LapiPrep®

LapiPrep Lapidus Preparation System

SYMBOL LEGEND LOCATED AT END OF DOCUMENT

Instructions for Use
LapiPrep Lapidus Preparation System
Non-Sterile Instruments

Please read this information carefully before using the LapiPrep Lapidus Preparation System.

DESCRIPTION AND USE

The LapiPrep Lapidus Preparation System contains instruments that are provided non-sterile. These instruments must be sterilized prior to each use. The LapiPrep System provides the surgeons with instruments for the correction and preparation of the metatarsal and cuneiform bones for Lapidus procedures.

Instruments include:

LapiPrep Compression Frame Assembly - Left
LapiPrep Compression Frame Assembly - Right
LapiPrep Positioning Paddle Attachment -Left
LapiPrep Positioning Paddle Attachment -Right
LapiPrep Cut Guide Attachment - Left
LapiPrep Cut Guide Attachment - Right
LapiPrep IM Closer Trolley - Left
LapiPrep IM Closer Trolley - Right
LapiPrep Pronation Rail
LapiPrep Pronation Trolley
LapiPrep Sagittal Plane Adjustment Screw
LapiPrep Tissue Retractor
LapiPrep Metatarsal Offset Paddle
LapiPrep ML positioning Pin
LapiPrep Screwdriver
K-Wire 2.0mm x 4in
LapiPrep Compression Screw
LapiPrep Ratcheting AO Handle
LapiPrep Instrument Case - Tray
LapiPrep Instrument Case - Lid
Saw Blade

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PRECAUTIONS

- It is mandatory that the user, surgeon, and surgery personnel are acquainted with the respective surgical technique. A detailed surgical technique in print and/or electronic formats can be obtained by contacting a Medartis Inc. representative or online at medartisusa.com.
- Surgical instruments may only be used for surgeries for which the designated application of the instrument and implant is explicitly necessary and defined.
- Only Medartis Inc. specially manufactured instruments (contained in the respective set) are to be used. If using other instruments , function, warranty and liability are omitted.
- The LapiPrep Lapidus Preparation System must be used only with the provided saw blades, K-wires and driver instrumentation.
- Cutting edges, blades, tips etc. can be very sensitive to mishandling. Thus, these instruments must be handled with care.
- This device should only be used by physicians with training in and a thorough understanding of orthopaedic surgery.

WARNINGS

- Cutting edges, blades, tips etc. can be very sensitive to mishandling. Thus, these instruments
  must be handled with care.
- This device should only be used by physicians with training in and a thorough understanding
  of orthopedic surgery.
- Safety glasses are recommended when using any active surgical instrument.
- Inspect instrumentation before use. Never use instruments with obvious signs of damage.
- K-wires and saw blades must be renewed for each procedure.
- The surgeon using a surgical instrument connected to power is responsible for the proper operation of the instrument as well as any accessories or equipment, including power equipment.
- Avoid using excessive force, twisting, or bending of the surgical instruments in a form they
  are unintended for.
- The surgical instrument must be properly inserted and securely locked before turning on and/or engaging the active surgical instrument.
- The surgical instrument connected to a power driver may become hot from friction and the surgeon should take appropriate care to ensure that the patient is not harmed.

DIRECTIONS FOR USE

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

STORAGE AND HANDLING

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The Medartis Inc. instruments that are provided non-sterile, must be cleaned and sterilized prior to each use, using the cleaning and disinfection instructions below.

The useable lifetime of any instrument is typically limited by normal wear and damage due to use. Instruments may be damaged by prolonged use, misuse, or improper handling. Always inspect instruments for signs of damage, cracking, deformation, wear or other signs of degradation prior to use. Ensure all trolleys move freely along the full length of the rails and joint paddle can be assembled and disassembled freely. Do not use instruments in need of repair or replacement.

Use instruments only for the purpose for which they were designed and intended.

K-wires and saw blades are available single use both sterile and non-sterile. Do not attempt to reuse instruments labeled for single use. For sterile single use instruments refer to IFU-1408.

Use caution when handling sharp instruments to avoid injury.

All users should be qualified personnel with documented evidence of training and competency. Training should include current applicable guidelines, standards, and hospital policies.

CLEANING

Wear protective equipment, including gloves, an apron, safety goggles, and a mask. Take care with sharp instruments to avoid injuries caused by penetration or cutting. Be particularly careful when removing debris from cannulas and cavities. Thoroughly wash all instruments and instrument case whether or not they were used or inadvertently came into contact with blood, other body fluids or saline solution.

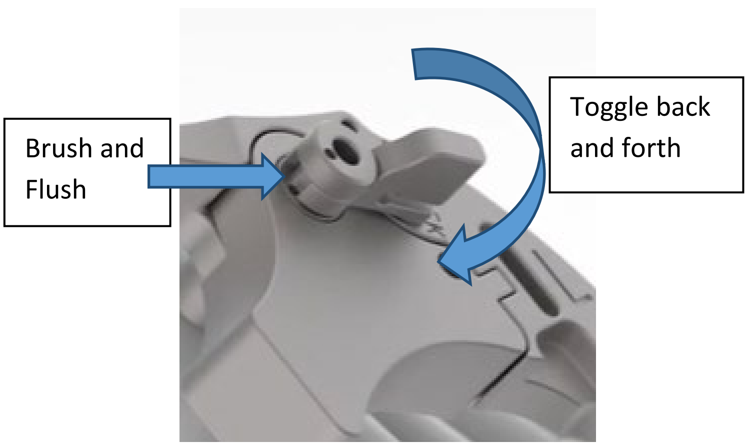
Do not use highly acidic (pH<4) or highly alkaline (pH>12) products for cleaning, as these can corrode metal, causing discoloration or damage.

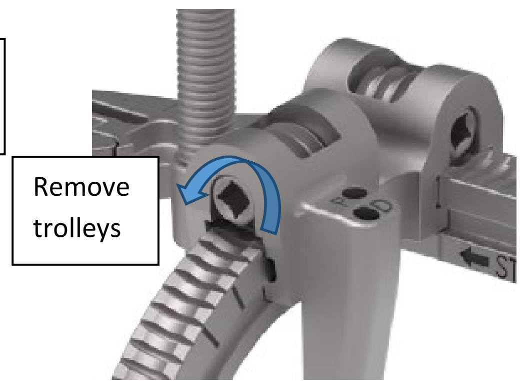
Manual Cleaning Instructions

The effectiveness of decontamination processes depends on first removing all visible debris, tissue, and bone fragments from the instruments. Thoroughly scrub and rinse instruments for at least one minute in room temperature (23°C) tap water, until visibly clean, prior to their initial sterilization and as soon as possible after use. If cleaning must be delayed, place groups of instruments in a covered container with an appropriate, neutral pH detergent or enzymatic cleaning solution (e.g. Enzol®), prepared according to the manufacturer's instructions, to delay drying. Do not allow soil to dry on the instruments.

Remove visible soil by soaking instruments in an ultrasonic bath of the enzymatic cleaning solution for a minimum of 20 minutes at room temperature. Use a soft bristle brush to remove all visible debris, paying close attention to textured surfaces, crevices, and hard-to-reach areas. Cannulas, lumens, or holes should be scrubbed for their entire length with a tight fitting, soft, non-metallic bottle brush or pipe cleaner, using an in-out and twisting motion. Use a syringe filled with cleaning solution to flush hard-to-reach areas. Instruments with moving parts should be manipulated while in the solution to expose all surfaces. Do not use metal brushes or scouring pads during the manual cleaning process.

Special cleaning instructions for Compression Rail Assembly: use a soft bristle brush on external and internal threads while performing the following during cleaning and rinse: cycling / manipulating knobs or screws in and out while brushing and flushing all surfaces. Remove all trolleys and compression screws from their rails and use a soft bristle brush on external and internal threads





Referencing the rinsing instructions for the enzymatic cleaning solution, rinse the instruments thoroughly with tap water for a minimum of 1 minute; flushing all cannulas, lumens, and holes. Instruments with moving parts should be manipulated during the rinse to rinse all surfaces. Distilled or deionized water should be used for a final rinse for at least one minute. Dry the instruments immediately after the final rinse, removing excess moisture with a clean, absorbent, non-shedding wipe, and using compressed air to dry hard-to-reach areas. Perform a final visual inspection for cleanliness to ensure that all visible soil is removed, paying close attention to hard-to-reach areas. If any visible soil is noted, repeat the cleaning procedure.

Visually inspect all instruments for damage or wear and to ensure complete removal of soil prior to sterilization. Damaged instruments, including instruments that are broken, cracked, visibly corroded or discolored, and those with dulled cutting edges, must be set aside and replaced. Instruments that are not completely cleaned must be cleaned again.

Combination Cleaning and Disinfection Instructions

1. Completely submerge the instruments in an enzyme or alkaline (pH ≤12) solution and allow to soak and sonicate for 10 minutes at 45-50 kHz. If using enzymatic cleaning agents, use a soft nylon bristled brush to gently scrub the device until all visible soil has been removed. Particular

attention must be given to crevices, lumens, mated surfaces, connectors, and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon bristled brush (i.e. pipe cleaner).

Note: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

2. Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes, and other difficult-to-reach areas.

3. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. The following minimum parameters are essential for thorough cleaning and disinfection.

Enzol® is a registered trademark of Advancd Sterilized Products, a Johnson & Johnson company.

Table 2. Typical U.S. Automated Washer/ Disinfector Cycle for Surgical Instruments

Step	Description
1	2 minute prewash with cold tap water
2	20 second enzyme spray with hot tap water
3	1 minute enzyme soak
4	15 second cold tap water rinse (X2)
5	2 minutes detergent wash with hot tap water (64-66 C/146-150 F)
6	15 second hot tap water rinse
7	2 minute thermal rinse (80-93 C/176-200 F)
8	10 second purified water rinse with optional lubricant (64-66 C/146-150 F)
9	7 to 30 minute hot air dry (116 C/240 F)

Note: The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/ disinfector. A washer/disinfector with approved efficacy (e.g. CE mark, FDA approval, and validation according to ISO 15883) should be used.

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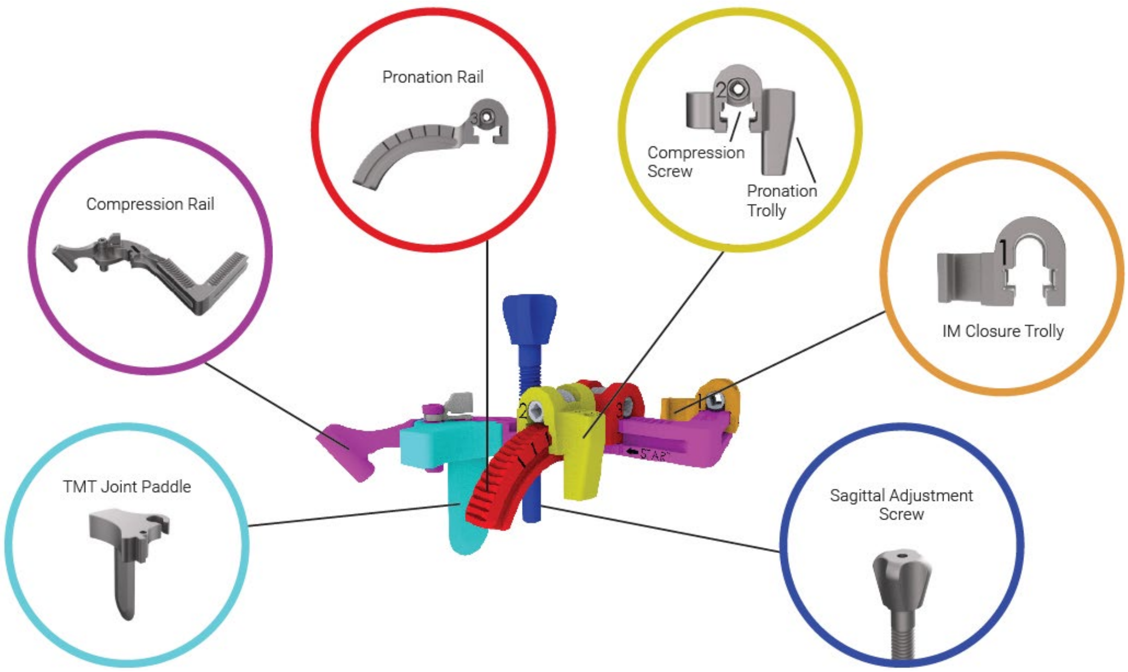
Part Configuration

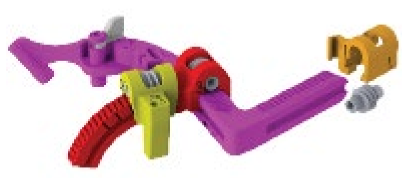


Assembly Instructions:

1. Snap fit Compression Screw into Pronation trolley, then thread Pronation Trolly onto Pronation Rail.*

2. Snap fit compression screw into Compression Trolly, then thread onto Compression Rail using the driver without the handle attached *

3. Compression Screw into IM Closure Trolly, then Thread IM Closure Trolly onto Compression Rail.*



4. Drop 1st TMT Joint Paddle into slot on Compression Rail.

5. Lock the Joint Paddle into the Compression Rail using the lever. Ensure lever is fully seated in LOCK divot.

6. Using AO Driver, ensure Compression Trolly is positioned to the engraved "START".

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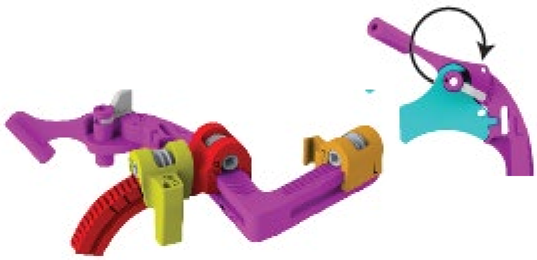
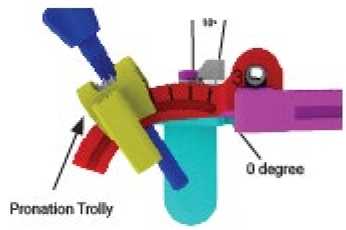
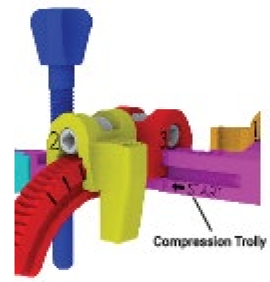






***follow assembly instruction in reverse for disassembly.**

Inspection and Wrapping

After cleaning and decontamination, instruments must be put in their proper locations in the instrument tray. Inspect all instruments before sterilization to ensure that they function properly. Do not include any materials incompatible with steam sterilization within the sterilization load.

Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA cleared sterilization wrap to maintain sterility.

Sterilization

Instruments must be completely dry before being steam sterilized.

The following parameters are recommended and have been validated for a sterility assurance level (SAL) of 10^{-6}. Flash sterilization is not recommended.

Cycle	Temperature	Minimum Exposure Time	Minimum Drying Time
Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

Do not stack trays during sterilization.

Storage

Non-Sterile instruments should be stored in a limited access area that is well ventilated and provides protection from dust, moisture, insects and extremes in temperature and humidity.

Please contact Medartis Inc. with any comments, questions or problems regarding the use or reprocessing of these products.

PACKAGING AND LABELING

1. Medartis Inc. devices should be accepted only if the factory packaging and labeling arrive intact.
2. Do not use and Contact Customer Service if the package has been opened or altered.

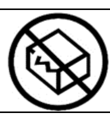
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

LapiPrep is a registered trademark of Medartis AG. These products are covered by one or more issued or pending U.S. and international patent(s) .

PRODUCT COMPLAINTS:
Report any dissatisfaction with the product quality, labeling, or performance to Medartis Inc. at medartisusa.com/qa.

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.
EC REP	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.

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**
	5.1.4	Use by date	Indicates the date after which the medical device is not to be used.
LOT	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
SN	5.1.7	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
REF	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
STERILE R	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

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**
			presented on the medical device itself.
Rx 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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