CoNextions™

CoNextions TR®

Tendon Repair System

INSTRUCTIONS FOR USE

This Instruction for Use applies to the following REF and UDI numbers:

REF	FA0001	UDI	00861445000303
REF	FA0002	UDI	00861445000310
REF	FA0004	UDI	00861445000327

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician

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Description

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 components (Implant Mechanism/Deployment Mechanism) of the CoNextions TR Tendon Repair System are offered together or individually. The system is designed for tendons at least 3 mm in width and 1.5 to 4 mm in thickness and requires at least 20 mm of surgical site access (**Table 1**).

Table 1. Tendon Sizes and Surgical Site Access Requirements

Tendon Width	Tendon Thickness	Minimum Surgical Site Access
At least 3.0 mm	1.5 – 4.0 mm	20 mm (10 mm/side)

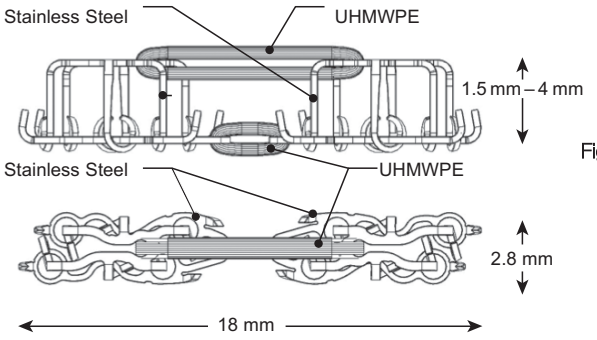

Figure 1. Formed CoNextions TR Implant

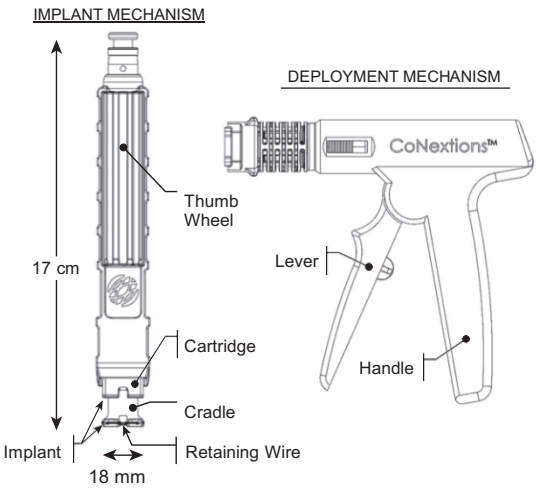

Figure 2. CoNextions TR Tendon Repair System

Indications for Use

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)

Materials (Implantable)

- 316 LS stainless steel per ASTM F-139
- Ultra High Molecular Weight Polyethylene (UHMWPE)
    - UHMWPE fiber loop is produced with 75 denier / 20-filament non-absorbable Ultra High Tenacity Polyethylene Yarn. The UHMWPE fiber loop does not contain any packing fluids, dyes, or coatings. The UHMWPE fiber loop has a fixed configuration. USP suture labeling standards are not applicable to the device.

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, 75 denier/20-filament non-absorbable ultra high tenacity polyethylene yarn)
5. The physical contact of the CoNextions TR™ Tendon Repair System 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 sections.
7. Tendon size or Surgical site access outside of specified range for the CoNextions TR Tendon Repair System (See Table 1).

Package Handling

Store in a cool dry place. This product has an expiration date and should be used before the labeled “use by” (expiration) date marked on the label. **DO NOT** use or store the device if the packaging has been compromised.

Warnings

1. Intended for single use. Do not reuse. 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.

Precautions

1. Carefully read and follow all instructions in these instructions for use.
2. Only qualified healthcare practitioners should insert/deploy, manipulate and remove this device.
3. The use of multiple CoNextions TR implants within the same digital sheath has not been evaluated in clinical studies.
4. The repair of multiple flexor tendons within the same carpal tunnel (Zone 4) with CoNextions TR has not been evaluated in clinical studies.
5. Remove items from the sterile package using sterile technique. Damaged or opened packages should not be used, should be clearly marked “DAMAGED-DO NOT USE”, and discarded immediately.
6. Correct handling of the implant is extremely important. Notches or scratches placed on the implant during the course of surgery may contribute to failure. Implant fraying or wear may contribute to failure. The implant should not be placed in a position where they will be subject to direct abrasion against edges of bone or other dissimilar implants during normal use.
7. These implants are not designed to withstand the unsupported stress of normal daily activities during healing.

8. Protective measures after tendon repair must be taken. This includes reduction in activity and possible use of immobilization devices until healing is established.
9. Factors such as the activity level and adherence to load bearing instructions may affect patient outcomes. Healing may be compromised in a variety of conditions and/or disease states.
10. Physical therapy programs should be administered with appropriate restrictions based on the level of patient healing and adherence to approved physical therapy protocols.
11. Postoperative care is critical. Adverse event incidences are more likely to occur if the patient is not compliant with the instructions of a qualified treating physician.
12. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management. These decisions should be made by the treating physician or another qualified medical professional.

Possible Adverse Effects

1. Infection
2. Inadequate or delayed healing
3. Tendon re-rupture and/or implant failure
4. Loosening or migration of the implant
5. Biomaterial sensitivity or allergic reaction to a foreign body
6. Pain, discomfort, or abnormal sensation due to the presence of the device
7. Nerve damage due to surgical trauma
8. Necrosis or inflammation of tissue
9. Intra-operative or postoperative tissue damage and/or postoperative pain
10. Bleeding from the surgical procedure
11. Tendon triggering, adhesion, and/or reduced range of motion
12. Joint contracture
13. Secondary Surgery

Sterility

The components of the CoNextions TR Tendon Repair System are sterilized by exposure to Ethylene Oxide. Do not re-sterilize. Do not use the CoNextions TR Tendon Repair System after expiration date. Ensure sterile management of the device at all times.

MRI Safety Information

Table 2. MRI Safety Information for CoNextions TR Implant

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 associatedwith that parameter.

Instructions for Use

Implantation Technique

1. Remove Implant and Deployment Mechanisms (as applicable) from package. Remove tape. Turn the thumb wheel counter-clockwise to remove the shipping block from cradle.

    a. Caution: If lever is accidentally actuated, squeeze the lever completely closed until it releases and returns to open position. Do not attempt to manually force the Deployment Mechanism lever open.

2. Approach and retrieve the lacerated tendon using a preferred surgical technique. You will need access to 10 mm of tendon on either side of the laceration. This should be accomplished through an aperture of 20 mm or greater. Ensure the tendon is appropriately sized per **Table 1** (1.5 mm to 4 mm thick and at least 3 mm wide).

3. Approximate tendon ends by placing epitendinous loops across the severed tendon (**Figure 3**). Alternatively use preferred technique to approximate tendon ends prior to deploying the CoNextions TR Implant.

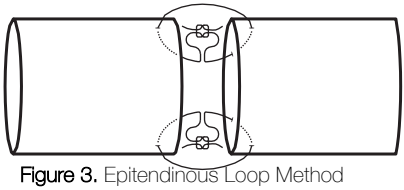

Figure 3. Epitendinous Loop Method

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

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

6. Observe the front and back of the tendon through the viewing window to ensure tendon ends are approximated (**Figure 4**). Turn thumb wheel counter clockwise to retract the cartridge and adjust the tendon positioning in the cradle as needed. Steps 5 and 6 can be repeated as necessary.

    a. Caution: Do not drag the tendon laterally when the teeth of the stainless steel plate are engaged with the tendon. The tendon must be lifted off the stainless steel plate before being repositioned.

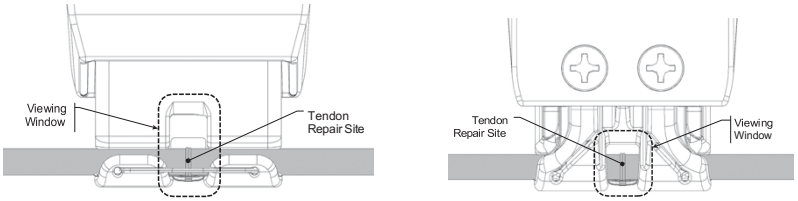

Figure 4. Viewing Window

7. When tendon is appropriately aligned in the cradle and the tendon is clamped until the audible clicking is heard, attach the Deployment Mechanism to the Implant Mechanism.

    a. **Caution: Do not deploy the implant until hearing the audible clicking noise, which indicates the torque limiter has engaged.**

    b. **Caution: Do not rotate the deployment mechanism once it is attached to the implant mechanism.**

8. Pull the Deployment Mechanism lever to deploy the implant. Complete deployment can be confirmed by automatic release of the Deployment Mechanism lever.

    a. **Caution: Do not attempt to manually force the Deployment Mechanism lever open. The Deployment Mechanism lever automatically releases when fully compressed.**

9. Remove and discard the implant retaining wire.
10. Turn the thumb wheel counter-clockwise and remove the cradle from the repair site.
11. In tendons with pulleys, evaluate triggering and gliding by tactile evaluation and flexing the finger if possible. Trim tendon or add epitendinous sutures as necessaryto achieve good gliding.

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 ofthe implant apart from one another to remove them. Perform a visual inspection to confirm the device is completely removed.
2. If post-operative device removal is necessary and the device is over grown with tissue, then excise the entire implant

Summary of Clinical Performance

Study Overview

A clinical evaluation was conducted at 4 sites with 5 fellowship-trained hand surgeons in order to compare the safety and effectiveness of the CoNextions TR System to a standard of care suture repair method (4-strand locked cruciate repair using PROLENE suture) for the repair of lacerations of the flexor digitorum profundus (FDP) tendon in Zone 2. Participants were randomized intraoperatively following confirmation of meeting all of the inclusion criteria. A standardized rehabilitation protocol was implemented during the first 12 weeks post-procedure. The participants and therapists performing the majority of the outcome assessments were blinded to the assigned treatment arm for the 12 weeks post-procedure with the final follow-up occurring 24 weeks post-procedure.

Ninety (90) participants were screened, met the study enrollment criteria (**Table 3**), and were randomized in to the study with 40 (40/90, 44.4%) participants randomized to the CoNextions TR group and 50 (50/90, 55.6%) participants randomized to the suture group. 8 participants were excluded from the final analysis as they were less than 22 years of age at the time of enrollment and an additional participant was excluded after suffering an injury to their affected limb unrelated to the study that could have impacted the outcome assessments. Of the remaining 81 participants, 72 (72/81, 88.9%) of them provided outcome data at the 12 week follow-up visit and 70 (70/81, 86.4%)) of them provided outcome data at the 24 week follow-up visit.

Table 3. Enrollment Criteria for Clinical Evaluation of CoNextions TR Tendon Repair System

Inclusion Criteria	Exclusion Criteria
1. At least 18 years of age 2. Willing and able to provide a signed and dated informed consent form. 3. Stated willingness to comply with all study procedures 4. Available for the duration of the study 5. Have one or two fully lacerated digital FDP tendon(s), with or without a concomitant injury of the flexor digitorum superficialis, in Zone 2 of the index, middle, ring, or small finger 6. Tendon laceration occurred within the previous 14 days	1. Pregnant or planning to become pregnant during the follow-up period 2. Autoimmune disorder(s) 3. Type 1 diabetes mellitus or clinical history of poorly controlled Type 2 diabetes mellitus 4. Lack of proper cutaneous coverage at repair site 5. Concomitant fracture 6. Amputated digit(s) 7. Arthritis of the hand 8. Prior hand trauma with residual impact to function 9. Congenital hand defect 10. Conditions that would affect comparative measurements in the uninjured hand 11. Tendon laceration caused by a crush injury 12. Prior sensory impairment in digits of either hand. Note: Participants with nerve injuries associated with the trauma causing the current flexor tendon injury are eligible for enrollment 13. Vascular injuries that require revascularisation procedures 14. Ischemia and/or blood supply compromise 15. Prior or current infections at or near the intended implant site

Inclusion Criteria	Exclusion Criteria
	16. Active sepsis, MRSA, or other conditions that may prevent healing 17. History of foreign-body sensitivity to 316 L Stainless Steel or UHMWPE 18. Implantation of CoNextions TR Implant would result in physical contact with other metal implants made of material other than implant grade stainless steel such as titanium, titanium alloys, cobalt chromium, or other dissimilar metals 19. Any condition(s) which, in the opinion of the investigator, may impact the participant's ability to properly follow-up or otherwise be at-risk for following protocol instructions 20. Currently participating in another clinical/device trial 21. Surgical site access less than 20 mm in total or less than 10 mm on either side of the intended implant site 22. Injured tendon outside of the width range (3.0-7.0 mm) and thickness range (1.5-4.0 mm) specified for the CoNextions TR Tendon Repair System

Primary Safety Outcome

The primary safety endpoint of the study was the incidence of re-rupture of the repaired Zone 2 FDP tendon laceration. Repaired digits were evaluated at all post-procedure follow-up visits for signs and symptoms of rupture of the repair. The target safety criterion was a rate of re-rupture of 8% or less at the 12 week follow-up visit. At the 12 week follow-up visit, one (1) of 33 (3.0%) participants in the CoNextions TR group experienced a rupture with 5 of 45 (11.1%) participants in the Suture group experiencing a rupture. For all study participants, 1 of 34 (2.9%) participants in the CoNextions TR group and 5 of 47 (10.6%) participants in the Suture group who experienced a rupture.

Secondary Safety Outcomes

Surgical site infection was assessed at all follow-up visits as a secondary safety outcome. For the study participants who experienced a surgical site infection and/or completed the 24 week follow-up visit, one (1) of 34 (2.9%) participants in the CoNextions TR group experienced a surgical site infection with 4 of 47 (8.5%) participants in the Suture group experiencing a surgical site infection. Twenty-six (26) of 34 (76.5%) participants in the CoNextions TR group and 37 of 47 (78.7%) participants in the Suture group experienced at least one adverse event. Four (4) of 34 (11.8%) participants in the CoNextions TR group and 7 of 47 (14.9%) participants in the Suture group experienced a serious adverse event. No statistically significant differences were seen between the two groups for these safety outcomes (**Table 4**).

Table 4. Safety Outcomes for the Clinical Evaluation

Safety Outcome	CoNextions TR	Suture
Rupture of Repair	1/34 (2.9%)	5/47 (10.6%)
Surgical Site Infection	1/34 (2.9%)	4/47 (8.5%)
At Least One Adverse Event	26/34 (76.5%)	37/47 (78.7%)
At least One Serious Adverse Event	4/34 (11.8%)	7/47 (14.9%)

Notes: All values are presented as Participants with Safety Outcome/Total Participants, %.

Adverse Events: There were 155 total adverse events (AE) in the CoNextions TR group with 29 (18.7%) of them not affecting or related to the injured digit(s). A listing of all adverse events related to the injured digit(s) for both study groups is shown in **Table 5**.

Table 5 Adverse Events Affecting the Injured Digit(s)

Adverse Event		CoNextions TR	Suture
Pain	Participants with AE (Y/N, %)	14/34 (41.2%)	21/47 (44.7%)
	Total number AE	44	52
Stiffness	Participants with AE (Y/N, %)	16/34 (47.1%)	21/47 (44.7%)
	Total number AE	28	31
Swelling	Participants with AE (Y/N, %)	13/34 (38.2%)	21/47 (44.7%)
	Total number AE	24	34
Neuralgia	Participants with AE (Y/N, %)	10/34 (29.4%)	16/47 (34.0%)
	Total number AE	18	21
Adhesion	Participants with AE (Y/N, %)	2/34 (5.9%)	2/47 (4.3%)
	Total number AE	2	2
Rupture of Repair	Participants with AE (Y/N, %)	1/34 (2.9%)	5/47 (10.6%)
	Total number AE	1	6
Septic Surgical Site Infection	Participants with AE (Y/N, %)	1/34 (2.9%)	1/47 (2.1%)
	Total number AE	2	1
Scarring of Surgical Incision	Participants with AE (Y/N, %)	1/34 (2.9%)	4/47 (8.5%)
	Total number AE	1	4
Flexion Deformity/Contracture	Participants with AE (Y/N, %)	1/34 (2.9%)	1/47 (2,1%)
	Total number AE	1	1
Delayed Healing of Incision	Participants with AE (Y/N, %)	1/34 (2.9%)	2/47 (4.3%)
	Total number AE	1	2
Hyperextension of Repaired Digit	Participants with AE (Y/N, %)	1/34 (2.9%)	0/47 (0.0%)
	Total number AE	1	0
Device Positioned Incorrectly During Surgery	Participants with AE (Y/N, %)	1/34 (2.9%)	0/47 (0.0%)
	Total number AE	1	0
Other AE not seen in CoNextions TR Group	Participants with AE (Y/N, %)	0/34 (0/0%)	(1-6)/47 (Range of 2.1-12.8%)
	Total number AE	0	28

Note: Adverse events related to Weakness, superficial surgical site infection, bleeding at surgical site, serious fluid drainage, triggering, dermatitis, blister/burn, post-surgical nerve entrapment, epidermal maceration, stitches retained in wound, and cellulitis were observed in the Suture group but not in the CoNextions TR group

There were no significant differences in the two study groups related to the frequency of any adverse events. Pain, stiffness, swelling, and neuralgia of the repair sites were the most common adverse events seen in both groups, accounting for 74 of the 126 (58.7%) adverse events affecting the injured digit(s) in the CoNextions TR group. These are known and common adverse events experienced in the postoperative recovery following the surgical repair of lacerated tendons. Adhesion, another known complication following the surgical repair of lacerated tendons is the only other adverse event affecting the injured digit(s) which occurred in more than one participant in the CoNextions TR group (occurring in 2/34 participants, 5.9%).

Serious Adverse Events: All (5) of the serious adverse events (SAE) in the CoNextions TR group affected the injured digit(s). None of these events occurred in more than one participant in the CoNextions TR group. A listing of all serious adverse events related to the injured digit(s) for both study groups is shown in **Table 6**.

Table 6. Serious Adverse Events Affecting the Injured Digit(s)

Serious Adverse Event		CoNextions TR	Suture
Rupture	Participants with AE (Y/N, %)	1/34 (2.9%)	5/47(10.7%)
	Total number AE	1	6
Septic Surgical Site Infection	Participants with AE (Y/N, %)	1/34 (2.9%)	1/47 (2.1%)
	Total number AE	2	1
Device Positioned Incorrectly	Participants with AE (Y/N, %)	1/34 (2.9%)	0/47 (0.0%)
	Total number AE	1	0
Hyperextension injury of injured finger	Participants with AE (Y/N, %)	1/34 (2.9%)	0/47 (0.0%)
	Total number AE	1	0
Superficial Surgical Site Infection	Participants with AE (Y/N, %)	0/40 (0.0%)	1/47 (2.1%)
	Total number AE	0	1
Flexion Deformity	Participants with AE (Y/N, %)	0/40 (0.0%)	1/47 (2.0%)
	Total number AE	0	1
Post-surgical Nerve Entrapment	Participants with AE (Y/N, %)	0/40 (0.0%)	1/47 (2.1%)
	Total number AE	0	1

There were no significant differences in the two study groups related to the occurrence of these serious adverse events. The rupture in the CoNextions TR group was surgically repaired using a conventional suturing technique (as were the ruptures in the suture group). The CoNextions TR implant was successfully removed as part of the treatment for the septic surgical site infection. In the case of the device being positioned incorrectly in the CoNextions TR group, the implant was removed and replaced with an additional implant at the time of the original surgical repair. The hyperextension injury was a result of additional trauma, considered unrelated to the CoNextions TR device, and treated with additional surgery.

Primary Effectiveness Outcome

The primary effectiveness outcome was the mobility of the repaired digit(s). Strickland's Revised scores were used to provide a descriptive measure of mobility.

Strickland Scores are the sum of the active flexion angle of the interphalangeal and metacarpal joints less the extension deficit and are presented as a percentage of a normal value (175). Flexion and extension deficit values were collected using standard finger goniometry methods. Target effectiveness criterion for the study was at least 80% of the CoNextions TR repairs achieving a Strickland Score of 50% or better at the 12 week follow-up visit. This goal was not met; however the primary analysis was supplemented with post-hoc analyses looking at the comparative performance of the two study groups at the final follow-up and the average Strickland mobility scores of the two groups at the 12 and 24 week follow-ups. At the 12 week follow-up, 11 of 27 (40.7%) participants in the CoNextions TR group and 18/41 (43.9%) participants in the Suture group had a Strickland Score of 50% or better. The average Strickland Scores was 47.8 for the CoNextions TR group and 44.0 for the Suture group at the 12 week follow-up. At the 24 week follow-up, 18 of 30 (60.0%) CoNextions TR participants and 24 of 42 (57.1%) Suture participants had a Strickland Score of 50% or better. The average Strickland Scores was 52.7 for the CoNextions TR group and 50.0 for the Suture group at the 12 week follow-up (**Table 7**). No statistically significant differences were seen between the two groups for these safety outcomes

Table 7. Primary Effectiveness Outcome for the Clinical Evaluation

Digital Mobility Outcomes	CoNextions TR	Suture
Strickland Score of At Least 50% at 12 Week Follow-up (Yes/Total, %)	11/27 (40.7%)	18/41 (43.9%)
Average Strickland Mobility Score at 12 Week Follow-Up (95% CI)	47.8% (40.50, 55.10)	44.0% (36.10, 51.90)
Strickland Score of At Least 50% at 24 Week Follow-up (Yes/Total, %)	18/30 (60.0%)	24/42 (57.1%)
Average Strickland Mobility Score at 24 Week Follow-Up (95% CI)	52.7% (44.96, 55.10)	50.0% (41.94, 58.06)

Note: An error at one site occurred early in the study and resulted in a passive mobility score being recorded for some participants at their 12 week follow-up visit. As a result of this error, there were more participants with active mobility scores at the 24 week follow-up than at the 12 week follow-up.

Secondary Effectiveness Outcomes

VAS Pain Scores, DASH Questionnaire Scores, Grip Strength, and Tip Pinch Strength were assessed as secondary effectiveness outcomes. A 0-10 cm VAS Pain scale was used to assess the patient's self-reported pain. The DASH Questionnaire is a validated metric of functional outcome following intervention in the upper extremity. This questionnaire consists of 30 questions assessing the participants ability to perform various activities of daily living with a score range of 0 (no disability) to 100 (completely disabled). Grip Strengths were collected using a dynamometer and Tip Pinch Strengths were collected using a pinch gauge. For both strength assessments, the participant was seated with the shoulder adducted and in neutral, the elbow flexed at 90 degrees and the forearm and wrist in neutral position. Both strength assessments are presented as a percentage of the corresponding strength for the contralateral digit (Tip Pinch Strength) or contralateral hand (Grip Strength). There were no statistically significant differences between the two groups for these outcomes at any time point with any differences with any differences between the two groups being less than the reported minimal clinically important difference for the outcome measure (**Table 8**).

Table 8. Secondary Effectiveness Outcomes at Final (24 week) Follow-up

Secondary Effectiveness Outcome	CoNextions TR	Suture
VAS Pain Score at 24 Weeks (N, Average, 95% CI)	N=33 1.2 (0.5, 1.8)	N=42 1.0 (0.5, 1.6)
DASH Questionnaire Scores at 24 Weeks (N, Average, 95% CI)	N=33 12.3 (7.7, 17.0)	N=42 11.5 (6.5, 16.5)
Tip Pinch Strength at 24 Weeks as a % of Contralateral Digit (N, Average, 95% CI)	N=32 73.2% (63.2, 83.3)	N=40 79.4% (72.8, 86.0)
Grip Strength at 24 Weeks as a % of Contralateral Hand (N, Average, 95% CI)	N=33 68.7% (61.8, 75.5)	N=40 73.1% (66.1, 80.2)

Definitions

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Use By		Catalogue Number		Keep Dry
	Caution		Batch Code		Manufacturer
	Consult Instructions for Use		Authorised Representative in the European Community		MR Conditional
	Do Not Resterilize		Sterilized using Ethylene Oxide		Caution:USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.
	Do Not Reuse		Do Not Use if Package is Damaged		

CoNextions™

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