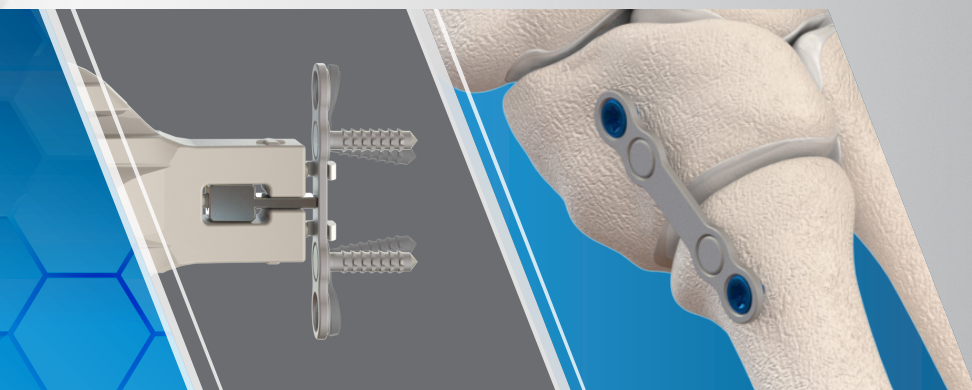




NeoSpan[®]

Compression Implant System



SURGICAL TECHNIQUE

NeoSpan® Compression Implant System

Product Overview

The **NeoSpan® Compression Implant System (CIS)** is a product expansion of the existing NeoSpan® Compression Staple System. The NeoSpan Compression Implant System consists of Nitinol implants offered in various configurations. Fixed-Leg and In-Line Implants feature two fixed legs and are available with up to three threaded screw holes for additional fixation to the bone. T-Shape Implants feature three fixed legs and up to two additional threaded screw holes for bone fixation. The screws that the additional holes accept are composed of Titanium alloy. The devices are sterile implants intended to provide fixation of fractures, fusions, or osteotomies of the hand and foot.

Compatible Screws for the system are the 3.0mm (10-30mm lengths) and 3.5mm (10-40mm lengths) Locking & Non-Locking CoLink® Screws. All Screws accept a T15 Driver.

All implants are provided in sterile packaging. In addition to the instruments that are packaged with the implant, the system utilizes separate sterile instrument sets. The instrument sets include trial plates for proper size determination prior to selecting the packaged implant and disposable instruments dedicated for screw implantation. Other standard orthopedic operating instrumentation may be required to perform the procedures.

SuperElastic Compression

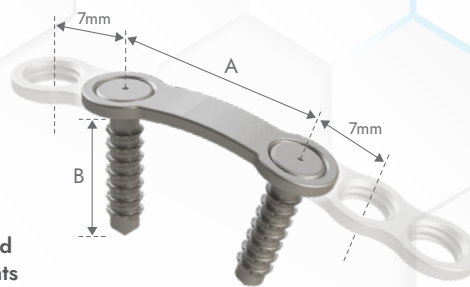
Leveraging the material properties of Superelastic Nitinol, the NeoSpan® CIS Implants arrive preloaded on an Inserter in their Natural State. Upon deployment from the Inserter from their Active State, the Implants return to their preformed bowed body which creates compression in the construct.

Barbed Legs

The legs of the NeoSpan® CIS Implants have a barbed feature to help resist pull-out once implanted.

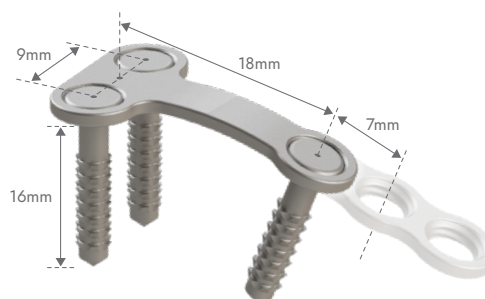
Threaded Screw Holes

Some of the Implants in the NeoSpan® CIS system feature threaded screw holes to allow for placement of screws for additional fixation. All threaded screw holes are compatible with 3.0mm and 3.5mm Locking and Non-Locking Screws.



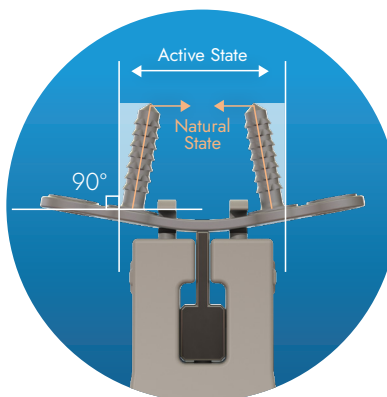
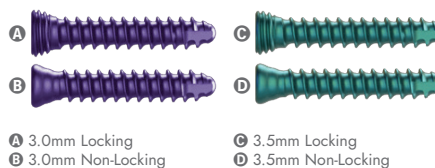
Fixed-Leg and In-Line Implants

CATALOG NO.	DESCRIPTION	SIZE (A x B)
T52 SN018	NeoSpan® Implant w/ Instruments, Sterile	18mm x 14mm
T52 SN118	NeoSpan® Implant w/ Instruments, Sterile	18mm x 16mm
T52 SN218	NeoSpan® Implant w/ Instruments, Sterile	18mm x 18mm
T52 SN020	NeoSpan® Implant w/ Instruments, Sterile	20mm x 20mm
T52 SN025	NeoSpan® Implant w/ Instruments, Sterile	25mm x 22mm
T52 SN181	NeoSpan® Implant +1H w/ Instruments, Sterile	18mm x 14mm
T52 SN182	NeoSpan® Implant +2H w/ Instruments, Sterile	18mm x 14mm
T52 SN183	NeoSpan® Implant +3H w/ Instruments, Sterile	18mm x 14mm
T52 SN184	NeoSpan® Implant +1H w/ Instruments, Sterile	18mm x 22mm
T52 SN185	NeoSpan® Implant +2H w/ Instruments, Sterile	18mm x 22mm
T52 SN186	NeoSpan® Implant +3H w/ Instruments, Sterile	18mm x 22mm



T-Shape Implants

CATALOG NO.	DESCRIPTION
T52 SN300	NeoSpan® Implant, T-shape w/ Instruments, Sterile
T52 SN301	NeoSpan® Implant, T-shape +1H w/ Instruments, Sterile
T52 SN302	NeoSpan® Implant, T-shape +2H w/ Instruments, Sterile



NeoSpan[®] Compression Implant System

Surgical Technique

Reduction and Provisional Compression

Reduction and preparation of the indicated site is necessary prior to the procedure steps associated with the NeoSpan[®] Compression Implant System.

The NeoSpan[®] Compression Implant System is designed to maintain established compression once in place.

Note: Provisional compression with standard instrumentation prior to preparation and implantation of the NeoSpan Compression Implant(s) may enable optimal utilization of the dynamic compression provided by the implants once deployed.

Trialing

A Sterile Implant Trial Kit with K-wires (T05 S0002) is available as part of the system, and may be opened to aid in the identification of the appropriate Implant configuration for each case.

During the trialing stage, K-wires may be used to hold the position of the Trial to allow for confirmation of placement and leg trajectory under fluoroscopy.

Upon confirmation of the desired Implant configuration, open the corresponding NeoSpan[®] CIS Implant Kit.

Note: Trials are representative of implant shape, and the leg and screw hole positions. The first hole(s) on either side of the trial's reference line are indicative of the locations of the implant legs, with the reference line indicating the center of the implants span.

Prepare First Pilot Hole

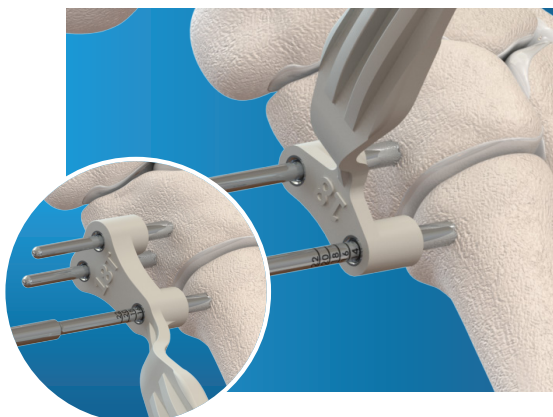
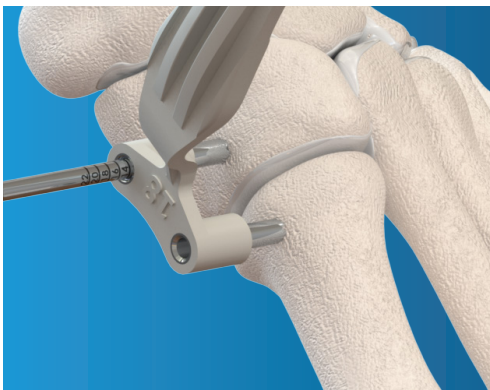
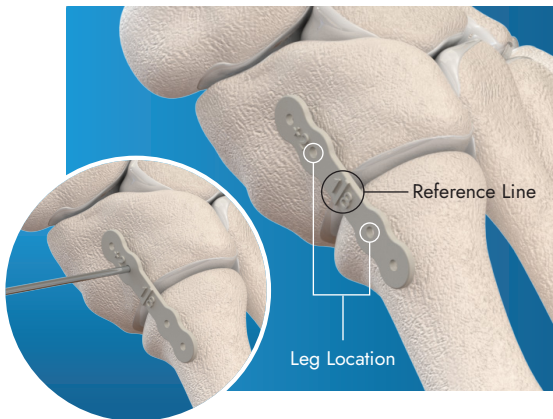
Using the provided calibrated Drill, prepare the first leg hole, referencing the laser markings to obtain the proper depth for the Implant.

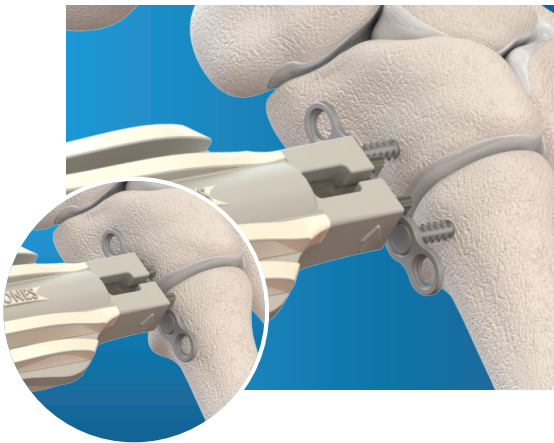
While retaining the Drill Guide location and orientation, remove the Drill and place a Locator Pin in the prepared hole.

Prepare Other Pilot Hole(s)

In a stepwise progression, prepare the remaining hole(s) using the calibrated Drill, referencing the laser markings to obtain the proper depth for the Implant legs.

Note: For T-Shaped configurations, place a second Locator Pin in the prepared hole to maintain the proper placement of the Guide while preparing the final hole.





Prepare and Insert Implant

Remove the Inserter and Implant Assembly from the sterile kit.

Note: *The Implant is not fully secured to the Inserter within the sterile kit. Care should be taken when collecting the components from the kit to avoid dropping.*

With the Implant firmly seated in the metal prongs of the Inserter, twist the Inserter Handle clockwise to extend the internal plunger and spread the legs of the Implant until they are parallel to one another.

Important: *The Implant legs must be parallel to enable proper insertion.*

While maintaining reduction, align the Implant legs with the prepared pilot holes and provisionally seat the Implant.

Use a mallet to advance the Implant until the prongs of the Inserter are in contact with the bone surface.

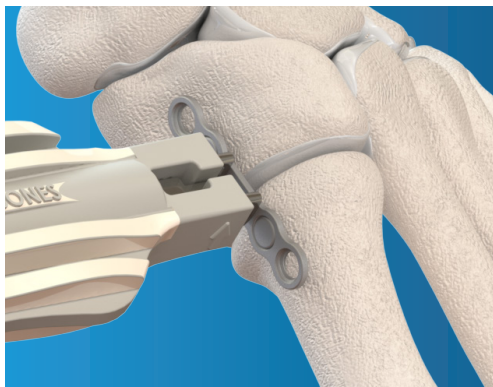
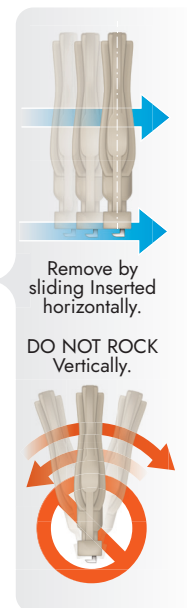


Release Implant and Remove Inserter

Release the Implant by twisting the Inserter Handle counterclockwise to retract the internal plunger and disengage the Inserter from the Implant.

Referencing the arrow on the Inserter, slide the Inserter away from the Implant parallel to the bone surface. Then, remove the Inserter from the surgical site.

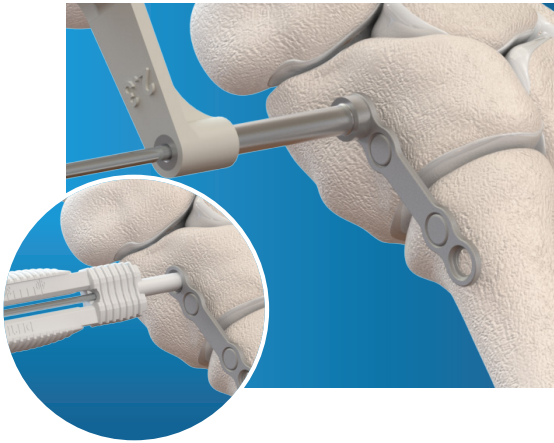
Important: *To avoid unintended lifting of the Implant from the bone surface, do not rock the Inserter during removal.*



Seat Implant

Final seating of the Implant may be performed by placing the Inserter Prongs in contact with the top surface of the Implant, with gentle tamping applied.

Note: *For all Implant configurations featuring threaded screw holes, complete seating of the Implant to the bone should be achieved prior to moving forward with preparation and seating of screws.*



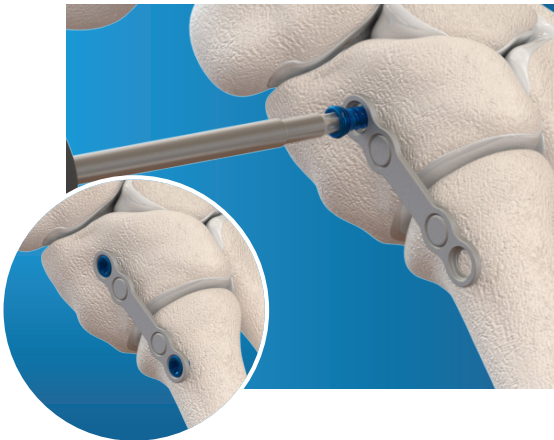
Prepare Screw Insertion

For NeoSpan® CIS Implant configurations with one or more threaded screw holes, the Sterile NeoSpan® Implant Screw Kit (T05 S0003) should be opened for placement of the desired 3.0mm and 3.5mm Locking and Non-Locking Screws.

Prepare the open screw holes for insertion by using the appropriately sized Drill and Drill Guide from the NeoSpan® Implant Screw Kit.

After drilling, use the included Depth Gauge to measure the depth and determine the appropriate screw length.

Tip: *The screw length may also be determined by referencing the calibrated markings on the Drill relative to the Drill Guide.*



Screw Placement

Retrieve the Disposable AO Quick Connect Fixed Handle and T15 Driver from the NeoSpan® Implant Screw Kit, and assemble the T15 Driver to the Handle.

Referencing either the Depth Gauge or the calibrated markings on the Drill relative to the Drill Guide, select and fully seat the chosen screw(s) into the prepared location(s).

Closure

Close by preferred methods.

Removal


Should removal be desired, all screws must be removed from the implant construct with the supplied T15 Driver prior to removal of the NeoSpan® CIS Implant.

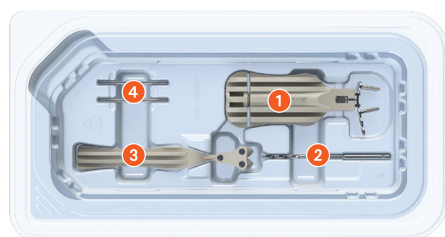
Once all construct screws are removed, the implant may be removed using an osteotome and/or the Inserter instrument from the system.

NeoSpan®

Compression Implant System

IMPLANT KITS (Implant Kits and Screws Sold Separately)

CATALOG NO.	DESCRIPTION	SIZE	
T52 SN018	NeoSpan® Implant w/ Instruments, Sterile	18mm x 14mm	 (Staple Style)
T52 SN118	NeoSpan® Implant w/ Instruments, Sterile	18mm x 16mm	
T52 SN218	NeoSpan® Implant w/ Instruments, Sterile	18mm x 18mm	
T52 SN020	NeoSpan® Implant w/ Instruments, Sterile	20mm x 20mm	
T52 SN025	NeoSpan® Implant w/ Instruments, Sterile	25mm x 22mm	
T52 SN181	NeoSpan® Implant +1H w/ Instruments, Sterile	18mm x 14mm	 (+3 Hole Shown)
T52 SN182	NeoSpan® Implant +2H w/ Instruments, Sterile	18mm x 14mm	
T52 SN183	NeoSpan® Implant +3H w/ Instruments, Sterile	18mm x 14mm	
T52 SN184	NeoSpan® Implant +1H w/ Instruments, Sterile	18mm x 22mm	
T52 SN185	NeoSpan® Implant +2H w/ Instruments, Sterile	18mm x 22mm	
T52 SN186	NeoSpan® Implant +3H w/ Instruments, Sterile	18mm x 22mm	
T52 SN300	NeoSpan® Implant, T-shape w/ Instruments, Sterile		 (+2 Hole Shown)
T52 SN301	NeoSpan® Implant, T-shape +1H w/ Instruments, Sterile		
T52 SN302	NeoSpan® Implant, T-shape +2H w/ Instruments, Sterile		

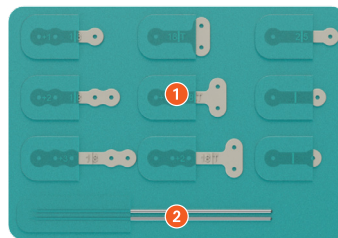


NeoSpan® CIS Sterile Instrument Kit

- 1 Inserter with Implant
- 2 3mm Drill
- 3 Drill Guide
- 4 3mm Locator Pin(s)

Implant Trial Kit

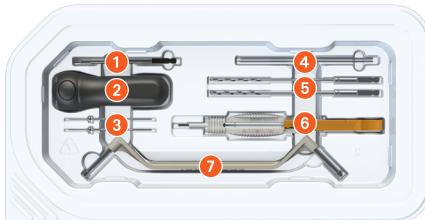
T05 S0002 NeoSpan Implant Trial Kit, Sterile



- 1 Trials
- 2 K-Wires

Implant Screw Kit

T05 S0003 NeoSpan Implant Screw Kit, Sterile



- 1 T15 Driver
- 2 AO Quick Connect Fixed Handle
- 3 Olive Wires
- 4 K-Wires
- 5 2.3mm and 2.8mm Drills
- 6 Depth Gauge
- 7 Double-Ended Drill Guide

SCREWS (Sold Separately)

CoLink® 3.0mm NON-LOCKING SCREW		CoLink® 3.0mm LOCKING SCREW		CoLink® Afx 3.5mm NON-LOCKING SCREW		CoLink® Afx 3.5mm LOCKING SCREW		CoLink® Afx 3.5mm NON-LOCKING SCREW		CoLink® Afx 3.5mm LOCKING SCREW	
	LENGTH				LENGTH				LENGTH		
P43 ST010	10mm	P43 ST110	P73 ST010	10mm	P73 ST110	P73 ST026	26mm	P73 ST126			
P43 ST012	12mm	P43 ST112	P73 ST012	12mm	P73 ST112	P73 ST028	28mm	P73 ST128			
P43 ST014	14mm	P43 ST114	P73 ST014	14mm	P73 ST114	P73 ST030	30mm	P73 ST130			
P43 ST016	16mm	P43 ST116	P73 ST016	16mm	P73 ST116	P73 ST032	32mm	P73 ST132			
P43 ST018	18mm	P43 ST118	P73 ST018	18mm	P73 ST118	P73 ST034	34mm	P73 ST134			
P43 ST020	20mm	P43 ST120	P73 ST020	20mm	P73 ST120	P73 ST036	36mm	P73 ST136			
P43 ST022	22mm	P43 ST122	P73 ST022	22mm	P73 ST122	P73 ST038	38mm	P73 ST138			
P43 ST024	24mm	P43 ST124	P73 ST024	24mm	P73 ST124	P73 ST040	40mm	P73 ST140			
P43 ST026	26mm	P43 ST126									
P43 ST028	28mm	P43 ST128									
P43 ST030	30mm	P43 ST130									

Indications

The NeoSpan® Compression Implant device is a nitinol implant intended to provide fixation of fractures, fusions, or osteotomies of the hand and foot.



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