INSTRUCTIONS FOR USE
Orthenix
Preoperative planning

English Version
2026-03-05

TABLE OF CONTENTS

GLOSSARY

PRRC	Person Responsible for Regulatory Compliance
MD	Medical Device
IFU	Instructions for Use
eIFU	Electronic Instructions for Use
SaaS	Software as a Service
SaMD	Sofware as a Medical Device
MRI	Magnetic Resonance Imaging
BMI	Body Mass Index
CT-scan	Computed tomography scan
GPU	Graphic Processing Unit
Fat-sat 3D PD	Fat-saturated 3 Dimension Proton Density
DICOM	Digital Imaging and Communications in Medicine
VPN	Virtual Private Network
URL	Uniform Resource Locator
UDI	Unique Device Identifier
	Caution
	Medical device manufacturer
	Date of manufacture
	Medical Device
	UDI
	Catalogue number
	Consult electronic instructions for use
	Rx only

MANUFACTURER INFORMATION

AREAS
2 rue Saint Laurent, 38000, Grenoble, FRANCE
PRRC: support@areas.ai
Website: https://areas.ai/

PRODUCT INFORMATION

Name: Orthenix™ Preoperative Planning
Software Type: SaMD, SaaS
UDI: (01)03760445581010(8012)1.0.1-fda
Product version: 1.0.1-fda
Language: English
IFU version: 1.0.0

PURPOSE OF THE DOCUMENT

This eIFU provide all information required for the safe installation, operation, interpretation, and maintenance of the Orthenix™ Preoperative Planning software.
It is addressed to orthopedic surgeons using the software for pre-operative ligament reconstruction planning. Areas staff using the application for reviewing and landmarking segmentation have a specific IFU document.

INTENDED USE

INTENDED PURPOSE

Orthenix™ Preoperative Planning is a web-based medical device designed to assist healthcare professionals in the pre-operative planning of knee ligament reconstruction procedures. By processing MRI images, the software generates patient-specific 3D anatomical models and offers tools to visualize the patient's knee anatomy, simulate knee joint kinematics within a defined range, and plan and adjust femoral and tibial tunnel placement for ligament reconstruction. Additionally, it can generate a PDF summary of the surgical planning. As a decision-support tool, Orthenix™ Preoperative Planning does not provide diagnoses, replace clinical judgment, or recommend specific surgical techniques. It serves as a supporting software to enhance the pre-operative planning process.

INTENDED USER POPULATION

- Orthopedic surgeons trained in knee ligament reconstruction
- AREAS administrators managing user accounts and system resources

INTENDED PATIENT POPULATION

The software may be used for planning procedures on:

- Patients ≥18 years old
- Any gender
- BMI ranges:
  - Male: 20.7 < BMI < 39.8
  - Female: 19.6 < BMI < 43.3
- All ethnic origins
- Either left or right knee

INDICATIONS

The device supports pre-operative planning for one or more of the following ligament reconstruction procedures:

- Anterior Cruciate Ligament (ACL) reconstruction
- Posterior Cruciate Ligament (PCL) reconstruction
- Medial Collateral Ligament (MCL) reconstruction
- Lateral Extra-Articular Tenodesis (LET)

Patients: ≥18 y, BMI within validated range, any ethnicity.

⚠ CONTRAINDICATIONS

The software is not expected to perform reliably in the following scenarios:

- Patients with severe knee osteoarthritis (Kellgren–Lawrence > 2)
- Patients with pre-existing bone tunnels in the knee joint from previous surgical procedures

SOFTWARE ARCHITECTURE

The figure below shows the high-level architecture of Orthenix™ Preoperative Planning.

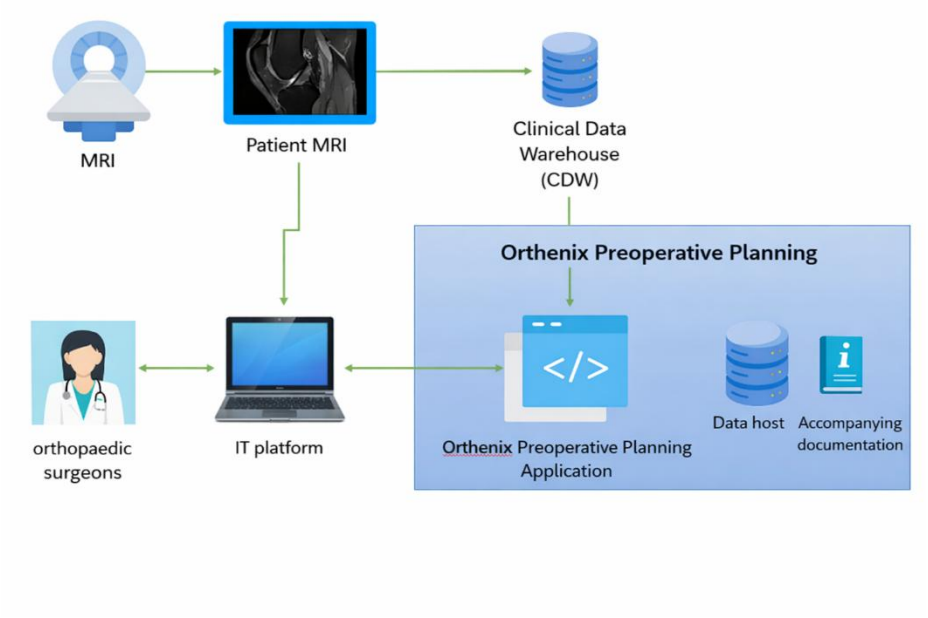

Figure 1: Software architecture

The software operates using Amazon Web Services servers.

WARNINGS AND PRECAUTIONS

GENERAL WARNINGS

Only trained AREAS administrators are allowed to register users.
The use of the device is restricted to surgeons and AREAS staff.
Accounts and credentials are personal and shall not be shared.
Incorrect patient data entry may lead to inappropriate planning results.
The software does not detect patient identity mismatches.
Users must verify that the uploaded MRI corresponds to the correct patient.
The software supports surgery planning and does not replace clinical judgement.
Planning output is guidance, not a surgical prescription.
The surgeon must review and validate all segmentation results, 3D model and planning data before surgery.
Kinematics are obtained using averaged data.

ENVIRONMENTAL PRECAUTIONS

Use in a quiet office environment is recommended.
Use in noisy, distracting environments may contribute to user error.

The software must be used on a stable internet connection.

CYBERSECURITY AND DATA PRIVACY

Store and access data only through authorized user accounts.
Do not share login credentials.
Ensure compliance with institutional data protection procedures.
Orthenix™ Preoperative Planning is not expected to be used in public space on public networks.

CLINICAL BENEFITS

The use of MRI data allows to obtain state-of the art planification for knee surgery (ligamentoplasty) by presenting tissues not visible from a CT scan.
The use of MRI data allows to obtain state-of the art planification for knee surgery (ligamentoplasty) without exposing the patient to the radiation level of a CT scan

SAFETY AND CLINICAL OVERVIEW

Clinical Overview

The software is designed as a planning support tool only. It does not provide diagnosis, prognosis, or treatment recommendations and does not determine whether a surgical procedure should be performed. All clinical decisions, including surgical strategy and intraoperative adjustments, remain under the sole responsibility of the qualified orthopedic surgeon.
The planning results generated by the software are intended to be used as informative guidance and must always be interpreted in conjunction with:

- the surgeon's clinical expertise,
- patient-specific clinical findings,
- intraoperative observations.

Safety Overview

The safety of Orthenix™ Preoperative Planning is based on:

- correct patient identification and data entry,
- use of MRI data that meet the specified imaging requirements,
- systematic review and validation of 3D model and kinematic simulation results.

Potential risks associated with the use of the software include, but are not limited to:

- use of incorrect or suboptimal MRI datasets,
- patient identification errors during MRI upload,
- inaccurate interpretation of the 3D anatomical model or kinematics,
- over-reliance on planning outputs without appropriate clinical verification.

These risks are mitigated through:

- clearly defined intended use and limitations,
- segmentation, 3D models and kinematics verification steps prior to planning,
- user warnings and precautions described in this IFU,
- professional-use restriction of the device.

The performance and safety of Orthenix™ Preoperative Planning have been evaluated only for:

- the indications described in this IFU,

- the specified patient population,
- the supported MRI modalities and acquisition parameters.

Use of the software outside these conditions may lead to reduced performance and is not supported.

After implementation of all risk control measures, **no intolerable residual risks have been identified** for Orthenix™ Preoperative Planning.
The remaining residual risks are considered **acceptable** when the device is used in accordance with its intended purpose, limitations, and the instructions provided in this IFU.

System Requirements

Hardware

- Standard desktop or laptop computer
- Sufficient processing and memory capacity for 3D rendering (no specialized GPU required)
- Minimum recommended monitor resolution: 1920x1080 pixels (any resolution or zoomed screen smaller than the recommended could lower the usability of the application)
- Smartphones and tablets not supported

Operating System:

- macOS 26 or more
- Windows 11 or more

Hardware contraindication:

- Portable or Tactile devices (smartphone/tablets)
- Touchpad instead of mouse

Software

- Web browser
  - Google Chrome: v143 or higher (downloadable here)
  - Safari (v26 or higher)

If the device cannot be used with the user's browser, it shall be updated.

- JavaScript enabled
- Cookies enabled for session management

Network

- Stable broadband internet connection
- HTTPS access to the official web platform

Supported Medical Imaging

The device supports:

- MRI modality: Fat-saturated 3D Proton Density sequence
- Minimum number of slices: 140
- DICOM format required

Unsupported MRI sequences will be rejected automatically.

Safety Warnings

- Software does not diagnose or prescribe.
- Surgeon user must validate segmentation and planning.
- Verify patient identity before uploading MRI.

WORKFLOW AND OPERATING INSTRUCTION

USER ACCOUNT MANAGEMENT

- Accounts are created by an Areas administrator upon request at support@areas.ai.
- Password reset is available through the login interface.
- **Credentials are personal and shall not be shared in any case.**

CASE MANAGEMENT

Users can:

- Create a new patient case (1)
- Enter patient data (name, date of birth, facility, surgery type, side, date) (2)
- Upload MRI for processing (3)
- Browse, modify, or delete their own cases (4)

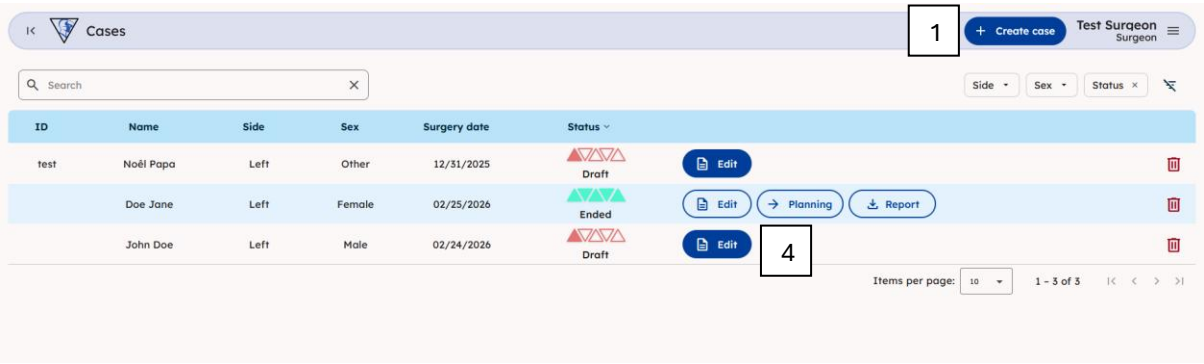

Figure 2: Case management interface

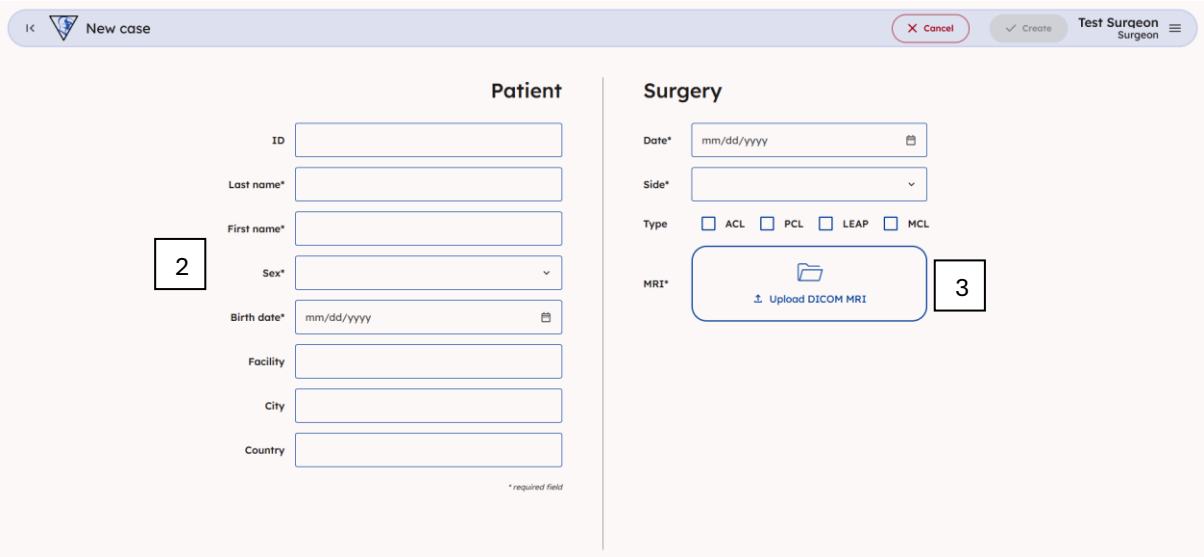

Figure 3: Case creation interface with the MRI upload area

MRI UPLOAD

- Upload MRI DICOM series via the web interface using the file explorer or with a drag and drop of the archive on the upload area
- The MRI shall be in an archive zip format

- **After uploading the MRI, double check the name of your file under the folder icon to make sure there was no confusion in the MRI selection**
- During its processing the MRI is verified and can be rejected (e.g. patient is a contraindication for the software)
- If the MRI is rejected, the surgeon receives a notification by email with an explanation from the reviewer

Automated 3D Model Generation

The system automatically produces a 3D patient-specific anatomical model, segmenting:

- Femur, Tibia, Patella, Fibula
- Menisci (internal and external)
- Femoral and tibial cartilages
- Footprints of Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL)

The segmentation of the MRI and the landmarking are then reviewed by a staff member of the company which might require 2 to 3 working days at minimum.

Joint Kinematics Simulation

The software simulates:

- Femur/Tibia relative motion
- Flexion range from 0° to 120°

It does not simulate:

- Patella motion
- Non-rigid deformation (e.g., menisci, cartilages)

⚠ MODEL 3D AND KINEMATICS VERIFICATION

Before planning, the user is asked to verify that the produced 3D model and kinematics match the original MRI

- **Verify that the superimposition of the 3D model on the MRI matches**

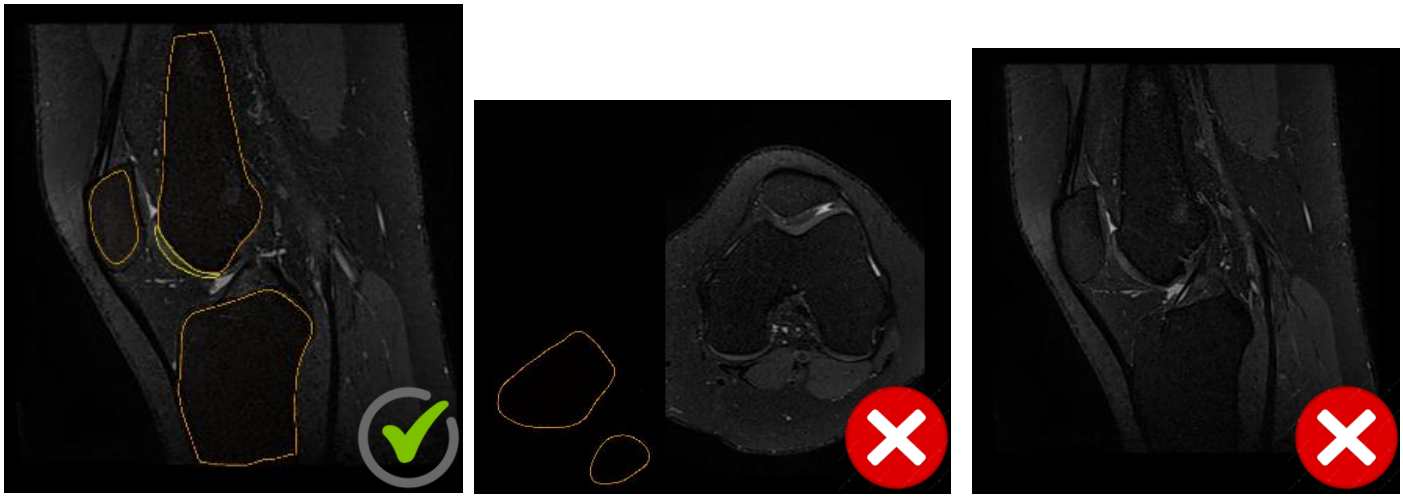

Figure 4: from left to right: (i) The 3D model contouring superimposes the MRI = acceptable, (ii) The 3D model contouring does not match the MRI = needs rejection, (iii) The 3D model contouring is absent = needs rejection

- **Verify that the knee flexion is anatomically credible. (relative motion tibia/femur & flexion angles)**

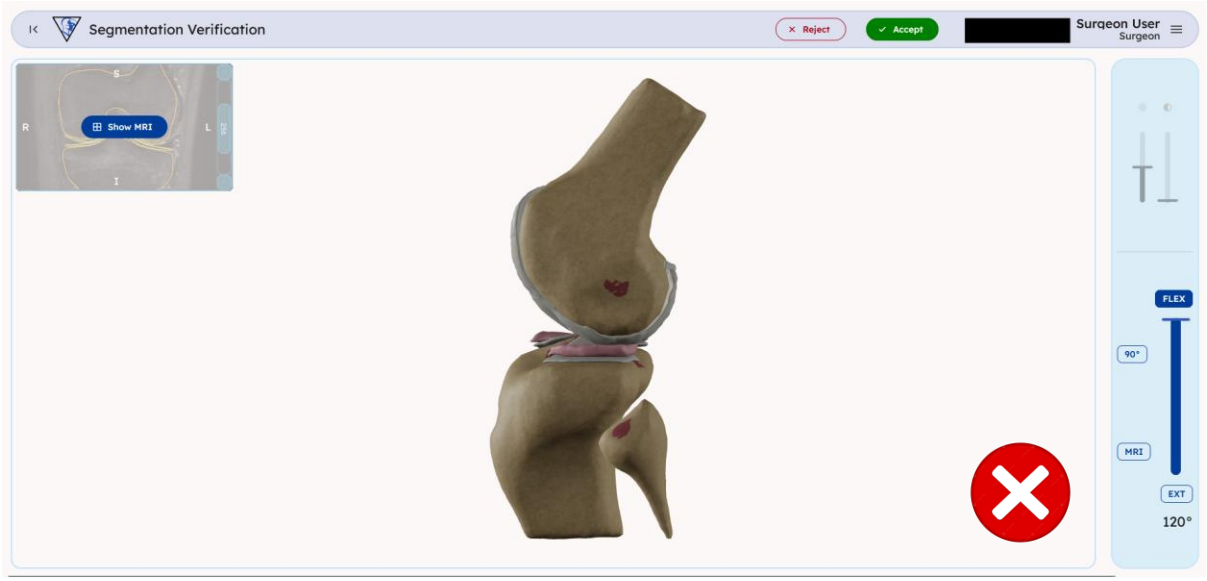

Figure 5: Rejection example for the knee flexion simulation. The slider is pushed to 120° though the knee flexion on the 3D model is far from 120°

⚠ SURGICAL PLANNING

The software enables surgeons to (see numbering on Figure 5):

- Navigate and visualize the 3D model (1)
- Adjust visibility of anatomical structures (2)
- Create, position, and edit bone tunnels (3)
- **Follow predefined workflows for ACL, PCL, MCL, or Lateral Extra-articular Tenodesis (LET) reconstructions (4)**
- Use the free "Add tunnel" mode to place additional tunnels (5). Any independent tunnel can then be linked to a reconstruction by selecting the tunnel and click the attachment icon next to "Reconstructions" in the tunnel menu (6)
- Move tunnels' apertures grabbing them directly in the 3D scene (7)
- Complete planning in under 10 minutes after initial familiarization

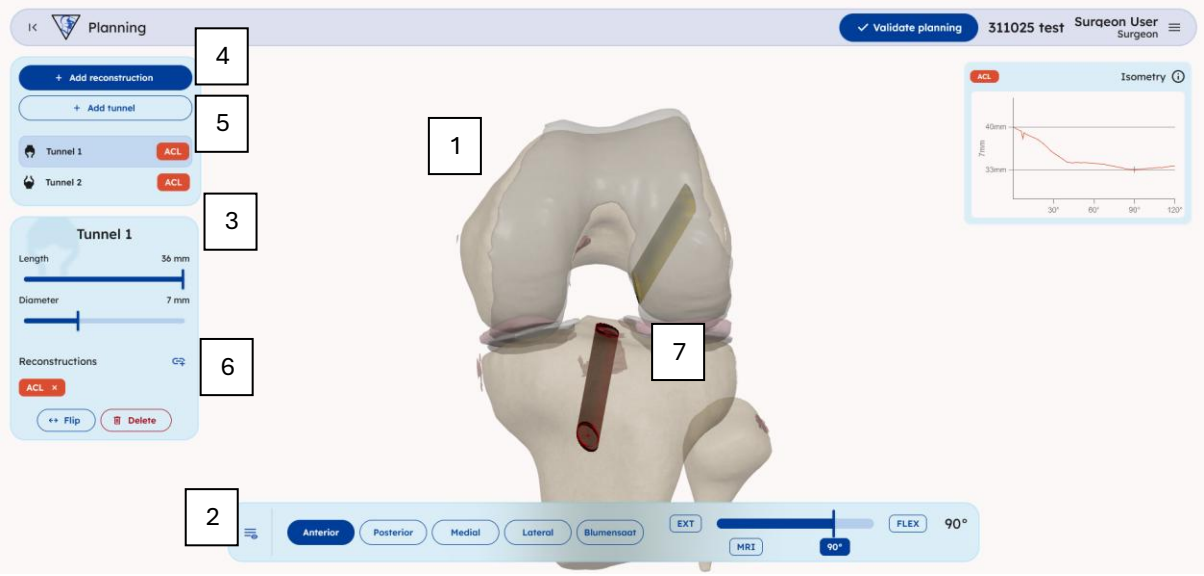

Figure 6: Planning view with reconstruction for an Anterior Cruciate Ligament

The planning provides the following measurements for each reconstruction:

- Isometry of the reconstruction depending on the flexion angle (top right graphic)
- Anisometry values in the range of flexion. This is the difference between the highest and lowest isometry values.
- Measurements are provided only if two tunnels are provided for a reconstruction

PLANNING SUMMARY GENERATION

A PDF planning summary is automatically generated, containing:

- Patient and surgeon information
- Images of tunnel endpoints
- Tunnel parameters
- Isometry and graft information
- Global procedure summary

Surgeons may print or export the document for intraoperative use. Users shall not use the results of planification to support surgery if the data displayed in the report are totally or partially missing.

The accuracy of the 3D reconstruction from the MRI ensures an averaged accuracy of 2mm at the MRI position (average surface distance).

Kinematics simulation ensures that the isometry error is in average below 5% (with a 2% standard deviation).

MAINTENANCE & UPDATES

SOFTWARE UPDATES

- Updates follow patch/minor/major versioning
- Minor and patch upgrades maintain full data compatibility
- Major upgrades do not maintain backward compatibility.
- Users are notified before deployments, including any planned service interruptions

DATA SECURITY

The system complies with:

- EU GDPR requirements: Regulation (EU) 2016/679
- Cybersecurity practices defined for the product in this document
- Storage of MRI and planning data in secure cloud environments

TROUBLESHOOTING

Common issues are listed in the following table:

Issue	**Possible Cause**	**Recommended Action**
Login failure	Incorrect login credentials	Reset the password via the user interface
Slow MRI upload	A slow internet connection may result in extended MRI upload times, particularly when the ZIP archive is large (typically > 50 MB)	Allow the upload process to complete without interruption
MRI upload failure or rejection	Incorrect MRI modality or insufficient number of slices	Verify that the MRI is a Fat-saturated 3D PD sequence with at least 140 slices
Inaccurate 3D model generation	Suboptimal MRI quality	Review and correction by an AREAS engineer are required
Unable to validate the surgical planning	No reconstruction is complete (two tunnels associated to the same reconstruction)	Associate existing tunnels with an existing reconstruction, or create a new reconstruction using the proposed workflow
Warning: tunnel protrudes outside of the bone	A tunnel defined in the planning creates a trench in the bone	Identify the tunnel associated with the warning and adjust the tunnel apertures so that the tunnel fully passes through the bone
Warning: intersecting tunnels detected	Tunnels in the planning intersect	Rotate the 3D view to determine where tunnels intersect. Adjust a tunnel aperture to eliminate the intersection
Unable to connect to the application due to a	Internet connection via a portal or VPN with an outdated certificate authority list	Change the internet connection source and/or avoid public web portals

Issue	Possible Cause	Recommended Action
Login failure	Incorrect login credentials	Reset the password via the user interface
Slow MRI upload	A slow internet connection may result in extended MRI upload times, particularly when the ZIP archive is large (typically > 50 MB)	Allow the upload process to complete without interruption
certificate issue ("unknown issuer").		

If the issue persists, contact AREAS Support via the following email address: support@areas.ai.

ELECTRONIC INSTRUCTIONS FOR USE (EIFU)

According to Regulation (EU) 2025/1234, these instructions are provided electronically.
AREAS maintains:

- A dedicated webpage containing the latest IFU versions: https://areas.ai/kp-ifu/
- Access on request, at support@areas.ai, to the instructions for use in paper form, with no additional cost and within 7 calendar days of receiving the request.
- Access on request to archived versions
- A URL to be registered in the EUDAMED UDI database once applicable

MATERIOVIGILANCE

If you experience any issue related to Orthenix™ Preoperative Planning (e.g., suspected malfunction, unexpected results, incorrect output, or any event that could affect patient safety), stop using the software for the concerned case.
Document the problem as precisely as possible by providing information on date and time, user role, software version, steps performed, screenshots/logs if available, patient/case identifier only where permitted by your privacy rules and report it without delay to the following email address: support@areas.ai.
AREAS shall confirm receipt of the user's report, initiate an investigation, and may request additional information where necessary to complete the assessment.
Where the reported event meets the criteria for a reportable incident, AREAS shall manage the case in accordance with the applicable vigilance requirements and communicate, as appropriate, any resulting corrective actions and/or safety information to users.

SUPPORT

Contact at support@areas.ai for technical assistance.