InCore® Lapidus

(Precision Guided Correction)

SYMBOL LEGEND LOCATED AT END OF DOCUMENT

Instructions for Use
InCore Lapidus System

Please read this information carefully before using the InCore Lapidus System

DESCRIPTION

InCore Lapidus System consists of a post and two screws. The system is provided with a set of accessory instruments designed for preparation of the implant site and inserting the implant into bone.

SYSTEM COMPONENTS

InCore Lapidus 5.9mm Left & Right Titanium Post

Post:	Implantable Ti-6Al-4V ELI

InCore Lapidus 3.5mm x 24 - 60mm Titanium Screws

Screw:	Implantable Ti-6Al-4V ELI

InCore Lapidus Post Plug Screw

Screw:	Implantable Ti-6Al-4V ELI

InCore Lapidus Disposable Kit 28mm Left & Right

Post:	Implantable Ti-6Al-4V ELI
Post Plug Screw:	Implantable Ti-6Al-4V ELI
Post Guide:	Polyarylamide
K-Wire:	Surgical Grade Stainless Steel
Reamer:	Surgical Grade Stainless Steel
Targeting Guide:	Polyarylamide and Surgical Grade Stainless Steel
Driver:	Surgical Grade Stainless Steel
Drill Bit:	Surgical Grade Stainless Steel
Bushing:	Surgical Grade Stainless Steel
Post Fastener:	Surgical Grade Stainless Steel
Depth Probe:	PolycarbonatePolyarylamide

InCore Lapidus K-Wire 2.0mm x 102mm

K-wire:	Surgical Grade Stainless Steel

InCore Lapidus T10 Driver Sterile

Driver:	Surgical Grade Stainless Steel

InCore Lapidus 3.6mm Drill Bit Sterile

Drill:	Surgical Grade Stainless Steel

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InCore Lapidus Torque Limiting Handle 2Nm

Handle: Polyetherimide, Surgical Grade Stainless Steel

INDICATIONS

The Nextremity Solutions InCore Lapidus System is a three-part construct intended for internal fixation for First Metatarsocuneiform arthrodesis (also known as Lapidus or First Tarsometatarsal Fusion).

CONTRAINDICATIONS

- Patient conditions including insufficient quantity or quality of bone.
- Blood supply limitations and previous or active infections that may inhibit healing.
- Surgical procedures other than for the indications listed.
- Patients with conditions that limit their ability or willingness to follow postoperative care instructions.
- The device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature.
- Where material sensitivity is suspected, appropriate testing should be performed and sensitivity ruled out prior to implantation.
- The InCore Lapidus System requires placement of a titanium post in the medial cuneiform bone. For optimum fixation strength, the post should be fully encapsulated in bone. The device may be unsuitable for patients with small, thin, bifurcated, split, fractured, or otherwise abnormally shaped bone.

POTENTIAL ADVERSE EFFECTS

- Infection, deep and superficial with possible sepsis
- Nerve damage due to surgical trauma
- Loosening or migration of the implant
- Bending or fracture of implant
- Pain, soft tissue discomfort or abnormal sensation due to the presence of the device
- Foreign body reactions, allergies or other reactions to implant materials
- Nonunion or delayed union which may lead to breakage of the implant
- Inadequate healing
- Thrombosis and embolism

PRECAUTIONS

- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective surgical technique and implants used. A detailed surgical technique in print and/or electronic formats can be obtained by contacting your local sales representative or found online at www.nextremitysolutions.com/InCore.
- Surgical instruments and implants may only be used for surgeries for which the designated application of the instrument and implant is explicitly necessary and defined.
- The trained expert staff is obligated to examine the surgical implant, sterile instrument,

and its sterile packaging for damage prior to use. In case of the implant, sterile instrument, or its packaging being damaged or deformed, it is not to be used.

- Only Nextremity Solutions, Inc. specially manufactured instruments and implants (contained in the respective set) are to be used. If using other instruments and implants, function, warranty and liability are omitted.

WARNINGS

- Cutting edges, blades, tips etc. can be very sensitive to mishandling. Thus, these instruments must be handled with care.
- Reusable instruments should be inspected prior to use. Signs of aging or damage include dulling of sharp edges, the presense of cracks, surface distortions, bends, burrs, loss of marking visibility, poor fit among components, reduced performance. Instruments that experience abnormal forces such as hard hammer blows or high torque should be assessed for proactive replacement. See Nextremity Solutions IFU-1397 for additional general reusable instrument handling instructions.
- Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws and plates.
- This device should only be used by physicians with training in and a thorough understanding of orthopaedic surgery.
- The InCore Lapidus System implants and sterile instrument are for SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE.
- The InCore Lapidus System has not been tested to withstand the forces needed for partial or full weight bearing or excessive activity until healing has occurred. The post-op regimen prescribed by the physician should be strictly followed to avoid stresses applied to the implant. Weight-bearing post operatively should be at the discretion of the surgeon.
- Any decision to remove the device should take into consideration the potential risk to the patient.

MRI SAFETY INFORMATION

- The InCore Lapidus System has not-been evaluated for safety and compatibility in the MRI environment. It has not been tested for heating, migration or image artifact in the MRI environment. The safety of the InCore Lapidus System in the MRI environment is unknown. Scanning a patient who has this device may result in patient injury.

DIRECTIONS FOR USE

Warning: The InCore Lapidus System should only be used with the supplied, dedicated instruments. See the InCore Lapidus System surgical technique for an illustrated description of the technique.

HOW SUPPLIED

The InCore Lapidus System is available as a sterile implant. The implant components and sterile instrument of the InCore Lapidus System are for single use only. DO NOT RE-STERILIZE. DO

NOT REUSE.
Re-use or reprocessing (cleaning and resterilization) of a device labeled for single use only may result in the transmission of infectious material from one patient to another or to the user. This could result in serious injury or death. In addition, re-use or reprocessing may weaken or damage the device, leading to mechanical failure. This could also result in death or serious injury to the patient or user.

STORAGE AND HANDLING
Store in a cool, dry place and in a manner that protects the integrity of the packaging of all implants and instruments.

PACKAGING AND LABELING

1. Nextremity Solutions devices should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

SYMBOL LEGEND

Standard: ISO 15223-1, Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements			
Symbol	**Symbol Reference No**	**Title of Symbol**	**Description of Symbol**
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	5.1.2	Authorized representative in the European Community	Indicates the authorized representative in the European Community.
	5.1.3	Date of Manufacture	Indicates the date when the medical device was manufactured.
	5.1.4	Use by date	Indicates the date after which the medical device is not to be used.

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Symbol	Symbol Reference No	Title of Symbol	Description of Symbol
	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	5.1.7	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	5.2.6	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.
	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	5.2.8	Do not use if package is damaged.	Indicates a medical device that should not be used if the package has been damage or opened.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instruction for use.
	5.4.4	Caution	Indicates that the instructions for use contain important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

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Symbol	Symbol Reference No	Title of Symbol	Description of Symbol
℞only	21 CFR 801.109	The symbol statement for Prescription Device	Indicates that the product is a medical device as defined in 21 CFR 820.3(l) and Federal Law (USA) restricts this device to sale by or on the order of a physician (21 CFR 801.109)
CE	European Medical Devices Directive 93/42/EEC of 14 June 1993 (as amended by Directive 2007/47/EC) as described in Article 17 of the Directive	Conformité Européene or European Conformity	Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.

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