

AAA Devices and Revision Procedures FAQs

Entering an aortic device

Within the procedure page of a AAA repair record on the NVR, there is now a devices section where you can record the implanted devices used.

There are two main ways to enter a device:

1. Select the manufacturer from the dropdown list and search for it using the product code
2. Scan the long barcode on the device sticker label

We have worked with the Association of

British HealthTech Industries (ABHI) to approach all the companies that manufacturer aortic devices and accessories. The vast majority of companies and devices should be included in the NVR, but we appreciate that not all are. If you are unable to find a device, please email the NVR inbox (nvr@rcseng.ac.uk) with the company's name, device name/description, product code and barcode number. We will then endeavour to see if the device can be added in the future.

Devices

Find Implant(s)

Manufacturer ⓘ

* Product Number ⓘ

* OR: Scan Barcode ⓘ

Matching Implant(s)

Manufacturer	Product Number	Brand Name	Description	GTIN	Select
<div style="display: flex; justify-content: space-between; align-items: center;"> ⏪ ⏩ 0 ⏪ ⏩ No items to display </div>					

If the required Component cannot be found and needs to be added to the system, please e-mail the NPS Support Team with the Component Manufacturer Name, Catalogue Number and Description.

Selected Implant(s)

Manufacturer * Batch/Lot Number

Product Number GTIN

Description

* Was this Device used on IFU? No Yes ⓘ

1. Manually entering the device information

These are the steps to follow to enter a device manually:

- Select the manufacturer from the drop-down list.
- In the Product Number field enter the product number on the device barcode sticker.
- Click 'Search' (the Scan Barcode field can be left blank).
- If the device can be found, the details will be shown below. Click on the 'Select' check box and then click on the Select button to add it to the procedure.
- Enter the batch/lot number from the device barcode sticker.
- Answer the question on whether the device was used on IFU or not.
- Ensure that you save the page by clicking on the 'Save' button or the 'Previous' or 'Next' button at the bottom of the page.
- Repeat the steps above for every device component.

The screenshots illustrate the manual entry process in three stages:

- Find Implant(s):** The user selects a manufacturer from a dropdown menu and enters the product number (PLA280300) in the 'Product Number' field. The 'Scan Barcode' field is empty.
- Matching Implant(s) - Exact Match:** The search results show a table with columns: Manufacturer, Product Number, Brand Name, Description, GTIN, and Select. A row is shown for W.L. Gore & Associates with product number PLA280300 and description 'EVAR Endovascular Stent Graft Aortic Extender Endoprosthesis: 28.5 mm, 3.3 cr'. The 'Select' checkbox is checked.
- Selected Implant(s):** The details for the selected device are shown, including the manufacturer (W.L. Gore & Associates), product number (PLA280300), and GTIN (00733132618781). The 'Batch/Lot Number' field is empty, and the 'Was this Device used on IFU?' checkbox is unchecked.

2. Scan the long barcode on the device sticker label

These are the steps you need to follow to scan a device barcode:

- Ensure your USB barcode scanner is plugged into your computer (we advise using a 2D scanner that is capable of scanning 'normal' barcodes and the newer QR codes).
- Click into the text box entitled 'OR: Scan Barcode' and scan the barcode.
- If scanned successfully, the long barcode number should appear in the box.
- Click 'Search' (the manufacturer and product number fields can be left blank).
- If the device can be found, the details will be shown below. Click on the 'Select' check box and then click on the Select button to add it to the procedure.
- The batch/lot number should automatically be populated (as this can be read from the long barcode number). If not, add the batch/lot number from the device barcode sticker.
- Answer the question on whether the device was used on IFU or not.
- Ensure that you save the page by clicking on the 'Save' button or the 'Previous' or 'Next' button at the bottom of the page.
- Repeat the steps above for every device component.




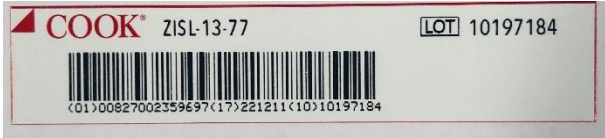
The screenshots illustrate the barcode scanning process in three stages:





- OR: Scan Barcode:** The user scans a long barcode, and the number '010073313261848411170518172005172116318903240RLT35' is entered into the 'OR: Scan Barcode' field.
- Matching Implant(s) - Exact Match:** The search results show a table with columns: Manufacturer, Product Number, Brand Name, Description, GTIN, and Select. A row is shown for W.L. Gore & Associates with product number RLT351416 and description 'EVAR Endovascular graft Trunk-Ipsilateral Leg Endoprosthesis: 35 mm, 14.5 mm'. The 'Select' checkbox is checked.
- Selected Implant(s):** The details for the selected device are shown, including the manufacturer (W.L. Gore & Associates), product number (RLT351416), and GTIN (00733132618484). The 'Batch/Lot Number' field is automatically populated with '20051721', and the 'Was this Device used on IFU?' checkbox is unchecked.


Current aortic device manufacturers included on the NVR (07/02/2022)




Company Name	On NVR Dropdown List?	Able to add devices?	Comments
B. Braun Aesculap	Yes	Yes	
Bard/BD	Yes	Yes	
Bentley Innomed	Yes	Yes	
Boston Scientific	Yes	No	
BVM Medical	Yes	No	
Cook Medical	Yes	Yes	
Cordis, A Cardinal Health Company	Yes	Yes	
CryoLife Inc. (includes Jotec)	Yes	Yes	
Endologix Inc.	Yes	Yes	
Getinge (includes Advanta, Maquet, Hemagard and Intergard)	Yes	Yes	
LeMaitre Vascular	Yes	Yes	
Lombard Medical	Yes	Yes	
Medtronic Inc.	Yes	Yes	
Terumo Aortic (includes Vascutek)	Yes	Yes	
W.L Gore & Associates Inc.	Yes	Yes	

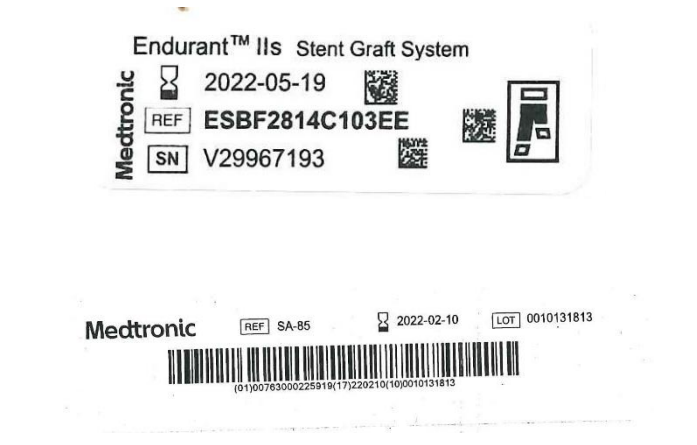

How to record devices from each company

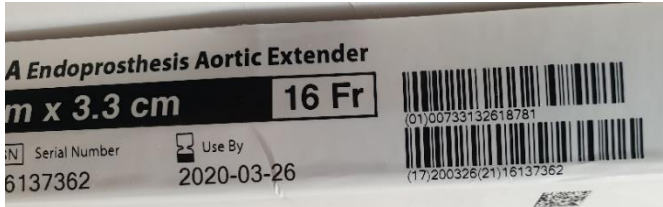
Company	Product Name	Product Number starts with	Batch/Lot number format	Example Barcodes
B. Braun Aesculap	Uni-Graft or Silver Graft	110	Starts with a 2	
Bard/BD	Fluency Lifestream	FVL or FVM LSM	Starts with AN	
Bentley Innomed	BeGraft Aortic BeGraft Peripheral BeSmooth	BGA BGP BSP	Starts with a 2	
Cook Medical	Custom-made infrarenal bifurcated Custom-made infrarenal inverted limb Custom-made branched graft Custom-made infrarenal inverted leg Custom-made infrarenal with fenestration Custom-made infrarenal Custom-made iliac leg extension Custom-made proximal body extension Zenith Renu ancillary graft converter Custom-made bifurcated with fenestrations Custom-made distal thoracic Zenith TAA distal extension Zenith flex converter Custom-made with fenestrations Formula balloon expandable stent Zenith dissection stent Custom-made iliac limb Embolisation coil Custom-made pre-loaded fenestrated Custom-made proximal thoracic Custom-made reinforced iliac side branch	AAA-BIF AAA-BODY AAA-BRANCH AAA-DIS AAA-FEN or AAA-REI AAA-INFRA AAA-LEG AAA-PROX AX1 BIFU DISTAL ESBE ESC FEN FOV GZSD HELICAL IMWC or MWCE PRE PROXIMAL REIN SIDE	Various formats. Lot number clearly documented on device label.	  

	<p>Custom-made side branch occluder Zenith TX2 proximal extension Zenith off the shelf thoraco-abdominal branch Zenith Flex Bifurcated main body Custom-made thoracic/thoraco branched Universal distal body grafts Zenith Iliac bifurcation graft Zenith TX2 dissection graft Zenith dissection stent Zenith Fenestrated body graft Zilver flex self-expanding stent Zenith Alpha main body Zenith iliac plug Zenith Alpha iliac leg graft Zilver drug eluting stent Zilver self-expanding stent Zenith Alpha main body extension Zenith Alpha converter Zenith iliac leg graft Zenith Alpha thoracic distal Zenith Alpha thoracic distal extension Zenith Alpha thoracic proximal Zenith TX2 TAA Zilver self-expanding stent</p>	<p>TBE TBRANCH TFFB THORAC UNIBODY ZBIS ZDEG ZDES ZFEN ZFV ZIMB ZIP ZISL ZISV ZIV ZLBE ZLC ZSLE ZTA-D ZTA-DE ZTA-P or ZTA-PT ZTEG ZVS</p>		
<p>Cordis, A Cardinal Health Company</p>	<p>Aortic bifurcate Aortic extension Iliac</p>	<p>AB AE IL</p>	<p>Starts with 17</p>	<p>  Cordis Cashel, Cahir Road Cashel, Co Tipperary, Ireland INCRAFT® AAA Stent Graft System LOT 17893850 REF AB3098  (01)20705032065099(21)1788956113  (17)210831(10)17893850</p>
<p>CryoLife Inc.</p>	<p>FlowLine FlowNit</p>	<p>10SW,10TW, 15SW or 15TW 35ST</p>	<p>Most start with 11</p>	

(includes Jotec)	FlowWeave E-NSIDE E-Liac E-Nya E-ventus E-tegra Custom devices	45ST 65MU 72IB 90SO or 90TC 91BX 93 V00CDM		
Endologix Inc.	VELA AFX2 Limb extension Alto/ovation Ovation extension Ovation iliac limb	A25, A28, or A34 BEA I16, I20, or IS20 TV-AB TV-EX TV-IL	Most start with FS	 <p>The image shows two medical device labels. The top label is for the Alto™ Abdominal Stent Graft System, size 34mm. It includes a reference number (REF) TV-AB3480-L, an expiration date (2023-08-03), and a lot number (LOT) FS072920-23. The bottom label is for the OVATION iX™ ILIAC STENT GRAFT, size 10mm x 160mm. It includes a reference number (REF) TV-IL1410160-I, an expiration date (2022-04), and a lot number (LOT) FS021519-14. Both labels feature barcodes and a unique device identifier (UDI).</p>

<p>Getinge (includes Advanta, Maquet, Hemagard and Intergard)</p>	<p>Advanta V12 Intergard or Hemapatch Hemagard knitted Intergard knitted Intergard woven Fusion Hemashield</p>	<p>853 HEW HGK IGK IGW M00 M00</p>	<p>V12 lot number is the SN on the label – starts with 4. For open repair grafts, lot number is clear on the label.</p>	 
<p>LeMaitre Vascular</p>	<p>Dialine Omniflow AlboGraft XenoSure Pledget Wovex</p>	<p>24 741 or 751 AMC, ASC, or ATC PL W</p>	<p>Lot number is clear on label.</p>	
<p>Lombard Medical</p>	<p>Altura Aorfix Hercules Minos</p>	<p>01 CL, DE, MB or PE HT CC, CL or CM</p>		

<p>Medtronic Inc.</p>	<p>Endurant Endurant cuff Endurant iliac Endurant limb Endurant tube Endurant aorto-iliac Endoanchor Occluder Valiant Captivia Valiant Navion</p>	<p>ESFB or ETFB ETCF ETEW ETLW ETTF ETUF HA, HG, SA, or SG OCL VAM VNM</p>	<p>The lot number is the SN on the label. Most start with a V.</p>	 <p>Endurant™ IIs Stent Graft System Medtronic 2022-05-19 REF ESBF2814C103EE SN V29967193</p> <p>Medtronic REF SA-85 2022-02-10 LOT 0010131813</p>
<p>Terumo Aortic (includes Vascutek)</p>	<p>Gelseal Gelsoft/Gelsoft Plus Gelweave Treo AUI Treo body Treo cuff Treo extension Anaconda cuff Anaconda flared limb Anaconda limb Anaconda body Anaconda tapered limb Custom Anaconda Custom flared fenestrated limb</p>	<p>43, 44, 45, 46, 47, or 49 63, 64, 65, 66, 67, 68, or 69 73 28-A1 28-B2 28-C2 28-L2 AEC AFL AL ALP ATL CFD CFLF</p>	<p>Lot number is clear on label.</p>	 <p>GTIN 05037881107059 REF 733018 LOT 17392741-1408 SN 2002594572 2021-07-31 18mm 30cm 733018-G CFD32-703 LOT 21470117 3391 SN 2002899862</p>

<p>W.L Gore & Associates Inc.</p>	<p>Viabahn balloon expandable stent Iliac branch Aortic extender Trunk-ipsilateral leg Internal iliac component Viabahn self-expanding stent Contralateral leg Iliac extender Stretch vascular graft TAG thoracic stent graft</p>	<p>BXA CEB CXA or PLA CXT or RLT HGB PAH or PAJ PLC PLL SA TGM</p>	<p>Lot number is the SN on the label.</p>	
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Dataset changes for aortic re-interventions

The dataset has also been amended so that it's now possible to capture aortic re-interventions in more detail.

The question on whether a patient has had a previous aortic repair has been moved higher up in the pre-op screen on the NVR.

Upon ticking anything but 'No,' 2 new questions appear – 'Indication for Re-intervention' and 'Pre-operative Endoleak.'

Pathway and Indications

* AAA/Aortic Diameter (mm) ⓘ

* Previous Aortic op No ⓘ
 Open repair
 Endovascular repair
 AAA repair - type unknown
 Both open and EVAR

* Indication for Re-intervention AAA sac expansion ⓘ
 Graft migration
 Graft stenosis or occlusion
 Graft infection
 New arterial disease (proximal or distal to original arterial graft)
 Pseudo-aneurysm
 Other

* Pre-operative Endoleak No endoleak ⓘ
 Type 1
 Type 2
 Type 3
 Type 4
 Type 5

A new question in the procedure page now appears, where you can select what re-intervention procedure(s) the patient had.

Additional OPCS codes have also been added to the page so it should be possible to record the correct one.

* Re-intervention procedure(s) Explant (partial or total)
 Extra-anatomical bypass
 Relining
 Endoanchors/Bare metal stent/Banding
 Distal extension
 Ligation of aortic branches
 Embolisation
 Proximal extension cuff/Fenestrated cuff
 Other

Other changes to the AAA dataset

Two new non-mandatory questions have been added to the risk scoring page for non-elective admissions – 'Highest Pulse Pre-op' and 'Lowest Systolic BP Pre-op.'

These were in the old NVD dataset, but not included in the NVR dataset in 2014. Despite poor levels of completeness, they were shown to be strong predictors of risk in a recent re-analysis of old data by the NVR team.

The questions on 'Neck angle,' 'Neck diameter,' and 'Neck length' have been added for open repairs.

This is in order to allow for better comparison of the patient's anatomy when comparing open and endovascular repairs.

* Haemoglobin [g/dl] ⓘ

* Sodium [mmol/l] ⓘ

* Potassium [mmol/l] ⓘ

* Creatinine [μ mol/l] ⓘ

Albumin [g/l] ⓘ

Highest Pulse Pre-op ⓘ

Lowest Systolic BP Pre-op ⓘ

* Type of Repair Open ⓘ
 EVAR
 Complex EVAR
 Revision Open
 Revision EVAR
 EVAS

* OPCS code of procedure 1 ⓘ

OPCS code of procedure 2 ⓘ

OPCS code of procedure 3 ⓘ

* Neck angle ⓘ

* Neck diameter (mm) ⓘ

* Neck length (mm) ⓘ

* AAA Clamp site ⓘ

* AAA Graft Tube ⓘ
 Bifurcated
 Any Groin Incision