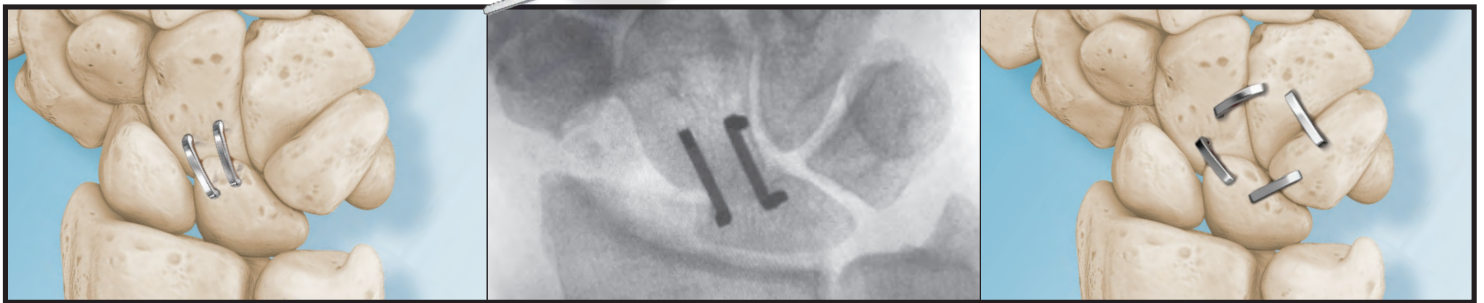


SUPERELASTIC COMPRESSION STAPLE

NeoSpan® SE



Low-profile, Constant Compressive Force



Inside / Outside Stepped-tooth Design Resists Pull-out



Sterile Kit with Single Use Instruments



A GLOBAL EXTREMITY COMPANY

SUPERELASTIC COMPRESSION STAPLE

NeoSpan SE

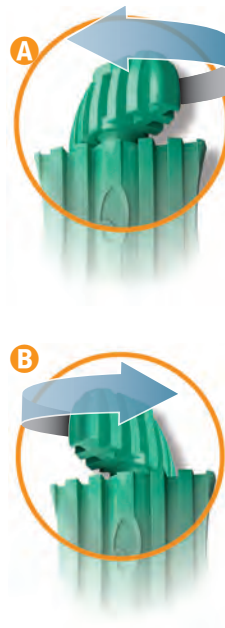
NeoSpan SE is a SuperElastic, compression-ready fixation system designed for fixation for fractures, fusions or osteotomies of the bones in the forefoot, midfoot and rearfoot. NeoSpan SE's

compressive properties and stepped-tooth design resists pull-out. See the accompanying Sizing Reference for examples of use from similar procedures.

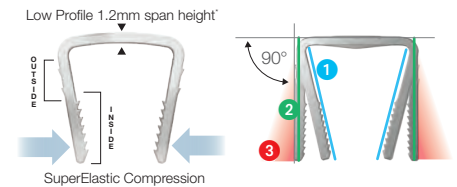


A Compression loading: With the Staple firmly in the Inserter's metal prongs, slowly twist the top handle **clockwise** extending the internal plunger to spread the staple's legs.

B Release: Slowly twist the top handle **counter clockwise**.

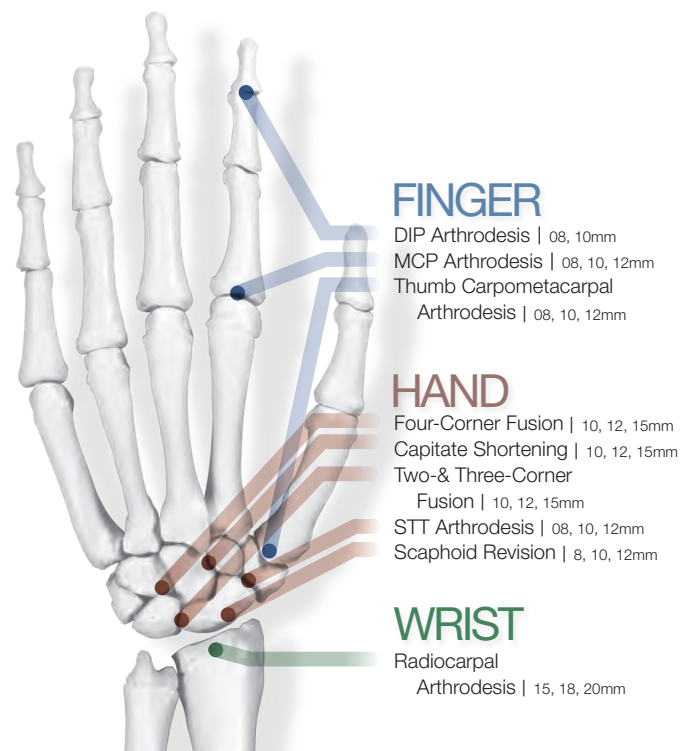
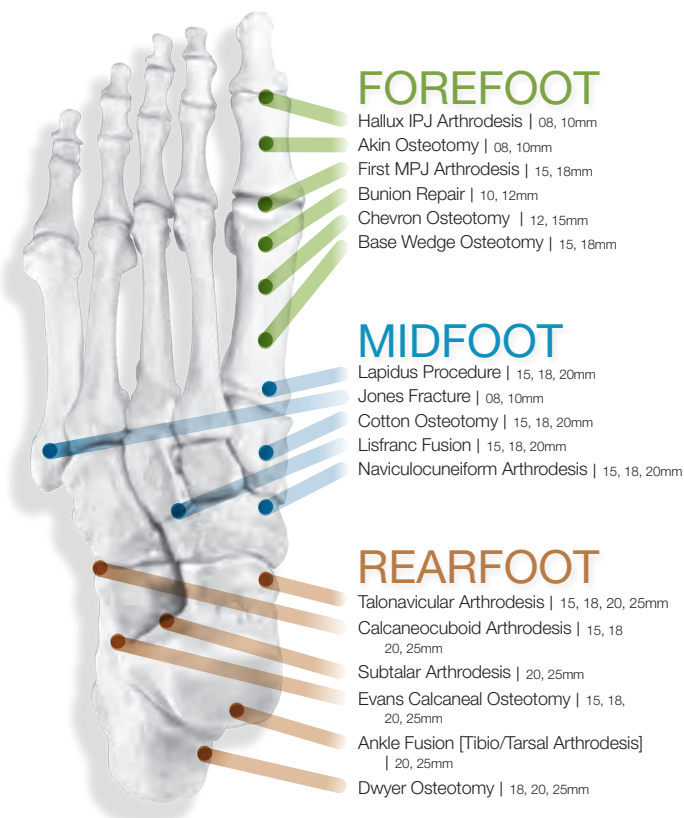


- Compression on release design
- Low-profile Design Delivers Constant Active Compression
- Inside / outside stepped- tooth design resists pull-out
- Multiple sizes from 8 to 25mm

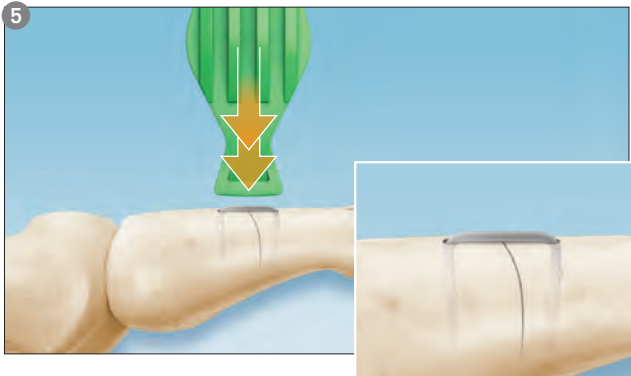
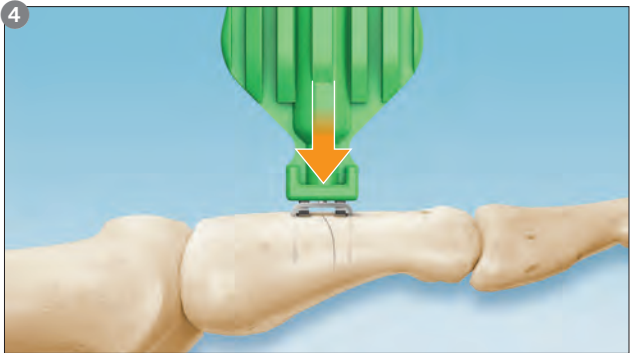
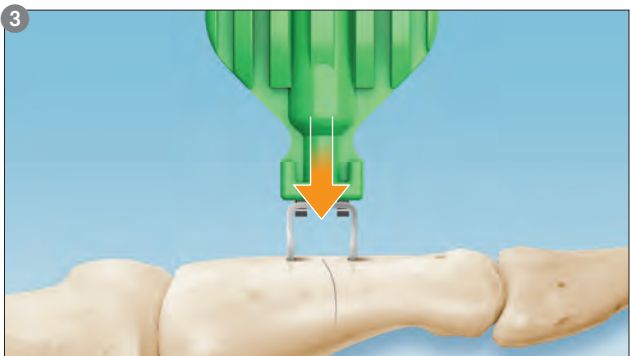
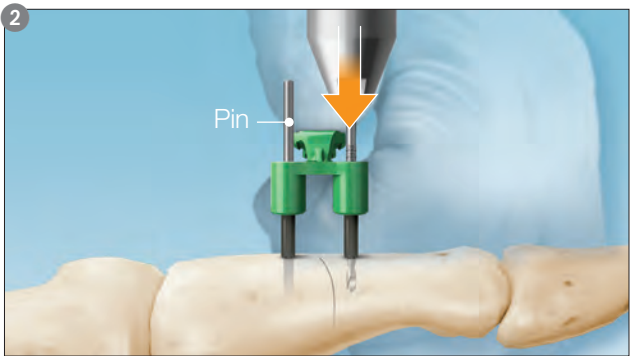
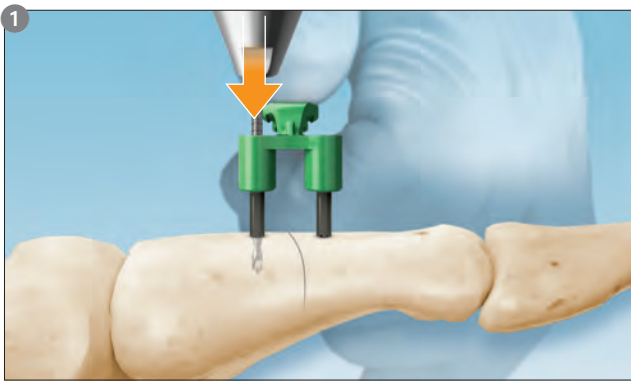


- 1 Natural compressed configuration
- 2 Spread for insertion
- 3 DO NOT SPREAD past 90°

Typical Fractures and Osteotomies



Surgical Technique



Determine the correct Implant size by using the sterile NeoSpan SE Sizer. Open the appropriate size NeoSpan SE Staple Kit with its corresponding Inserter with Staple, Drill, Drill Guide, Locator Pin and Tamp.

1 Prepare first hole

While maintaining desired reduction, place Drill Guide across the fusion site with both guide legs contacting bone.

Drill the first hole to the proper depth using the laser marked Drill provided in the Kit.

2 Prepare second hole

Insert a Locator Pin into the first hole to maintain proper placement while the second hole is drilled. Drill second hole to the proper depth using the laser marked Drill.

3 Prepare & insert Staple

Remove the Inserter / Implant assembly from the sterile Kit.

Note - Compression loading. With the Staple firmly in the Inserter's metal prongs, slowly twist the top handle clockwise extending the internal plunger to spread the staple's legs.

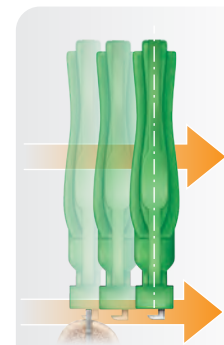
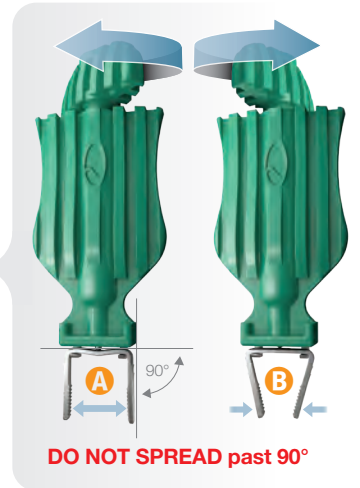
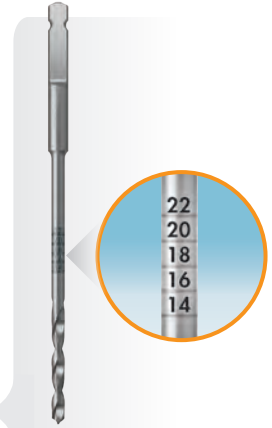
- A** Clockwise extends legs
- B** Counter clockwise releases

4 Release Staple & remove Inserter

Remove the Drill, Locator Pin and Drill Guide. While maintaining reduction, align and insert the tips of the NeoSpan SE Staple into the drilled holes. Press the NeoSpan SE Staple as flush to the bone as possible. Implant positioning may be evaluated radiographically. To release Staple and remove the Inserter, twist the top handle counter-clockwise to retract the internal plunger and disengage the implant. Slide the inserter horizontal and parallel*.

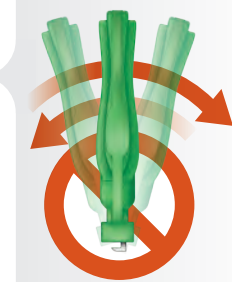
5 Seat Staple

Place the Tamp on the implant and apply pressure, manually or using a mallet, to fully seat the NeoSpan SE Staple.



Remove by sliding Inserter horizontally.

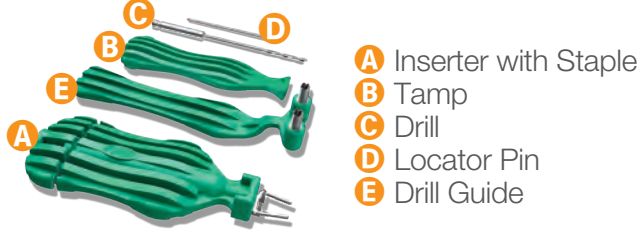
*DO NOT ROCK Vertically.



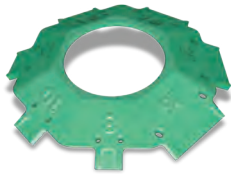
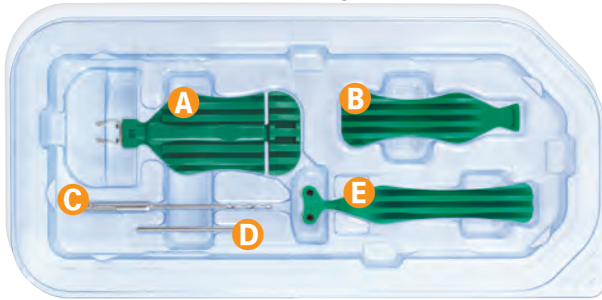
SUPERELASTIC COMPRESSION STAPLE

NeoSpan SE

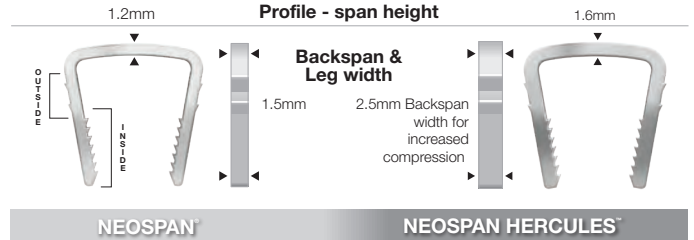
STERILE, SINGLE USE IMPLANT KIT / INSTRUMENTATION



Sterile Delivery Pack



Optional, Sterile NeoSpan SE Sizer / template available separately



NEOSPAN STAPLE / INSTRUMENT SETS

CAT NO.	DESCRIPTION	SIZE: A x B x C
T50 SN008...	Staple with Instruments, Sterile	8x8x8
T50 SN010...	Staple with Instruments, Sterile	10x10x10
T50 SN110...	Staple with Instruments, Sterile	10x15x13
T50 SN012...	Staple with Instruments, Sterile	12x12x12
T50 SN112...	Staple with Instruments, Sterile	12x15x13
T50 SN015...	Staple with Instruments, Sterile	15x12x12
T50 SN215...	Staple with Instruments, Sterile	15x15x15
T50 SN115...	Staple with Instruments, Sterile ...	15Wx15x15
T50 SN118...	Staple with Instruments, Sterile	18x14x14
T50 SN018...	Staple with Instruments, Sterile	18x16x16
T50 SN120...	Staple with Instruments, Sterile	20x15x15
T50 SN020...	Staple with Instruments, Sterile	20x20x20
T50 SN025...	Staple with Instruments, Sterile	25x22x22
T50 S0001 ...	NeoSpan Staple Sizer	

INDICATIONS

The In2Bones NeoSpan® Compression Staple Implant w/instruments is indicated for hand and foot bone fragments, osteotomy fixation and joint arthrodesis.

CONTRAINDICATIONS

- General contraindications for the use of these implants for fusion, osteotomy and arthrodesis include:
- Significant bone demineralization
 - Inadequate neurovascular status
 - Inadequate skin or musculotendinous system
 - Inadequate bone stock
 - Physiologically or Psychologically unsuitable patient
 - Possibility for conservative treatment
 - Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis
 - Known metal allergy
 - Diabetes
 - Active infection
 - Possibility of conservative treatment
 - Growing patients with open epiphyses
 - Patients with high level of activity

MANUFACTURER

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EC REP

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Prinsessegracht 20
2514 AP The Hague
The Netherlands

RECOMMENDATION

It is recommended to carefully read the instructions for use available in the package insert.

DEVICES

- Implants : Class IIb – CE2797
- Single use instruments and instruments connected to an active device: class IIa - CE2797
- Instruments with a measuring function : Class Im - CE2797

REIMBURSEMENT

Reimbursement may vary from countries to countries. Check with local authorities.

DOCUMENT

Reference : ST-DIG-NEOSPAN-SE-EN-072020

All content contained herein is furnished for informational purposes only. In2Bones does not recommend a particular surgical product or procedure suitable for all patients. Each surgeon must evaluate the appropriateness of a device and corresponding techniques based on medical training, clinical judgment and surgical experience. The proper surgical technique and/or procedure are the responsibility of the medical professional. Indications, contraindications, warnings, and precautions are listed in the implant package insert and should be reviewed carefully by the physician and operating room personnel prior to any proposed procedure. Availability of these products might vary from a given country or region to another as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

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



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