WRIGHT™

STABILIZATION AND FRACTURE FIXATION
150838-1

The following languages are included in this packet:

English (en)
Español (es)
Deutsch (de)
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Português (pt)
Français (fr)
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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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EN

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL
STABILIZATION AND FRACTURE FIXATION
SYSTEM (150838-1)

OUTLINE:

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II. SPECIFIC PRODUCT INFORMATION

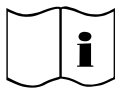
The specific products described below may not be available for distribution in all countries/territories. Please contact Wright Medical Technology for availability.

A. DARCO™ LOCKING BONE PLATE SYSTEM
B. DARCO™ 3.2 MM HEADLESS SCREW
C. DARCO™ 4.3 MM HEADLESS SCREW
D. DARCO™ 7.0 MM HEADLESS SCREW
E. DART-FIRE™ SMALL SCREWS

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
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
	Do not use if packaging is ripped or damaged
℞ ONLY	For prescription use only

Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

I. 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. 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 immediate package label contain essential warnings and precautions 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.

- **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 surgical fusion 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. 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.

C. 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 bony fusion. 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 below
- Identify prior pathology
- Stabilize collapse deformities
- Bone graft pre-existing cysts
- Use a properly sized implant

Avoid flawing implant surfaces or excessive bending to minimize the potential for early fatigue failure.

If complications develop, possible corrective procedures include:

- Implant removal
- Bone grafting of cysts
- Replacement of the implant

Over time, metallic implants may loosen, fracture, or cause pain after bone fracture or osteotomy is healed. Removal of metallic implants is at the surgeon's discretion, and the appropriateness of the selected procedure will be based on the surgeon's personal medical training and experience. It is imperative that adequate post-operative care and protection be provided by the surgeon.

Recommendations Regarding Device Fragments

1. Use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
2. 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.
3. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
4. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
5. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
6. 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 more specific product information.

D. HANDLING AND STERILIZATION

IMPLANTS

The implants described in this package insert are either provided sterile or non-sterile as indicated on the individual product's label. Implants that are presented in instrument trays are provided non-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.

Implants provided non-sterile should be processed according to the recommended parameters for instruments (below).

INSTRUMENTS

Surgical instruments (and non-sterile implants) should be cleaned and sterilized according to the following parameters:

Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly/flush with deionized/reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. **Rinse** thoroughly/flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Sterilization

The minimum recommended steam sterilization conditions for Wright reusable instruments are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Type	**Parameter**	**Minimum Set Point**
Prevacuum 270°F (132°C)	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with AAMI ST79 Table 5 guidelines and have been developed and tested using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

For additional information see Wright's "Cleaning and Handling of Wright Medical Instruments".

E. STORAGE CONDITIONS

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

II. SPECIFIC PRODUCT INFORMATION

The specific products described below may not be available for distribution in all countries/territories. Please contact Wright Medical Technology for availability.

A. DARCO™ LOCKING BONE PLATE SYSTEM

DESCRIPTION

The DARCO™ Locking Bone Plate System is designed with rhombus (parallelogram) plates of biocompatible titanium. The plates use either 2.7mm or 3.5mm screws which intersect each other in pairs. The drill holes of the plates are aligned to assure the screws do not touch. The plates vary essentially through different curvatures, material strengths, lengths, number of plate holes and through different grades or bridge widths.

INDICATIONS

The DARCO™ Locking Bone Plate System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet, ankles and toes. The system can be used in both adult and pediatric patients.

This implant should only be used with a DARCO™ plate and screw system. Combination with other implants or instruments is not permissible.

B. DARCO™ 3.2 MM HEADLESS SCREW

DESCRIPTION

The DARCO™ 3.2 mm Headless Screw is a self drilling, self tapping and self countersinking 3.2 mm hex drive cannulated screw with a reverse cutting nib designed into the thread pattern. The cannulated feature allows for the use of a drill guide for precise placement while the smooth shank between the threaded portions of the screw allows the bone surfaces to be compressed to facilitate healing. The screws are made of Ti 6-Al 4-V biocompatible titanium alloy and coated with an anodized finish.

INDICATIONS

The DARCO™ 3.2 mm Headless Screw is to be used on indications that are common for currently marketed compression screws. The primary indication for use is the fixation and stabilization of fractures and non-unions of small bones and small bone arthrodeses including but not limited to intra-articular fractures of the tarsals, metatarsals, carpals and metacarpals, bunionectomies and osteotomies, and arthrodeses of small joints (i.e.phalanges).

C. DARCO™ 4.3 MM HEADLESS SCREW

DESCRIPTION

The DARCO™ 4.3 mm Headless Screw is offered in various diameters and lengths. It is offered in short and long thread lengths and has self drilling and self tapping features on both distal and proximal threads. All screws are manufactured from titanium.

INDICATIONS

The DARCO™ 4.3 mm Headless Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Mono or Bi-Cortical osteotomies in the foot or hand
- Distal or Proximal metatarsal or metacarpal osteotomies
- Weil osteotomy
- Fusion of the first metatarsophalangeal joint and interphalangeal joint
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)
- Akin type osteotomy
- Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
- Calcaneus/ cuboid arthrodesis
- Talar/ navicular arthrodesis

D. DARCO™ 7.0MM HEADLESS SCREW

DESCRIPTION

The DARCO™ 7.0mm Headless Screw is a self drilling screw offered in various lengths and distal thread lengths. Washers are offered for oblique and straight screw placement. All screws and washers are manufactured from titanium.

INDICATIONS

The DARCO™ 7.0mm Headless Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of bone fragments, in long bones or small bones fractures
- Fracture management in the foot or hand
- Arthrodesis in hand, foot or ankle surgery
- Mono- or Bi-cortical osteotomies in the foot or hand or in long bones
- Hindfoot arthrodesis

E. DART-FIRE™ SMALL SCREWS

DESCRIPTION

The DART-FIRE™ Compression Screws are cannulated screws offered in various diameters and lengths. Screws are available both headed and headless, and all screws are manufactured from titanium alloy.

INDICATIONS

The DART-FIRE™ Compression Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.