



Patient information text in accordance with Section 7 (4) of the IRegG
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Implant Register

Information for all people who will have an implant inserted, replaced or removed

Dear Patient,

This text gives you important information about the Implant Register. Implants are things like an artificial knee or hip joint, aortic valve or breast implant. They are inserted during an operation. These operations are recorded in the register.

Thank you very much for taking the time to read this information. In this text, we will explain to you what the Implant Register is. We will also explain its purpose.

In Germany, operations that involve breast implants must be reported to the Implant Register. This will also apply to knee and hip joints and aortic valves. It is precisely regulated which data is entered into the register. Every hospital and every doctor's surgery that performs such operations has to do this. It does not matter whether it is an operation to insert, replace or remove an implant. This is in accordance with the Implant Register Act.

Our text will explain why this register exists. We will also inform you about how your data is protected. This data protection is strictly regulated by the Implant Register Act, too.

Do you have any questions? Or would you like to get more information? Your doctor can inform you about this topic, too.

What is the Implant Register Germany?

There is one Implant Register for the whole of Germany. Information on all operations that involve specific kinds of implants is collected there. You are having such an implant inserted, replaced or removed? Then, information on the implant and the operation will also be stored in the Implant Register.

Why is this information collected in the register?

The register provides us with various information. For instance, we would like to know:

- How good are the implants?
- How well does the provision of medical implants work?

We can use this information to work towards improvements. This way, we make sure that:

- implants are of high quality
- the provision of medical implants is of high quality
- the implants in use are thoroughly monitored by the authorities
- we have an overview of all implants. This way, detailed reports on their number and quality can be created.

In addition, scientists can use the data to improve the implants. They can also use it to improve medical care.

What information may be collected? What information may be passed on?

This is laid down in several provisions.

- Since 1 January 2020, there is the Implant Register Act – short: IRegG.
- There is also the Implant Register Operating Ordinance – short: IRegBV.

Would you like to learn more about the Implant Register? You can find more information on the internet. The link is:

<https://www.implantateregister-deutschland.de>

There you can also find a report that is published every year. In language that is easy to understand, it informs you about

- statistical evaluations of the stored data. For instance, it states how often breast implants were inserted.
- the quality of implants in Germany
- how well people are provided with implants
- which data was passed on to scientists.

The information in this report is meant to help you. You can use it to find out more about different implants before you have an operation.

Who is responsible for processing my data in the Implant Register?

The **Registration Centre** stores information such as data about the implant. It also stores medical data regarding your operation. The Registration Centre is based at the Federal Ministry of Health – short: BMG. The address is:

Bundesministerium für Gesundheit
- Registerstelle des Implantateregisters Deutschland -
53107 Bonn

The link to the website is: www.implantateregister-deutschland.de

Please note: The Registration Centre is not the proper point of contact if you have any questions concerning your data. You can find information about exercising your rights in relation to your data further down on page 5.

Do you have any questions about data protection? Then you can write an email. The email address of the data protection office is: DSB@bmg.bund.de

If you contact the office, the BMG's general data protection provisions apply. You can access these provisions at: <https://www.bundesgesundheitsministerium.de/en/data-protection.html>.

The **Trust Centre** stores data that could identify you as a person. The Robert Koch Institute – short: RKI – is responsible for the Trust Centre. This way, your personally identifiable data is stored separately from your medical data. The address is:

Robert-Koch-Institut
- Vertrauensstelle des Implantateregisters Deutschland -
Nordufer 20
13353 Berlin

Please note: The Trust Centre is not the proper point of contact if you have any questions concerning your data. You can find information about exercising your rights in relation to your data further down on page 5.

Do you have any questions about data protection? Then you can write an email. The email address of the data protection office is: Datenschutz@RKI.de

If you contact the office, the RKI's general data protection provisions apply. You can access these provisions at: https://www.rki.de/EN/Service/data_protection/data_protection_node.html.

For what purposes is my personal data processed in the Implant Register?

Your data is collected to answer medical, technical and scientific questions.

For instance, hospitals get anonymised reports about the operations and treatments performed. They can then compare themselves to other hospitals. This comparison enables them to continuously improve their services.

The same goes for implant makers. They, too, receive anonymised reports.

The reports describe how well their implants work for the patients. The companies can then also compare the data to that of other makers. This way, makers can further improve their implants.

Sometimes, implants can pose a danger to health. Such dangers can be identified through reports. If that happens, patients can be informed right away.

Doctors can make use of the information about the different implants. This way, they are better able to treat their patients.

In addition, scientists can access the data.

Authorities can also receive the data to check and supervise the makers. This is important for all patients who have an implant. It is also important for those who will receive an implant in the future. It is for the benefit of their health and safety.

What personal data is processed in the Implant Register?

Your personal data is divided into different groups.

1. Data that could identify you as a person

This data is also known as “patient identifiable data”. Only your health insurance number is stored. This number has ten digits. You keep this number for your whole life. You can find this number on your health card. If you are insured in Germany you are obligated to share this number with the healthcare facility. Even when your insurance does not cover the operation.

Your name and contact details are not processed in the register. The health insurance number is only stored at the Trust Centre. The Trust Centre is based at the Robert Koch Institute – short: RKI. It will create a “pseudonym” for your health insurance number. A pseudonym is a random combination of letters and numbers. Only this pseudonym is transmitted to the Registration Centre. The Registration Centre is based at the Federal Ministry of Health – short: BMG. The pseudonym is not linked to other data. So it cannot be used to identify you. You may have several operations over the course of your life. In this case, the Register can store information about these operations in one place. It may be possible to gain new insights this way. Such as new findings on the implants and on medical care.

2. Data on the healthcare facility, health insurance and your stay due to your operation

This organisational data includes information about

1. the healthcare facility where you were operated on.
2. The legal body under which you are insured in Germany. For instance, this may be the statutory health insurance or a private health insurer. It may also be the medical insurance of the Federal Armed Forces or the Federal Police.
3. the kind of stay at the healthcare facility. Did you only stay for your treatment or did you spend more time at the hospital?
4. the appointments. When were you admitted to hospital? When were you discharged? And what was the reason for your discharge?

3. Medical data:

These include

1. Your age, height, body weight and sex.
2. detailed information about the performed operation. This also includes hints or findings that may affect the implant.
3. possibly earlier operations that are directly associated with the current operation.

4. detailed information about the implants. This may include, for instance, the product or serial number.
5. the codes of the illnesses you were discharged with. These are known as “discharge diagnoses”.

4. information on whether you are deceased

This “vital status” provides information on whether you are still alive or have become deceased in the meantime. In case of death, this also includes the exact date of death.

To whom is data transmitted?

Several bodies are given access to the register’s data for specific purposes. These bodies generally receive the data as “anonymised” evaluations. This means that the data cannot be used to identify individual people.

A few bodies may also access data that is not anonymised. These bodies may access “pseudonymised” data instead. This is data that is stored under a pseudonym. A pseudonym is a random combination of letters and numbers.

This data is known as “pseudonymised data”. It may only be accessed when anonymised data is not sufficient.

The evaluations that are not anonymised may only be accessed at the Registration Centre. Only the Federal Institute for Drugs and Medical Devices may process them. This is done on the Institute’s premises. People who receive access to pseudonymised data must first sign a Non-Disclosure Agreement.

Who has access to anonymised data, but not to pseudonymised data?

The name is on the left side, the purpose on the right:

Recipients	Intended use
Competent healthcare facilities such as hospitals	Assuring the quality of their healthcare services that are linked to implants.
Manufacturer of implants	The manufacturer must comply with legal regulations. They are better at doing so when they can use anonymised data. This is regulated by the medical devices law.
Statutory health insurance funds, private health insurance companies, statutory accident insurance, medical insurance of the Federal Armed Forces and the Federal Police	Examining claims for damages regarding implants and implantation-related health damage.
Competent authorities	To monitor the market for medical devices.
Other German and international implant registers	To further the purpose of the Implant Register.

Who has access to anonymised and pseudonymised data?

The name is on the left side, the purpose on the right:

Recipients	Intended use
Medical professional societies	Working on scientific questions
Joint Federal Committee under Section 91 of Book V of the German Social Code. This law contains almost all the rules that concern statutory health insurance holders.	Provisions to ensure a high quality of treatments that involve implants.
Federal Association of Panel Doctors	Further development of a concept to ensure high-quality medical treatments. More specifically, the concept concerns outpatient treatments that involve implants.
Universities, other institutions that conduct scientific research and public institutions	Conducting scientific research.
Other bodies such as the Federal Statistical Office	Preparing and drafting statistics.
Federal Institute for Drugs and Medical Devices – short: BfArM	Fulfilling its tasks in the area of monitoring medical devices. As well as conducting research on the safety of medical devices.

How long will my data be stored?

There is no date by which your data must be deleted. Your data will remain stored permanently. This is stipulated in the Implant Register Act.

However, the data must be anonymised. This must happen when the complete individual data sets are no longer needed.

What are my rights concerning my data?

Data about you and your operation is stored in the register. You cannot object to this data storage. The register can only be successful if as many operations as possible are documented. This concerns all interventions in which an implant is inserted, replaced or removed.

All healthcare facilities, such as hospitals, must report such operations to the register. This is laid down in the Implant Register Act. Therefore, you cannot restrict the processing of your personal data.

However, you will be informed about which data has been reported to the register. You will receive this data from the healthcare facility that performed your operation. It must provide you with a copy of the data.

You can demand to know which of your personal data has been stored. To do this, contact a hospital that is connected to the register. You will also need your health insurance number in the process. This number has ten digits. You keep this number for your whole life. For instance, you can find this number on your health card. If you do not have a German health insurance you do not have such a number. Then, only the healthcare facility that performed your operation can inform you.

Have you found out that the data stored about you is wrong? In this case, you have the right to have this data corrected. To do this, contact a hospital that is connected to the register. You will also need your health insurance number in the process.

Other bodies will not be able to give you any information. This also includes the Registration Centre and the Trust Centre.

Was your data unlawfully stored? In this case, you can demand that your data be deleted.

Where can I file a complaint about the processing of my data in the Implant Register?

Do you think that your data is not being processed correctly? Then you have the right to file a complaint. For such cases, we have a supervisory authority. You can inform it in case of a data protection breach. The competent supervisory authority will look into your complaint.

In such a case, please contact:

Federal Commissioner for Data Protection and Freedom of Information
Graurheindorfer Straße 153
53117 Bonn

Phone: 0228 997799-0

Fax: 0228 997799-5550

The email address is: poststelle@bfdi.bund.de

The De-mail address is: poststelle@bfdi.de-mail.de

The link to the website is: www.bfdi.bund.de