

Implant Analysis Service

Independent analysis of used medical devices.

www.implantanalysis.nth.nhs.uk

The NHS Implant Analysis Service is an independent, fast, efficient and cost-effective service, which conducts physical analysis and issues reports on Used Medical Devices (UMD's) to the benefit of the NHS, surgeons, patients and manufacturers.



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4. NHS IMPLANT ANALYSIS

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Government, regulators and advisory groups are aligned on the benefits of analysis of explanted joints.



"...explanted joints should be analysed, and subsequent data generated should be reported to the NJR and published."

GOVERNMENT RESPONSE TO THE HOUSE OF COMMONS SCIENCE & TECHNOLOGY COMMITTEE REPORT OF SESSION REGULATION OF MEDICAL IMPLANTS IN THE EU AND UK



"Examination of explanted joints that have failed or caused problems in the body is one of the most valuable sources of data about how and why implants fail—they can be thought of as the 'black box'. Revision operations, which remove such problem implants have to be reported to the National Joint Registry (NJR) but conservation of the failed joint itself is not required and many are simply thrown away [...] We call for the conservation and analysis of explanted joints to be made mandatory as part of the NJR reporting procedure."

THE HOUSE OF COMMONS SCIENCE & TECHNOLOGY COMMITTEE REPORT OF SESSION REGULATION OF MEDICAL IMPLANTS IN THE EU AND UK



"In BC (Beyond Compliance) we have always thought that explant analysis of all retrieved implants, particularly if they are novel, should be undertaken. To date this has hardly happened and BC and ODEP are delighted that the NHS Implant Analysis Service is going to facilitate this essential part of implant monitoring."

KEITH TUCKER, CHAIR OF ODEP AND THE BEYOND COMPLIANCE ADVISORY GROUP. AUTUMN 2022

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"...spotting trends in practice and outcomes that give rise to safety concerns... Innovation in medical care has done wonderful things and saved many lives. But innovation without comprehensive pre-market testing and post-marketing surveillance and long-term monitoring of outcomes is, quite simply, dangerous. Crucial opportunities are lost to learn about what works well, what does not, what needs special measures put around its use, and what should be withdrawn because the risks over time outweigh the benefits."

FIRST DO NO HARM. THE REPORT OF THE INDEPENDENT MEDICINES AND MEDICAL DEVICES SAFETY REVIEW, BARONESS CUMBERLEGE CROWN COPYRIGHT 2020

THE BENEFITS

PATIENT SAFETY

The physical product provides the solid evidence, the so called "black-box' providing more information and intelligence around medical devices for improved patient safety and outcomes.

SURGEON

Combined with National Joint Registry data, surgeons will have access to an analysis rapid report, as well as the longer term data. Through this service greater understanding of implants, surgical techniques, fixation options within different patient cohorts may be gained. The service is an adjunct to the current registry and ongoing research.

HOSPITAL

Independent used medical device analysis, when combined with x-rays, ct scans, blood tests is a crucial to discover failure mechanisms early enough to protect patients and the NHS. Explant analysis performed on an ad hoc basis to date has not worked since data was too late, or the results did not trigger preventative measures. The service seeks to address such issues becoming mass costly patient safety problems.

MANUFACTURER

To gain an accurate picture of implant performance as opposed to sporadic events, all failures should be reported for whatever reason (including trauma and infection), so they can be related to the number of implantations, Furthermore, by analysing those implants which appear to have performed as anticipated, or better than anticipated, we will be able to assess devices of the future should be considered in different patient indications and cohorts.

RESEARCHERS

The service provides explant retrieval and independent analysis whilst allowing for further long term research. Without a suitable system of logistics, analysis and reporting, many revisions reported through the NJR are disposed of at the time of surgery. Conservation of used medical devices ensures independent analysis is conducted regardless of the reason for revision.



8. NHS IMPLANT ANALYSIS

WHAT DOES THE **SERVICE COVER?**

The IAS provides two service options



SURVEILLANCE AND STORAGE

Full service covering all explanted joints

Hospital sends all its explanted joints to IAS for analysis and storage

Explanted joints are analysed and lab provides hospital with a simple report with the following outcomes

'device performed within expected parameters' -'device has a potential issue and a detailed report is recommended' -

Enhanced reporting is then provided for explants with an identified issue

Option to order annual trend report Summary report of all findings from analysed explants over previous 12 months -



ENHANCED REPORTING SERVICE

Where surgeons have already identified a clear issue with an explanted joint, the full enhanced report can be requested immediately

Hospitals can purchase single boxes or consignments of ten boxes

Service also covers 12 months storage

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What's covered	Surveillance & Storage	Enhanced Reporting Service
Packaging & Shipping	\odot	\odot
Explant Analysis	\odot	\bigcirc
Basic Reporting	\odot	$\overline{\mathbf{x}}$
Detailed Report	\bigotimes	\bigcirc
Option to Order Detailed Report	\odot	NA
Option to Order Trend Report	\bigcirc	\bigcirc
12 Months Storage	\odot	\odot

10. NHS IMPLANT ANALYSIS

SETTING UP THE SERVICE

Hospital and IAS liaise to implement the service

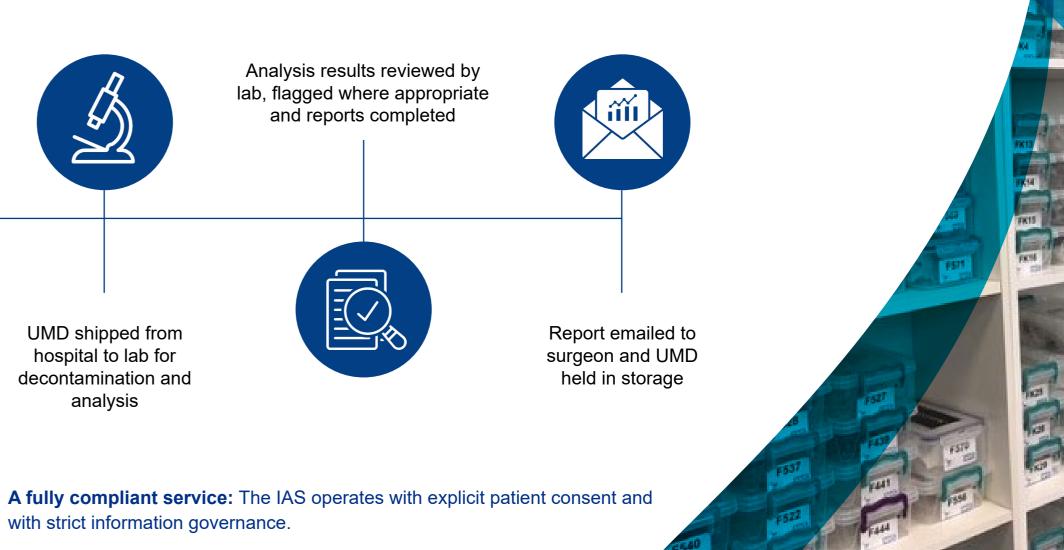


IAS provide approved containers for shipping of biohazardous materials

Processes and training supported by IAS with procurement, theatres and logistics



NHS IMPLANT ANALYSIS 11.



GET IN TOUCH

For more information about the NHS Implant Analysis Service and how it can be implemented in your Trust, simply contact us using the details below.

This brochure is printed onto FSC certified material which is made from up to 50% recycled materials

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