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Legal manufacturer
Endospan
4 Maskit Street, Herzliya, 4673304 Israel

Coordinating organization and contact for questions and acknowledgment forms:
Artivion, Inc.
1655 Roberts Blvd.
Kennesaw, GA 30144, USA
Email: fieldactions@artivion.com

Urgent: Field Safety Notice
NEXUS Supplemental Bailout Technique

Dear Healthcare Professional,

Reason for Field safety notice:
Endospan (an Artivion Affiliate), is issuing this field safety notice notice due to reported difficulty releasing the stent graft of NEXUS™ Aortic Arch Stent Graft System (NEXUS System). The NEXUS System includes an Arch Stent Graft, an Ascending Stent Graft (Ascending Graft) along with an optional Descending Extension Stent Graft. Difficulty releasing the stent graft has been encountered for the Arch Stent Graft and Ascending Graft, which have similar delivery systems. See Appendix I for list of NEXUS™ Aortic Arch Stent Graft System part numbers. This field safety notice affects all lots of Nexus Aortic Arch Stent Graft Systems.

Note that this field safety notice does not require product use to be discontinued or returned; rather, this field safety notice is intended to provide additional instructions. No actions are required for patients already implanted with a NEXUS System.

Risk To Health:
Potential risks associated with incomplete release wire removal include extended procedure time, inaccurate stent graft deployment, branch vessel coverage or occlusion, additional endovascular treatment or surgical conversion, vascular injury, embolic or other neurological complications including stroke, and potentially death.

Reported Events:
Between April 2024 and September 2026, Endospan received 5 complaints/adverse reports of Arch or Ascending Stent Graft procedures worldwide in which physicians experienced difficulty releasing the release wires, which represents a total estimated occurrence rate of 0.44% during this time period. Four of the complaints resulted in reported clinical consequences that included stent graft migration or

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suboptimal positioning requiring additional stent or stent graft implantation. One complaint reported a patient experiencing a stroke, followed by intracranial hemorrhage during thrombectomy and death.

Standard Release-wire Steps and Supplemental Bailout Instructions:

If release wire withdrawal cannot be completed using the standard deployment instructions in the applicable IFU, first perform the initial release wire troubleshooting technique described below in Technique 1. This technique addresses loss of tension in the capture release mechanism. If unsuccessful, proceed to the supplemental manual withdrawal procedure detailed in Technique 2.

Technique 1:

If the capture release mechanism fails to maintain release wire tension, rotate the roller knob to build tension on the release wires. While maintaining tension with one hand, reposition the other hand to continue rotating without reverse rotation of the knob. Repeat until full stent graft release is confirmed under fluoroscopy. If the release wires cannot be withdrawn, proceed to Technique 2 below.

Technique 2:

1. Using a 2.5mm hexagonal (6-sided) wrench (Figure 1), remove the two (2) set screws on the underside of the delivery system handle that secure the release mechanism handle cover (Figure 2).
2. Remove the handle cover to expose the nitinol release wires (Figure 3).
3. One at a time, manually grasp each of the exposed wires using hemostats and pull on the wire in the direction away from the delivery system to complete stent graft release.



Figure 1


Figure 2



Figure 3

For both adjunctive release wire techniques, fluoroscopy should be used to ensure the stent graft remains in the desired anatomical location.

If both additional bailout procedures are unsuccessful (e.g., if one or more release wires cannot be located or accessed after opening the handle), the inability to withdraw the wires may result in further procedural delays. In such cases, physicians should use their clinical judgment to determine the most appropriate course of action, which may include alternative endovascular techniques, surgical cut-down, or conversion to open surgery.

Corrective Actions

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Artivion is actively investigating the reported release wire withdrawal difficulties to identify potential contributing factors and determine the underlying cause(s). While the investigation remains ongoing, the supplemental bailout instructions are being provided as an immediate risk mitigation measure. Artivion will evaluate the investigation findings and implement any additional corrective actions determined to be necessary to address the identified risks and prevent recurrence.

Actions to be Taken:

1. You may continue to use the device as is. For those instances in which you experience release wire challenges, please follow the supplemental bailout techniques to assist should the standard release procedure described in the Instructions for Use (IFU) prove unsuccessful.

2. Please circulate this notice to all those who require awareness within your organization or to any organization to whom the affected devices have been transferred.

3. Complete and return the attached Confirmation of Notification to the Endospan contact identified on the form, whether or not affected devices remain in your inventory, so that receipt of this Field Safety Notice can be documented.

4. Report suspected adverse events or device malfunctions associated with the NEXUS System to Artivion Customer Service at +49-7471-922-300 or fieldactions@artivion.com. Adverse incidents may also be reported to the appropriate national competent authority in accordance with local requirements.

We remain firmly committed to the quality, safety, and performance of our products and are actively investigating this issue to identify its root cause.

We appreciate your assistance and prompt attention to this matter. If you have questions or require clarification, please contact Customer Service at +49-7471-922-300 or fieldactions@artivion.com. Thank you for your cooperation in this matter

Sincerely,

Artivion Field Assurance Team

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Confirmation of Notification

I have read and understand the recall instructions provided in the letter. Yes __ No__

Any adverse events associated with recalled product? Yes __ No __

If yes, please explain:

_____
_____
_____

Return this signed Confirmation of Notification to fieldaction@artivion.com confirming that the above instructions have been received and understood.

_____
Hospital Representative

_____ _____
Signature, Title Date

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Appendix I- List of NEXUS™ Aortic Arch Stent Graft System part numbers

UDI Barcode Number	Catalog #	Description
07290116281117	ESN200MSCP142032180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L20, Ø32-L180
07290116281124	ESN200MSCP172032180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L20, Ø32-L180
07290116281131	ESN200MSCP142036180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L20, Ø36-L180
07290116281148	ESN200MSCP172036180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L20, Ø36-L180
07290116281155	ESN200MSCP142040180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L20, Ø40-L180
07290116281162	ESN200MSCP172040180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L20, Ø40-L180
07290116281179	ESN200MSCP202040180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L20, Ø40-L180
07290116281186	ESN200MSCP142044180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L20, Ø44-L180
07290116281193	ESN200MSCP172044180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L20, Ø44-L180
07290116281209	ESN200MSCP202044180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L20, Ø44-L180
07290116281216	ESN200MSCP202032180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L20, Ø32-L180
07290116281223	ESN200MSCP202036180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L20, Ø36-L180
07290116281230	ESN200MSCP143032180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L30, Ø32-L180
07290116281247	ESN200MSCP173032180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L30, Ø32-L180
07290116281254	ESN200MSCP143036180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L30, Ø36-L180
07290116281261	ESN200MSCP173036180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L30, Ø36-L180
07290116281278	ESN200MSCP143040180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L30, Ø40-L180
07290116281285	ESN200MSCP173040180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L30, Ø40-L180
07290116281292	ESN200MSCP203040180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L30, Ø40-L180
07290116281308	ESN200MSCP143044180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L30, Ø44-L180
07290116281315	ESN200MSCP173044180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L30, Ø44-L180
07290116281322	ESN200MSCP203044180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L30, Ø44-L180
07290116281339	ESN200MSCP203032180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L30, Ø32-L180
07290116281346	ESN200MSCP203036180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L30, Ø36-L180
07290116281353	ESN200MSCP144032180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L40, Ø32-L180
07290116281360	ESN200MSCP174032180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L40, Ø32-L180
07290116281377	ESN200MSCP144036180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L40, Ø36-L180
07290116281384	ESN200MSCP174036180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L40, Ø36-L180
07290116281391	ESN200MSCP144040180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L40, Ø40-L180
07290116281407	ESN200MSCP174040180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L40, Ø40-L180
07290116281414	ESN200MSCP204040180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L40, Ø40-L180
07290116281421	ESN200MSCP144044180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L40, Ø44-L180
07290116281438	ESN200MSCP174044180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L40, Ø44-L180
07290116281445	ESN200MSCP204044180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L40, Ø44-L180
07290116281452	ESN200MSCP204032180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L40, Ø32-L180
07290116281469	ESN200MSCP204036180	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L40, Ø36-L180
07290116281476	ESN200MSCP142032160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L20, Ø32-L160
07290116281483	ESN200MSCP172032160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L20, Ø32-L160
07290116281490	ESN200MSCP142036160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L20, Ø36-L160
07290116281506	ESN200MSCP172036160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L20, Ø36-L160
07290116281513	ESN200MSCP142040160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L20, Ø40-L160
07290116281520	ESN200MSCP172040160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L20, Ø40-L160
07290116281537	ESN200MSCP202040160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L20, Ø40-L160
07290116281544	ESN200MSCP142044160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L20, Ø44-L160
07290116281551	ESN200MSCP172044160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L20, Ø44-L160
07290116281568	ESN200MSCP202044160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L20, Ø44-L160
07290116281575	ESN200MSCP202032160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L20, Ø32-L160
07290116281582	ESN200MSCP202036160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L20, Ø36-L160
07290116281599	ESN200MSCP143032160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L30, Ø32-L160
07290116281605	ESN200MSCP173032160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L30, Ø32-L160
07290116281612	ESN200MSCP143036160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L30, Ø36-L160

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07290116281629	ESN200MSCP173036160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L30, Ø36-L160
07290116281636	ESN200MSCP143040160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L30, Ø40-L160
07290116281643	ESN200MSCP173040160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L30, Ø40-L160
07290116281650	ESN200MSCP203040160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L30, Ø40-L160
07290116281667	ESN200MSCP143044160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L30, Ø44-L160
07290116281674	ESN200MSCP173044160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L30, Ø44-L160
07290116281681	ESN200MSCP203044160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L30, Ø44-L160
07290116281698	ESN200MSCP203032160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L30, Ø32-L160
07290116281704	ESN200MSCP203036160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L30, Ø36-L160
07290116281711	ESN200MSCP144032160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L40, Ø32-L160
07290116281728	ESN200MSCP174032160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L40, Ø32-L160
07290116281735	ESN200MSCP144036160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L40, Ø36-L160
07290116281742	ESN200MSCP174036160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L40, Ø36-L160
07290116281759	ESN200MSCP144040160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L40, Ø40-L160
07290116281766	ESN200MSCP174040160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L40, Ø40-L160
07290116281773	ESN200MSCP204040160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L40, Ø40-L160
07290116281780	ESN200MSCP144044160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø14-L40, Ø44-L160
07290116281797	ESN200MSCP174044160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø17-L40, Ø44-L160
07290116281803	ESN200MSCP204044160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L40, Ø44-L160
07290116281810	ESN200MSCP204032160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L40, Ø32-L160
07290116281827	ESN200MSCP204036160	CE NEXUS System Gen 2.0: Arch Stent-Graft Branch Ø20-L40, Ø36-L160
07290116281834	ESN200AOC3670	CE NEXUS System Gen 2.0: Ascending Curved Stent-Graft Ø36mm, L=70mm
07290116281841	ESN200AOC4070	CE NEXUS System Gen 2.0: Ascending Curved Stent-Graft Ø40mm, L=70mm
07290116281858	ESN200AOC4370	CE NEXUS System Gen 2.0: Ascending Curved Stent-Graft Ø43mm, L=70mm
07290116281865	ESN200AOC3655	CE NEXUS System Gen 2.0: Ascending Curved Stent-Graft Ø36mm, L=55mm
07290116281872	ESN200AOC4055	CE NEXUS System Gen 2.0: Ascending Curved Stent-Graft Ø40mm, L=55mm
07290116281889	ESN200AOC4355	CE NEXUS System Gen 2.0: Ascending Curved Stent-Graft Ø43mm, L=55mm
07290116281896	ESN200AOC3640	CE NEXUS System Gen 2.0: Ascending Curved Stent-Graft Ø36mm, L=40mm
07290116281902	ESN200AOC4040	CE NEXUS System Gen 2.0: Ascending Curved Stent-Graft Ø40mm, L=40mm
07290116281919	ESN200AOC4340	CE NEXUS System Gen 2.0: Ascending Curved Stent-Graft Ø43mm, L=40mm
07290116281926	ESN200ASC3650	CE NEXUS System Gen 2.0: Ascending Straight Stent-Graft Ø36mm, L=50mm
07290116281933	ESN200ASC4050	CE NEXUS System Gen 2.0: Ascending Straight Stent-Graft Ø40mm, L=50mm
07290116281940	ESN200ASC4350	CE NEXUS System Gen 2.0: Ascending Straight Stent-Graft Ø43mm, L=50mm
07290116281957	ESN200ASC3660	CE NEXUS System Gen 2.0: Ascending Straight Stent-Graft Ø36mm, L=60mm
07290116281964	ESN200ASC4060	CE NEXUS System Gen 2.0: Ascending Straight Stent-Graft Ø40mm, L=60mm
07290116281971	ESN200ASC4360	CE NEXUS System Gen 2.0: Ascending Straight Stent-Graft Ø43mm, L=60mm
07290116281988	ESN200ASC3675	CE NEXUS System Gen 2.0: Ascending Straight Stent-Graft Ø36mm, L=75mm
07290116281995	ESN200ASC4075	CE NEXUS System Gen 2.0: Ascending Straight Stent-Graft Ø40mm, L=75mm
07290116282008	ESN200ASC4375	CE NEXUS System Gen 2.0: Ascending Straight Stent-Graft Ø43mm, L=75mm
07290116282022	ESN200DETS3612531	CE NEXUS System Gen 2.0: Descending Extension Tapered Stent-Graft ØPROX36mm, L=125mm, ØDIST31mm
07290116282046	ESN200DETS4012536	CE NEXUS System Gen 2.0: Descending Extension Tapered Stent-Graft ØPROX40mm, L=125mm, ØDIST36mm
07290116282169	ESN200DETS4313040	CE NEXUS System Gen 2.0: Descending Extension Tapered Stent-Graft ØPROX43mm, L=130mm, ØDIST40mm
07290116282077	ESN200DETS3615731	CE NEXUS System Gen 2.0: Descending Extension Tapered Stent-Graft ØPROX36mm, L=157mm, ØDIST31mm
07290116282091	ESN200DETS4015736	CE NEXUS System Gen 2.0: Descending Extension Tapered Stent-Graft ØPROX40mm, L=157mm, ØDIST36mm
07290116282176	ESN200DETS4316240	CE NEXUS System Gen 2.0: Descending Extension Tapered Stent-Graft ØPROX43mm, L=162mm, ØDIST40mm
07290116282121	ESN200DETS3618931	CE NEXUS System Gen 2.0: Descending Extension Tapered Stent-Graft ØPROX36mm, L=189mm, ØDIST31mm

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07290116282145	ESN200DETS4018936	CE NEXUS System Gen 2.0: Descending Extension Tapered Stent-Graft ØPROX40mm, L=189mm, ØDIST36mm
07290116282183	ESN200DETS4319440	CE NEXUS System Gen 2.0: Descending Extension Tapered Stent-Graft ØPROX43mm, L=194mm, ØDIST40mm
07290116282015	ESN200DECS3112531	CE NEXUS System Gen 2.0: Descending Extension Stent-Graft ØPROX31mm, L=125mm, ØDIST31mm
07290116282039	ESN200DECS3612536	CE NEXUS System Gen 2.0: Descending Extension Stent-Graft ØPROX36mm, L=125mm, ØDIST36mm
07290116282053	ESN200DECS4012540	CE NEXUS System Gen 2.0: Descending Extension Stent-Graft ØPROX40mm, L=125mm, ØDIST40mm
07290116282190	ESN200DECS4313243	CE NEXUS System Gen 2.0: Descending Extension Stent-Graft ØPROX43mm, L=132mm, ØDIST43mm
07290116282060	ESN200DECS3115731	CE NEXUS System Gen 2.0: Descending Extension Stent-Graft ØPROX31mm, L=157mm, ØDIST31mm
07290116282084	ESN200DECS3615736	CE NEXUS System Gen 2.0: Descending Extension Stent-Graft ØPROX36mm, L=157mm, ØDIST36mm
07290116282107	ESN200DECS4015740	CE NEXUS System Gen 2.0: Descending Extension Stent-Graft ØPROX40mm, L=157mm, ØDIST40mm
07290116282206	ESN200DECS4316643	CE NEXUS System Gen 2.0: Descending Extension Stent-Graft ØPROX43mm, L=166mm, ØDIST43mm
07290116282114	ESN200DECS3118931	CE NEXUS System Gen 2.0: Descending Extension Stent-Graft ØPROX31mm, L=189mm, ØDIST31mm
07290116282138	ESN200DECS3618936	CE NEXUS System Gen 2.0: Descending Extension Stent-Graft ØPROX36mm, L=189mm, ØDIST36mm
07290116282152	ESN200DECS4018940	CE NEXUS System Gen 2.0: Descending Extension Stent-Graft ØPROX40mm, L=189mm, ØDIST40mm
07290116282213	ESN200DECS4320043	CE NEXUS System Gen 2.0: Descending Extension Stent-Graft ØPROX43mm, L=200mm, ØDIST43mm

List of Nexus Multi Branch

Catalog #	Description
ENDCMD0001	**NEXUS DUO**
ENDCMD0002	**NEXUS TRE**

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Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Shiran Mor Yossef	QA/RA Director	11-Nov-2026 09:25
Review	Doc-Control (Sharon Katherine Haviv)	Senior Quality Manager	11-Nov-2026 12:13
Send for Approval	Shiran Mor Yossef	QA/RA Director	11-Nov-2026 12:19
Approve	Shiran Mor Yossef	QA/RA Director	11-Nov-2026 12:20
QA Approval - Skip Training	Shiran Mor Yossef	QA/RA Director	11-Nov-2026 12:20

* Dates are displayed according to the system time zone: (GMT+02:00) Israel Standard Time (Asia/Jerusalem)