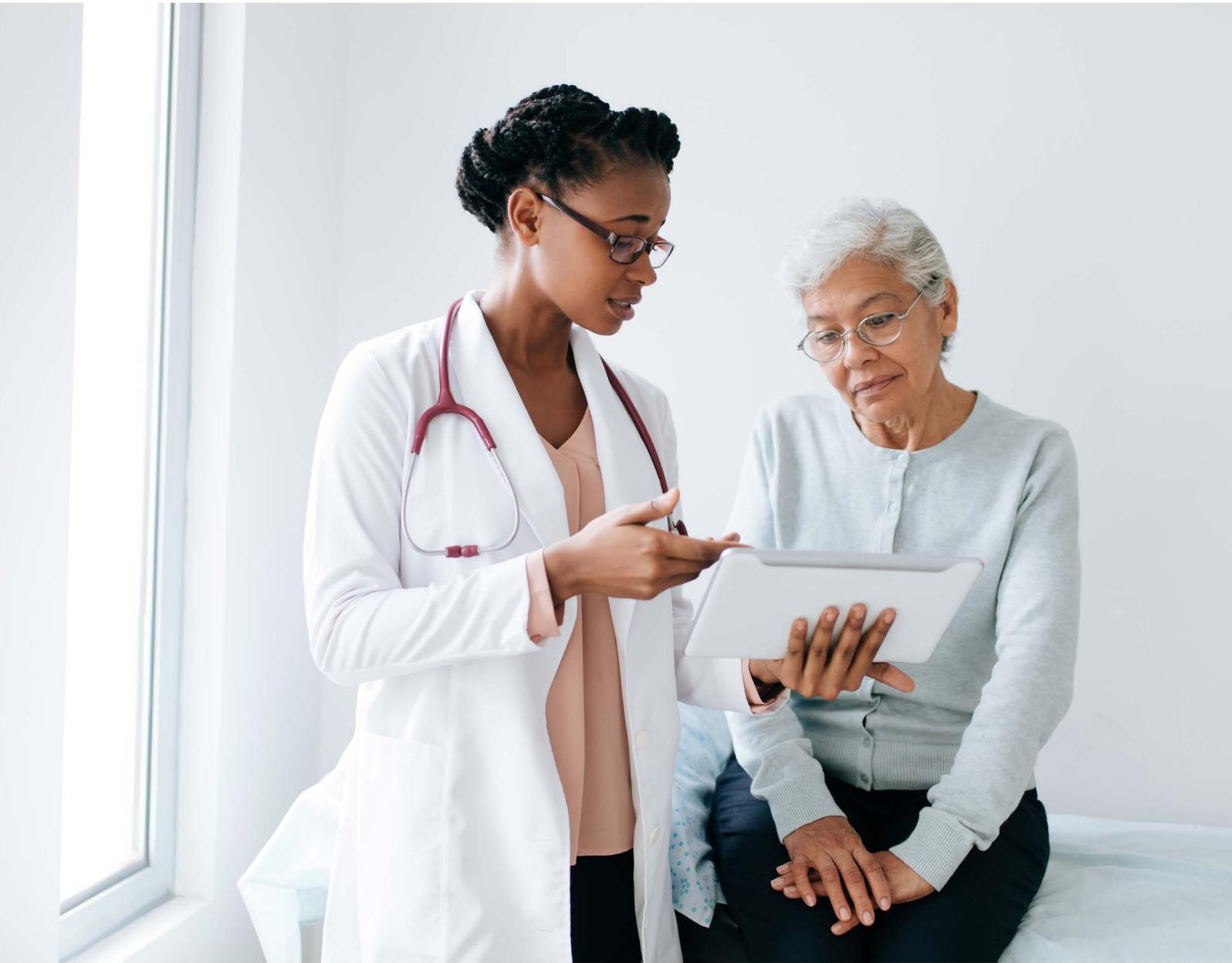




Surgical Outcomes System

Frequently Asked Questions



General

What is the purpose of the Surgical Outcomes System™ global registry?

The primary purpose of the SOS global registry is to monitor and evaluate the global outcomes of various standard-of-care orthopedic and sports medicine medical procedures. This leads to the development of evidence-based protocols for the best methods for treating patients with different conditions. For US physicians, SOS global registry is a specialized clinical data registry that is ready to accept data generated from certified electronic health record technology (CEHRT) of physicians and other clinicians who are participating in the Medicare Quality Payment Program. SOS pain and functional measures are aligned with the American Academy of Orthopaedic Surgeons (AAOS) and orthopedic specialty societies.

What is the goal of the SOS global registry for physicians?

The SOS global registry is an orthopedic and sports medicine registry that enables physicians to easily collect and analyze patient outcomes and treatment procedures to quantify results for health care operations, performance improvement, marketing, patient engagement, and research. Arthrex's developmental efforts focus on streamlining the SOS global registry to decrease administrative time and resources for the site.

What is the goal of the SOS global registry for administration?

The SOS global registry is valuable for hospital administration for health care operations and quality assurance, cost-effectiveness of procedures and products, key performance indicators of employed physicians, and marketing of the hospital. SOS patient-reported outcome measures and risk variables are aligned with the US CMS Comprehensive Joint Replacement bundled payment plan.

What is the goal of the SOS global registry for patients?

It is important that the physician explain to the patient that the SOS global registry allows the physician to monitor the patient's treatment progress and well-being. It's in the patient's best interest that their physician monitors their treatment progress. Knowing that the SOS global registry is a critical part of their treatment recovery, no matter where they live or how often they visit their physician after treatment, is reassuring and comforting for patients and motivates them to complete surveys on time. The SOS global registry provides patients with an additional "voice" to their physician through surveys based on pain, function, and quality of life.

What is the goal of the SOS global registry for Arthrex?

Arthrex's mission is Helping Surgeons Treat Their Patients Better™. Historically, our focus has been on product and technique innovation in arthroscopy and less invasive orthopedics. Our aim to design and manufacture the highest quality products grew into the responsibility to provide physicians with a surgical skills learning environment using the latest technology. This obligation has now evolved into aligning experienced in-house software and multimedia design talent in order to provide the simplest and most comprehensive global, web-based surgical outcomes registry in orthopedics—one that is paperless, time- and cost-efficient, secure, and comprehensive for physicians. Outcomes data collection and analysis are important not only to help physicians quantify and validate their treatment outcomes for their patients, peers, publishers, and payers, but also to ensure that our products help provide safe and effective patient outcomes long after they are used or implanted. It's taking our quality-assurance responsibility to the highest level. A global registry in orthopedics with thousands of physicians and patients enrolled has become one of our greatest achievements in a history of contributions to arthroscopy, sports medicine, and minimally invasive orthopedics, as well as a worthy contribution to health care and humanity.

What is the goal of the SOS™ global registry for societies and associations?

The SOS global registry collaborates with societies and associations to unify their members' patient outcomes collection for health care operations, research and publication, and validation of outcome measures. The SOS global registry is aligned with the recommendations of the AAOS and orthopedic specialty societies for patient-reported outcomes measures of pain and function. Arthrex offers tiered pricing and additional options to allow consistent outcomes collection across multiple sites.

What is the goal of the SOS global registry for health plans?

The SOS global registry provides health plans with the ability to consistently collect outcomes data across multiple sites, allowing for aggregate averages and benchmarking. Health care plans are able to use the SOS global registry data to determine the cost-effectiveness of interventions, to measure and observe key performance indicators of providers, to enhance marketing, and to generate valuable metrics.

Does the SOS global registry have the ability to customize the specific outcome measures that are important to my site's data collection or research goals?

The SOS global registry includes "core registry" outcome measures that are automatically emailed out to all patients at predefined time points. These measures are aligned with the AAOS and orthopedic specialty societies recommendations for pain and function patient-reported outcomes measures. This would be considered the "minimal data set," which includes a global health score and a general disability and pain score. This consistency allows for benchmarking and analysis using the global de-identified average. The SOS global registry gives the physician flexibility to add selected disease-specific measures and create customized study modules. There is no additional cost for this feature. Arthrex secures permissions and licenses for the measures we offer within the platform.

What impact does the SOS global registry have on a site's workflow, addressing time, and resources required?

The SOS global registry has minimal impact on the site's time and resources required. Enrolling a patient takes an average of 20 seconds. The site can have their surgical scheduler, a coordinator, a medical assistant, or a physician assistant do this. Once the patient is enrolled, the system sends automatic personalized emails from the physician to the patient. It also sends reminder emails to patients who have not completed the survey.

Patient compliance tracking is organized through the SOS global registry dashboard and the "indicator lights." These indicator lights appear next to the patient's information on the dashboard and tell the site that the patient is within a "time window" of needing to complete a survey. This is the opportunity for the provider to follow up with the patient by sending an alert from the system, phoning the patient, or launching the survey on a tablet or PC during a clinic visit. Once the initial procedure has been entered, the process of adding treatment details is streamlined using the template builder. Most orthopedic physicians perform the same 5 to 10 surgeries or treatments. Therefore, each procedure can be built into a template that allows treatment data entry to be minimized. Templates are added to each customer's portal and will be dependent on the study module access. Templates will be added to the physician's portal and to designated assistant(s) who have been given security clearance to access the physician's patients. Our SOS team will work with your site to develop the best workflow and use of resources during final training.

Data and IT

Which patients may be included in the SOS™ global registry?

The SOS global registry is designed for patients receiving orthopedic sports medicine, arthroscopy, and related surgeries or procedures. The patient portal is available in multiple languages, making the SOS global registry a resource for comparative analysis of medical treatment techniques within different regions.

Does the SOS global registry integrate with my electronic health record?

Yes, the SOS global registry provides an application programming interface (API), which can allow integration with an EHR. There is an additional fee for this service.

Does the SOS global registry have data entry error checks?

Yes, the SOS global registry does have data entry error checks. It is the responsibility of the site to enroll patients and enter treatment details. The SOS global registry includes field-by-field data entry error checks; where appropriate, drop-down selection lists are used. When necessary, an alert system prompts the user of an error, such as in the case of duplicate custom IDs. The SOS global registry also has an audit trail in place, which provides a record of users who have entered data.

What protected health information is collected in the SOS global registry?

The SOS global registry only collects the minimum necessary protected health information (PHI).¹ All PHI is encrypted and transferred over secure data communication lines.

- Various elements of dates directly related to an individual, including birth date and date of treatment;
- E-mail addresses;
- Medical record numbers, if chosen by the site (custom ID)
- Internet protocol (IP) address number²

Where is the SOS global registry data stored?

The SOS global registry is hosted on servers operated for Arthrex by Amazon Web Services, Inc (AWS). The servers are located in data centers in Virginia for US customers and in Frankfurt, Germany for European customers.³ Multiple layers of operational and physical security to ensure the integrity and safety of the data. The data centers use state-of-the-art electronic surveillance and multifactor access control systems. Trained security guards staff the data centers 24x7 and access is authorized on a least-privileged basis.

Does the SOS global registry use any components that will require installation at the surgeon/site facility?

No, the SOS global registry is web-based and only requires modern browsers with JavaScriptSM enabled.

For entities in the European Economic Area, is use of the SOS global registry compliant with EU privacy laws?

Arthrex, along with its subsidiaries and affiliates, is committed to respecting and protecting the privacy of those who entrust us with their personal information. When patients from the European Economic Area enroll in the SOS global registry, they are advised, and asked to expressly consent, that their data will be processed by designated SOS team members outside of the European Economic Area in countries in which, in the view of the European Commission, there is no assured, reasonable level of data protection for the purposes of the technical operation of the SOS global registry. The patients' informed consent provides the legal basis for the processing of their data.

For US covered entities, will Arthrex sign the site's business associate agreement?

Yes, Arthrex will sign a business associate agreement (BAA) with the site. According to the Department of Health and Human Services (HHS), the site is a covered entity (CE) and the SOS™ global registry is their business associate (BA); Arthrex, as the BA, will sign the site's BAA. HHS requires the BA to ensure that any subcontractors it may engage on its behalf that will have access to PHI agree to the same restrictions and conditions that apply to the BA with respect to such information: <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html>.

Does the system maintain an audit trail that provides documentary evidence of user transactions?

Yes, the SOS global registry maintains an audit trail that provides documentary evidence of user data entry.

Does the system encrypt data?

Yes, the SOS global registry encrypts data while transmitted and while stored.

Is there a disaster recovery plan established for the SOS global registry?

Backups of all SOS global registry data are retained for auditing and disaster recovery purposes. The most recent backups (typically 1 day or less) may be used in cases of total failure or data loss to restore the system to a functional state. Backups older than this are kept strictly for auditing purposes in case older changes to the data need to be reviewed. All backups are stored within a secure facility, and encrypted for security purposes.

Data privacy is important to patients and physicians. How does Arthrex protect it?

Arthrex's SOS global registry program is a service to meet the global research and quality-assurance needs of orthopedic physicians. Extensive measures have been taken to ensure the security of PHI according to HIPAA regulations. The SOS global registry only collects the minimum necessary PHI, and all PHI is encrypted and transferred over secure data communication lines. Arthrex actively performs due diligence with regard to third-party validation of information security controls. Following industry best practices, Arthrex strives to meet the highest level of security and privacy protection possible. The SOS global registry is a leading physician advisory board that oversees all SOS global registry policies and procedures to validate patient and surgeon data privacy protection. Each physician or site enrolled in the SOS global registry owns their own data and has exclusive, private access to their data. This policy is secured with a binding legal agreement with the SOS global registry and Arthrex. Arthrex does not use physicians' personalized data. In fact, identifiable data is immediately transformed and de-identified or anonymized prior to any aggregation of the shared global average. All users enrolled in the SOS global registry have access only to the shared de-identified global averages on treatment outcomes, allowing for patient education and benchmarking for medical decision making.

Legal

The SOS™ global registry must adhere to individual country privacy laws for data collection with written approval from government authorities in that country. Additionally, as a privately held corporation without outside investors, our core mission is scientific and not economic, with an unwavering commitment to physicians, scientific principles, and evidence-based medicine since 1981.

Will Arthrex disclose personal information to third parties?

Arthrex is contractually bound to protect the privacy and security of personal information. As your sponsor or service provider, Arthrex will use all reasonable efforts to protect the privacy and security of personal information and will require its business associates to do the same. For example, the SOS global registry is hosted on servers operated exclusively for Arthrex by Amazon Web Services, which is legally bound to Arthrex's privacy practices and policies and is permitted to use personal information only for the purpose of operating the SOS global registry on behalf of Arthrex.

For what purposes does Arthrex use the de-identified data?

Arthrex uses the de-identified data set for research and development, quality control of our products and procedures, and educating physicians on the efficiency of our products and procedures. De-identified data is anonymized on the physician level and the patient level. Contractually, Arthrex cannot access your PHI for any purpose other than for technical operation or maintenance purposes.

Is the data submitted discoverable? Can it be subpoenaed?

Generally, an individual's data is potentially discoverable and can be subpoenaed. However, we believe it is unlikely that the SOS global registry data would be subpoenaed. In the event your data were subpoenaed, Arthrex would take reasonable steps to notify you and limit the disclosure as allowed by law.



Footnotes

1. The minimum necessary standard is a key component of the HIPAA Privacy Rule.
2. The SOS global registry uses patient IP addresses to audit actions the patient takes for troubleshooting and security purposes.
3. The EU-US Privacy Shield certification program is aimed at assisting US companies to comply with the European Union General Data Protection Regulation (GDPR) on the protection of personal data. By joining and adhering to the EU-US Privacy Shield, US companies demonstrate that their data protection practices meet European Union data protection requirements.



This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience, and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level and/or outcomes.

View U.S. patent information at www.arthrex.com/corporate/virtual-patent-marking

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