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Data protection information for patients in accordance with Art. 13 and 14 GDPR

Gender note: For ease of reading, we use the masculine form in the following, but the information nevertheless refers to members of all genders, known and as yet unknown.

Dear patient,

You have been supplied with one of our medical devices. Your attending physician has recommended or already carried out the replacement of the product and asks us as the manufacturer to investigate the cause of the damage.

We attach great importance to the secure and confidential processing of your personal data and observe the applicable regulations in this regard, in particular the GDPR (General Data Protection Regulation). Personal data in the sense of this data protection declaration is all information that has a reference to your person.

In the following, we inform you about the processing of your personal data and the rights to which you are entitled under data protection law.

1. Name and contact details of the responsible body

The responsible party within the meaning of data protection law is the

PETER BREHM GmbH

Am Mühlberg 30

D-91085 Weisendorf

Germany

Phone: +49 9135 7103-0

eMail: info@peter-brehm.de

You will find further information on our company, details of the persons authorised to represent it and also further contact options in our imprint on our website: <https://www.peter-brehm.de/impressum/>

2. Our data protection officer

We have appointed a data protection officer in our company. You can reach her as follows:

Dr Marion Herrmann

eMail: datenschutz@peter-brehm.de

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3. Processing of personal data

We process your personal data for the complaint about the medical device. This serves to investigate the products complained about with regard to the cause of a possible malfunction or complication. On the one hand, we are legally obliged to do this, on the other hand, this investigation is essential to maintain our quality and safety standards. In some cases, your data is required in order to comply with further legal requirements, for example, in the case of notifiable complaints.

3.1. Categories and types of data

For this purpose, we process the following data from you in particular:

- Name
- Patient ID
- Age/Date of birth
- Weight
- Size
- Implantation and explantation date
- Description of the malfunction/complication

Furthermore, we use the data for evaluations and statistics, which are pseudonymised or anonymised and generally no longer have any personal reference.

The processed data is protected against unauthorised access and inspection by technical and organisational measures as defined by the GDPR. In particular, medically relevant data is subject to special protection, which is guaranteed by PETER BREHM GmbH.

3.2. Purpose of the data processing

We process and use your personal data exclusively for the purpose of the complaints procedure. This includes all information that serves to determine the causes, quality management and continuous improvement.

The processing of personal data takes place,

- to correspond with the complaints manager. This could also be your treated doctor
- to be able to identify you as a patient;
- on causation
- in order to be able to fulfil our contractual obligations to you,
- in order to comply with our legal obligations (e.g. reporting obligations, archiving and storage obligations) ;
- for quality assurance and continuous improvement
- to assert any claims against you or third parties.

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3.3. Legal basis of the processing

The processing of personal data takes place on the occasion of the complaint with us and is necessary for the stated purposes for the processing of your order and for the fulfilment of obligations from the underlying contract.

The legal basis for processing your personal data is regularly the fulfilment of contractual obligations or processing in the course of initiating a contract pursuant to Art. 6 (1b) GDPR. In the case of voluntary information, the processing is based on the consent given in accordance with Art. 6 (1a) GDPR.

In addition, a legal obligation within the meaning of Art. 6 (1c) GDPR may also justify data processing. This applies in particular to the storage and retention of reportable, business or tax-relevant documents.

3.4. Recipients of your data

Recipients of your data are internal departments for which this is necessary to fulfil the above-mentioned purposes. These may also be service providers for whom an order processing relationship exists in accordance with Art. 28 GDPR.

3.5. Storage period of your data

Your personal data will be deleted or blocked as soon as the purpose of storage no longer applies. Data may also be stored if this is necessary to comply with regulatory or legal requirements.

Legal retention obligations may result from, for example, Regulation (EU) 2017/745. Information related to medical device complaints is essential for public health. Therefore, manufacturers of implantable devices are obliged to keep documents related to the respective devices, including the corresponding personal data, available to the competent authorities for at least 15 years and up to 30 years after market withdrawal in the last country where the device was offered.

4. Disclosure of data to third parties

Your personal data will be passed on within PETER BREHM GmbH to the extent necessary, insofar as this is required for the fulfilment of the respective purpose or the internal organisation requires the passing on.

For the purpose of damage analysis, the transmission of the above-mentioned types of data (see point 3.1) to external testing laboratories cannot be excluded. For this purpose, however, the data is anonymised, i.e. any personal reference to the data is removed before transmission. Data will not be transferred outside the European Union (EU).

In the event of a reportable event, it is also possible to transfer the data to the relevant competent authority. You as the data subject will be informed separately about such a transmission.

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5. Your rights as a data subject

As a data subject, you have various rights:

- **Right of revocation:** You can revoke your consent at any time. The data processing based on the revoked consent may then no longer be continued for the future.
- **Right to information:** You can request information about your personal data processed by us. This applies in particular to the purposes of the data processing, the categories of personal data, the categories of recipients, if applicable, the storage period, the origin of your data, if applicable, and the existence of automated decision-making, including profiling, if applicable, and meaningful information on its details.
- **Right to rectification:** You can request the rectification of incorrect or the completion of your personal data stored by us.
- **Right to erasure:** You can request the erasure of your personal data stored by us, insofar as its processing is not necessary for the exercise of the right to freedom of expression and information, for the fulfilment of a legal obligation, for reasons of public interest or for the assertion, exercise or defence of legal claims.
- **Right to restriction of processing:** You can request the restriction of the processing of your personal data if you dispute the accuracy of the data, the processing is unlawful, but you refuse to delete it. You also have this right if we no longer need the data but you need it to assert, exercise or defend legal claims. Furthermore, you have this right if you have objected to the processing of your personal data;
- **Right to data portability:** You may request that we transfer the personal data you have provided to us in a structured, commonly used and machine-readable format. Alternatively, you may request the direct transfer of the personal data you have provided to us to another controller, where this is possible.
- **Right to complain (complaints body):** You can complain to a data protection supervisory authority, e.g. if you believe that we are processing your personal data in an unlawful manner. You have the right to complain about our processing of personal data to a data protection supervisory authority.

Our competent and lead data protection supervisory authority is:

Bavarian State Office for Data Protection Supervision (BayLDA)
Promenade 18, 91522 Ansbach
Phone: +49 (0) 981 180093-0
eMail: poststelle@lda.bayern.de

6. Your right to object

If we process your personal data on the basis of a legitimate interest, you have the right to object to this processing. If you wish to exercise your right to object, a notification in text form is sufficient. You are therefore welcome to write to us or contact us by e-mail. You can find our contact details under point 1 of this data protection notice.

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7. Data processing online

The processing of certain personal data, including the IP address of website visitors, also takes place via our website at www.peter-brehm.de. Supplementary data protection information can therefore be found online at: www.peter-brehm.de/datenschutz.

8. Amendment of this data protection notice

Status of this data protection information: August 2023.

We reserve the right to make changes. A change may be made for technical, organisational or data protection reasons. Please note the currently valid version of our data protection information.