EN
RX Only

Important information - please read prior to use
INSTRUCTIONS FOR USE

Device System Name:
Contours Lapidus
Plating System (bone plate)

Orthofix Srl
Via delle Nazioni 9 - 37012 Bussolengo (VR) Italy
Telephone +39 045 671 9000 - Fax +39 045 671 9380

INDICATIONS FOR USE
The Contours Lapidus Plating System is intended for revision procedures and joint fusion in the small bones of the foot.

DESCRIPTION
The Contours Lapidus Plating System consists of plates, screws and instrumentation. The anatomically contoured titanium plates are low-profile and designed specifically for 1st metatarsal and cuneiform allowing compression across the joint achieved through a delta-shaped hole and compression screws. Contours Lapidus System screws are titanium, low-profile and selftapping, and include locking, non-locking, and bone compression screws in a variety of lengths. Instrumentation includes a threaded drill guide, drill bits, depth gauge, screw sleeve, ratcheting AO wrench, and plate bender.

WARNINGS
- Bone plates, bone screws, drill bits and K-Wires are SINGLE USE ONLY. Reuse could result in injury or require reoperation due to breakage or infection. DO NOT attempt to resterilize implants that come in contact with body fluids.
- The Contours Lapidus Plating System has not been evaluated for safety and compatibility in the MR environment. The Contours Lapidus Plating System has not been tested for heating or migration in the MR environment.
- All instruments should be used for their intended purpose only.
- The Contours Lapidus plate should be used in skeletally mature patients only.

PRECAUTIONS
- The Contours Lapidus Plating System is intended for use with the Lapidus Surgical Procedure.
- It is essential that proper operative technique be followed for implantation. Refer to Operative Technique Guide.
- It is recommended that the Contours Lapidus plate and associated screws be implanted prior to implantation of any additional hardware.
- Patient selection is important to achieving a successful outcome. The following factors and/or conditions may impact overall success: appropriateness of implant size, patient's occupation and/or activity level, ability to understand and follow postoperative instructions, potential for material sensitivity, adequate bone stock and soft tissue coverage, poor quality bone or metabolic bone disorders such as severe osteopenia, osteomyelitis, poorly controlled diabetes mellitus, neurovascular status, overall general health, etc.
- Examine all components carefully PRIOR to use. If you believe any component to be faulty, damaged or suspect, **DO NOT USE**.
- The Steri-Tray is for sterilization of Contours Lapidus Plating System components **ONLY**.

POTENTIAL COMPLICATIONS AND ADVERSE EFFECTS
- Intrinsic risks associated with anesthesia and surgery.
- Infection and/or painful, swollen or inflamed implant site.
- Failure to achieve the desired correction.
- Breaking of the plate or loosening, bending, or breaking of the bone screws.
- Re-operation may be necessary to replace or remove the plate and/or screws.
- Complications associated with metal sensitivity including allergic reaction to the implant material.
- Migration of particle wear debris that could possibly result in a bodily response.
- Embolism.
- Untoward histological responses that could involve macrophages and/or fibroblasts.
- Bone resorption or over production.

IMPORTANT
A successful result is not achieved in every surgical case. Additional complications may develop at any time due to improper use, abnormal or excessive loading, other medical reasons or device failure. Complications may require surgical reintervention to remove or replace the Lapidus plate and/or bone screws.

MATERIALS
The Contours Lapidus Plates and Bone Screws are made from implant grade titanium alloy.

CLEANING
Prior to use, NON-STERILE product should be cleaned using a mixture of 70% medical grade alcohol and 30% distilled water or with compatible detergent. After cleaning, the device and/or system components should be thoroughly rinsed in sterile distilled water and dried using clean non-woven fabric.

STERILITY
The Contours Lapidus Plating System components are supplied NON-STERILE and require sterilization prior to use. The recommended, validated sterilization cycle is:

METHOD	ITEM	CYCLE	TEMPERATURE	EXPOSURE TIME	DRYING TIME
Steam	Steri-Tray; single wrapped (FDA cleared wrap recommended)	Pre-Vacuum (minimum 4 pulses)	132°C /270°F	4 minutes	30 minutes
Steam	Steri-Tray; single wrapped (FDA cleared wrap recommended)	Gravity Displacement	132°C /270°F	15 minutes	30 minutes

The Steri-Tray is for Contours Lapidus Plating System components **ONLY**.

The Contours Lapidus plate, bone screws, drill bits and K-Wires are intended for **SINGLE USE ONLY**.

Validation and routine monitoring should be performed as per AAMI recommended practice ANSI/AAMI ST79:2010 Comprehensive Guide to Steam Sterilization and A1:2010 and A2:2011–Sterility Assurance in Health Care Facilities.

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

RX Only	**Federal (U.S.A.) law restricts this device to sale by or on the order of a physician**		
	See Instructions for Use	LOT	Lot Number
	Single Use Only Do Not Reuse	REF	Catalogue Number
T	Titanium and its Alloys		Manufacturer
	Provided Non-Sterile		
S	Stainless Steel		