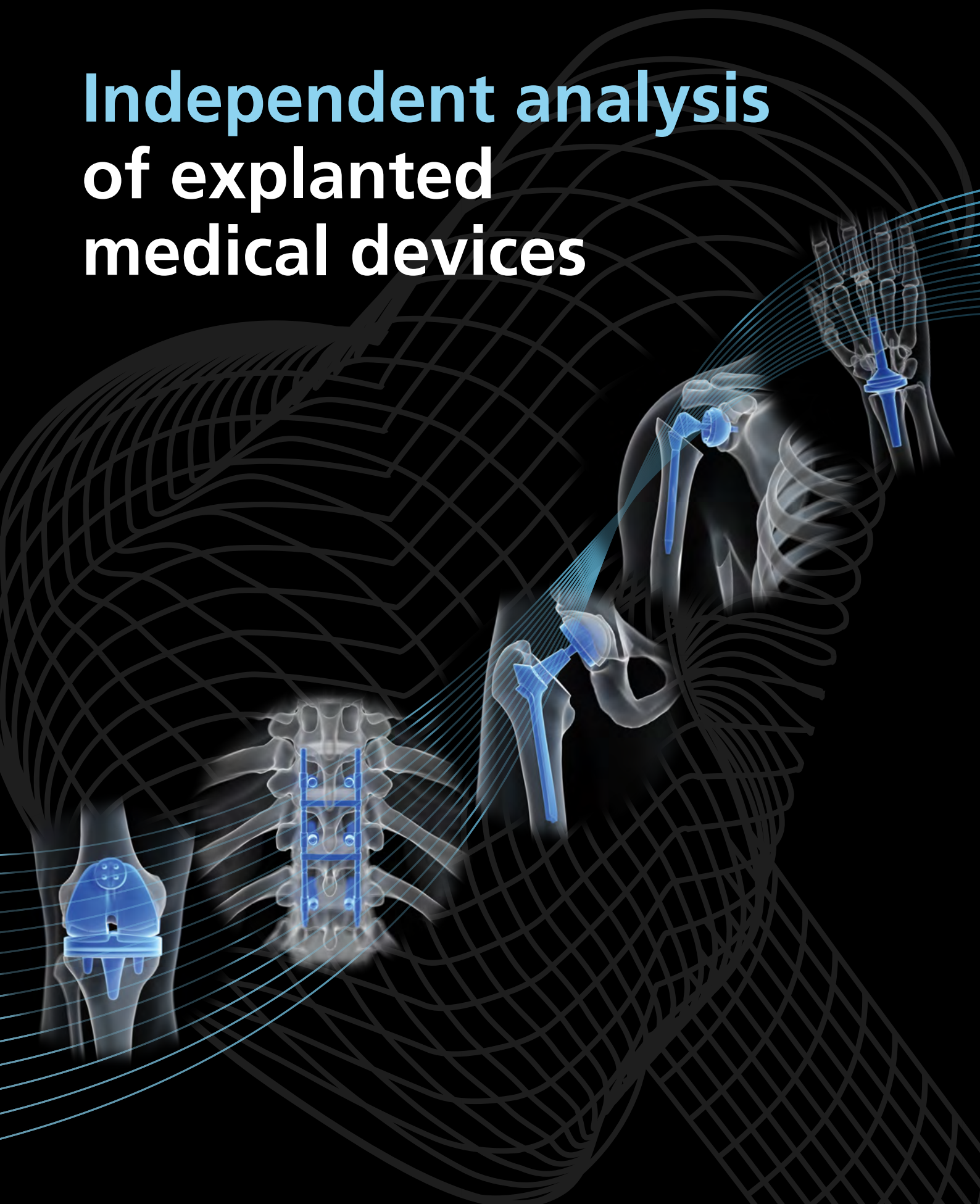


# Independent analysis of explanted medical devices



## A fast, cost effective, NHS led service providing independent analysis of explanted medical devices.

Our service enables surgeons and hospitals to access a **fast, validated analysis service available at a previously unattainable price point**. We can provide expert reports and **completed MHRA Yellow Cards** for adverse event submission to national reporting authorities.



"...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



"The Medicines Healthcare products Regulatory Agency (MHRA) is actively involved in discussions and supports the development of implant explant centres. Benefits of implant explant centres include the potential for earlier detection of safety signals relating to medical devices which contributes to improving patient safety. The MHRA would support manufacturers having access to this information and the device post explant for further investigation."

MHRA

"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 202



# How it works

Here's how the service works in six simple steps



1. Explant is removed and immediately placed into IAS analysis box



2. IAS analysis box is sealed and sent special delivery from your post room



4. The explant is then screened to check if it has performed within expected parameters



3. Explant arrives at our lab and is decontaminated



5. If an issue is found a report can be provided for an additional uplift fee



6. All explants are stored for five years

# The Benefits

## Rapid and accurate analysis

- Explants can be analysed rapidly and accurately to identify issues which may not be visible to the naked eye.

## Post market surveillance

- Explant analysis can help manufacturers assess the safety and performance of their products, and fulfil their regulatory obligations.

## Improving implant technology

- Knowledge gained through explant analysis is an essential part of the design process for new improved products.

## Early identification of sub-optimally performing products

- Quantification and mapping of areas of wear can identify sub-optimally performing products. The same analytical techniques can confirm satisfactory in vivo performance of new devices.

## Confirmation of manufacturing accuracy

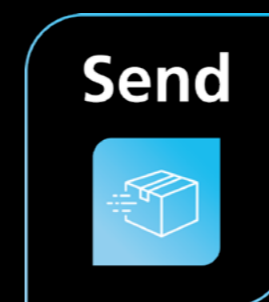
- Examination of explanted devices can confirm whether components conform to their manufacturing specifications.

## Information regarding surgical alignment

- Mapping of wear scar locations can confirm the accuracy of advanced alignment techniques.

## Helping when the clinical picture is unclear

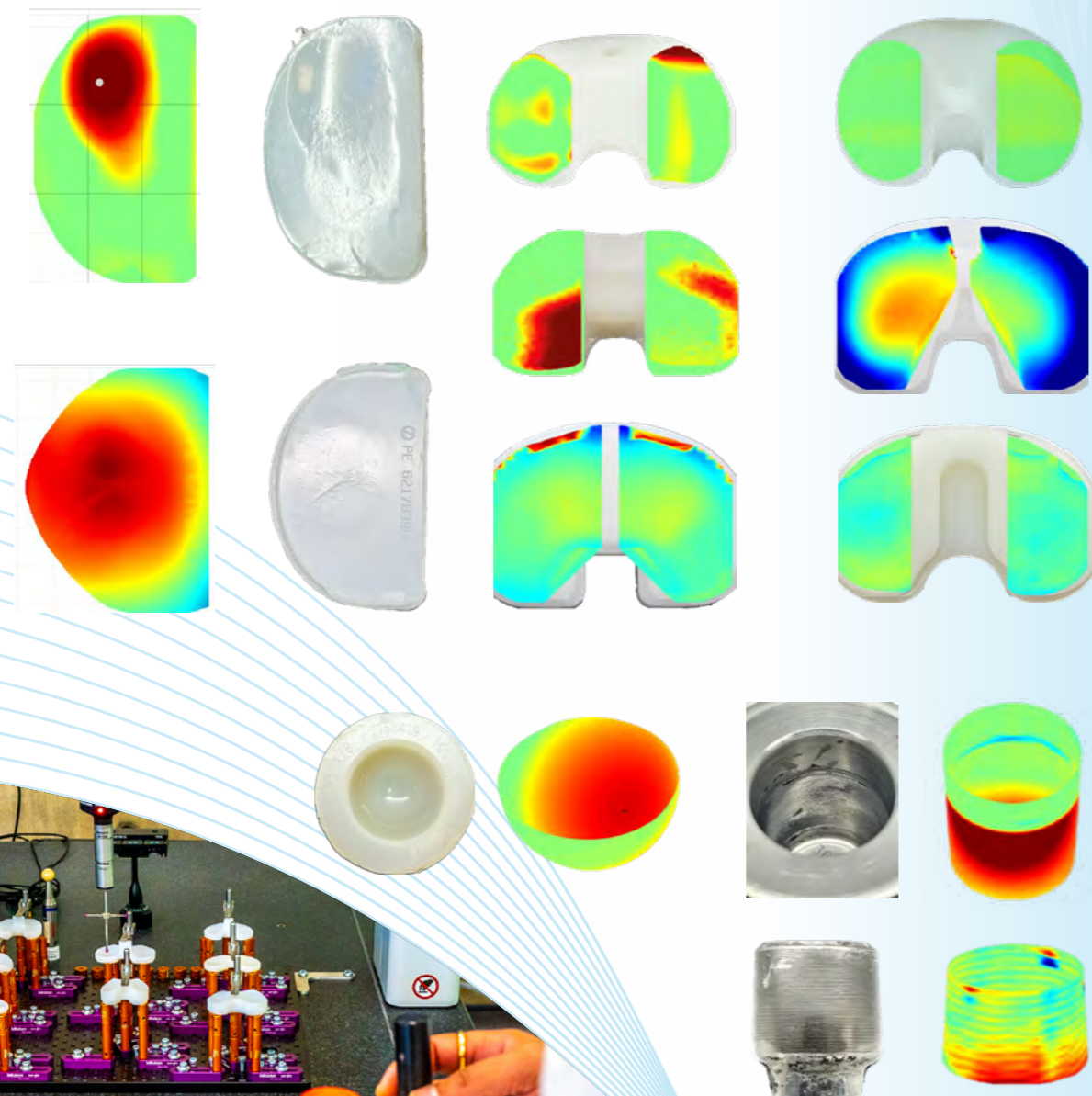
- Adverse reactions to metal debris (ARMD) can often mimic infection in their clinical presentation. Analysis of explanted components may identify abnormal wear or corrosive processes commonly associated with ARMD. This may be important in patients with unexplained pain following a revision procedure.



# How we analyse explants

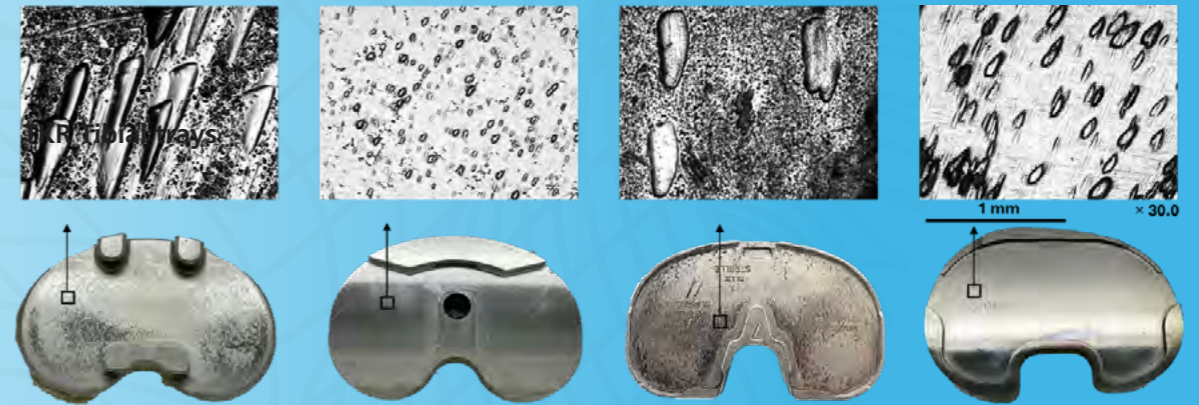
## Coordinate Measuring Machine (CMM) analysis

Using bespoke, validated methodology, we can accurately quantify and map the volumetric wear of explanted prostheses.

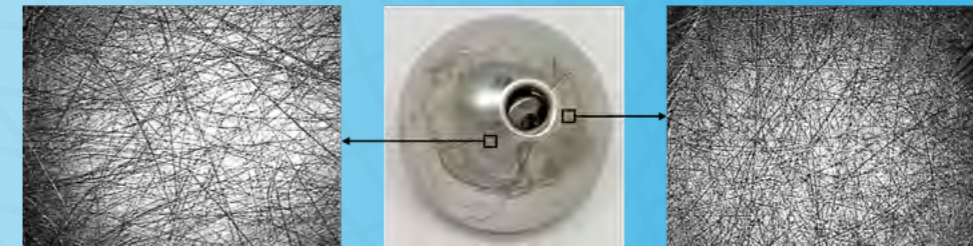


## High-resolution light microscopy

We use a light microscope capable of producing high-resolution images at up to x1000 magnification.

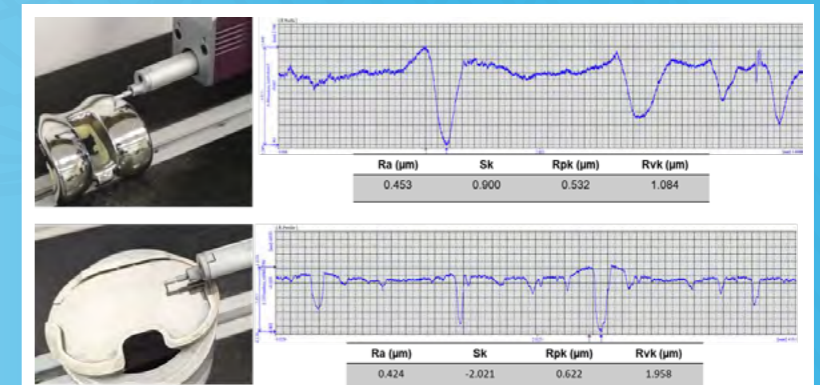


## Shoulder Glenosphere component



## Submicron characterisation of surfaces

We use a contacting profilometer to examine component surfaces. This machine employs a fine stylus to stroke over the surface under examination, providing measurements to sub-micron levels of accuracy.



The IAS uses bespoke, validated and peer reviewed methodologies to accurately quantify and map the volumetric wear of explanted prostheses. Our methodologies have been extensively published.



## 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.implantanalysisupport@nhs.net

 implantanalysis.nth.nhs.uk