



Field Safety Notice

NeoSpan® SuperElastic Compression Staple w/ Instruments

08 May 2026

Dear Device Customer/Distributor:

(1) Purpose of Notification

The purpose of this notification is to advise you that In2Bones USA LLC (In2Bones), a CONMED Corporation owned company, is issuing a field safety notice (FSN) for the NeoSpan® SuperElastic Compression Staples with Instruments. In2Bones was notified by its supplier of an issue affecting certain lots of the NeoSpan® SuperElastic Compression Staples with Instruments, in which the Magnetic Resonance (MR) Conditional symbol was missing at the packaging level. This communication affects the catalog and lot numbers listed in **Table 1** below.

Table 1: Catalog and Lot Numbers

Catalog Number	Lot Number	Device Identifier	Device Name	Quantity Remaining in Field	Expiration Date
T50 SN010	1962242	00817906020083	NeoSpan® SuperElastic Compression Staple w/Instruments, Size 10x10x10	46	12AUG2030
	1964665			27	12AUG2030
	2054541			20	09JAN2031
	2039361			24	12JAN2031
T50 SN012	1963511	00817906020090	NeoSpan® SuperElastic Compression Staple w/Instruments, Size 12x12x12	38	12AUG2030
T50 SN020	1971252	00817906020151	NeoSpan® SuperElastic Compression Staple w/Instruments, Size 20x20x20	46	21AUG2030
	1990642			34	30SEP2030
	2027441			27	22DEC2030
T50 SN110	1971241	00817906020113	NeoSpan® SuperElastic Compression Staple w/Instruments, Size 10x15x13	5	21AUG2030
T50 SN115	19647210	00817906020137	NeoSpan® SuperElastic Compression Staple w/Instruments, Size 15Wx15x15	40	12AUG2030
T50 SN118	1990631	00810021861364	NeoSpan® SuperElastic Compression Staple w/Instruments, Size 18x14x14	0	30SEP2030



(2) Reason for the FSN:

The NeoSpan® SuperElastic Compression Staple w/Instruments are sold as sterile, single-use devices. In2Bones has identified that the above devices are missing the MR Conditional symbol on the carton, inner tray, and patient label. The NeoSpan® SuperElastic Compression Staple with Instruments have been tested under 1.5T and 3.0T Magnetic Resonance Imaging (MRI) conditions and have been confirmed to be safe when used in accordance with the specified MR Conditional requirements. However, the absence of the MR Conditional symbol on packaging levels such as the carton, inner tray, and patient label may expose patients to MRI related hazards. In2Bones has received no failures or complaints associated with this incident.

(3) Risk to Health:

3a) The NeoSpan® SuperElastic Compression Staple with Instruments has been evaluated under 1.5T and 3.0T MRI conditions and meets MR Conditional requirements when used as specified. However, the absence of the MR Conditional symbol on certain packaging levels (including the carton, inner tray, and patient label) could increase the risk of MRI-related hazards

3b) In some cases, the labeling issue may result in the delay of scheduling a surgical procedure while the end user reviews the IFU to ensure compliance with the applicable MR Conditional scanning criteria.

(4) Actions to be taken by the Customer/User:

The MR conditional use information included in the Instructions for Use are as follows

Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	30 T/m or 3,000 gauss/cm
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Volume RF Body Coil
Operating Mode	Normal
Maximum Whole-Body SAR	2 W/kg (normal operating mode)
Maximum Head SAR	3.2 W/kg (first level control mode)
Scan Duration	Under the scan conditions defined, patients can be scanned continuously for 10 minutes and wait time 20 minutes. This can be repeated up to 2 times in a 60-minute period.
MR Image Artifact	The presence of this implant may produce an image artifact at 10 mm away from the device.

If you have provided these devices to other facilities or distributors, or if you are a distributor, please forward this notice as appropriate. It is imperative that all end users of these devices receive this notice.

Customers must please follow the instructions below and respond directly to CONMED with their acknowledgement for the NeoSpan® SuperElastic Compression Staple w/Instruments.

Step 1: Please review your inventory for any of the devices with the affected lot numbers listed in **Table 1**. We ask that you contact all departments within your facility and any other facilities within your organization that may have received affected products. It is imperative that all end users of these devices receive this notice and respond immediately.



Step 2a: If you HAVE inventory of any of the devices from the affected lot numbers listed in **Table 1**, please complete the Field Safety Notice Response Form (Attachment I) and return acknowledgement via email to neospan2026@conmed.com.

Please do not return any devices, as this is a Medical Device Correction, not a Removal.

Step 2b: If the device has been implanted, please update the patient chart using the provided IFU, and complete the Field Safety Notice Response Form (Attachment I) and acknowledge it via email to neospan2026@conmed.com.

The affected products were distributed from August 12, 2025, through January 12, 2026.

(5) Product and Distribution Information:

Refer to **Table 1** above.

(6) Type of Action by the Company:

In2Bones has revised and updated the procedures and labeling to correct the incident.

(7) Other Information:

In2Bones remains committed to patient safety and to providing safe, reliable products to our customers. We uphold rigorous quality standards in the manufacture of our products and sincerely regret any inconvenience this matter may cause you or your staff.

The appropriate international competent authorities have been notified of this action.

If you have any questions or requests, please contact the Field Action Support Team at 1-800-448-6506 (8:00am to 7:00pm ET, Monday through Friday) or email neospan2026@conmed.com.

Sincerely,

A handwritten signature in blue ink that reads 'Kavita Amin'.

Kavita Amin
Regulatory Affairs Manager and Recall Coordinator

Attachments:

NeoSpan Compression Staple Instructions for Use (IFU-15002-01, Rev. K)



ATTACHMENT I
FIELD SAFETY NOTICE RESPONSE FORM
Response is Required

NeoSpan® SuperElastic Compression Staples with Instruments

Affected Catalog Numbers: T50 SN010, T50 SN012, T50 SN020, T50 SN110, T50 SN115, T50 SN118
Affected Lot Numbers: 1962242, 1964665, 2054541, 2039361 1963511, 1971252, 1990642, 2027441, 1971241, 19647210, 1990631

I have read and understood the MR conditional use criteria provided in the letter 08 May 2026. Yes No

In addition, please check all that apply:

- We **DO NOT** have any stock of the affected lots as referenced in **Table 1**.
- We **HAVE** stock of the affected lots as referenced in **Table 1**.
- We have forwarded this field safety notice to all our end users and/or distributors.
- One or more devices received have been implanted. The charts of all affected patients will be updated with the use criteria listed in the attached IFU.

Have you identified any adverse events associated with the affected products? Yes No

If yes, please explain:

Signature Acknowledging Receipt: _____

Account # (if available):	
Name/Title:	
Address:	
Telephone #:	
Email Address:	

Please return this completed response form via email to neospanspan2026@conmed.com as soon as possible.