



# Implant Analysis Service

Independent analysis of used medical devices.

[www.implantanalysis.nth.nhs.uk](http://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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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

CLINICAL WASTE ONLY



**“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



**“...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lost to learn about what works well, what does not, what needs special measures put around its use, and what should be withdrawn because the risks over time outweigh the benefits.”**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.

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## 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.

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## 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.

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## 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.

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## 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.

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Im

**Acetabular cup**  
There were scattered, multidirectional scratches over most of the bearing surface. In the 12 o'clock position, there was a rimming of fibrous ingrowth with signs of metal staining.



**Femoral head**

A prominent broad discolouration of the bearing surface in the form of isolated scratches, degradation and debris removal.



**Patient details**  
Patient name: XXXXXXX  
Patient DOB: XXXXXXX  
Patient gender: XXXXXXX  
NHS number: XXXXXXX  
NJR index number: XXXXXXX  
Referring surgeon: XXXXXXX  
Referring hospital: XXXXXXX

**Implant details**  
Reason for revision as listed: XXXXXXX  
Implantation side: Left  
Explanted prosthesis: XXXXXXX  
Implantation date: XXXXXXX  
Implantation date: XXXXXXX  
Implantation duration: XXXXXXX  
Acetabular cup lot no: XXXXXXX  
Femoral head lot no: XXXXXXX

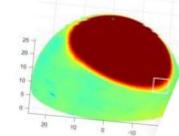
**Additional findings**

There was scalloping of the posterior femoral neck consistent with femoral head rotation. This is shown by the red rectangle in extension/external rotation.



**Femoral head**

**Coordinate Measuring Machine (CMM) analysis**  
The apex of the wear scar (white box) is in the following position:



	Max Linear Wear (µm)	Volume Wear (mm³)
Femoral Head	54	3

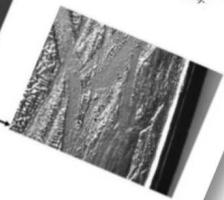
The diametrical clearance was 0.15mm.

Service provided by NTH Solutions LLP, a wholly owned NHS company.

Probing of the femoral bone revealed large cyst, over 10mm in depth, which was filled with necrotic, metal stained bone debris (above). Image below shows the cyst in extension/external rotation.



Reported by: XXXXXXX  
Verified by: XXXXXXX  
Signed off by: XXXXXXX



- Summary**  
The main findings of the analysis of this explanted BHR were:
1. Excessive wear of the analysis of this explanted BHR were:
  2. Edge wear of the bearing surfaces
  3. Degradation of the cup
  4. Signs of posterior of the normal femoral bone architecture secondary to metallosis

The total wear of the bearing surfaces was over 79 mm<sup>3</sup>, meaning that the device wore at a mean rate of approximately 8mm<sup>3</sup> per year. Successfully functioning MoM devices wear at less than 1 mm<sup>3</sup> /year. The increase in wear occurred due to posterior impingement of the femoral neck on the rim of the cup leading to anterior subluxation of the femoral head. The effects of this anterior subluxation on the rim can clearly be seen in the images below, with gross surface disruption over the anterior rim (right) compared to as manufactured surface (left).

# 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

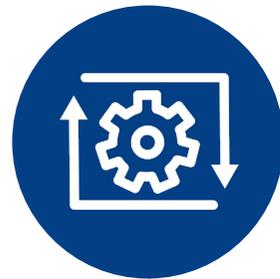
Service also covers 12 months storage

What's covered	Surveillance & Storage	Enhanced Reporting Service
Packaging & Shipping	✓	✓
Explant Analysis	✓	✓
Basic Reporting	✓	✗
Detailed Report	✗	✓
Option to Order Detailed Report	✓	NA
Option to Order Trend Report	✓	✓
12 Months Storage	✓	✓



# SETTING UP THE SERVICE

Hospital and IAS  
liaise to implement  
the service

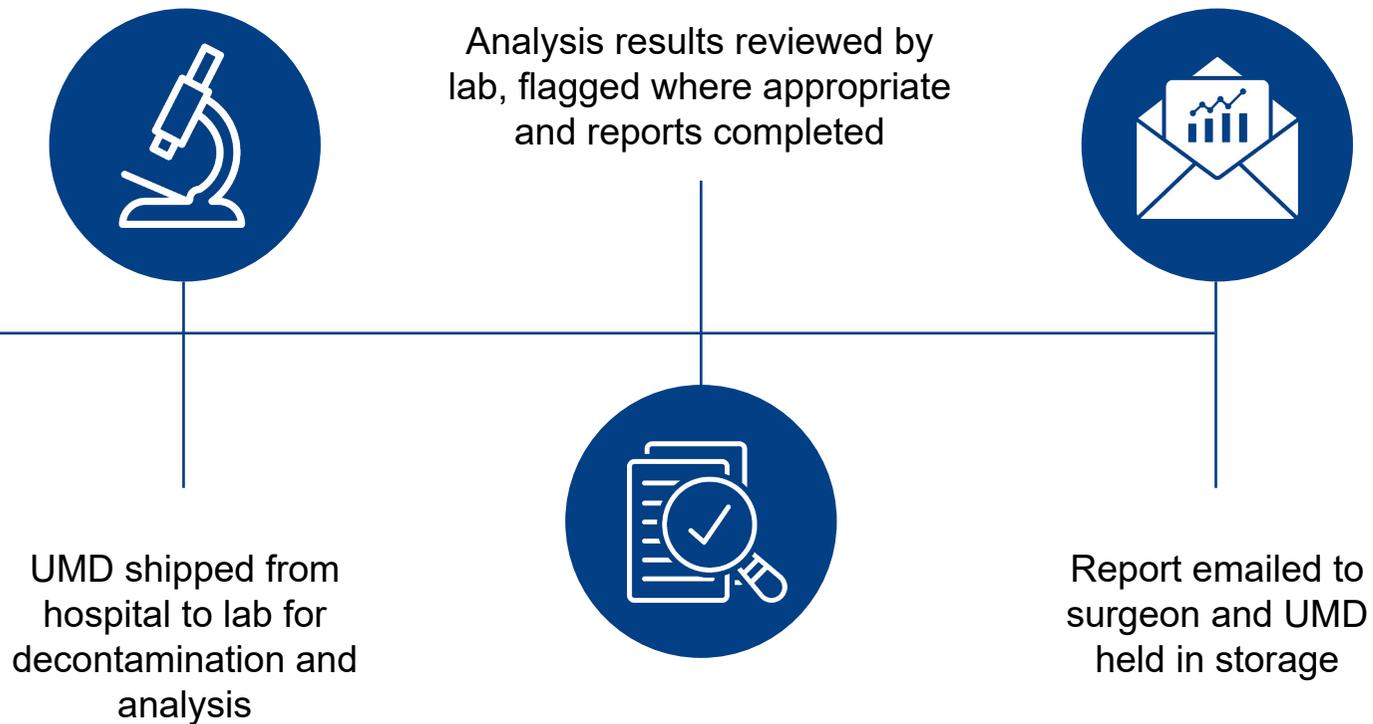


IAS provide approved  
containers for shipping of  
biohazardous materials



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





**A fully compliant service:** The IAS operates with explicit patient consent and with strict information governance.





## 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.



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[nth-tr.implantanalysisissupport@nhs.net](mailto:nth-tr.implantanalysisissupport@nhs.net)



[www.implantanalysis.nth.nhs.uk](http://www.implantanalysis.nth.nhs.uk)