Instructions For Use: **LINK™ External Fixator**

Caution: Federal law restricts this device to sale by or on the order of a physician

METRIC BRINGING BONES TOGETHER™

I. General

The LINK™ is a single use External Fixator that uses a single piece split box shaped spring with pairs of holes that become misaligned when released. This misalignment applies moments and forces to Bone Pins to pull together and compress bony structures percutaneously. The Bone Pins are its only implant components. The LINK™ and its Cover is external to the body and is designed to be in proximity to but non-skin contacting.

II. Basic Structure

The LINK™ External Fixator consists of a 17-7 stainless steel box shaped spring that applies forces and moments to K-wires or pins embedded in bone to actively pull together and compress bone. In clinical use the LINK™ is held with its holes aligned using surgical needle drivers while wires or pins are advanced through the LINK™, skin and into bone. Once pins are placed and the needle drivers are released, the LINK™ bridge shortens to apply forces and the LINK™'s side elements swing outward to create moments on the wires or pins. The LINK™ External Fixator is available with two pins in line with a 20 mm separation (2-200020) and four pins in an H shaped configuration (4H201020) with a 20 mm and 10 mm separation.

Pin Configuration	LINK™	Silicone Cover	Bone Pins Required (sold separate)
2 in line	2-200020	C-20	2ea
4 H shape	4H201020	CH2010	4ea

The LINK™ includes a silicone cover to hide its structure and cover the cut ends of the Bone Pins (C-20 and CH2010). Grooved, threaded and smooth pins/k-wires are compatible for use with the LINK™. The fixation of the pin/k-wire to the LINK™ is greatest with grooved, threaded and smooth pins/k-wires, listed from greatest to least.
Common surgical needle drivers are used to operate the LINK™ and are not provided. It is recommended that the needle drivers be sterilized prior to use.

III. Indications for Use

The LINK™ External Fixator is indicated for 1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy and 3) adjunctive fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude LINK™ Bone Pin placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula and sternum.

IV. Contraindications

DO NOT USE the LINK™ External Fixator if a surgical candidate exhibits or is predisposed to any of the following contraindications:

- mental or physiological conditions who are unwilling or incapable of following postoperative care instructions
- severe osteoporosis
- active blood borne infectious diseases
- patients suspected or with documented foreign body or metal sensitivity reactions should be tested prior to implantation.

V. Intended Patients

Proper patient selection and the patient's ability to comply with physician instructions and follow the prescribed treatment regimen will greatly affect the results. It is important to screen patients and select optimal therapy given physical and/or mental activity requirements and/or limitations.

VI. Intended Users

The product is intended for use by Healthcare Professionals (HCP) only and such HCP must have full awareness of the appropriate orthopedic procedures and must be familiar with the devices, instruments and surgical procedures (including application and removal).

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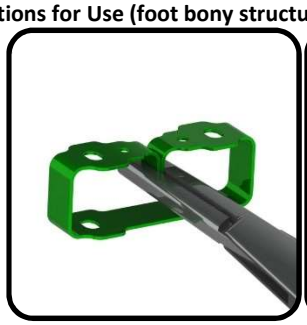
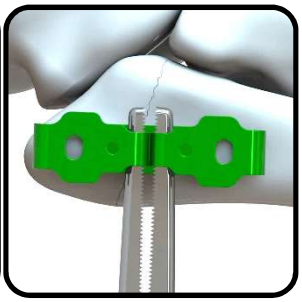
VII. LINK™ Placement Instructions for Use (foot bony structures are shown without soft-tissue)

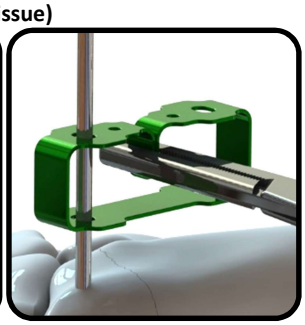
Step 1
Grasp LINK™ with Needle Drivers



Step 2
Close LINK™ with Needle Drivers

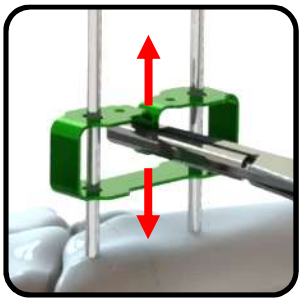


Step 3
Using x-ray, position LINK™ over fracture

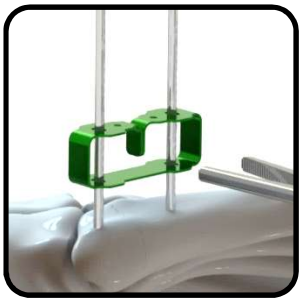


Step 4
Insert 1st bone pin through hole and into bone

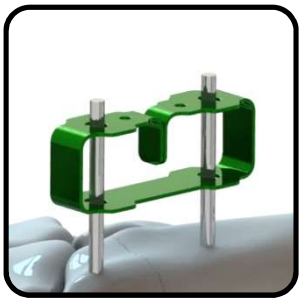
Step 5
Insert remaining bone pins through holes and into bone



Step 6
Move LINK™ above skin to adjust fixation

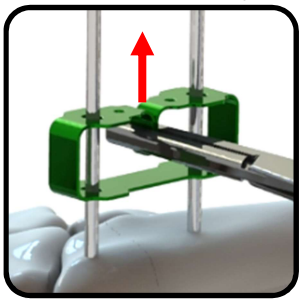


Step 7
Release LINK™

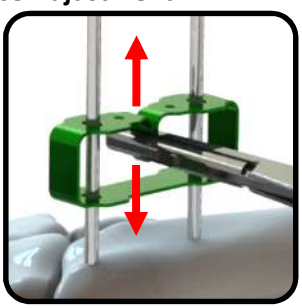


Step 8
Cut bone pins to appropriate length

VIII. LINK™ Removal , Force Adjustment



Removal:
Recompress the LINK™ with needle drivers and slide the LINK™ off the bone pins. Remove the wires using standard technique.



Compression Force:
Recompress the LINK™ with needle drivers and slide the LINK™ down to increase force or up to lower.

Once the treatment with external fixation is complete, the LINK™ and Bone Pin implant must be removed. HCP should consider premature removal in case of adverse events.

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IX. Warnings

Immobilization such as braces, boots, splits or cast, in addition to this fixation, should be used until bone healing occurs and the LINK™ is removed.
Reduction of the bony structures should be achieved and maintained prior to placement of the LINK™. The LINK™ should not be relied upon to achieve closure or reduction of bone.
Use of smooth or threaded k-wires lowers the forces associated with pulling the LINK™ from the wires or pins.
The LINK™ has not been evaluated for safety, compatibility, heating or migration in the Magnetic Resonance environment.

X. Precautions

An external fixation cannot be expected to withstand activity levels to the same extent as a normal healthy bone. The LINK™ and Bone Pin system will not have the same strength, reliability, and durability as a normal human bone and the longevity of the device and its ability to remain fixated in bone may be dictated by load bearing and patient activity.

LINK™ and Bone Pin stability must be checked intra-operatively before the patient leaves the operating theater.
The physician must check the stability of the LINK™ and Bone Pins at follow-up visits.
During and after insertion, ensure correct positioning of the LINK™ and Bone Pins under image intensification.
Particular care should be taken that Bone Pins do not enter the patient's joints.

XI. Possible Adverse Reactions

Superficial infection
Deep infection
Non-union, delayed union or malunion
Bone fracture during or after treatment
Bending breakage or migration of the device
Loss of fixation
Reoperation to replace a Bone Pin
Pain, discomfort or abnormal sensations due to the presence of the device
Arthritic changes
Heterotopic ossification
Wound healing complications
Events caused by the risk associated with anesthesia and surgery
Nerve or vessel damage associated with insertion of the Bone Pins
Fracture of original defect or through Bone Pin holes following removal
Loosening of breakage of Bone Pins
Complications associated with severe or poorly controlled diabetes mellitus

Xi. Use and Storage Considerations

LINK™ and instruments should not be subjected to storage or shipping temperatures in excess of 76.7 °C (170 °F).

XII. If loosening occurs:

LINK™ forces increase the closer to bone the LINK™ is placed. If loosening occurs the LINK™ can be recompressed and slid closer to skin to tighten the construct. If the LINK™ remains loose it should be removed.

XII. If LINK™ breakage occurs:

If breakage occurs the LINK™ can be slid off of the wires/pins intact or in separate pieces and a new LINK™ placed over the wires or the wires removed.

XIII. Sterilization and Shelf Life

The LINK™, Bone Pins, and silicone cover are single use sterile devices distributed in a Tyvek pouch. The pouches are placed in a labeled protective box or tube. The LINK™ is sterilized by gamma radiation to a sterility assurance level (SAL) of 10^{-6} with a minimum dose of 25kGy and a maximum dose of 45kGy. The minimum permissible dose required to achieve the required SAL level was determined and validated as set out in ANSI/AAMI/ISO 11137-Parts 1, 2, and 3. A 5 Year shelf life was established in accordance with industry standards for barrier packaging as set out in ASTM-F1140, Burst Test; ASTM-F1929, Dye Penetration Test; ASTM-F1980, Accelerated Aging & ASTM-F1886, Visual Inspection.

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