

PATIENT CONSENT FORM TO USE AND TRANSFER OF PERSONAL DATA

Conformis is delighted that you have chosen to be treated using a Conformis personalized knee implant. Your Conformis implant will be designed to fit the specific size and shape of your knee.

CONTROLLER'S IDENTITY AND CONTACT DETAILS

The controller of the Processing is Conformis, Inc., 600 Technology Park Drive, Billerica, MA 01821 USA.

Conformis has appointed as its representative in the EU for data protection: Data Protection Coordinator, who can be contacted at: dataprivacy@conformis.com or Conformis Europe GmbH, Schwabacher Str. 261, 90763 Fürth, Germany.

PURPOSES OF THE PROCESSING

For Conformis to design and manufacture your personalized knee implant and support your doctor before, during and after surgery, Conformis will need to receive personal data about you, your body and your health. Conformis also collects, stores and uses this personal data to meet regulatory requirements in the EU and in the United States, and to improve our development, manufacture and sales of our knee implants. Your personal data is only used by Conformis for the above purposes and is not transferred to any unnecessary third parties for their commercial use.

TYPES OF DATA COLLECTED

- Your name and date of birth.
- Imaging data such as X-rays, MRIs, or CT scans that capture the required images of your body to design your personalized knee implant, including any personal data included in the imaging data.
- Health data concerning your medical condition and treatment involving your knee.
- Your physician's name and address.

In addition, your personalized knee implant will be labeled with your name and date of birth and your doctor's name to ensure that your implant is fully traceable to you for your surgery.

We may collect these data directly from you or obtain them from your doctor or imaging centers.

We are aware that this information is sensitive personal data, which may only be processed and transferred in compliance with applicable data protection laws, including the General Data Protection Regulation (EU) 2016/679. Every precaution will be taken to respect your privacy and the confidentiality of your information in compliance with applicable data protection laws.

RECIPIENTS OF YOUR PERSONAL DATA

By signing this consent form, you are allowing Conformis access to the personal data as described above provided by you, your doctor and the applicable imaging center. Those that will have access to your personal data include Conformis employees and agents, affiliates of Conformis and their employees and agents and any third-party entities and their employees involved in the provision of services required for the design and manufacture of your Conformis knee implant and to support your surgeon before, during and after surgery. We inform you that representatives of Conformis, and possibly regulatory health authorities may have access to your personal data if necessary for legal or compliance reasons, such as to report serious adverse events.

TRANSFER OF PERSONAL DATA OUTSIDE THE EUROPEAN UNION

Your Conformis knee implant will be designed and manufactured in the USA, with the exception of the patella which will be manufactured in Quebec, Canada, both of which are outside of your jurisdiction. Therefore, your personal data mentioned above will be recorded on paper and/or electronically and transferred outside of your jurisdiction to the USA which may not be deemed by your jurisdiction to provide an adequate level of protection in processing your personal data. By signing this form, you are providing explicit consent and contractual agreement to the cross-border transfer of your personal data mentioned above for the purposes mentioned above.

RETENTION PERIOD

We will retain your personal data indefinitely due to government regulations and other legal reasons.

YOUR DATA SUBJECT’S RIGHTS

You have the right to receive, free of charge, a copy of your personal data which has been stored in relation to your person, including in a structured, commonly used and machine-readable format that you can transmit to any person you want. If applicable, you also have the right to have this data corrected. Although the General Data Protection Regulation (EU) 2016/679 allows you the right to have your data deleted, often referred to as a right of erasure, by signing this form, you are expressly waiving such right to complete deletion. Conformis retains personal data for regulatory compliance and other reasons. Should you have any question on this data processing you may contact the Data Protection Coordinator at dataprivacy@conformis.com or Conformis Customer Service at support@conformis.com.

If you consider that your data protection rights have been breached, you have a right to lodge a complaint with a data protection supervisory authority.

RIGHT TO WITHDRAW CONSENT

Your consent to the collection or processing of personal data can be withdrawn by you at any time with effect for the future unless the processing is based on another legal basis according to the GDPR and/or the applicable national law in particular health regulations.

To withdraw your consent, please contact the Data Protection Coordinator at dataprivacy@conformis.com. As stated above, a withdrawal of consent will not result in the automatic deletion or removal of all your personal data from Conformis’ records, some must be retained for regulatory purposes.

DECLARATION OF CONSENT

By signing below, you confirm that you have read and that you understand the information in this consent form. Further, your signature below indicates your consent to the processing and transfer of your personal data for the purposes mentioned above.

Patient’s Signature: _____ **Date:** ____ ____ ____
(day) (month) (year)

Patient’s Name (printed): _____ **Surgeon’s Name:** _____

Patient’s DOB: ____ ____ ____
(day) (month) (year)