



Evolve34™
Lapidus Correction System
Instructions for Use

Rx Only

Federal (USA) law restricts this instrument set to sale by or on the order of a physician.

1. DEVICE DESCRIPTION

The Evolve34™ Lapidus Correction System, is a system comprised of orthopedic manual surgical instruments which allow for manipulation of the first Metatarsal and first Tarsometatarsal joint during orthopedic surgery.

2. INDICATIONS FOR USE

The Evolve34™ Lapidus Correction System is intended for use during surgical procedures associated with Hallux Vallgus (Bunion Deformity) correction.

3. CONTRAINDICATIONS

The Evolve 34™ Lapidus Correction System does not have product specific contraindications.

General surgical contraindications include:

- Infection
- Patient conditions including blood supply limitations, obesity, and insufficient quantity or quality of bone.
- Patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions.

4. WARNINGS

The instruments in the Evolve34™ Lapidus Correction System are provided non-sterile. The Evolve34™ Lapidus Correction System instruments must be thoroughly cleaned and sterilized prior to first use and before each subsequent use in accordance with the guidelines provided herein.

The instruments should be checked for proper function prior to use. If the instruments do not function properly and smoothly, immediately discontinue use, and contact an Enovis Customer service representative or your local Enovis sales representative.

As with any surgical instrument, careful attention should be paid to assure that excessive force is not placed on the instruments. Excessive force can result in failure.

The Evolve34™ Lapidus Correction System instruments should not be reused if visible deterioration such as corrosion or damage resulting from use or handling is evident. Please remove any damaged device or instrument from use and call your Enovis™ sales representative for a replacement.

5. PRECAUTIONS

A surgeon should not begin clinical use of the instruments without reviewing the Instructions For Use and Surgical Technique Guide prior to use. Additional precautions include those applicable to any surgical procedure. In general, careful attention must be paid to avoid all hazards.

6. HOW SUPPLIED

The Evolve34™ Lapidus Correction System instruments are provided NON-STERILE. Each instrument must be properly cleaned and sterilized prior to first use and before each subsequent use in accordance with the guidelines provided herein.

7. CLEANING AND STERILIZATION

CLEANING

Each Evolve34™ Lapidus Correction System instrument must be cleaned in accordance with appropriate healthcare facility procedures prior to sterilization.

Instruments should be cleaned as soon as reasonably practical after use, according to the health care facility's infection control and hazardous waste management procedures. Ideally, all components should be cleaned within 30 minutes and after no more than 4 hours of use to minimize the potential for saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on the instrument prior to cleaning. Keep instruments moist after use to prevent soil from drying on them.

The Lapidus Correction System instruments should be fully disassembled into component parts prior to cleaning. Refer to the Instrument Tray and/or illustration in Enovis' Surgical Technique Guide for the completely disassembled components. No reassembly is necessary as the instruments remain in their fully disassembled form during cleaning and sterilization. Note: If you have questions concerning the disassembly of the instruments, contact the Enovis™ Customer Service or your local Enovis sales representative.

Do not rely upon automated cleaning using a washer/disinfector alone as this may not be effective for devices and instruments with cannulations, blind holes, mated surfaces, and other complex features. A thorough manual or combination manual/automated cleaning process is required.

For manual washing, Enovis recommends using cold demineralized or distilled water along with a neutral pH (7-8.5) enzymatic detergent. Follow the manufacturer's instructions for mixing, preparing, and using such detergents. Manual cleaning should be done while the instrument is immersed. All instruments should be thoroughly cleaned.

Cannulated portions should be cleaned with a soft-bristled nylon brush, pipe cleaner, or appropriately sized guidewire. In the case of very small dimension cannulations, a wire can be used to ensure that foreign material has been removed from the cannulation. Visually inspect all instruments to ensure that all blood, saline, and traces of tissue are removed, and instruments are "visibly clean."

Refer to Table A for further cleaning instructions.

TABLE A. Additional Enovis Cleaning Instructions

Warnings	These guidelines are not intended for Enovis™ implants or single-use disposable instruments - only for reusable instruments that are supplied non-sterile but are intended to be used in a sterile state.
	Use care in handling and storage of the instruments. Prior to surgery, instruments should be fully inspected for any evidence of damage or corrosion.
	Prolonged exposure to saline may result in corrosion of stainless-steel instruments.
	The quality of water should be carefully considered for use in cleaning reusable devices. Water hardness is a concern because deposits left on medical devices may result in ineffective cleaning and sterilization. The health care facility is responsible for maintaining water quality that is compliant with AAMI TIR34.
	All cleaning should be performed in a manner designed to minimize exposure to bloodborne pathogens.
Manual Cleaning	<p>Follow Universal Precautions for handling and transporting contaminated instruments to the designated cleaning area. Contaminated instruments should be transported to the area for cleaning in a way that avoids contamination of personnel and hospital.</p> <ol style="list-style-type: none"> 1. Use flowing water and disposable wipes to remove excess soil. 2. Presoak the instruments with an enzymatic solution for a minimum of five (5) minutes. 3. Following the presoak, the instruments should be wiped or scrubbed using a brush, cloth or sponge that does not mar the surface of the instrument. 4. Rinse parts under cold (<45°C) potable water for a minimum of one (1) minute. 5. Repeat the process until no visible debris remains. 6. Soak the instruments in Ultra Clean System Low Foam Detergent (pH neutral) for a minimum of one (1) minute. Remove soil from surfaces with a soft-bristled nylon brush and from cannulated parts with a soft-bristled nylon brush, pipe cleaner, or appropriately sized guidewire. Ensure that all blood, saline, and traces of tissue are removed. The use of abrasive compounds or excessively acidic or alkaline solutions may cause damage to the instruments and should be avoided. 7. Rinse parts under warm or hot flowing, potable water for a minimum of one (1) minute including direct contact with all surfaces for at least ten (10) seconds. 8. Repeat rinsing step using distilled, reverse osmosis or deionized water.
Automated Cleaning/Disinfection	Washer-decontaminators may also be used in addition to manual cleaning. When utilizing an automated cleaner, follow equipment manufacturers' instructions for use, incorporating a low foaming, pH neutral detergent. Take care to place difficult-to-clean parts near the center of the rack, open-side down, minimizing touching between parts. Place small parts in baskets to prevent dislodging.
Cleaning Verification	Visually inspect all instruments for any remaining debris prior to sterilization. According to ANSI/AAMI standards ST79:2017, the accepted standard for the degree of cleanliness is visibly clean. To deduct any residual blood or protein particulates that may be trapped in visually obstructed areas, the instrument may be submerged in a 2% hydrogen peroxide solution. The appearance of bubbles confirms the presence of protein, and the instrument should be re-cleaned. Rinse instruments following exposure to hydrogen peroxide. If bubbles were present or instruments were not deemed visibly clean, steps 1-8 of the manual cleaning process should be repeated.
Inspection and Functional Testing	Repeated reprocessing has minimal effect on the devices. Visually inspect all instruments for damage and wear. Cutting edges should be free of nicks and present a continuous edge. Discard blunt or damaged instruments. Confirm that any moving parts function properly. End of life is normally determined by wear and damage due to use. Contact Enovis™ customer service for replacements.
Packaging	Single: A standard packaging material may be used. Ensure that the pack is large enough to contain the instrument without stressing the seals.
	In Sets: Load Enovis Surgical Instruments into the appropriate instrument trays. Ensure that cutting / sharp edges are protected.
Storage	Packaged and sterilized instruments should be stored in an area that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity. Containment devices can be stacked for storage.

STERILIZATION

Recommended sterilization methods have been validated to sterility assurance levels (SAL) in compliance with federal and international standards. It is the responsibility of the user to ensure that the sterilization process is actually performed using qualified equipment, materials, and personnel such that the recommended parameters are achieved. The adequacy of any healthcare facility sterilization procedure must be suitably evaluated. It is critical that the appropriate process parameters be validated for each healthcare facility's sterilization equipment and product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility.

Any recommendations provided herein are provided as general guidelines only. It is important that adequate cleaning be conducted prior to sterilization. The healthcare facility is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Reusable instruments should be placed in suitable packaging for the sterilization process (i.e., central supply room wrap (CSR), paper/plastic pouches, rigid containers, etc.) and sterilized prior to surgical use.

Always follow the sterilizer manufacturer recommendations. When sterilizing multiple sets, ensure that the manufacturer's maximum load is not exceeded.

The Evolve34™ Instrument Tray is designed to hold all of the Evolve34™ Surgical Instruments during sterilization. All Evolve34™ Surgical Instruments must be placed in the designated location within the Evolve34™ Instrument Tray. Do not add other instruments to the Evolve34™ Instrument Tray that are not part of the standard configuration supplied by Enovis. Do not stack the Evolve34™ Instrument Trays during sterilization.

Moist heat/steam is the only method that has been validated for reprocessing by Enovis. Sterrad or hydrogen peroxide-based gas systems have not been validated. Gravity displacement sterilization is not recommended due to extended cycle times.

RECOMMENDED STEAM STERILIZATION PARAMETERS

Time and temperature parameters required for sterilization vary according to type of sterilizer and cycle design. Please review the instructions of the sterilizer, manufacturer, or healthcare facility procedures prior to sterilization.

Cycle Type	Minimum Temperature	Minimum Exposure Time Wrapped	Minimum Drying Time
Pre-vacuum/Pulsating Vacuum/Flash Autoclave	132° C (270° F)	4 minutes	30 minutes

1. AAMI/AORN steam sterilization cycles with cycle times longer than those listed are also acceptable. In the US, users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (132°C, 4 minutes).
2. FDA-cleared medical grade steam sterilization compatible wrap that has been validated to allow sterilant penetration and to subsequently maintain sterility.
3. Rigid sterilization container that complies with ANSI/AAMI ST46.
4. Drying times vary according to load size and should be increased for larger loads.

Packaged and sterilized instruments should be stored in an area that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity. Containment devices can be stacked for storage.

8. REUSE LIFE

The Evolve34™ Surgical Instruments should not be reused if visible deterioration such as corrosion or damage resulting from use or handling is evident. Please remove any damaged device or instrument from use and call your Enovis™ sales representative for a replacement.

9. STORAGE

Store the Evolve34™ Surgical Instruments in the Evolve34™ Instrument Tray.

10. WARRANTY INFORMATION

LIMITED LIABILITY

The Evolve34™ Lapidus Correction System instruments are guaranteed to be free from defects due to materials or workmanship and have a one (1) year limited warranty.

Enovis shall not be liable, expressly or implied for any damage which might arise or be caused, whether by the customer or by any of the users of the product, as a result of:




- Misuse, mishandling and/or improper operation.
- Repairs or modifications performed other than by Enovis or an Enovis authorized repair facility.
- Use in any manner or medical procedure other than those for which it is designed; and any special, indirect and/or consequential damages of any kind and however caused arising from the sale or use of the product.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED, AND/OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS, AND/OR SUITABILITY FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON ENOVIS' PART.

Return Conditions

In the event the device must be returned for any reason, return the product in the original packaging. Contact Customer Service or an authorized Enovis™ representative to receive a return authorization number prior to return shipment.

11. SYMBOLS GLOSSARY

Symbol	Standard	Ref #	Title	Definition
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	5.1.6	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified. NOTE: Synonyms for "catalog number" are "reference number" and "reorder number."
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	5.1.5	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified. NOTE: Synonyms for "batch code" are "lot number" and "batch number."
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
R _x Only			Prescription Only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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