanying documents</td>
<td></td>
</tr>
<tr>
<td>h</td>
<td>Consult operating instructions</td>
</tr>
<tr>
<td>Use by</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td></td>
<td>Keep dry</td>
</tr>
<tr>
<td></td>
<td>Keep away from sunlight</td>
</tr>
<tr>
<td></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
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<tr>
<td>Authorized EC Representative in the European Community</td>
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<tr>
<td>Sterilized using ethylene oxide</td>
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<tr>
<td>Sterilized using radiation</td>
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<tr>
<td>Sterilized using aseptic processing techniques</td>
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<tr>
<td>i</td>
<td>Consult operating instructions</td>
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<tr>
<td></td>
<td>Do not use if packaging is ripped or damaged.</td>
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Material</th>
</tr>
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<tbody>
<tr>
<td>Ti</td>
<td>Titanium</td>
</tr>
<tr>
<td>Ti6Al4V</td>
<td>Titanium Alloy</td>
</tr>
<tr>
<td>CoCr</td>
<td>Cobalt-Chromium alloy</td>
</tr>
<tr>
<td>SS</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>UHMWPE</td>
<td>Ultra High Molecular Weight Polyethylene</td>
</tr>
<tr>
<td>PEEK</td>
<td>Poly(ether-ketone)</td>
</tr>
</tbody>
</table>

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OUTLINE:

I. GENERAL PRODUCT INFORMATION

A. PATIENT SELECTION

B. CONTRAINdicATIONS

C. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

D. PRECAUTIONS

E. HANDLING AND STERILIZATION

F. STORAGE CONDITIONS

II. SPECIFIC PRODUCT INFORMATION

A. ANCHORLOK® SOFT TISSUE ANCHOR SYSTEM
II. SPECIFIC PRODUCT INFORMATION

A. ANCHORLOK ® Soft Tissue Anchor System

F. STORAGE CONDITIONS

E. HANDLING AND STERILIZATION

D. PRECAUTIONS

C. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

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

Recommendations Regarding Device Fragments

- 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.

Concerning Magnetic Resonance Environments

- The implants described in this package insert have not been tested for heating or migration in the MR environment. The devices described in this package insert have not been evaluated for safety and compatibility concerning Magnetic Resonance Environments.

- Physical conditions tending to adversely affect stable fixation such as systemic/metabolic conditions, chronic infections, or an allergy to the implant material(s)

- Conditions which, singularly or concurrently, tend to impose severe loading at the fixation site such as death, decay, 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 associated with these implants include, but are not limited to:

- Significant degradation in device performance, cross-contamination between patients or from reusable devices, potentially result in serious patient harm. Examples of hazards related to the reuse of these implants include, but are not limited to:
  - In the repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, or metatarsal tendons/ligaments, or midfoot tendons/ligaments.
  - In the repair of knee instability secondary to tear or separation of the medial collateral ligament, or posterior oblique ligament, or posterolateral oblique ligament, or collateral ligament.

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 anchor 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 stress and cause defects which could become the focal point for an anchor fracture.

- 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.

Concerning Magnetic Resonance Environments

- Clinical results depend on surgeon and technique, pre-operative and post-operative care, the implant and materials that are a means for firmly securing soft tissue to bone.

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

- 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:

- 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

- 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 may invalidate the method 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 retaining vs. leaving the fragment in the patient.

- Advise the patient of the nature and safety of unretrieved device fragments including the following:
  - There is no evidence that the ANCHORLOK® is self-tapping. In cases where the clinician encounters unusually hard bone, predrilling an appropriate pilot hole may be necessary.

Concerning Magnetic Resonance Environments

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

- 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:

- In the repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, lateral collateral ligament, or radial collateral ligament.

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 heating or migration in the MR environment. The implants described in this package insert have not been tested for heating or migration in the MR environment.

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, or labral capsulolabral reconstruction.
  - In the repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or lateral or radial collateral ligament/separation.
  - In the repair of hand/wrist instability secondary to biceps tendon detachment, tennis elbow, or lateral collateral ligament/separation.
  - In the repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, or patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tendinosis.
  - 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.

See Section II for specific product information.
CAUTION
Federal Law (U.S.A.) restricts this device to sale, distribution, and use by or on the order of a physician. Trademarks™ and Registered Trademarks® are owned or licensed by Wright Medical Technology, Inc.