CoNextions®
Revolutionizing Tendon Repair®

Operative Technique

CoNextions TR® Tendon Repair System

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Contents

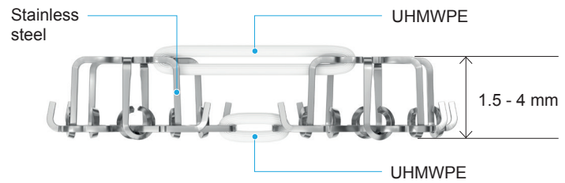
System overview

The CoNextions TR® Tendon Repair System is designed for the repair of severed or lacerated tendons. The system includes a disposable Implant Mechanism and Deployment Mechanism that are designed to place a permanent implant. The implant is comprised of 316 LS stainless steel and Ultra High Molecular Weight Polyethylene (UHMWPE) fiber.
The CoNextions TR Implant is designed to fit anatomically in intra- and extra-synovial tendons. The Implant Mechanism and Deployment Mechanism of the CoNextions TR Tendon Repair System are offered packaged together or individually. The system is designed for tendons at 3 to 9 mm in width and 1.5 to 4 mm in thickness and requires at least 20 mm of surgical site access. When deployed, the CoNextions TR Implant is 18 mm in length and 2.8 mm wide. The delivery instrumentation requires 20 mm (10 mm on either side of the repair site) of surgical access to allow for proper implant deployment.

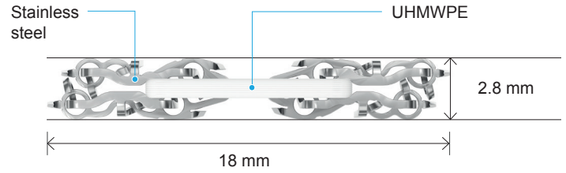
Table 1. Tendon Sizes and Surgical Site Access Requirements

Tendon Width	Tendon Thickness
3.0 - 9.0 mm	1.5 - 4.0 mm
Minimum Surgical Site Access	
20 mm (10 mm/side)	

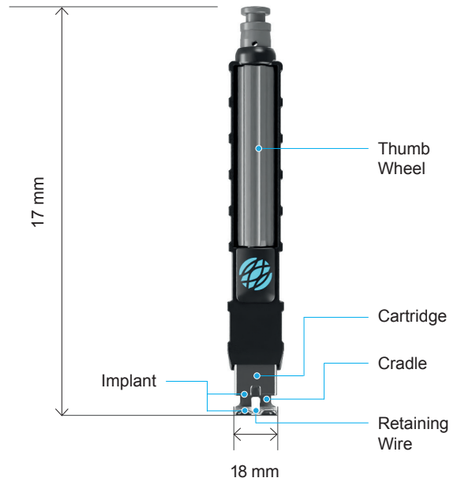
Side View



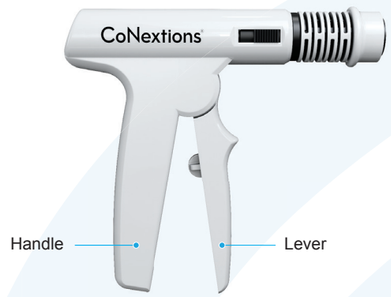
Top View



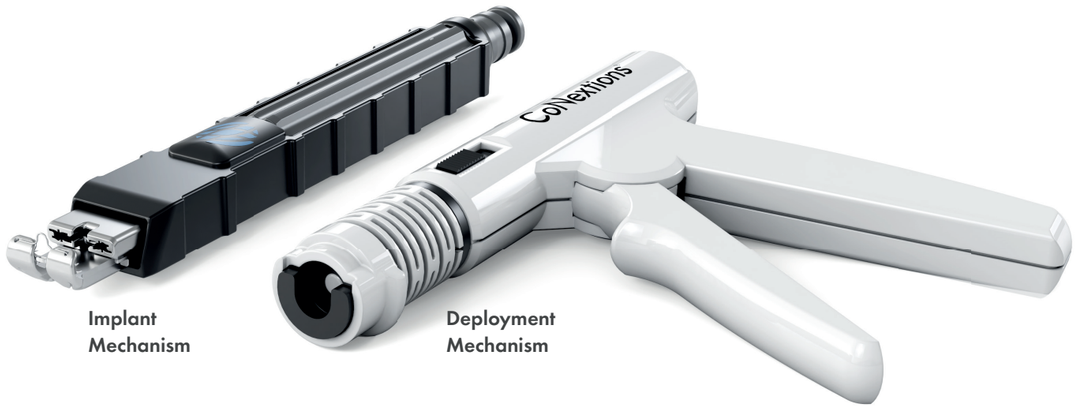
Implant Mechanism



Deployment Mechanism



Device components & packaging



FA0001
Combination Kit

FA0002
Deployment Mechanism

FA0004
Implant Mechanism

Indications and contraindications

Indications

CoNextions TR Tendon Repair System is indicated for the repair of severed or lacerated tendons in adults (22 years of age or older). The product is intended for the following indications:

- Digital Flexor Tendons
- Digital Extensor Tendons Proximal to the metacarpophalangeal joints (Zones 6-8)

Contraindications

1. Ischemia, blood supply compromise, and/or inadequate wound coverage.
2. Prior or current infections at or near the implant site.
3. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
4. Foreign-body sensitivity: Where material sensitivity is suspected, appropriate tests should be done, and sensitivity ruled out prior to implantation.
   The implant consists of Stainless Steel (316 LS per ASTM F-139) and UHMWPE (Ultra High Molecular Weight Polyethylene).
5. The physical contact of the CoNextions TR Tendon implant with metal implants made of anything other than the implant grade of stainless steel, such as titanium, titanium alloys, cobalt chromium, or other dissimilar metals.
6. Surgical procedures other than those listed in the indications section.
7. Tendon size or Surgical site access outside of specified range for the CoNextions TR Tendon Repair System (See Table 1).

Table 1. Tendon Sizes and Surgical Site Access Requirements

Tendon Width	Tendon Thickness
3.0 - 9.0 mm	1.5 - 4.0 mm
Minimum Surgical Site Access	
20 mm (10mm/side)	

Warnings

1. Implant Mechanism is intended for single use. Deployment Mechanism can be used more than once in the same procedure. Reuse and/or repackaging may create the following risks:
   - Patient or User Infection
   - Compromised Device Effectiveness
   - Device Failure
   - Patient Injury, Illness or Death
2. The use of CoNextions TR in tendon transfer procedures has not been evaluated.
3. The CoNextions TR Implant Mechanism contains sharp tips at the distal end; handle with care. Sharp tips are exposed after removing the shipping block.
4. Use only the supplied implant and deployment Mechanisms to form the implant.
5. Resistive activities of the repaired tendon should not be allowed until tendon healing has been confirmed by the treating physician.
6. After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
7. If the device becomes contaminated, do not use the device, and discard the device immediately.
8. As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

MRI Safety Information

Table 2. MRI Safety Information for CoNextions TR Implant

MR

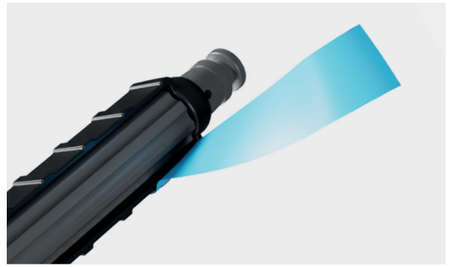
A patient implanted with CoNextions TR Tendon Repair System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Device Name	CoNextions TR Tendon Repair System
Static Magnetic Strength (B_0)	1.5 T and 3.0 T
Maximum spatial field gradient	20 T/m (2000 Gauss/cm)
RF Excitation	Circularly polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2.0 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2.0 W/kg whole-body average SAR for 15 minutes of continuous RF (A sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Prepare device for use

Remove Implant and Deployment Mechanisms (as applicable) from package. Remove tape.



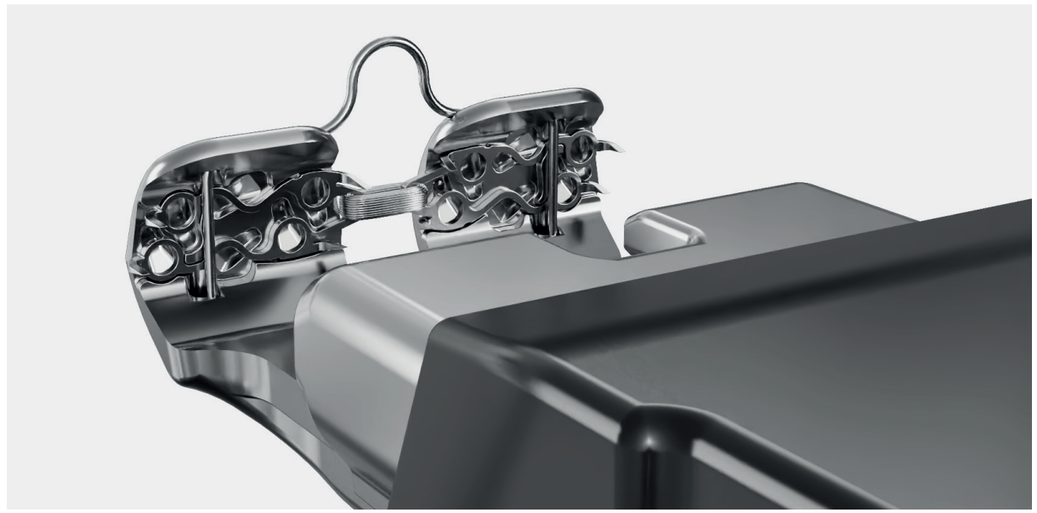
Note: Blue shipping tape prevents thumb wheel from moving during shipping.

Turn the thumb wheel counter clockwise until met with resistance to remove the shipping block from cradle.

Note: The shipping block keeps implant in place during shipping.

Close up of Tendon Cradle

With shipping block removed, the bottom (dorsal) component of the implant can be seen in tendon cradle.
The implant is held in tendon cradle by a retention wire that will be removed following final placement of implant.



Operative technique

Step 1

Approach the lacerated tendon using a preferred surgical technique. Create an access point in the sheath by creating a two-centimeter incision over the laceration. Receive tendon ends using a standard technique and approximate the ends using two epitendineous corner sutures or a preferred alternative approximation technique.

Assess Injured Tendon

Tendon Size and Surgical Access Requirements

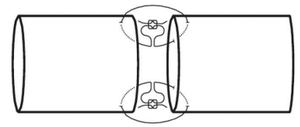
- **1.5 to 4.0 mm in thickness**
  Within this range implant will size to thickness of tendon.
- **At least 3.0 to 9.0 mm in width**
  Implant is 2.8 mm in width.
- **20 mm of access (10 mm on either side of injury)**
  Implant and tendon cradle are 18 mm in length.

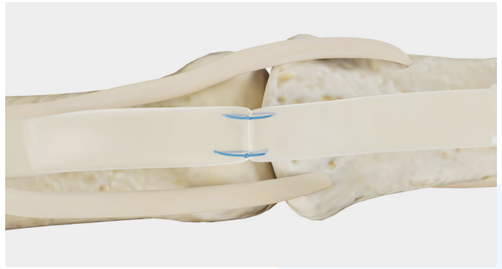
Criteria Assessed During Clinical/Bench Testing	Tendon Met Criteria
Tendon at least 1 mm thick	99.5% (425/427)
Tendon less than 4 mm thick	99.5% (425/427)
Tendon at least 3 mm in width	96.3% (411/427)
At least 20 mm of access	99.7% (385/386)

Note: All these criteria were met for the majority of tendons assessed during clinical and bench testing.

Prepare Injured Tendon

Approximate tendon ends by placing epitendinous suture loops across the severed tendon.





Clinical trial summary

- This was the **technique for the clinical study**[4].
- Two corner sutures control edges of repair.
- **Controlling edges is critical** when repair will interface with pulleys.

Surgeon may use preferred technique to approximate tendon ends.

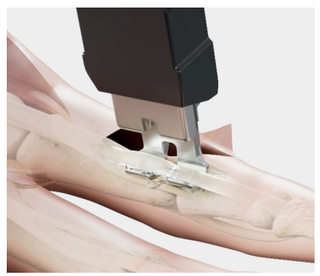
Operative technique

Step 2

Position the tendon in the cradle and fully engage the tendon by rotating the thumbwheel in a clockwise direction until the click occurs. Observe the tendon through the viewing windows in the front or back to ensure proper positioning and centering in the cradle. The process of positioning and engaging the tendon in the cradle can be reversed and repeated as many times as necessary prior to the deployment of the implant.

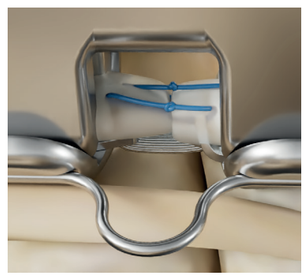
Place Implant Mechanism at Repair Site

Caution: Do not drag tendon across tendon cradle. Lift tendon off cradle to reposition it.



1. Insert the tendon cradle under the tendon and position the tendon repair site in the center of the cradle in both the lateral and anterior/posterior plane.

2. Advance the cartridge by turning the thumb wheel clockwise. **Optimal tendon compression is indicated by an audible clicking sound.**



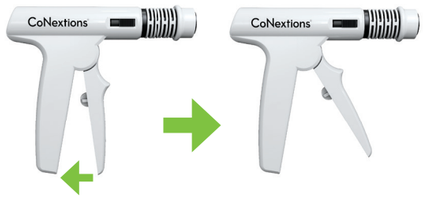
3. Observe the front and back of the tendon through viewing window to ensure proper positioning. Turn thumb wheel counter clockwise to retract cartridge and adjust tendon position as needed.

A Caution Regarding the Deployment Mechanism

Prior to connecting Deployment Mechanism to Implant Mechanism, make sure the Lever is not partially depressed.

Lever is in normal position

Lever is partially depressed



Fully depress
Lever until it automatically releases to normal position

Do not attempt to pull
partially depressed Lever back to normal position

Operative technique

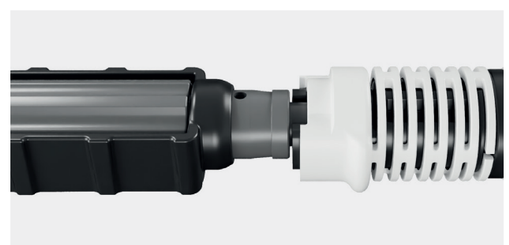
Step 3

When the tendon is appropriately aligned and engaged, attach the deployment mechanism by pulling back on spring and sliding top of the implant mechanism to the tip of deployment mechanism. Release spring to secure hold and pull the trigger to delpoy the implant. The trigger will release back to its original position when the implant has been fully deployed.

Pull Back on Spring

Slide top of the implant mechanism to the tip of the deployment mechanism.

Connect Deployment Mechanism to Implant Mechanism



Caution: Do not rotate Deployment Mechanism once it is attached to Implant Mechanism.

Deploy Implant

Fully pull the Deployment Mechanism lever to deploy the implant.

Complete deployment is confirmed when the lever of Deployment Mechanism automatically releases to original position.

Operative technique

Step 4

The last step is to remove the retention wire from the implant cradle and discard it.
Disengage the implant mechanism from the tendon by rotating the thumbwheel counterclockwise and remove from the surgical site.

Remove Retention Wire and Implant Mechanism

Remove retention wire from Tendon Cradle.

Turn Thumb Wheel counter clockwise to remove Tendon Cradle from the repair site.

Final repair.

Notes

Implant Removal Technique

1. During the primary surgery, if implant removal is necessary, position a thin pair of scissors (or equivalent instrument) between the top and bottom UHMWPE loops. Open the scissors to apply force to the UHMWPE loops and pry the components of the implant apart from one another to remove them. Perform a visual inspection to confi rm the device is completely removed.
   - Do NOT cut the UHMWPE.
   - If the device does not come completely apart, it may be necessary to use a needle driver to grasp the bottom UHMWPE and a second needle driver to grasp the top UHMPE and pull the top and bottom portions of the implant away from one another.
2. If post-operative device removal is necessary and the device is overgrown with tissue, then excise the entire implant.

References:

1. MC0010.B. CoNextions internal testing. Benchtop testing. May not be indicative of clinical performance.
2. Reed, ER, Hendrycks H, Graham EM, Rosales M, and SD Mendenhall. Tendon Repairs at the wrist Utilizing a Novel Tendon Stapler Device: An Efficiency and Biomechanical study Across Different Experience Levels. Presented at 76th Annual Meeting of the American Society for the Surgery of the Hand (San Francisco, California, September 30th-October 2, 2021).
3. MC0015.A. CoNextions internal testing. Benchtop testing. May not be indicative of clinical performance.

IFU:

4. https://www.conextionsmed.qarad.eifu.online/str/CNX.

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