

Patient Information and Consent

The manufacturer of the implant that your surgeon has recommended for you, which will replace your affected joint, has chosen to include it in the **Beyond Compliance** service.

“**Beyond Compliance**” was introduced in 2012, by the Association of British Healthcare Industries (ABHI), the British Orthopaedic Association (BOA) and the Medicines & Healthcare products Regulatory Agency (MHRA), as a service available to manufacturers of implants used for joint replacements, such as total hip or total knee replacements, which supports their safe introduction.

Beyond Compliance collects information about patients who receive these implants and then tracks their post-surgical progress to make sure that each new design or design modification is performing as required. The information that is collected is reviewed by an independent group of voluntary experts, including very experienced surgeons, on a regular basis so that if any problems are noted the manufacturer is contacted and the appropriate remedial action can be instituted. For more information go to <http://www.beyondcompliance.org.uk/Home.aspx>

Beyond Compliance would like you to consent to our partner, Northgate Public Services (UK) Ltd. (“NPS”), collecting information about your surgery and link this information to other relevant information on a confidential basis. NPS are an independent company who are expert in collecting and analysing information about joint replacements. They manage the National Joint Registry data on behalf of the Healthcare Quality Improvement Partnership (HQIP) and are an accredited supplier of Patient Reported Outcome Measures (PROMs) data collections.

Your personal information is treated with high standards of confidentiality in accordance with data protection laws and the duty of confidentiality. Any information that is published will always be in pseudonymised form and will not directly identify you.

Your consent for your personal information to be processed in this way is entirely voluntary. You do not have to give consent and are free to withdraw consent at any time without giving any reason, and without your medical care or legal rights being affected.

What information will be collected?

If you provide consent, Beyond Compliance (BC) will collect the following information about you and your operation: Your name, NHS number, home address, date of birth, operation date, operation type, operation side, Hospital, Lead Surgeon, Consultant in Charge, Beyond Compliance implants used, x-ray images and results of examinations and tests. We will also link this information to all information stored about you for this operation or any subsequent operation or outcome held on the National Joint Registry (NJR). For more information about NJR please go to njr.org.uk.

We will also send the following identifiers to NHS Digital (digital.nhs.uk): Your BC Index Number, gender, date of birth, NHS Number and postcode. If you have chosen to participate in the national NHS PROMs survey your responses, held by NHS Digital, will be sent back to NPS, with all these identifiers, except your BC Index Number, removed (for more information see content.digital.nhs.uk/proms).

All information will be held until such time that the implant is no longer monitored through the Beyond Compliance service, at which point your personal identifiers will be removed from our records.

HQIP is the Data Controller for the National Joint Registry. NPS is the Data Controller for Beyond Compliance and, after BC consent has been recorded, we will only use the information for the BC service.

If you have not provided consent to the National Joint Registry, the procedure details will be stored without any personal details. Personal details may only be added by the surgeon responsible for your care.

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Confidentiality

Your personally identifiable information will be handled securely, and will be shared only with those professionals directly involved in your health care and with staff at NHS Digital so that the data collected by the Beyond Compliance service can be linked to other data NHS Digital may already hold about you, such as PROMs data if you participated in the survey. Such transfers of data will be fully encrypted and be over a secure network.

Information about your joint replacement surgery, **with your personally identifiable information removed**, will be made available to the manufacturer of your implant, to independent advisors to the Beyond Compliance service, and to other healthcare professionals using the same implant.

Questionnaires

To help us to monitor and report upon the outcomes achieved following surgery we may send you questionnaires asking about your pre-operative state of health, your recovery and your health outcomes. Your participation in these surveys is entirely optional, but all answers will be for the benefit of future patients and will help us to assure the safety and effectiveness of implants. If you have an e-mail address it will be much easier for us to contact you and for you to reply.

Your participation is voluntary. You do not have to give consent and are free to withdraw consent at any time without giving any reason, and without your medical care or legal rights being affected. If you do not want to take part, do not complete this form. If you do consent, you may withdraw your consent at any time, by notifying us using the contact details listed, at which point your personal details will be removed from our records.

Please discuss any queries about this questionnaire with your surgeon or call the Beyond Compliance on 0845 263 6376 or email: enquiries@beyondcompliance.org.uk

PERSONAL DATA

I have read and understood how my personal data may be used, and agree to the purpose described above:

Name of Patient	Date	Signature
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EMAIL

You are not obliged to but you may also provide an electronic mail address below that will allow NPS to contact you:

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I have read and understood how my email may be used, and agree to the purpose described above:

Name of Patient	Date	Signature
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EXPLANT

You are not obliged to but, should your implant be removed, you agree to it being sent for analysis by a retrieval-centre.

I have read and understood how my explant may be used, and agree to the purpose described above:

Name of Patient	Date	Signature
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