ENDO-FUSE® INTRA-OSSEOUS FUSION SYSTEM
150843-0

The following languages are included in this packet:

- English (en)
- Deutsch (de)
- Nederlands (nl)
- Français (fr)
- Español (es)
- Italiano (it)
- Português (pt)
- 中文- Chinese (sch)
- Türkçe (tk)

For additional languages, visit our website www.wmt.com
Then click on the Prescribing Information option.

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

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

IMPORTANT MEDICAL INFORMATION
ENDO-FUSE® INTRA-OSSEOUS FUSION SYSTEM
(150843-0)

OUTLINE
DEFINITIONS
GENERAL PRODUCT INFORMATION
   A. INDICATIONS
   B. CONTRAINDICATIONS
   C. POTENTIAL COMPLICATIONS
   D. PRECAUTIONS
   E. ADVERSE EFFECTS
   F. HANDLING & STERILIZATION
   G. STORAGE CONDITIONS

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Batch code</td>
</tr>
<tr>
<td>REF</td>
<td>Catalog number</td>
</tr>
<tr>
<td>2</td>
<td>Do not re-use</td>
</tr>
<tr>
<td>!</td>
<td>Caution, consult accompanying documents</td>
</tr>
<tr>
<td>i</td>
<td>Consult operating instructions</td>
</tr>
<tr>
<td></td>
<td>Use by</td>
</tr>
<tr>
<td></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></td>
<td>Manufacturer</td>
</tr>
<tr>
<td></td>
<td>Authorized EC Representative in the European Community</td>
</tr>
<tr>
<td></td>
<td>Sterilized using ethylene oxide</td>
</tr>
<tr>
<td></td>
<td>Sterilized using radiation</td>
</tr>
<tr>
<td></td>
<td>Sterilized using gas plasma</td>
</tr>
</tbody>
</table>
STERILE A

Sterilized using aseptic processing techniques

Rx ONLY

For prescription use only

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ti</td>
<td>Titanium</td>
</tr>
<tr>
<td>Ti6Al4V</td>
<td>Titanium Alloy</td>
</tr>
<tr>
<td>CoCr</td>
<td>Cobalt Chrome Alloy</td>
</tr>
<tr>
<td>SS</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>UHMWPE</td>
<td>Ultra High Molecular Weight Polyethylene</td>
</tr>
</tbody>
</table>

GENERAL PRODUCT INFORMATION

Through the advancement of surgical fusion 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 that no implant can be expected to withstand the activity levels and loads as would normal, healthy bone after fusion occurs.

Each patient must be evaluated by the surgeon to determine the risk/benefit relationship.

The ENDO-FUSE® Intra-Osseous Fusion System consists of titanium alloy triangular-shaped rods and “barbell”-shaped beams intended for surgical implantation within the bone to create fixation. The rods are available in various lengths and diameters, and the beams in various widths and lengths. Both rods and beams are coated with CP titanium plasma spray.

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.
- 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 implant, 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. INDICATIONS

The ENDO-FUSE® Intra-Osseous Fusion System Rods are generally indicated for the reduction and fixation of fractures appropriate for the size of the devices. They are indicated for use in the internal fixation of fractures, boney fusions, and non-unions. They are also indicated for reconstructive procedures where reduction and fixation of bone fragments are required (e.g. osteotomies).
The ENDO-FUSE® Intra-Osseous Fusion System Beams are indicated for lateral column lengthening and for fusions of any joint in the foot appropriate for the size of the device, including the tarso-metatarsal, metatarsal-cuneiform, calcaneal-cuboid, talo-navicular, Lis Franc, Four-Corner, subtalar, and ankle joint.

B. CONTRAINDICATIONS

Absolute contraindications include:

1) overt infection;
2) distant foci of infections (which may cause hematogenous spread to the implant site);
3) cases where there is poor or insufficient bone stock;
4) metal sensitivity or allergic reaction to foreign bodies;
5) the presence of any clinical or functional abnormalities that would preclude the potential of achieving a good result for the patient;
6) other conditions that may place the patient at risk physiologically.

Conditions presenting increased risk of failure include:

1) uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2) marked bone loss or severe osteoporosis;
3) metabolic disorders that may impair bone formation or cause bone loss;
4) osteomalacia; and
5) poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

C. POTENTIAL COMPLICATIONS

Improper selection, placement, positioning, or fixation of the implants may result in unusual stress conditions and a subsequent reduction in service life of the implant. The surgeon must be thoroughly familiar with the implants, instruments, and surgical procedure prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bones.

Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure used based on personal medical training and experience. Although Wright Medical Technology, Inc. (Wright) cannot recommend a particular surgical technique suitable for all patients, a detailed surgical technique is available for surgeon reference. Medical procedures for optimal utilization of the implant should be determined by the physician. However, the physician is advised that there is recent evidence that the potential for deep sepsis following surgery may be reduced by:

1. Consistent use of prophylactic antibiotics.
2. Utilizing a laminar flow clean air system.
3. Having all operating room personnel, including observers, properly attired.
4. Protecting instruments from airborne contamination.
5. Impermeable draping.

Materials. The ENDO-FUSE® Intra-Osseous Fusion System is manufactured from Commercially Pure Titanium or Titanium Alloy conforming to ASTM/ISO standards.
D. PRECAUTIONS

1. The patient should be made aware of the limitations of the implant and that physical activity and full weight bearing prior to bony union have been implicated in premature failure of similar devices.

2. The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the implant does not replace normal healthy bone and that the implant can break or become damaged as a result of certain activity or trauma. The patient should also be advised of other risks that the surgeon believes should be disclosed.

3. Specialized instruments are available and must be used to assure the accurate implantation of implants. Do not mix instruments from different manufacturers. While rare, breakage of instruments may occur especially with extensive use or excessive force. For this reason, instruments should be examined for wear or damage prior to surgery.

4. Careful attention to selecting the proper size implant for the patient is required. A concerted effort must be made pre-operatively to determine the correct size and shapes of implants to be used for the patient. It is critical that larger and smaller implant sizes are on hand in case it is determined that a different size is required.

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’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.

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.

E. ADVERSE EFFECTS

The following are specific adverse effects, which should be understood by the surgeon and explained to the patient. These do not include all adverse effects, which can occur with surgery in general, but are important considerations specific to metallic internal stabilization devices. General surgical risks should be explained to the patient prior to surgery.

1. Infection.
2. Pain, discomfort, or abnormal sensations due to presence of the implant.

3. Although rare, metal sensitivity reactions in patients following implantation have been reported. Implantation of foreign material in tissues can result in cellular reactions involving lymphocytes, macrophages, and fibroblasts.

4. Migration of the implant, loosening or fracture of the implant.

5. Decrease in bone density due to stress shielding.


7. Allergic reactions to the implant materials can occur.

F. HANDLING AND STERILIZATION

Implants

This product has been sterilized and should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the manufacturer for instructions. Remove from package, using aseptic OR technique, only after the correct size has been determined and the operative site has been prepared for final implantation. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product.

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.

WARNING: All packaging materials MUST be removed from the implant prior to implantation.

WARNING: You must NEVER steam sterilize/resterilize the components of the ENDO-FUSE® Intra-Osseous Fusion System.

Instruments

For additional information regarding instruments, see Wright’s Cleaning and Handling of Wright Medical Instruments.

G. STORAGE CONDITIONS

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

CAUTION: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

Trademarks™ and Registered Trademarks® are owned or licensed by Wright Medical Technology, Inc.