

# INSTRUCTION FOR USE

# spineEOS

## Surgical Planning Software

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**NOTE**

Any personal data appearing in the screen captures of this document is fictional.

**WARNING**

The instructions for use may be updated at any time by the manufacturer. To benefit from the latest content, always consult the version available online.

**NOTE**

Alphatec Spine (ATEC) is referenced within this document. ATEC is the parent company of EOS imaging.

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## 1 Introduction

The spineEOS software is an online medical device accessible from the EOS Portal platform at the following address:

- <https://eos3dservices.com> from the United States.
- <https://eos3dservices.eu> from the rest of the world.

Using spineEOS requires training by a qualified employee from Alphatec Spine or EOS imaging.

The functions of the EOS Portal are described in a dedicated instruction for use accessible from the home page ("Online Support").

The current instruction for use document is accessible on the ATEC webpage: <https://atecspine.com/ifu-documentation/>.

An electronic version of the spineEOS User Manual as a PDF can be sent by contacting EOS Imaging service (see "Contact " section).

In the event of a minor software update that does not require additional training, the user will receive a report by email listing the changes included in the new version available.

### 1.1 Indication for use

spineEOS software is indicated for assisting healthcare professionals with preoperative planning of spine surgeries. spineEOS provides access to EOS images with associated 3D datasets and measurements. spineEOS includes surgical planning tools that enable users to define a patient specific surgical strategy.

### 1.2 Target population

spineEOS is recommended in the preoperative planning of primary and revision spine surgeries for:

- Degenerative spine and adult spinal deformity.
- Adolescent Idiopathic Scoliosis (AIS) patients

### 1.3 Users profile

spineEOS can only be used by a trained user including:

- Spine surgeons to define and validate the surgical plan.
- EOS staff and implant distributors to define and save the optional pre-planning.

#### NOTE

spineEOS offers premium features to ATEC interbody spacer users allowing them to access ATEC 3D implant portfolio.

### 1.4 Compatibility with other medical devices

#### 1.4.1 sterEOS

The sterEOS Workstation is a general system for acceptance, transfer, display, storage, and digital processing of 2D X-ray images of the musculoskeletal system, including interactive 2D measurement tools. When used with 2D X-ray images obtained with the EOS imaging's EOS and EOSedge systems, the sterEOS Workstation provides interactive 3D measurement tools to aid in the analysis of skeletal deformities in spine, pelvis, and lower limbs.

The inputs of the product, including 3D models of bones, EOS images, and additional metadata come exclusively from sterEOS. The compatible versions are versions starting from 1.8.3.

#### 1.4.2 EOS Portal

EOS Portal is the software which manages the use of the product by including an authenticator feature, a user management feature, and a patient data management feature. EOS Portal manages the loading of initial patient dataset and the access to output data of the product.

#### 1.4.3 ATEC interbody spacer system

The interbody spacer system is an implantable intervertebral fusion device of various lengths, widths, heights, and degrees of lordosis to accommodate individual patient anatomy. ATEC offers interbody spacers manufactured from

different materials like PEEK (polyetheretherketone) and porous titanium. The 3D model of these implants is available in spineEOS to allow surgeons to choose the implant that they will use during surgery.

#### 1.4.4 Personalized shaped rods

spineEOS allows the surgeon to configure the shape of the rods which will be installed on the patient and therefore can provide the information to bend the rods for the surgery. The personalized shaped rod product uses this information as input in the aim to bend and deliver to the surgeon rods with the shape defined during the planning.

### 1.5 Precaution for use



#### IMPORTANT

Read the instruction for use carefully before use.

### 1.6 Contraindications

spineEOS is not intended to be used in the following cases:

- Patients under the age of 7.
- Patients with vertebrae with congenital deformities (e.g., hemivertebrae, spina bifida, etc.).

The 3D models delivered by sterEOS can only be used for diagnostic purposes in association with the corresponding 2D images. They are intended for the visualization of the spatial relationship between anatomical structures and do not allow the identification of local bone alterations such as:

- Bones with a significant change in geometry following surgery,
- Fractures,
- Osteophytes
- Fibrocartilage calluses

### 1.7 Warnings

#### 1.7.1 Prerequisites and context of use



#### WARNING

spineEOS can only be used by trained and experienced users.

Users must ensure that the patient's identity matches that of the patient they are preparing to operate on.

Users shall also check that the date of birth displayed in the software is identical to the date indicated in the patient file. Dates in spineEOS are displayed in international format: YYYY-MM-DD (Year-Month-Day).

spineEOS is an online planning solution designed as a decision support for trained medical specialists. The software should not be used as the sole basis for making clinical decisions relating to patient diagnosis, treatment, or care.



#### WARNING

spineEOS uses 3D models based on EOS images generated with a specific software, sterEOS. Inherently, spineEOS limitations are the same as sterEOS limitations. More precisely, 3D modeling can be imprecise, or even impossible, when anatomical structures cannot be identified as in the following cases:

- prostheses or instrumentation masking or replacing anatomical landmarks.
- some pathological conditions that alter the bone composition, such as osteoporosis,
- impossibility to differentiate the medial condyle from the lateral condyle or the medial tibial plateau from the external

#### 1.7.2 Validity limit of patient data



#### WARNING

The patient's anatomy is subject to change. A case will be posted for planning if the time between the acquisition of the patient's images and surgery does not exceed six months.

### 1.7.3 Operation of the software

The browser may crash and lose WebGL functionality, making planning impossible. WebGL enables 3D elements to be managed in the browser (display of bones, etc.). Software detects WebGL accidents and proposes, through an information message, to relaunch the planning to continue.

#### NOTE

To ensure that the software works properly, the user must not launch the same planning at the same time.

### 1.7.4 Precision on values

All values displayed in the software are rounded to the nearest degree or millimeter.

### 1.7.5 Planning validation



#### WARNING

During the planning validation, the browser must not be closed, the page actualized, or the computer switched off before the end and the automatic feedback of the intervention details to the EOS Portal.

## 1.8 Possible secondary effects

There are no known side effects associated with the use of spineEOS.

## 2 Minimum required configurations

spineEOS is not intended for use on mobile devices.

### 2.1 Minimal configuration advised

A stable internet connection is required (see "Internet configuration" section).

- With Windows 10 or 11: Google Chrome in version 111 or higher, and Edge in version 111 or higher.
- With Mac OS Monterey or Ventura: Google Chrome in version 111 or higher, and Safari in version 16.2 or higher.

It is the user's responsibility to keep his/her web browser up to date for the better functioning of the software.



#### WARNING

For optimal use of spineEOS, the web browser and computer zoom must be set to 100%.

### 2.2 Screen resolution

The minimum screen resolution ensuring full display of the interface is 1600 x 900.

#### NOTE

HD screens are compatible with the application.

### 2.3 Mouse and trackpad

An optical mouse is recommended for better software use. A trackpad may be sufficient for planning (in Mac and PC environments) but not recommended.

#### NOTE

In the Mac environment, the use of a "Magic Mouse" is not certified (in the Mac environment) and can cause undesired effects.

## 2.4 Internet configuration

A stable high speed internet connection is required: DSL 100Mb/s connection or higher, Wi-Fi or Ethernet.

### NOTE

Other connections such as a 5G/4G/3G connection can be used, but they must be stable. The user may then experience a relatively long load time for the software.

## 2.5 Web browser cache

When a new version of the software is deployed, it is strongly recommended that the web browser cache be emptied. The “Appendix 1: Clearing your browser ” explains how to perform this operation.

## 2.6 Automatic translation of pages in browsers

Some browsers may offer an automatic translation of the application's page. It is strongly advised not to use this feature. The application is available in French and English. If you do not have the correct language when loading the application, you can change the language in your user profile in EOS portal using the “Profile” button, at the top right of the page containing the list of interventions.

## 2.7 WebGL activation for SAFARI

Users of Safari versions 10 and lower must activate WebGL on their browser to access the planning function. Appendix 2: Activating WebGL in SAFARI describes the manual operations to be performed.

## 2.8 Enabling hardware acceleration

It is possible to improve the fluidity of some browsers by activating the hardware acceleration of the computer. The following are the methods to be used for each browser:

- Google Chrome:
  - Type chrome://settings/ in the address bar, then press Enter.
  - In the web page displayed, enable “Use hardware acceleration.”
- Microsoft Edge:
  - Click on the “three dots” button at the top right of the browser window.
  - In the drop-down menu, select “settings” Click on “system” on the left side.
  - In the web page displayed, enable “Use hardware acceleration”.
- Safari: As of macOS Catalina (version 10.15), Hardware acceleration is automatically enabled, and there is no way turn this on and off. For users using older versions of macOS:
  - Click on the "Safari" then "Settings".
  - In the web page displayed, click on “Advanced” at the top right of the window, enable “Use hardware acceleration”.

### 3 Security recommendations

The use of the products does not require any additional software on the user's computer except an up-to-date web browser.

The product provides access to sensitive patient health information (PHI), and user should be mindful while using the product. The user is responsible for the security aspects of his computer.

The following section provides common recommendations about security on the web that applies to the product's use.

#### 3.1 User Credentials

The product requires users to login before accessing any data or resources. An automatic logout is configured (24 minutes of inactivity).

Each user has a unique account created when purchasing the product. Accounts and credentials shall not be shared among multiple users.

The product uses the following security measures to protect accounts:

- User must define strong password:
  - The size of the password must be at least 8 characters included 3 out of the 4 below:
    - Has at least one uppercase
    - Has at least one lowercase
    - Has at least one number
    - Has at least one symbol (!@#\$%^&\*()\_+~[]{}|;':",.<>/?).
- Accounts use multi-factor authentication:
  - The user identity is verified by sending a message, to the phone when attempting to login.
  - The phone number is defined when creating an account.

ATEC and EOS employees do not have access to your password, and in any event, would never ask you to provide your password.

If this happens, contact immediately your ATEC/EOS representative, or use the contact information available in §6 Contact us.

#### 3.2 User environment

The use of a modern, auto-updated, browser is recommended.

The user must respect the common recommendations about security on the web:

- Apply security updates to the user's computer as soon as they are available
- Use antivirus software on the user's computer
- Download applications only from official websites
- Don't diffuse any information, especially about application's access and patient data on social networks
- Separate personal and professional uses
- Avoid public or unknown Wi-Fi networks

#### 3.3 User access

The product implements HTTPS protocol for communication between the user's web browser and the application's server. The protocol encrypts end-to-end communication to ensure confidentiality, and integrity, of information.

The user must respect the common recommendations about security on the web:

- Use only the following address to access the application
  - <https://eos3dservices.com> from the United States
  - <https://eos3dservices.eu> from the rest of the world
- Make sure that the connection uses HTTPS protocol to access the application
- Log out from the application after each use



ATEC and EOS products use a trusted certificate authority to enable https. If your browser notifies an untrusted certificate when using the product, close your browser and contact immediately your ATEC/EOS representative, or use the contact information available in §6 Contact us.

### 3.4 Application's Servers

The product and EOS Portal are web application hosted and deployed on a datacenter certified for hosting Patient Health Information and is HIPAA compliant. The product relies on EOS Portal for support capabilities such as user access control, and data acquisition access.

The main feature of the server is to protect personal health information. The server is installed in an environment that complies with the standards in force for this type of use. Moreover, the https protocol is used to connect to it, thus ensuring data transfer security.

Server's security is under the responsibility of the manufacturer.

### 3.5 Information to the user

The deployment of a new version of the device is followed by an information to the user on what updates have been performed on the device. The user has directly access to the last version of the device is a web application.

If a cybersecurity vulnerability or event is detected on the device, depending on its severity and impact on the user, a communication is performed with details on vulnerabilities and recommendations.

### 3.6 Report a cybersecurity incident

If you believe a potential security vulnerability occurs in one of our products or services, please contact us immediately. Contact details are available at §6 Contact us.





So, we can proceed to proper investigation and initiate corrections as soon as possible, please provide at least the following:

- Contact details (name and address of the site, contact person name, function, phone number and email address)
- Product impacted (Model and serial number)
- Date and time of incident
- Any error message that has appeared
- Any action made by the user before and after the security vulnerability was suspected
- Any other event or source from which the security vulnerability is suspected to come from
- Any additional information you judge necessary to understand and investigate the event

## 4 Product information

Information for product identification is available from the about page of the software.

The following symbols are used on this page:

Symbol	Meaning
	Medical device
	Unique Device Identifier
	Manufacturer
	Consult the provided documentation
<b>Rx only</b>	Valid for the United States: Caution: Federal law restricts these devices to sale by or on the order of a physician.

## 5 Technical/Clinical Performance and Benefits

When used as intended, spineEOS has the following technical or functional characteristics that enable users to achieve the intended purpose described above and thereby lead to a clinical benefit to patients:

### 5.1 Technical Performances

- **spineEOS** allows user to display EOS images with the patient in a functional position, scale 1:1 without the need for complex calibration protocols.
- **spineEOS** is a unique didactic tool that allows surgeons to visualize the treatment strategy in 3D to discuss the results of the operation with their patient. As web-based, spineEOS allows surgical case planning from any personal computer.

#### NOTE

The 3D modeling data and measurements provided in spineEOS are prepared by EOS 3DServices, a unique team of experts

- Thanks to **spineEOS**, surgeons can review and make measurements on functional and dynamic images.
- **spineEOS** gives the surgeons the ability to understand their patient's global alignment based on published normative ranges.
- **spineEOS** offers value added features for all spine surgeons independently of implants and technologies that they are using in the OR as it allows:
  - to determine UIV and LIV.
  - to determine the size of interbodies and their impacts on global alignment.
  - to plan osteotomies.
  - to measure the grade of spondylolisthesis/retrolisthesis and plan its correction.
  - to plan rod length, diameter, and shape
- **spineEOS** is the only spine surgical planning solution that leverages full potential of EOSedge images, associated patient specific 3D spine models and ATEC 3D implant portfolio. More precisely, spineEOS offers premium features to ATEC implants users allowing them to access and plan ATEC specific interbody cages and specific interbody devices in 3D.

### 5.2 Clinical Performances

spineEOS allows surgeons:

- To have a better understanding of their patient's global alignment and deformity.
- To have a better understanding of their patient's age-adjusted targeted alignment.
- To plan their construct strategy and anticipate their patient's sagittal and coronal alignments.
- To plan the rod length and shape for their patients.

### 5.3 Clinical Benefits

spineEOS allows users to improve understanding of a patient's anatomy and optimization of the surgical plan for more efficiency in the operating room.

## 6 Contact us

For any questions or assistance, you can contact:

- Telephone: +1 514 875 0030
- Email: [3dservices@eos-imaging.com](mailto:3dservices@eos-imaging.com)
- Website: <https://www.eos-imaging.com>

In case of unavailability of this electronic instruction for use, a paper version may be sent to any user who requests it by using the contact information above or by using the contact tool in EOS Portal.

## **Appendix 1: Clearing your browser cache.**

### Google Chrome:

- In Chrome, at the top right, click.
- Click on “More tools” then “Delete browsing data”.
- At the top of the page, choose “All time” in the “Time range” drop down list.
- Check the boxes “Cookies and website data” and “Cached images and files”.
- Click on “Delete Data”.
- Close the page.

### Edge:

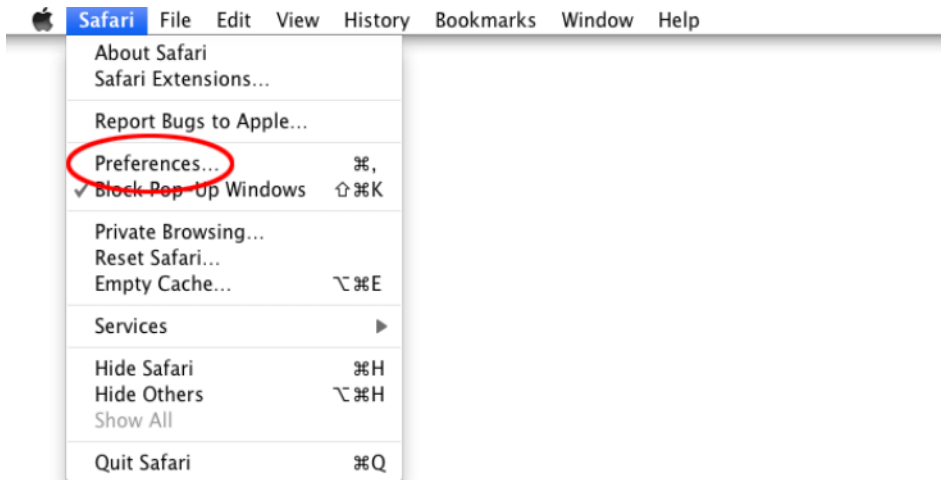
- In Edge, at the top right, click.
- Click on “Settings” then “Privacy, search and services” in the left panel.
- In the part “Clear browsing data” click on the button “Choose what to clear”.
- At the top of the page, choose “All time” in the “Time range” drop down list.
- Check the boxes “Cookies and other site data” and “Cached images and files”.
- Click on “Clear now”.
- Close the page.

### Safari:

- In Safari, click on the Safari drop-down menu and select Preferences.
- Click on the Advanced tab and select the “Show Develop menu in menu bar” checkbox.
- Close the Preferences window.
- Select the Develop drop-down menu in the tool bar.
- Click on “Empty Cache”
- Close the page.

## Appendix 2: Activating WebGL in SAFARI

- Enable the Safari develop menu: Safari menu → Preferences...



- In the Advanced tab, check "Show Develop menu in menu bar"



- In the Develop menu, select "Enable WebGL"

