



# DEVICE REMANUFACTURE 'HOW TO' GUIDE

## MEDICAL DEVICES



# The Business Case



Many medical devices (e.g. catheters and surgical instruments) are durable and expensive products that can be remanufactured to quality assured standards, extending their useful life, offering carbon and cost savings.

Why remanufacture

Remanufacture roadmap

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## Revenue and savings

Generate income through collection of used devices.  
Remanufactured products cost upto 50% less. NHS Supply Chain gain-share returns offer 80% of savings back to trusts.



## Quality assured

Remanufactured devices are regulated in line with MHRA guidelines and must be CE marked to be on the market.  
All products are checked for safety, performance and conformity assessment. A unique identifier ensures traceability.



## Greener NHS ambition

Remanufactured devices generate 50% less CO<sub>2</sub> emissions, avoiding extraction and consumption of new material.  
Device reuse contributes to the NHS Net Zero Plus target and trusts Green Plan delivery actions.



## Ease of implementation

Setting up a collection scheme is simple, and remanufactured devices can be purchased through NHS Supply Chain.

**'The use of remanufactured circular mapping catheters is safe, efficient and reliable. Widespread use of remanufactured single use devices offers the possibility of significant economic benefit'**

*[Leung et al. Journal of Interventional Cardiac Electrophysiology](#)*

## Case study example

Leeds General Infirmary Cath Labs diverted over 102 kg of waste, generated over £13k in revenue, and a further 50% savings of some £12k to the NHS for remanufactured devices used in 2020 alone.

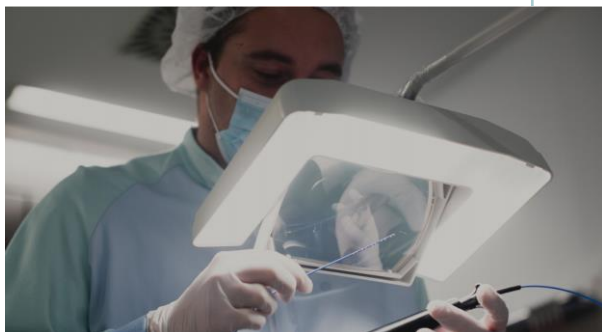


# NHS wide cost and carbon savings



There is substantial potential to accelerate the number of SUDs collected, remanufactured and reused across the NHS, with most participating hospitals focussing on device collection to date. NHS potential is based on sites undertaking electrophysiology procedures and will increase with the inclusion of the broader portfolio of remanufactured devices.

	2020	2021 (Q2)	NHS potential
Hospitals on board - collections	24	34	62+
Devices collected	18,094	12,032	22,000
Weight of devices collected	1,476 kg	1,799 kg	3.3 tonnes
<b>Payments for collections</b>	<b>£142,037</b>	<b>£94,152</b>	<b>£170k</b>
Hospitals on board - purchase	1	4	62+
Remanufactured devices purchased	81 (one trial site)	502	7.7k
<b>Estimated savings</b>	<b>£12,120</b>	<b>£78,385</b>	<b>£1.2m</b>
<b>CO<sub>2</sub> reduction</b>	<b>70 kg</b>	<b>437 kg</b>	<b>6.7 tonnes</b>



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# How to set up a programme



Recommendation: establish a used device collection service first, followed by purchasing of remanufactured devices. It's simple to do and can halve both the cost and emissions of the devices.

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## Part 1: Collecting used devices

- Procurement team engages NHS Supply Chain and the remanufacturing supplier to establish collection agreement
- Supplier trains clinicians to clean and handle used devices safely for collection
- All identified used devices placed in a collection bin with supplier's collection document, supplier organises shipment
- Collection payments delivered to the trust
- A carbon and cost savings report is provided by the supplier

## Part 2: Purchasing and using remanufactured devices

- Procurement team engages NHS Supply Chain and the remanufacturing supplier to establish purchase contract
- Clinicians order remanufactured devices through NHS Supply Chain
- Savings delivered to the Trust (for surgical devices), or through the NHS Supply Chain gain share model for HCTED (EP catheters)
- Used devices are returned to the same remanufacturer to ensure traceability of devices
- A carbon and cost savings report is provided by the supplier

***“Our experience of collecting and using remanufactured devices has been positive. All stakeholders have embraced the programme and recognise the benefits. The collection/pick up process is extremely simple, quick and we really value the environmental benefits and saving on public spending. The next phase is to widen the portfolio of products that we use.”***

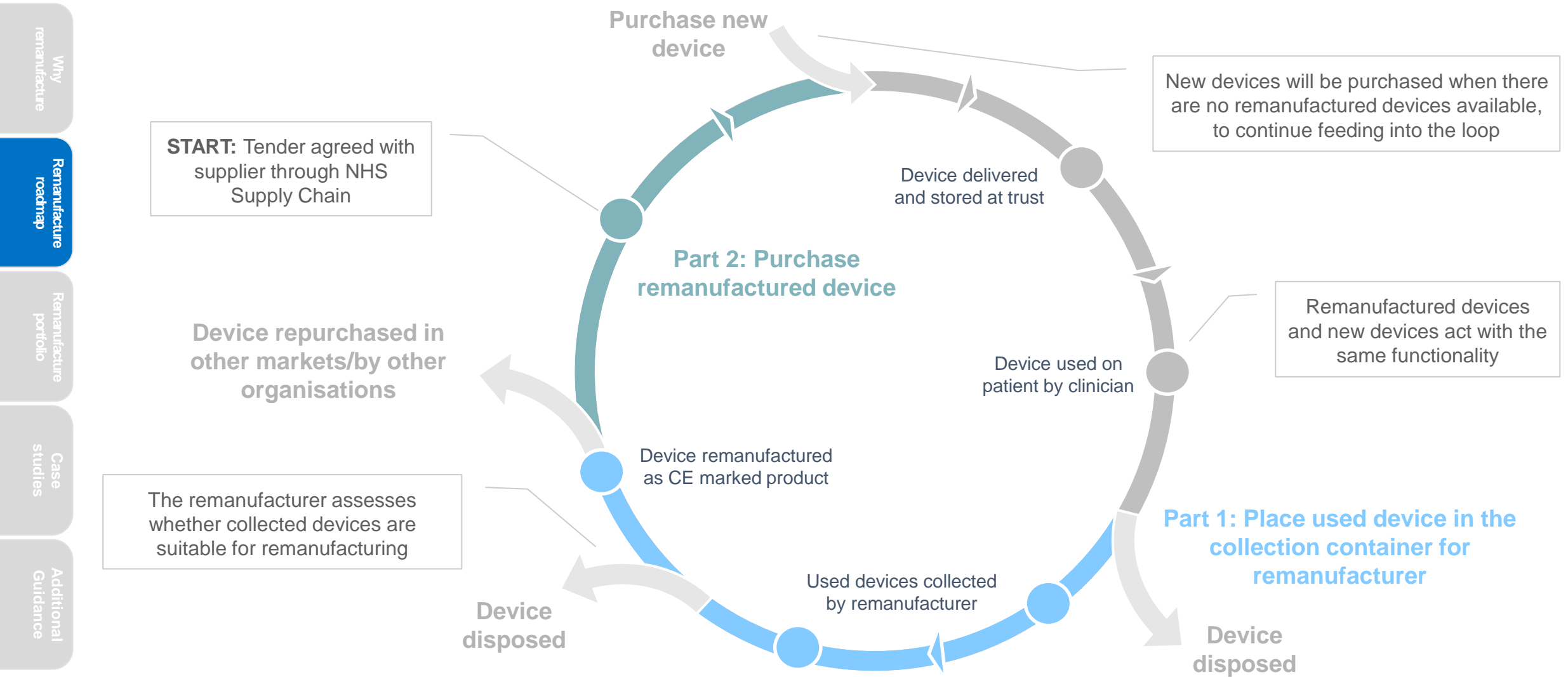
**Nicola Hill & Lindsay Davison**  
Specialist Cardiac Physiologists  
Leeds Teaching Hospital



# Medical device lifecycle



Close the loop and create a circular economy for medical devices within trusts and ICSs, by arranging collection of used devices and purchasing remanufactured devices. Devices are CE marked, with no clinical difference in functionality or safety.



# Key stakeholders and programme leads



To set up a remanufacturing programme, contact NHS Supply Chain to begin engaging with the relevant supplier.

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**Clinicians: cath lab and/or theatre staff**



Reach out to procurement lead to begin engagement with NHS Supply Chain and supplier



**Procurement team**



Reach out to NHS Supply Chain to begin engagement with supplier



**Infection control lead**



Review hospital protective regulations to cover re-manufacturing and liaise with the supplier to confirm



**Sustainability or finance lead**



Reach out to the procurement team to begin the remanufacturing programme, to make carbon and cost savings

**Would you like to see examples of remanufacturing success?**



Go to the **Case Studies** section

**Would you like additional guidance and information on:**

- Quality Assurance of remanufactured medical devices
- Examples of the processes involved in setting up and running a remanufacturing programme



Go to the **Additional Guidance** section

# Remanufacturing portfolio



This guide focusses on the remanufacturing of single use devices (SUDs) to reduce the volume of single use plastics used in theatre, and reduce the costs involved in procuring and disposing\* of these items.

Why remanufacture

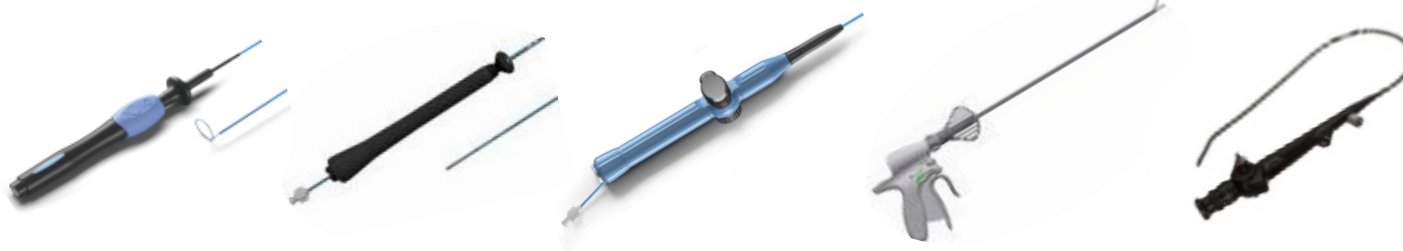
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Categories of SUDs available for reuse, as part of a remanufacturing programme:



Diagnostic Catheters

Ablation Catheters

3D Mapping Catheters

Surgical and Orthopaedic Instruments

Endoscopic and Further Medical Devices

\*Soiled surgical instruments sent away for preparation for reuse are not classified as waste as noted in the Health Technical Memorandum 07-01: [Safe Management of Healthcare Waste](#)

## NHS Supply Chain

Remanufactured devices are available through NHS Supply Chain: [Surgical Instruments Framework](#)

NHS Supply Chain: [Cardio-vascular, Radiology, Endoscopy, Audiology and Pain Management](#) supplies a range of remanufactured products.

To find out more about the remanufactured devices available contact your local NHS Supply Chain [Customer Relationship Manager](#).

# Case Studies & Additional Guidance

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**1 | Trust level programme**

**2 | NHS wide savings**

**3 | Additional guidance**



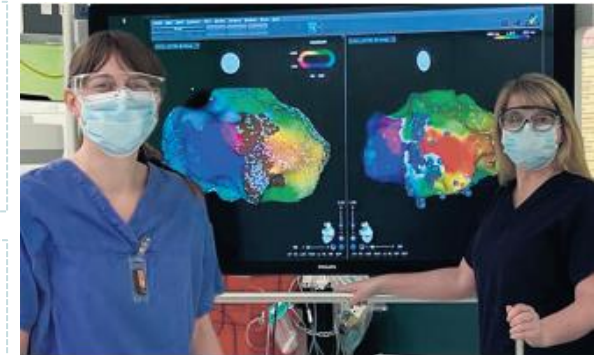
# Trust level programme



Leeds earned £13,350 in one year from device collection, diverting over 100kgs of high-value devices from incineration to be repurposed, saved circa 50% on each remanufactured device used and reduced the related carbon footprint by 50%

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<b>Organisation</b>	<b>Leeds Teaching Hospitals NHS Trust</b>
<b>Issue</b>	Leeds aspired to become one of the greenest NHS Trusts in the UK, as supported by their <a href="#">Green Plan</a> and Sustainable Action Plan, with objectives and targets for reducing carbon, air pollution and waste. Medical device remanufacturing was introduced as an initiative, in line with the 'NHS Carbon Footprint Plus' priorities of supply chain, estates/facilities and pharmaceuticals/medical devices.
<b>Action</b>	Working with the remanufacturing supplier, they started collecting used electrophysiology catheters in 2019. The supplier collects the used devices and sends them to their plant to be remanufactured. Following this, physicians in Leeds Cath Labs started using remanufactured EP Catheters.
<b>Impact</b>	The collection service in 2020 diverted 102 kg of waste and generated £13k in revenue. The use of 81 remanufactured EP Catheters with a 50% lower product CO <sub>2</sub> footprint, saved some 70 kg of CO <sub>2</sub> , and £12k on purchase price, at some 50% less than the Original Equipment Manufacturer (OEM) product cost.
<b>Lessons learned</b>	Cleaning and collection procedures are similar to disposal and do not require additional resource. Training is essential to success and should include, why the procedures are important and the scheme benefits. Staff really valued knowing they were contributing to waste and CO <sub>2</sub> reduction and saving public money. Start with the collection/pick up as a quick win, followed by buying remanufactured EP devices, phasing in the wider portfolio of products purchased.



# Quality assurance of remanufactured devices



Each single use remanufactured device must follow [MHRA guidance](#) and be CE marked, indicating they fulfil EU safety and performance standards recognised by the UK until 2023; after this the UK standards will be identified by a UKCA mark.

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## All remanufactured devices have the CE, or UKCA, certification mark...

A CE Mark is a symbol that must be affixed to class II & III medical devices to be sold on the European market. The mark indicates that a product:

- Fulfils the requirements of relevant European device directives
- Meets the relevant performance and safety standards for full functionality and application, including associated accessory devices
- Is fit for its purpose and will not endanger lives or property
- Is EN ISO 13485 EU MDD 93/42/EWG compliant



CE mark

## ... what this means for a trust:

- Remanufactured medical devices share a similar risk profile to a new single-use medical device
- Preparation and handling processes for used devices must be followed to ensure any infection risk is minimised
- All medical devices used must show the CE mark, to confirm product liability is provided by the remanufacturer; do not use a device if the mark is not present
- Implement and follow an effective quality and safety assurance programme (i.e. protective regulations), to include procedures to safely handle and transfer devices from locality to remanufacturer



UKCA mark

## Infection Risk

Following the device preparation and handling process mitigates the risk of used medical devices causing an infection:

- Handle and store medical devices according to relevant protective regulations
  - Use protective gloves and goggles

## High Risk Exposure

Devices that are, or have the potential to have been, exposed to high risk infectious diseases are treated in the same way as any other medical device: **destroyed, with no exceptions**

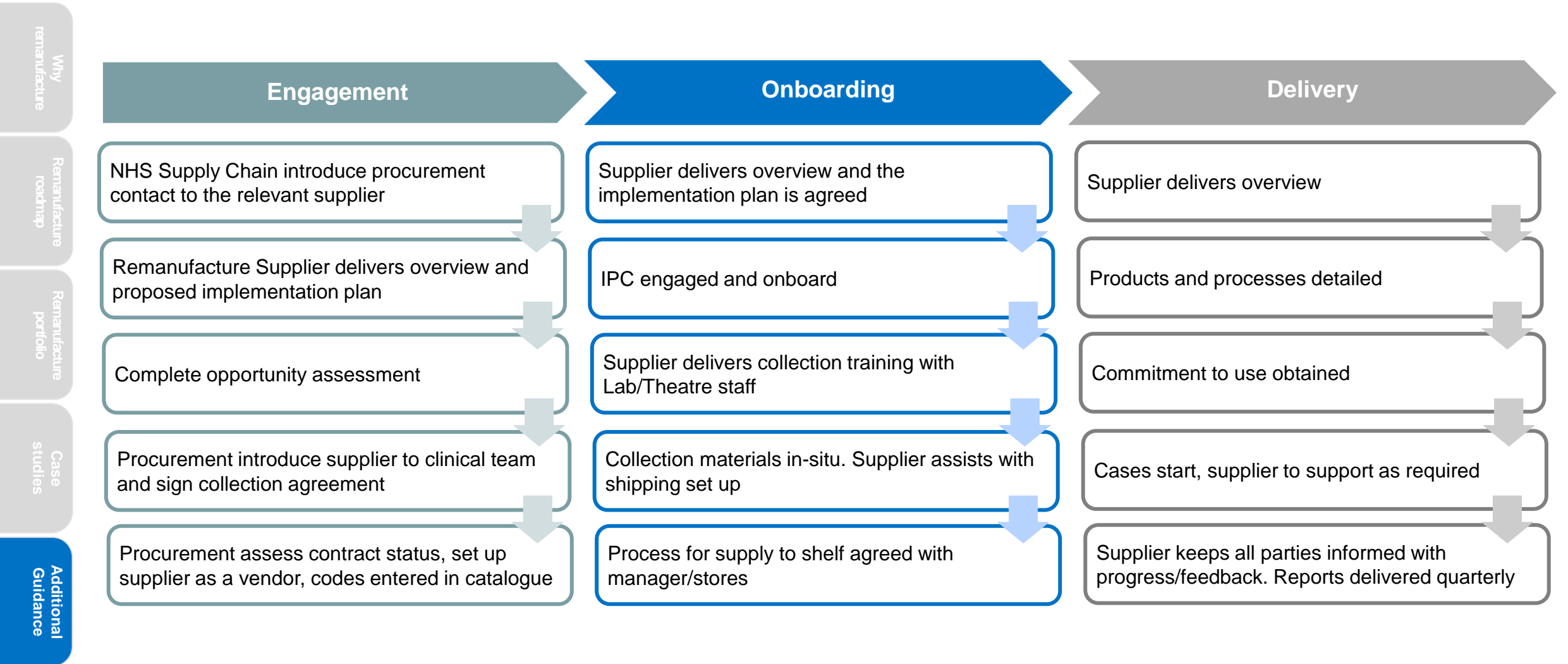


Single use mark

# Collection delivery model and onboarding process



NHS Supply Chain have supplier relationships, contract management, and onboarding processes to support the delivery model for collection of used devices. Contact your local [Customer Relationship Manager](#) at NHS Supply Chain.












# Encouraging the right behaviours from staff



Buy in from all relevant staff is essential for a remanufacturing programme to be successful. Staff must be aware of their responsibilities and understand the benefits of making the change, guided by tools such as procedural documents and training.

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Encouraging the right behaviours			
Staff 	Responsibilities 	Tools 	
<i>Any staff member responsible for the preparation, handling, and cleaning of devices</i>	<i>Encourage and reinforce the right behaviours at each step in the preparation and handling process and effective contract management</i>	<i>Visual aids and procedural documentation detailing step-by-step guidance for appropriate preparation and handling of device</i>	
<b>Clinical leads- theatre/cath lab managers, lead EP Physiologists</b>	Clinical and theatre staff are typically involved with the preparation and handling process and should understand correct procedure for each of the following steps: 1. Preparation & testing 2. Cleaning & drying 3. Packaging 4. Storage & collection 5. Disposal	 <b>Procedural documents</b>	 <b>Posters/ Signage</b>
<b>Theatre or Cath Lab staff i.e. scrub team, nurses, runners, ODPs</b>	Administrative staff typically responsible for: 1. Contract management 2. Inventory management i.e. supply 3. Performance reporting i.e. commercials	 <b>Training sessions</b>	 <b>Labels</b>
<b>Administrative staff i.e. material/stock managers, procurement</b>	Administrative staff typically responsible for: 1. Contract management 2. Inventory management i.e. supply 3. Performance reporting i.e. commercials	 <b>Procedural documents</b>	 <b>Commercial reporting</b>