Aesclepius Corporation
Orthopaedic devices

Clamp+Cinch™ Instructions for Use

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

DESCRIPTION AND INTENDED USE

The Aesclepius Clamp+Cinch™ System is a set of manual, non-powered, hand-held orthopaedic instruments intended to support and perform plantar plate repair surgeries involving the creation of bone tunnels and reattachment of the plantar plate ligament of the metatarsophalangeal joint. The Clamp+Cinch™ System is comprised of two instruments: the Locking Clamp™ and the Suture Cinch™ with curled nitinol snare. The Locking Clamp™ is a stainless steel reusable instrument with an integrated drill guide designed to clamp the proximal phalanx of the toe and create two parallel bone tunnels. The Suture Cinch™ is a sterile, single-use instrument with raised dots that indicate directionality the nitinol snare curvature for shuttling sutures through bone tunnels.

GENERAL INFORMATION

- These INSTRUCTIONS FOR USE are designated only for persons with the required knowledge and training in a healthcare facility.
- Any surgical procedures must be performed by licensed healthcare professional trained and familiar with the surgical technique of plantar plate repair.

WARNINGS

- Avoid excessive force when using Clamp+Cinch™ devices.
- Avoid impinging on nerves or blood vessels when clamping bones using the Locking Clamp™, as that can lead to neurovascular injury.
- Improper positioning and angulation of the drill guide can result in injury to cartilaginous tissues when drilling bone tunnels.
- The Suture Cinch™ a single use device, not intended for re-use.
- Inspect the Suture Cinch packaging for any visible damage such as pouch tears, contamination, or pinholes that can compromise the sterile integrity of the device. Do not use the device if any visual defects are present.
- Before use, the user must check the instruments for visible damage such as cracks, fractures, or sharp tips.
- Incorrectly selected, positioned, or sized instruments may lead to unusual stress that may negatively affect efficacy of the repair.
- Instruments must be used exclusively for the intended indication.

INDICATIONS FOR USE

The Aesclepius Clamp+Cinch™ System is indicated for the reattachment of the plantar plate ligament to the proximal phalanx of the toe.

CONTRAINDICATIONS

Use of the Clamp+Cinch™ System is contraindicated in cases of:

- Poor bone quality or quantity that either poses a risk for iatrogenic bone fracture, or adversely affects the secure fixation of the ligament/tendon
- Active or latent infection (local or systemic)
- Suspected sepsis
- Osteoporosis or insufficient bone quality and / or quality
- Sensitivity to the instrumentation material
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant diseases that may pose a risk to fixation or the success of surgery or negatively affect them, such as obesity, impairment of the circulation, etc.
- Nicotine use that may pose a risk for the success of the procedure/surgery due to delayed bone/wound healing
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment

DEVICE INSPECTION, STORAGE, & HANDLING

- Surgical instruments must always be treated with care to prevent damage or wear.
- Mishandling of the Suture Cinch and Locking Clamp may impact their performance.
- Devices must be inspected prior to use for any visible damage. Do not use devices, if damaged.
- The reusable Locking Clamp is subject to wear over time and must not be used if performance is compromised or surface defects are present (i.e., corrosion, rough surfaces, sharp edges, nicks, scratches).

CLAMP+CINCH SURGICAL USE

1. Prepare the surgical site per standard technique.
2. Open jaws of the Locking Clamp™.
3. Apply and lock clamp securely to the proximal phalanx at the desired location.
4. Create bone tunnels using a K-wire through drill guides.
5. With the Locking Clamp™ in place, insert the Suture Cinch™ through the drill guide and bone tunnel.
6. Use the raised Braille dots to orient the Suture Cinch™ in the desired curling direction of the nitinol snare.
7. Extend and open the nitinol snare loop by manually pushing on the back end of the nitinol filament.
8. Insert the end of the suture through the snare loop.
9. Manually pull back on the nitinol filament to cinch the snare loop around the suture.
10. Pull the entire Suture Cinch™ back through the bone tunnel and drill guide, and extend the nitinol filament to release the suture.

LOCKING CLAMP CLEANING & STERILIZATION

Point of Use

Reprocessing begins at the point of use and prompt initial cleaning steps and/or measures to prevent the drying of soil on the device surface prior to cleaning should be taken to facilitate subsequent cleaning steps. Reprocessing procedures should minimize or eliminate delays between steps. Delays may create conditions favorable to microbial growth, which may increase the challenge to subsequent steps such as cleaning, disinfection, and sterilization.

Containment and transport

1. The instruments should be reprocessed as soon as possible.
2. Always keep instruments in a suitable container to protect personnel from contamination during transport to the decontamination area.

Preparation for decontamination and cleaning

1. Unlock and open the jaws of the Locking Clamp™ to facilitate access to all parts of the instrument.
2. Submerge the Locking Clamp™ in a solution of 1% Alconox or an enzymatic medical device cleaning detergent. Ensuring that all surfaces are thoroughly wetted, remove gross soil using a nylon scrub brush or stylet. Do not use saline agents or any agents containing bleach, hypochlorite solutions, sodium chloride, formalin, and glutaraldehyde. These may discolor or corrode the instrument.
3. If possible, use a syringe to flush the detergent solution through each drill guide tubes to remove trapped air.
4. Ultrasonically clean the instrument(s) in the detergent for a minimum of ten (10) minutes. The detergent solution should be changed before it becomes heavily soiled so that effective ultrasonic cleaning is not inhibited.

Manual Cleaning

1. Unlock and open the jaws of the Locking Clamp™ to facilitate access to all parts of the instrument.
2. Submerge the Locking Clamp™ in a fresh bath of 1% Alconox or enzymatic medical device cleaning detergent, ensuring that air is not trapped in the drill guide tubes.
3. Use a nylon scrub brush or stylet to clean the entire instrument while it is completely submerged, particularly parts that have grooved features. Firm bristle brushes may be required on a heavily soiled instrument. Do not use metallic brushes or steel wool—these can damage the surface of the instrument.

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4. With the Locking Clamp™ still entirely submerged, use 0.08” nylon hypo tube brush or stylet to clean the lumens of the drill guide tubes. Pass the brush / stylet down the entire length of each tube at least five (5) times. Drill guide tubes must be cleaned thoroughly.
5. Operate moving parts, paying particular attention to hard to reach areas.
6. Rinse the Locking Clamp™ with warm (38 - 49°C or 100 - 120°F) deionized water.
7. Place the Locking Clamp™ in a bath containing warm (38 - 49°C or 100 - 120°F) deionized water and agitate by hand for a minimum of three (3) minutes.
8. Dry the exterior of instrument(s) with a clean lint-free cloth.
9. Visually inspect the instrument(s) for any remaining soil and repeat the above steps if necessary.
10. Check Locking Clamp™ for proper jaw alignment, working hinges, and locking ratchet. Check for wear on jaw surfaces.

Drying
Dry the Locking Clamp™ with a lint-free surgical wipe or blow the instrument dry with micro-filtered pressurized medical grade air. When blowing dry with pressurized air, ensure a secure grip on the Locking Clamp™ to avoid damage caused by air pressure.

Maintenance, Inspection and Testing
Following cleaning, inspect the Locking Clamp™ to ensure that all visible soil has been removed and that moving parts operate smoothly. Use of a water-soluble lubricant prior to sterilization will help maintain effective operation and prolong the life of the Locking Clamp™.

Preparation for Sterilization
The Locking Clamp™ can be sterilized in a sterilization wrap, packaged in a sterilization pouch, or placed in an instrument tray lined with soft silicone mats. Instruments should not be touching each other.

Sterilization
- Use the sterilizer manufacturer’s instructions for operation and loading of steam sterilizers. There must be direct steam exposure to all surfaces of the instruments being sterilized including the internal surface and tubes channels.
- The instrument and/or instrument tray should be processed through a complete sterilization drying cycle as residual moisture from autoclaves can promote staining, discoloration, and rust.
- The table below represents steam sterilization parameters that have been validated for the Aesclepius Locking Clamp™.

Minimum cycle times for pre-vacuum steam sterilization

	Wrapped Instruments
Exposure at 132°C (270°F)	4 min
Drying	30 min

STORAGE
Following sterilization processing, packaged instruments may be stored in a clean area free of temperature and humidity extremes in accordance with your institution’s policies.

DISPOSAL
Handle and dispose of these devices in accordance with accepted medical practice and with applicable local, state and national laws and regulations.

WARRANTY
Aesclepius Corporation medical devices are guaranteed to be free from defects in material and workmanship when used for their intended surgical purpose. Any Aesclepius Corporation device that proves defective in workmanship or material will be replaced, at the discretion of Aesclepius Corporation, without charge.

Warranties are not valid for instruments and products that prove defective as a result of improper care and cleaning or misuse. Instruments or products that are damaged in the fire, flood, or other acts or disasters are also excluded from warranty. Aesclepius Corporation makes no other representations and warranties regarding its instruments or products, either express or implied. In no event will Aesclepius Corporation be liable for any incidental, special or exemplary damages or loss of profits in connection with the use of Aesclepius Corporation instruments and products.

PRODUCT RETURNS
Contact your Aesclepius representative for information regarding product return or to report any issues with product performance or packaging.

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SYMBOLS USED
REF Product Number

LOT Lot Number

Manufacturer

Do not re-use

Use-by date

STERILE R Sterilized using irradiation

Do not use if package is damaged and consult instructions for use

℞ ONLY **CAUTION!** Federal law restricts this device for sale to licensed healthcare practitioners only

HIBC Health Industry Bar Code (HIBC) standard for Unique Device Identifier (UDI)

eIFU Indicator

Electronic Instructions for Use available on the manufacturer’s website shown on label:
https://aesclepiusmedical.com/ifu