Surgical Outcomes System™

Patient Information

on use of personal data in the scope of SOS

Internet-based register for monitoring of treatment results in the area of orthopaedics, sport medicine and adjacent surgical areas
(Surgical Outcomes System™, "SOS™")

Provider: **Arthrex, Inc., 1370 Creekside Boulevard, Naples, Florida 34108-1945, USA**

Attending physician:
Physician Facility:

Dear patient,

We would like to invite you to participate in SOS.

Your participation in SOS is voluntary. You will only be involved in SOS if you declare your consent to this in writing. You will not incur any disadvantages if you do not want to participate or if you want to leave later.

You have already been informed on SOS. The following text is to explain the targets and process to you. Subsequently, your doctor will conduct the information interview with you. Please do not hesitate to mention anything that is still unclear to you. You will then have sufficient time to think and decide on your participation.

What is SOS and what purpose does it serve?

In the scope of SOS, health information of patients in standard procedures in orthopaedics, sports medicine and adjacent surgical areas is recorded online using validated questionnaires.

The doctor can use these data to learn about pain, performance and well-being of his patient. Doctors and hospitals also can get an idea of the costs, efficacy and economic efficiency of medical standard interventions.

The data recorded in SOS provide information on how a medical treatment progresses on average in a large number of patients and permit comparison between different treatment methods and implants. This may help further improve the treatment methods and implants.

What does it mean for me to participate in SOS?

No additional examinations will be necessary for you to participate in SOS. You merely need to regularly submit information on your health condition that is then processed in the scope of SOS for the purposes described below.

Procedure:

If you participate in SOS, your doctor will register you in the SOS. You will then receive an email with a link to a web-based input screen that contains standardized questionnaires on your health status. You will be asked to complete the questionnaires before treatment or the intervention and after treatment at various times during the first six months, after six months, after one year and after five years and to submit the data to SOS. Depending on the type of treatment, you will be asked to complete the corresponding questionnaires for a period of up to 15 years. Answering the questionnaires will take 15 minutes at most.

Participation in SOS is also possible of you do not want to receive any emails or do not have any access to the internet. You can inform your doctor and he can complete the questionnaires for you. Alternatively, you can also complete the questionnaires in your doctor's rooms on an iPad or comparable device.

Benefits:

Participation in SOS makes it easier for your doctor to regularly monitor your health status and your treatment progress. SOS also serves to expand medical knowledge. You will not necessarily profit directly from participating in SOS. However, other patients will profit from the information gained with your help in SOS in future.

Risks:

No health risks are known in connection with participation in SOS. Participation in SOS does not affect your treatment. Arthrex, Inc. manufactures orthopaedic medical devices. It is possible that medical devices of Arthrex, Inc. may be used during your treatment. However, SOS is not limited to medical devices of Arthrex, Inc., but comprises medical devices of other manufacturers as well. Arthrex, Inc. has no influence on your doctor's decision of whether to use a medical device of Arthrex, Inc. or the treatment you receive.

No financial advantages or burden:

Participation in SOS does not affect your treatment costs. You will not receive any payment for participation in SOS.

Where and by whom are data saved in SOS?

Arthrex, Inc. operates SOS and decides as the responsible person (i.e., the data controller) on the purposes and means of processing personal data in the scope of SOS.

SOS is operated on a server run by Amazon Web Services, Inc. [or one of its affiliated companies] ("AWS"). Arthrex, Inc. uses a safe data storage system to protect your data from unauthorized access and destruction, loss or modification; this system is customized to protect patient data and meets the requirements of the US Health Insurance Portability and Accountability Act (HIPAA).

Your patient profile is stored solely on the server in Germany/Frankfurt. As such, it is not exported into the USA or any other country outside of the European Economic Area (the USA and such countries are also called "third countries"). This also particularly applies to information required to link the identification number issued by Arthrex, Inc. to information concerning you. Only the pseudonymized data records are also used in third countries if applicable. Arthrex, Inc. is, however, headquartered in the USA. Employees of Arthrex, Inc., including those headquartered in the USA, may access personal information of your patient profile, too, as described below in the scope of operation of SOS. The limited data record (cf. the following sections on this) may also be submitted to third countries when your treating facility has made a data exchange agreement with recipients in a third country. Whether this is the case or not can be taken from paragraph c) Limited data record.

Since the USA and most other third countries do not warrant an appropriate data privacy level according to the opinion of the European Commission and in particular access of public offices to data may be possible at a wider scope than this would be permitted in the European Economic Area, we expressly ask you to consent to data exchange with third countries.

Arthrex, Inc. has concluded an agreement with AWS to protect your data. Arthrex, Inc. may also outsource data processing in connection with SOS to further third-party contractors ("Data Processing Contractors"). Where Arthrex, Inc. passes on your data to such Data Processing Contractors, Arthrex, Inc. shall carefully select the respective Data Processing Contractors and obligate them to take suitable technical and organizational measures to protect your data from unauthorized access and destruction, loss or change. Such Data Processing Contractors may have their registered seat in a third country as well.

What data are used in SOS for what purposes?

With your consent to participate in SOS, you consent to your data being used as described below. All data shall only be collected from you or from your medical file, and not from any third parties.

Step 1: Your attending physician shall register you

When registering, your attending physician will set up a patient profile in SOS with the following data under an individual identification number: place of injury, date of surgery or start of non-surgical treatment. The attending physician shall also submit your email address if you have chosen to participate by email.

All data will in any case be passed on to Arthrex, Inc. encrypted and then saved encrypted in the database by Arthrex, Inc.

Your doctor may also enter the following further data into your patient profile with your consent: the date of initial treatment, medical history (e.g. diabetes, smoker), type of injury (acute, subacute, chronic), duration of symptoms, previous medical treatment, date of birth, size, weight, gender, body-mass index, origin, right- or left-handed, sports done by the patient and their intensity, as well as details regarding surgery, such as number of persons in the surgery team,

duration of surgery, pre-and post-surgery findings (e.g. range of motion, strength, weakness, etc.), diagnosis, results of imaging procedures, type of surgery, medical device and/or biopharmaceutical product used.

Step 2: Arthrex, Inc. saves the data from the questionnaire in the SOS

Once you have submitted your questionnaire, Arthrex, Inc. will save your answers in your patient profile. Depending on the type of injury and treatment, this may include the following information: course of treatment, pain situation, function of the treated body part, development of your general health status and well-being and information on your expectations to treatment and satisfaction with the course of treatment.

Furthermore, your doctor will collect personal data in the scope of post-surgical treatment and shall submit them to SOS. This may include information on additional treatments that are required after your initial treatment, as well as information on complications that may influence your treatment.

Step 3: Storage of personal data in data records

The data saved in your patient profile according to the above steps are accessible to different groups of persons at different scopes:

a. **Complete patient profile**
Your doctor and his/her staff are able to access your complete patient profile to monitor your course of treatment. Your doctor may individually specify which staff (other doctors and medical staff) may access your data. They are subject to doctor-patient confidentiality. Arthrex, Inc. can access your complete patient profile in order to ensure technical operation of SOS. Arthrex, Inc. can also access your complete patient profile in order to compile the patient-specific result reports, data records and average values as explained below.

b. **Patient-specific result reports**
Your doctor can request patient-specific result reports from Arthrex, Inc. The patient-specific result report links the course of your treatment to the averages (step 4) to enable your doctor to compare your treatment process to the average of all comparable patients. Your doctor will specify to Arthrex, Inc. for which treatments and based on which criteria the averages are to be linked to your data. The patient-specific result report contains information that can be linked to your person and will only be sent to your doctor through a secure connection.

c. **Limited data record**
The limited data records are to enable different treating facilities to exchange treatment courses of their respective patients and to compare them in order to gain an understanding of the costs, efficacy and economic efficiency of medical standard interventions and to improve them.
The limited data record shall be limited so as to make conclusions as to your identity more difficult for the recipient. Therefore, the limited data record shall especially not include the

email address or the individual identification number.
The limited data record must only be submitted to other doctors, hospitals or treating facilities with which your doctor or treating facility has entered into a data exchange agreement.

Your treating facility has not entered into any data exchange agreement.

Your treating facility will inform you [and ask for your consent] if any (further) data exchange agreements that affect your data are concluded in future.

d. **Pseudonymized data record**
With the exception of the above uses, your data will always be used pseudonymously. Arthrex, Inc. will create data records for this purpose which are pseudonymized. This will involve the replacement of information which could allow you to be identified with an identification number which only Arthrex, Inc. can associate with your personally identifiable information. This means that recipients of the pseudonymized data records generally cannot associate the data with your person, or can do so only with a disproportionate amount of time, cost or manpower. However, you should be aware that this does not apply unrestrained because even without knowledge of your name or email address, a recipient may be able to associate data records with your person solely on the basis of their combination of features (if applicable, in conjunction with other information available to the recipient or which is publicly known).
The pseudonymized data records can be used by participants in SOS, as well as by third parties, in order to gain an understanding of the costs, efficacy and economic efficiency of medical standard interventions and to improve them. Arthrex, Inc. will use your pseudonymized data records to compile the average values (cf. step 4) and possibly for product development and sales.

Step 4: Compilation of the averages

Arthrex, Inc. compiles averages based on all data present in the SOS. Based on the averages, statistical analyses can be compiled that provide a conclusion to the average course of treatment. These statistical averages do not identify you as an individual. They are no longer personal data. These statistical averages can be used by participants in SOS, as well as by third parties, in order to gain an understanding of the costs, efficacy and economic efficiency of medical standard interventions and to improve them. Arthrex, Inc. may also use these for product development and sales.

Deletion of data

You may at any time withdraw your consent to storage and use of your data and end your participation in SOS. In this case, all information that can identify you will be deleted and the remaining data will be anonymised (see section below on "Withdrawal of consent"). Until you withdraw your consent and end your participation in SOS, a special deletion deadline for deletion of your patient profile is not intended, because this is to be available to your attending physician

as well, and we have no information on the continuation of the treatment relationship.

What rights do I have regarding my personal data?

Voluntary consent

Participation in SOS is voluntary. You will only participate if you have consented to this in writing. Refusing consent does not affect your treatment.

For how long is my consent valid?

Your consent is valid without limitation in time. However, you can withdraw your consent at any time, without stating reasons.

Withdrawal of consent and consequences of revocation

You can refuse your consent and end your participation at any time without stating reasons. Revoking consent does not affect your treatment. The revocation shall not require any special form. Below, you will find information on to whom you can send your revocation.

After you have withdrawn your consent, you will no longer be able to participate in SOS. Your identifying data will be deleted (including your pseudonym) and the remaining data will be anonymized so that neither your doctor nor Arthrex, Inc. will be able to connect you to the data. No further data on you and your health status will be collected after your revocation. Withdrawal shall not affect legality of the processing that has taken place until the withdrawal of consent. In particular, the data saved until the time of withdrawal will still be used and transferred in anonymized form (e.g. as part of average values) for the purposes set out in this patient information.

Deletion shall only exclude any data subject to statutory archiving obligations. Such data shall only be deleted after the end of the legally required archiving period; they shall, however, be blocked for any other uses (cf. limitations of processing below).

Arthrex, Inc. or your doctor can exclude you from participation in SOS at any time – under indication of a reason. In this case, the above statements on deletion shall apply accordingly.

General rights

You have certain rights under data protection laws including the right to:

- withdraw your consent and end your participation in SOS at any time. In this case, all information that can identify you will be deleted and the remaining data anonymised (see section above on "Withdrawal of consent");
- request access to or erasure of your personal information;

- obtain rectification of inaccurate personal information;
- obtain restriction of processing or to object to processing of your personal information (in certain cases);
- have a copy of your personal information provided to you, or, a third party specified by you, in a digital format;

Please be aware that you will need to identify yourself in order to exercise the preceding rights and that the preceding rights can only be exercised over data which Arthrex, Inc. can actually associate with you.

Whom can I contact if I have any questions, to withdraw the consent or to exercise my rights?

You may send any questions on withdrawing consent or exercising any other rights directly to Arthrex, Inc. or to its representative in the European Union, Arthrex GmbH. You may also contact your attending physician about this.

The representative of Arthrex, Inc. for data privacy matters registered in the European Union is **Arthrex GmbH, Erwin-Hielscher-Str. 9, D-81249 Munich**, phone: 0049 89 90 90 05 0, email: SOS@arthrex.de.

The data privacy officer of Arthrex GmbH is Mr. Leif-Eric Langguth. You can contact him at Arthrex GmbH, Erwin-Hielscher-Str. 9, D-81249 Munich, phone: 0049 89 90 90 05 3400, e-mail: leif-eric.langguth@arthrex.de.

Supervisory authorities

You may address any complaints about Arthrex, Inc. either to the US "Food and Drug Administration" (FDA, www.fda.gov) or regarding processing your data to the Bayerisches Landesamt für Datenschutzaufsicht (BayLDA) (www.lda.bayern.de) as the supervisory authority relevant for the representative Arthrex GmbH registered in the European Union. You may also address any complaints about Arthrex GmbH to the BayLDA. Regarding the supervisory authorities competent for your doctor or treating facility, please inquire from them directly.