WRIGHT™

FRACTURE FIXATION

150846-0

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 additÚnal languages, visit our website www.wmt.com. Then click on the **Prescribing Information** optÚn.

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

CE 0086*

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
U.S.A.
.

EC REP

Wright Medical UK Ltd
3rd Avenue
Letchworth
Herts, SG6 2JF
UK

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

℞ ONLY

October 2013
Printed in U.S.A

2

EN

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL FRACTURE FIXATION (150846-0)

OUTLINE:

G. CHARLOTTE™ MULTI-USE COMPRESSION SCREW
H. CHARLOTTE™ COMPRESSION STAPLE
I. CHARLOTTE™ QUICK STAPLE
J. CHARLOTTE™ SNAP-OFF SCREW
K. CHARLOTTE™ CLAW® PLATE
L. CHARLOTTE™ 7.0 MULTI-USE COMPRESSION SCREW
M. CHARLOTTE™ CAROLINA™ JONES FRACTURE SYSTEM
N. CHARLOTTE™ LISFRANC BONE SCREW
O. CHARLOTTE™ LISFRANC PLATE

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
	Do not re-use

	CautÚn, consult accompanying documents
	Consult operating instructÚns
	Use by
	Temperature limitatÚn
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
EC REP	Authorized EC Representative in the European Community
STERILE EO	SterŠized using ethylene oxide
STERILE R	SterŠized using radiatÚn
STERILE GAS	SterŠized using gas plasma
STERILE A	SterŠized using aseptic processing techniques
℞ ONLY	For prescriptÚn 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.

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

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. CONTRAINDICATIONS

- Infection
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity

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

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 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 flawing 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

Over time, metallic implants may loosen, fracture, or cause pain after the 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 specific product information.

E. HANDLING AND STERILIZATION

IMPLANTS

The implants in this system are either provided sterile or non-sterile; the individual product's labeling will determine whether or not it is packaged sterile. 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. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

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

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

INSTRUMENTS

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

Cleaning & Disinfection

Clean to remove gross contamination and disinfect to reduce the number of viable microorganisms.

1. **Disassemble** 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

1. Double wrap the component in CSR wrap or a 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".

F. 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

A. LOCON-T® DISTAL RADIUS PLATING SYSTEM

DESCRIPTION

The LOCON-T® Distal Radial Plating System consists of right and left dorsal bone plates, volar T-plates, cancellous screws, cortical screws, buttress pins, and a dorsal plate extender. All components are manufactured from stainless steel.

INDICATIONS

Use of the LOCON-T® Distal Radial Plating System is intended to be used for fixation of unstable distal radial fractures in which closed reduction is not suitable:

- Joint destruction and/or subluxation visible on x-ray;
- Failed fracture fixation with or without bone graft;
- Osteotomy and repair of distal radius malunion with or without bone graft;
- Displaced or non-displaced fracture which may or may not involve angulation or fragmentation of bone;
- Dorsal plates are indicated for use with comminuted articular fractures, shearing fractures of the articular surface, severely comminuted extra-articular fractures, and fractures in which reduction has been lost following fixation with percutaneous pins with or without an external fixator;
- T-plates are indicated for use with volar articular shearing fractures.

CONTRAINDICATIONS

The LOCON-T® Distal Radial Plating System is contraindicated for the following:

- In patients with probable history of infection or current infection
- Overt infection
- Skeletally immature patients

B. LOCON® VLS DISTAL RADIUS PLATING SYSTEM

DESCRIPTION

The Locon® VLS Distal Radius Plating System consists of right and left volar bone plates, cancellous screws, and cortical screws. All components are manufactured from stainless steel.

INDICATIONS

Use of the Locon® VLS Distal Radius Plating System is intended to be used for fixation of unstable distal radial fractures in which closed reduction is not suitable:

- Joint destruction and/or subluxation visible on x-ray;
- Failed fracture fixation with or without bone graft;
- Osteotomy and repair of distal radius malunion with or without bone graft;
- Displaced or non-displaced fracture which may or may not involve angulation or fragmentation of bone;
- Volar plates are indicated for use with comminuted articular fractures, shearing fractures of the articular surface, severely comminuted extra-articular fractures, and fractures in which reduction has been lost following fixation with percutaneous pins with or without an external fixator;
- Locking Volar plates are indicated for use with volar articular shearing fractures.

CONTRAINDICATIONS

The Locon® VLS Distal Radius Plating System is contraindicated for the following:

- In patients with probable history of infection or current infection
- Overt infection
- Skeletally immature patients

C. EVOLVE® RADIAL HEAD PLATE SYSTEM

DESCRIPTION

The EVOLVE® Radial Head Plate System consists of plates, cancellous screws, and locking screws. All components are manufactured from stainless steel.

INDICATIONS

Use of the EVOLVE® Radial Head Plate System is intended to be used for fixation of unstable radial fractures in which closed reduction is not suitable.

CONTRAINDICATIONS

The EVOLVE® Radial Plate System is contraindicated for the following:

- In patients with probable history of infection or current infection
- Overt infection
- Skeletally immature patients

D. EVOLVE® EPS SYSTEM

DESCRIPTION

The EVOLVE® EPS System consists of a variety of pre-contoured plate geometries. The plates feature compression slots and locking screw holes. The associated screws are available in a range of lengths. All components are manufactured from stainless steel.

INDICATIONS

The EVOLVE® EPS System is intended for fixation of fractures, osteotomies and non-unions of the olecranon, humerus, radius and ulna.

CONTRAINDICATIONS

The EVOLVE® EPS System is contraindicated for the following:

- In patients with probable history of infection or current infection
- Overt infection
- Skeletally immature patients

E. MICRONAIL® INTRAMEDULLARY DISTAL RADIUS SYSTEM

DESCRIPTION

The MICRONAIL® Intramedullary Distal Radius System consists of Distal Radius Implants, Cortical Bone Screws, and Buttress Screws. All components are manufactured from Titanium.

INDICATIONS

The MICRONAIL® Intramedullary Distal Radius System is intended to be used for the fixation of unstable distal radius fractures in which closed reduction is not suitable:

- Joint destruction and/or subluxation visible on x-ray;
- Failed fracture fixation with or without bone graft;
- Osteotomy and repair of distal radius malunion with or without bone graft;
- Displaced or non-displaced fracture which may or may not involve angulation or fragmentation of bone;
- Comminuted articular fractures, shearing fractures of the articular surface, severely comminuted extra-articular fractures, and fractures in which reduction has been lost following fixation with percutaneous pins with or without an external fixator.

CONTRAINDICATIONS

The MICRONAIL® Intramedullary Distal Radius System is contraindicated for the following:

- In patients with probable history of infection or current infection
- Overt infection
- Skeletally immature patients

F. CHARLOTTE™ MTP BONE FUSION PLATE

DESCRIPTION

The CHARLOTTE™ MTP Bone Fusion Plate System consists of plates in left and right configurations and screws. All screws and plates are manufactured from stainless steel.

INDICATIONS

The CHARLOTTE™ MTP Bone Fusion Plate System is intended to help increase the rate of bony union, and to maintain the position of the toe during fusion. Once the joint has fused, the plate is secondary in the transmission of gait forces.

Indications for Use:

- Fractures, osteotomies or arthrodesis of the first metatarsal-phalangeal joint
- Deformity due to hallux valgus
- Deformity due to arthritis in the first metatarsal-phalangeal joint
- Loss of motion- hallux rigidus
- Pain associated with osteoarthritis or rheumatoid arthritis in the first metatarsal-phalangeal joint
- Revision procedures where other treatments or devices have failed; and
- Chronic instability in the first metatarsal-phalangeal joint

G. CHARLOTTE™ MULTI-USE COMPRESSION SCREW

DESCRIPTION

The CHARLOTTE™ Multi-Use Compression 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 stainless steel.

INDICATIONS

The CHARLOTTE™ Multi-Use Compression 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

H. CHARLOTTE™ COMPRESSION STAPLE

DESCRIPTION

The CHARLOTTE™ Compression Staple is offered in several sizes with barbs to prevent back out and a diamond shape slot compression feature. All staples are manufactured from stainless steel.

INDICATIONS

The CHARLOTTE™ Compression Staple is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

I. CHARLOTTE™ QUICK STAPLE

DESCRIPTION

The CHARLOTTE™ Quick Staple features barbs to prevent back out. All staples are manufactured from stainless steel.

INDICATIONS

The CHARLOTTE™ Quick Staple is intended to be used for wedge osteotomy of the first phalanx (Akin osteotomy), in the treatment of hallux-valgus in order to correct a remaining valgus or pronation of the first ray, and external rotation, and wind-swept toes.

J. CHARLOTTE™ SNAP-OFF SCREW

DESCRIPTION

The CHARLOTTE™ Snap-Off Screw is offered in various diameters and lengths. All screws are manufactured from titanium.

INDICATIONS

The CHARLOTTE™ Snap-Off Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of Small Bone Fragments
- Weil osteotomy
- Mono-cortical fixation
- Osteotomies and fractures fixation in the foot and hand

K. CHARLOTTE™ CLAW® PLATE

DESCRIPTION

The CHARLOTTE™ CLAW® Plate consists of plates and locking-screws in various lengths. All plates and screws are manufactured from stainless steel.

INDICATIONS

The CHARLOTTE™ CLAW® Plate is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation

of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

L. CHARLOTTE™ 7.0 MM MULTI-USE COMPRESSION SCREW

DESCRIPTION

The CHARLOTTE™ 7.0 mm Multi-Use Compression 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 stainless steel.

INDICATIONS

The CHARLOTTE™ 7.0 mm Multi-Use Compression 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

M. CHARLOTTE™ CAROLINA™ JONES FRACTURE SYSTEM

DESCRIPTION

The CHARLOTTE™ Carolina Jones Fracture Screw is offered in various diameters and lengths. All screws are manufactured from stainless steel.

INDICATIONS

The CHARLOTTE™ Carolina Jones Fracture System is indicated for fixation of bone fractures or for bone reconstruction of the 5th Metatarsal. Examples include:

- Fixation of malunions and nonunions
- Acute fractures
- Avulsion fractures
- Repetitive stress fractures
- Jones Fractures
- Malleolar Fractures
- Talus Fractures
- Greater Tuberosity Fractures

N. CHARLOTTE™ LISFRANC BONE SCREW

DESCRIPTION

The CHARLOTTE™ LisFranc Bone Screw is offered in various diameters and lengths. All screws are manufactured from stainless steel.

INDICATIONS

The CHARLOTTE™ LisFranc Bone Screw is intended to be used for fixation such as: LisFranc arthrodesis, first metatarsophalangeal arthrodesis, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf

and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

O. CHARLOTTE™ LISFRANC PLATE

DESCRIPTION

The CHARLOTTE™ LisFranc Plate consists of plates, non-locking screws, and locking screws. All components are manufactured from stainless steel.

INDICATIONS

The CHARLOTTE™ LisFranc Plate is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

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