

Beyond Compliance Service Patient Information Sheet and Consent Form

The manufacturer of your implant has chosen to include it in the **Beyond Compliance** Service, to provide an additional level of independent scrutiny of the performance of the implant.

“**Beyond Compliance**” is a service available to manufacturers of implantable medical devices to support the safe introduction of new or modified implants. The Service collects and reports information about patients receiving these implants and their subsequent recovery following surgery. Beyond Compliance is supported by an independent Advisory Committee made up of experts who review the information that is collected so as to provide on-going assurance that implant’s performance is satisfactory.

For the purpose of providing the Beyond Compliance Service, Northgate Information Solutions UK Limited (“**Northgate**”), wish to collect information about your surgery and link this to other information held in NHS databases. Northgate PLC are an independent company who are expert in collecting and analysing information about Joint Replacements. They manage the National Joint Registry and are an accredited supplier of PROMS data collections.

Follow-up Questionnaires

To help us monitor and report upon the outcomes achieved following surgery we may, from time to time, send you a questionnaire asking about your recovery and health outcomes. Your participation in these surveys is optional, but all answers will be for the benefit of future patients and help us to assure the safety and effectiveness of implants.

Confidentiality

Your personal information will be handled securely, and will only be shared with professionals directly involved in your health care. Northgate will not release your personal information unless in the unlikely event it is required by law or where there is a clear overriding public interest. We think the likelihood of this ever being required is remote. Information about your joint replacement surgery, **with your personal details 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.

By signing this form you are giving your consent to:

- Your personal details (and relevant information including x-ray images, results of examinations and tests), being held for the lifetime of your prosthesis and used by Northgate for the Beyond Compliance Service.
- Linking relevant information held about you by the National Joint Registry, the Patient Reported Outcome Measures (PROMs) and other NHS databases.
- Allowing your personal details to be used for the purpose of sending you follow-up questionnaires for the lifetime of your prosthesis.

Your participation is voluntary. If you do not want to take part, do not complete this form. 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. If you have any queries about this questionnaire please discuss them with your surgeon or call the Beyond Compliance helpline on 0845 345 9991 or go to www.beyondcompliance.org.uk

YOUR CONSENT:

I confirm I have read through the information on this form and I understand it. I agree to my details being used as described above.

Printed Name of Patient

Date

Signature