AUTHORIZATION FOR USE AND DISCLOSURE OF HEALTH INFORMATION TO DEPUY ORTHOPAEDICS FOR RESEARCH

INFORMATION COLLECTION

Your surgeon has recommended that you have knee replacement surgery. If you consent to have your knee replacement performed with the support of a TRUMATCH™ Personalized Solutions instrument, then images of your knee, together with limited personal information, will need to be collected to allow the creation and manufacturing of the instrument.

HOW WE USE AND DISCLOSE INFORMATION

By consenting to have your knee surgery performed with the customized instrument, you accept that limited personal data will be collected and processed for

1. The purposes of creating and manufacturing the patient specific instrument, traceability, and product performance monitoring of the instruments in compliance with appropriate privacy laws. This data consists of images of your knee, your name, date of birth, gender, height, weight, and results of the preoperative examination of your knee including the operating bone and varus/valgus profile. Details of the postoperative alignment, range of motion, postoperative implant sizing, function of your knee, and data created for the execution of the knee replacement surgery including boney resection amounts, femoral bow angle, flexion angle, flexion contracture and impingement angles, implant rotation angles, tibial slope angle, cartilage values, boney landmarks, and the case number may also be collected.

2. Additionally, this information may be used for the purposes of product registration and scientific research including investigating new treatments, interventions and management procedures so that patient care outcomes are continually improved. This data may also be used for internal analytical, development and research purposes which may be used to improve surgical techniques, materials, and protocols for joint replacement. Any reports produced on TRUMATCH™ Personalized Solutions customized instruments from such data may be used for regulatory, scientific, or commercial purposes and may be published, but it will not be possible to identify you. Data used for this purpose will be anonymized.

CROSS-BORDER TRANSFER

Your personal information may be stored and processed at affiliated companies of DePuy Orthopaedics, Inc. By using our Service or by providing consent to us (where required by law), your information may be transferred to countries outside of your country of residence, including to the United States, which may provide for different data protection rules than in your country. Appropriate contractual and other measures are in place to protect personal information when it is transferred to our affiliates or third parties in other countries.

Some non-European Economic Area (EEA) countries are recognized by the European Commission as providing an adequate level of data protection according to EEA standards (the full list of these countries is available here: **http://ec.europa.eu/justice/data-protection/international-transfers/adequacy/index_en.htm**. For transfers from the EEA to countries not considered adequate by the European Commission, we have ensured that adequate measures are in place, including by ensuring that the recipient is bound by [EU Standard Contractual Clauses, EU-US Privacy Shield Certification, or an EU-approved code of conduct or certification], to protect your Personal Information. You may obtain a copy of these measures by contacting our data protection officer in accordance with the “Contacting Us” section below.

HOW YOU CAN ACCESS, CHANGE, OR DELETE YOUR PERSONAL INFORMATION

If you would like to review, correct, update, restrict, or delete your personal information, or if you would like to request to receive an electronic copy of your personal information for purposes of transmitting it to another company (to the extent these rights are provided to you by applicable law), please contact TRUMATCH™ Case Coordinator Team at **TruMatchsupport@its.jnj.com**. We will respond to your request as soon as reasonably practicable and no later than one month after receipt. If circumstances cause any delay in our response, you will be promptly notified and provided a date for our response.

CONTACTING US

DePuy Orthopaedics, Inc., located at 700 Orthopaedic Drive, Warsaw, IN 46582, is the company responsible for collection, use, and disclosure of personal information under this Patient Information and Patient Consent Form and Privacy statement.

If you have any questions about this Patient Information and Patient Consent Form and Privacy statement., please contact us via TRUMATCH™ Case Coordinator Team at TruMatchsupport@its.jnj.com or please write to the above address.

You may also contact our data protection officer responsible for your country or region, if applicable, at **emeaprivacy@its.jnj.com.**

LODGING A COMPLAINT WITH A REGULATOR

You may lodge a complaint with a supervisory authority competent for your country or region. Please click here, or visit (http://ec.europa.eu/justice/article-29/structure/data-protection-authorities/index_en.htm), for contact information for such authorities.

SECURITY

We seek to use reasonable organizational, technical, and administrative measures designed to protect personal information under our control. Unfortunately, no data transmission over the Internet or data storage system can be guaranteed to be 100% secure. If you have reason to believe that your information is no longer secure, please immediately notify your doctor and notify us in accordance with the “Contacting Us” section above.

RETENTION PERIOD

We will retain your personal information for as long as needed or permitted in light of the purpose(s) for which it was obtained. The criteria used to determine our retention periods include:
(i) the length of time we have an ongoing relationship with you and provide the Service to you;
(ii) whether there is a legal obligation to which we are subject; and
(iii) whether retention is advisable in light of our legal position (such as in regard to applicable statutes of limitations, litigation, or regulatory investigations).
For example, if we collect your personal information for the manufacturing of your TRUMATCH Patient Specific Instrument, we will store it for a period of 25 years from end of marketing of product by DePuy Orthopaedics, Inc.

Please note, however, that this is not an exhaustive list of retention periods. Your personal information may be stored for a longer period using the criteria set forth in the first paragraph of this section, especially points (ii) and (iii).

PATIENT CONSENT FOR PROCESSING PERSONAL DATA

I have read the TRUMATCH™ Personalized Solutions Information Sheet and I understand that limited personally identifiable data, as specified in this consent form is required by the manufacturer DePuy Orthopaedics, Inc. for the purpose of designing and manufacturing my patient specific instrument, to allow traceability for my surgery, and to monitor outcome of the surgery, as recommended by my orthopedic surgeon for use in my joint replacement surgery. This personal data will be collected and forwarded to DePuy Orthopaedics, Inc. in the USA, for processing. This consent form will be kept on file at my surgeon's office or hospital.

I understand that this data consists of images of my knee, my name, date of birth, gender, height, weight, and results of preoperative examination of my knee including the operating bone and varus/valgus profile. Information on my postoperative knee alignment, range of motion, postoperative implant sizing, function of my knee, and data created for the execution of the knee replacement surgery including boney resection amounts, femoral bow angle, flexion angle, flexion contracture and impingement angles, implant rotation angles, tibial slope angle, cartilage values, boney landmarks, and the case number may also be collected. I confirm that I have received information on the purpose for the collection, processing, recording, the privacy policy of managing this data, who will have access to the data, and on my rights to access and correct the data.

I have been informed that my data will be transferred to an entity established in the USA, a country which the EU has determined currently employs different privacy protection laws than the EU. Nonetheless, DePuy Orthopaedics, Inc, as well as other affiliates of the Johnson & Johnson group of companies and respective agents, will apply adequate privacy safeguards equivalent to those required in the EU to protect such personal data. I am aware that personal data may also be disclosed as required by individual regulatory agencies or applicable law, such as to report serious adverse events.

1. I give permission for this data collection, processing, transfer and recording of my personal data for the purpose of designing and manufacturing my customized instrument, to allow traceability for my surgery, and to monitor outcome of that surgery:

_____	_____
Patient's name (printed)	Patient's signature
_____	_____
Date	Place

2. In addition, I give permission for the purpose of use of the data collected in the TruMatch processing, transfer, and recording process, for the purpose of product registration, and scientific research to investigate new treatments, interventions, and management procedures so that patient outcomes are continually improved. The data collected may also be used for internal analytical, development and research purposes which may be used to improve surgical techniques, materials, and protocols for joint replacement. Any reports produced on TRUMATCH™ Personalized Solutions customized instruments from such data may be used for regulatory, scientific, or commercial purposes and may be published, but it will not be possible to identify you. Data used for this purpose will be anonymized.

   Note: I acknowledge that consent to the use of my data for the purpose of product registration and scientific research is optional. Should I choose not to consent to this use, it will not affect the use of my personal data for the purpose of designing and manufacturing my customized instrument, to allow traceability for my surgery, and to monitor outcome of that surgery, as provided above.

_____	_____
Patient's name (printed)	Patient's signature
_____	_____
Date	Place