



CustomSurg™

CUSTOMSURG ORTHOPLANNER

INSTRUCTIONS FOR USE



MANUFACTURER:

CustomSurg AG
Bubenbergstrasse 1
8045 Zurich
Switzerland

support@customsurg.com

CAUTION: Federal law restricts this device

to use by qualified surgeons only.

DISCLAIMER

Planning supported by CustomSurg OrthoPlanner is a feature designed for surgeons to visualize surgical plans in 3D and is not to be considered medical advice. Provided is solely a 3D representation of the surgical plan and must be reviewed by a trained surgeon in conjunction with diagnostic tools (e.g. CT). Surgeons should use their clinical judgement for final patient management decisions; not to expect a completely safe and effective outcome with the use of the device in all cases. CustomSurg supplies a service to HCP in which the HCP receive surgical planning information. This information is prepared by CustomSurg employees utilizing the device for preoperative planning which is then provided to the HCPs. The HCPs use the device to upload (input) data and retrieve planning data.

For complete information on device features, limitations, and intended use, please refer to the product labeling.



1. DEVICE DESCRIPTION

CustomSurg OrthoPlanner is a medical software that supports surgeons in orthopedic pre-surgical planning in the musculoskeletal system in a healthcare environment.

It is a web-based application that allows surgeons to upload the required data, provide details of planning the surgery and receive 3D visualization of the submitted plan. To properly use the device, clinical judgment and experience is mandatory, and it shall be used in conjunction with diagnostic tools. CustomSurg OrthoPlanner does not perform any diagnostic evaluations and will not have intra-operative functionality.

CustomSurg OrthoPlanner includes an upload interface/module provided to the user through a personalized link to enter case information and upload medical data.

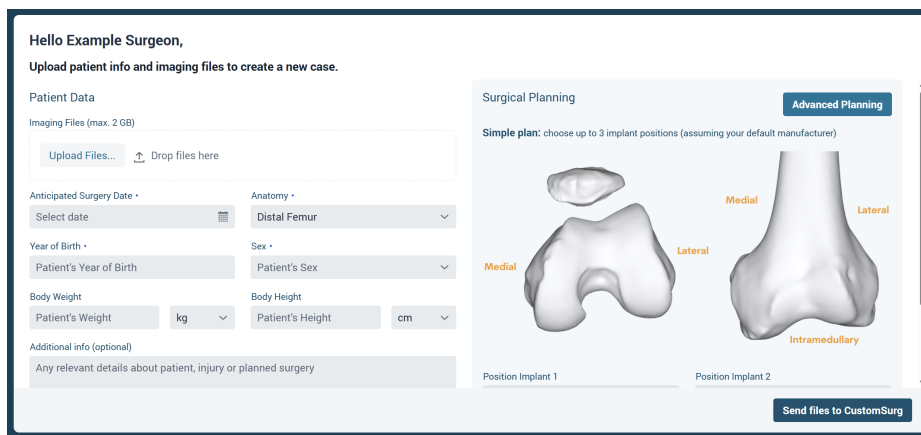


Figure 1 Upload interface / module of the device.

CustomSurg OrthoPlanner includes a visualization interface/module provided to the user through a personalized link to visualize a surgical plan.

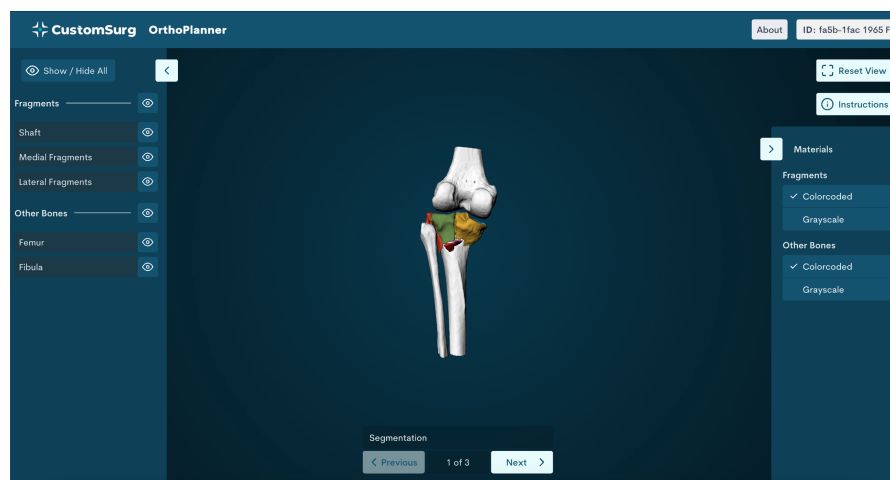


Figure 2 Visualization interface / module of the device.
The case data in the top right corner of the image is fictional.



A detailed description of the functionality for CustomSurg OrthoPlanner can be found in the device's user manual (see GETTING STARTED).

2. INTENDED USE

CustomSurg OrthoPlanner is a preoperative planning software intended for orthopedic surgery.

The software facilitates the generation and visualization of patient-specific surgical plans based on the surgeon's data upload, whereby planning outputs are processed by trained CustomSurg personnel using the software.

3. INDICATIONS FOR USE

CustomSurg OrthoPlanner is a software system designed to support pre-operative planning for orthopedic surgical procedures based on patient-specific imaging studies.

The software is intended to be used by surgeons and trained CustomSurg personnel. The software enables the import of patient-specific input, including diagnostic imaging studies such as x-rays and CT images and planning parameters. The software includes a database of digital representations of implant systems supplied by their producing companies. Trained CustomSurg personnel use the software, which is processing imaging data, to generate patient-specific surgical plan visualizations.

The software enables surgeons to review and visualize patient-specific surgical plans in 3D.

CustomSurg OrthoPlanner is to be used in conjunction with the planned device's instructions for use, the patient's clinical history, symptoms, and other pre-procedural evaluations by a surgeon who is responsible for making all final patient management decisions.

It is not intended to replace the planned device's instructions for use.

4. CONTRAINDICATIONS

- 4.1** CustomSurg OrthoPlanner is not indicated to perform any diagnostic evaluations.
- 4.2** CustomSurg OrthoPlanner requires a CT scan of the broken bone.
- 4.3** CustomSurg OrthoPlanner should not be used as the sole basis for clinical decision-making.
- 4.4** CustomSurg OrthoPlanner is also not indicated to be used for emergency surgical procedure.

5. INTENDED USER

CustomSurg OrthoPlanner should only be used by surgeons (Rx only).



6. TARGET POPULATION

CustomSurg OrthoPlanner is intended for patients requiring orthopaedic surgery.

No clinical data are available for the use of this device in pediatric patients. The treating surgeon shall take this limitation into account prior to use.

7. SUPPORTED PROCEDURES

CustomSurg OrthoPlanner is suitable for pre-operative planning of the following orthopedic subspecialties and procedures:

Subspecialties	Procedures
Adult Trauma	Distal Femur fractures
Pediatric Trauma	Proximal Tibia fractures
	Distal Tibia fractures
	Malleoli fractures
	Pelvic ring fractures
	Acetabulum fractures
	Distal radius fractures

8. COMPATIBILITY WITH MEDICAL DEVICES

CustomSurg OrthoPlanner is continuously expanding available manufacturers / implants for pre-operative planning.

The list of currently available implants: customsurg.com/supported-hardware.

9. REQUESTING CHANGES TO SURGICAL PLAN

9.1 If you would like to request a change to the final surgical plan or are not satisfied with any step in the planning process (e.g. segmentation) you can request a change to be implemented by contacting support@customsurg.com. Please mention the case ID of the case you are requesting changes for.

10. REPORTING BUGS, DEVICE MALFUNCTIONS OR REQUESTING SUPPORT

10.1 In case you detect device malfunctions, bugs or encounter any other obstacles either during case submission or surgical plan visualization, please don't hesitate to contact CustomSurg at support@customsurg.com. Please provide a description of your problem in as much detail as possible and please mention on which platform you were trying to access the device, e.g. laptop or mobile and Windows, iOS or Android. In case



you encounter problems with a surgical plan visualization, please also mention the affected case ID, such that the CustomSurg team can reproduce your problem.

- 10.2** In case of a serious incident occurring in relation to the use of this device, contact support@customsurg.com and report the incident to the respective competent authorities.

11. UNITS OF MEASURE

CustomSurg OrthoPlanner can receive both imperial and metric units as input in the upload interface / module for the patient's weight and height.

CustomSurg OrthoPlanner displays measurements in the metric system, and where applicable units that are standard medical convention.

12. SYSTEM REQUIREMENTS

1. Upload Interface / Module

- 64-bit desktop computer (MacOS & Windows)
- No mobile devices
- Modern web browser with HTML 5 and Java Script support (Google Chrome Version ≥ 130 , Microsoft Edge Version ≥ 128 , Safari: version ≥ 15)
- Minimum network requirements: 100Mbps

2. Visualization Interface / Module

- 64-bit desktop computer (MacOS & Windows) or high-end mobile device (Android & iPhone, iPad)
- Modern 64-bit web browser with Java Script, HTML 5, WebAssembly support, must be WebGL2 capable (Google Chrome Version ≥ 130 , Microsoft Edge Version ≥ 128 , Safari: version ≥ 15)
- Minimum network requirements: 10Mbps

3. Requirements for Imaging Data

- The maximum imaging slice thickness that can be processed by CustomSurg OrthoPlanner is 3mm and the maximum in-plane pixel spacing that can be processed by CustomSurg OrthoPlanner is 1mm x 1mm.

13. INSTALLATION INSTRUCTIONS

As CustomSurg OrthoPlanner is a web-based application, it is accessible via the listed compatible browsers.

14. WARNINGS AND PRECAUTIONS



- 14.1** The software should be operated by surgeons, and the output should always be reviewed and approved by a trained surgeon before implementation.
- 14.2** No clinical data are available for the use of this device in pediatric patients. The treating surgeon shall take this limitation into account prior to use.
- 14.3** It is the surgeon's ultimate obligation to exercise their professional judgment in any decision to follow or not follow the treatment plan made. The software is a software as medical device intended for support surgeons in pre-operative planning. It does not intend to replace a clinical user in diagnosing any clinical conditions, nor does it recommend any treatment.
- 14.4** Whenever possible all medical images should be uploaded through the upload interface in a de-identified format.
- 14.5** When specifying your anticipated surgery date, keep in mind that CustomSurg needs a minimum of four days to prepare the visualization of your surgical plan. Please submit your case as early as possible.
- 14.6** The personalized links for the upload interface and the visualization interface of the surgical plan do not require authentication. There is no patient-identifying information displayed in any place of the software. Nonetheless, please do not share links with unauthorized third parties.
- 14.7** Please contact CustomSurg support (support@customsurg.com) in case of any suspicion or concern on cyber security malfunctioning or attack. CustomSurg OrthoPlanner is continuously monitored, and identified vulnerabilities are communicated to the user. CustomSurg support will assess the criticality of the event and respond within 2-3 business days.
- 14.8** Please contact CustomSurg support (support@customsurg.com) in case of any suspicion or concern that your personalized upload interface or visualization interface links have been compromised. The support at CustomSurg will be able to deactivate the link or regenerate a new one for you. CustomSurg support will assess the criticality of the event and respond within 2-3 business days.
- 14.9** Please ensure that you are using the latest version of the supported browsers, and you have antivirus protection, and a firewall installed on your end user device. To access the service, all communication is via HTTPS, and only port 443 is required to be open allowing inbound and outbound traffic. Any issues with the service will be communicated to you via your registered email address.
- 14.10** Actual measurements and specifications may vary between the PDF of your visualized surgical plan and the real-world situation. The PDF document should always be used in conjunction with clinical judgment.
- 14.11** Be aware that the anatomical models visualized in the software are derived from the images of the patient. The quality of the anatomical models is limited by the quality of the images. If the patient's anatomy has changed significantly since the time of the images, the visualization should not be used.

15. GETTING STARTED



15.1 After Sign-Up to CustomSurg OrthoPlanner

15.2 CustomSurg will ask you to provide certain information concerning your contact details and preferences after you are onboarded. This information will be stored by CustomSurg.

15.2.1 User information: full name, email address and phone number

15.2.2 Select anatomy for the case you want to create a plan. Changing the anatomy will also change the preview image on the right accordingly. For a list of supported anatomies refer to Section 7

15.2.3 Preferences: A default implant manufacturer / model will be recorded, that will be used for all surgical plans where you do not specifically request other implants to be used (i.e. Simple Plans, detailed explanation see below). CustomSurg will also ask you to indicate if you prefer the surgical plans to be displayed using colors that are suitable for individuals with color vision deficiencies.

15.3 At the end of this onboarding procedure, you will receive a personalized upload link, where you can submit cases for visualization in CustomSurg OrthoPlanner.

15.3.1 This link is personalized for you and should not be shared with unauthorized individuals.

15.3.2 Should you lose access to your personalized link, please send a request to support@customsurg.com and you will receive a new link.

15.4 Submitting a Case to CustomSurg OrthoPlanner

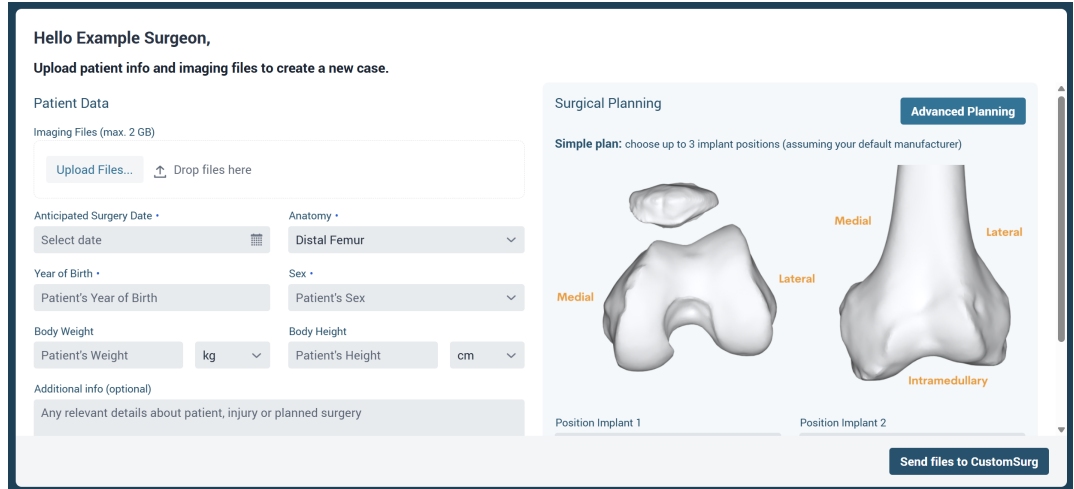
The screenshot shows a web interface for uploading patient data and imaging files. On the left, under "Patient Data", there is a section for "Imaging Files (max. 2 GB)" with an "Upload Files..." button and a "Drop files here" area. Below this are fields for "Anticipated Surgery Date" (a date picker), "Anatomy" (a dropdown menu set to "Distal Femur"), "Year of Birth" (a text input), "Sex" (a dropdown menu), "Body Weight" (a text input with a "kg" unit selector), and "Body Height" (a text input with a "cm" unit selector). There is also an "Additional info (optional)" section with a text area. On the right, the "Surgical Planning" section has a "Simple plan" instruction and two 3D anatomical models of a knee joint. The left model is labeled "Position Implant 1" and the right model is labeled "Position Implant 2". Both models have "Medial" and "Lateral" labels. The right model also has an "Intramedullary" label. At the bottom right of the Surgical Planning section is a "Send files to CustomSurg" button.

Figure 3 Upload form reached through personalized upload link.

15.4.1 To submit a new case for CustomSurg OrthoPlanner you need to navigate to your personalized upload link that you received after signing on. You will see a

webpage

like



15.4.2 Figure 3.

15.4.2.1 To know that this is your link you will be greeted with your name at the top left of the page.

15.4.2.2 This upload form is only supported for use on a computer; it is not supported on mobile phones.

15.4.2.3 Through the “About” button at the top right of the page, you can always access software information and directly get access to this instructions for use document.

15.4.3 **⚠ ATTENTION:** All data entered in this upload form, incl. the surgical planning section, is not saved before you click “Send files to CustomSurg”. Please do not close the tab or reload the window during your case submission process, or your progress will be lost.

15.4.4 To upload your CT scan, you need to upload the DICOM files individually or in a zip file using the button “Upload Files” or through drag-and-drop into the “Drop files here” area. You can upload additional files like X-Rays, drawings or other supporting documents as well. Please make sure to de-identify your DICOM data before uploading it to this portal.

15.4.4.1 CustomSurg cannot process your case without a submitted CT scan, if you forget to upload a CT scan you will be contacted by CustomSurg.

15.4.4.2 To be able to submit a case, you need to upload at least 1 file.

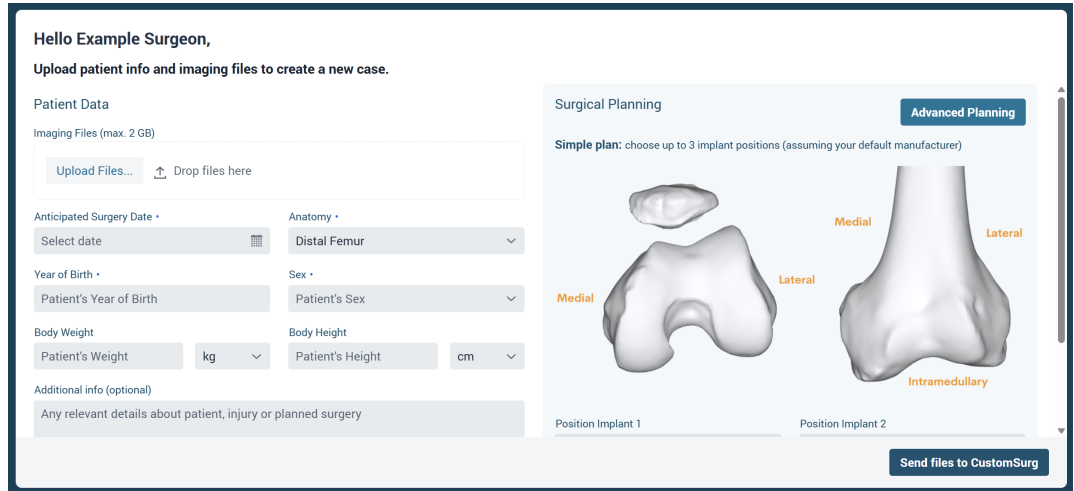
15.4.4.3 You can upload a maximum of 2GB per case.

15.4.5 Before you can submit the case you also need to provide some supporting information on the surgery and the patient. The required fields on the left half of the page are labelled with an asterisk.

15.4.5.1 The anticipated surgery date will define how your case is prioritized at CustomSurg. Please select the date as accurately as you can, at the time of submission.

15.4.5.2 When providing the height and weight of the patient in the respective fields, you need to also provide a unit, which you can select using a drop-down. By default, the selected units are kilogram (kg) and centimetres (cm).

15.4.6 The right half of the page in



The screenshot displays the CustomSurg web interface. On the left, the 'Patient Data' section includes fields for 'Imaging Files (max. 2 GB)' with an 'Upload Files...' button and a 'Drop files here' area. Below this are dropdown menus for 'Anticipated Surgery Date', 'Anatomy' (set to 'Distal Femur'), 'Year of Birth', 'Sex', 'Patient's Year of Birth', and 'Patient's Sex'. There are also input fields for 'Body Weight' (with a 'kg' unit dropdown) and 'Body Height' (with a 'cm' unit dropdown). An 'Additional info (optional)' text area is at the bottom of this section. On the right, the 'Surgical Planning' section features an 'Advanced Planning' button and a 'Simple plan: choose up to 3 implant positions (assuming your default manufacturer)' instruction. It shows two 3D bone models: 'Position Implant 1' and 'Position Implant 2'. The first model has 'Medial' and 'Lateral' labels. The second model has 'Medial', 'Lateral', and 'Intramedullary' labels. A 'Send files to CustomSurg' button is at the bottom right of the interface.

15.4.7 Figure 3 is all about specifying your surgical plan for visualization. This section is not mandatory to fill in before submitting a case.

15.4.7.1 If you leave the surgical planning section empty, you will be contacted by a CustomSurg employee via your registered email address to discuss the surgical planning details.

15.4.7.2 How to specify a surgical plan will be explained in more detail in section 14.5.

15.4.8 After filling in all mandatory fields on the left, uploading your CT scan data and specifying the surgical planning details, you can click “Send files to CustomSurg” and it will submit your case. You will then be shown a success message, and your case number will be displayed to you (Figure 4).

15.4.8.1 The case number is assigned automatically and will be used in communication to identify your case. Once your case starts being processed you will receive an email from support@customsurg.com confirming the case number for you and letting you know processing has started.

15.4.8.2 The case number will be used in all communications with CustomSurg, therefore it is recommended to write down your case number somewhere you will find it again.

15.4.8.3 You will also be contacted via your registered email address; in case anything is unclear during processing of your case.

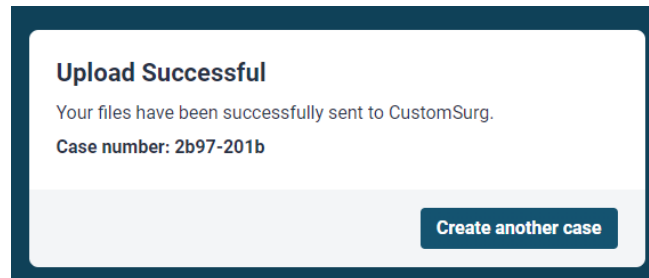
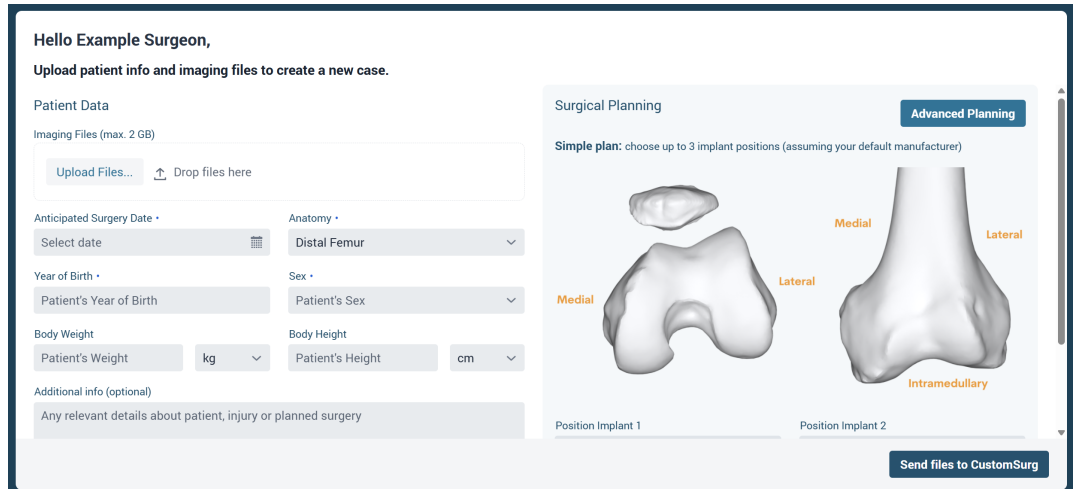


Figure 4 Success Screen after submission of your case.

15.5 Specification of Surgical Planning Details when creating a new Case

15.5.1 To specify surgical planning details, you need to use the right side of the page shown in



15.5.2 Figure 3. You can either submit a *Simple Plan* directly from the main page of the upload form, or you can enter *Advanced Planning details*.

15.5.3 Simple Plan:

15.5.4 In a *Simple Plan* you can define up to three implant positions, using the dropdowns at the bottom right of the main upload form. The values that can be selected in the dropdown match the image of the planned anatomy directly above (see Figure 5).

15.5.4.1 For the *Simple Plan* you do not have to select a manufacturer; CustomSurg will create the visualization of your plan, using the basic surgical technique of your default manufacturer / implant model, selected during onboarding.

15.5.4.2 You can always request changes to your plan when receiving the visualization for review from CustomSurg.

- 15.5.4.3 A valid *Simple Plan* consists of at least one selected implant position. You do not have to select multiple positions, if you do not want multiple implants to be used in your surgical plan.
- 15.5.4.4 If you want to submit multiple surgical plans for visualization you need to use the *Advanced Planning* feature explained in Section 14.5.4.
- 15.5.4.5 An example of a *Simple Plan* could be that you select a *Lateral* and a *Posteromedial* implant from two of the dropdowns for a proximal tibia. The engineers at CustomSurg would then prepare your case with a lateral and a posteromedial implant from your default implant manufacturer / model.



Figure 5 Example of a Simple Surgical Plan.

15.5.5 Advanced Planning:

- 15.5.6 To create an *Advanced Plan*, you need to open the *Advanced Planning* editor (see Figure 6). using the button at the top right of the page In the *Advanced Planning* editor, you will be able to specify the implant positions in more detail, chose a specific implant model for each position and state which screws you would like to use in the implant. Additionally, you can define individual screws that you would like to place.
- 15.5.7 Even if you decide to submit an *Advanced Plan*, you do not need to specify all the possible details.
- 15.5.8 In the *Advanced Planning* editor, you can create up to three different surgical plans that you would like to receive a visualization for. Using the button “Create Plan” at the top-right of the Editor you can add a new plan and delete an existing plan using the “Delete Plan” button.
- 15.5.9 You can add up to six different implants and six different individual screws in the *Advanced Plan*.

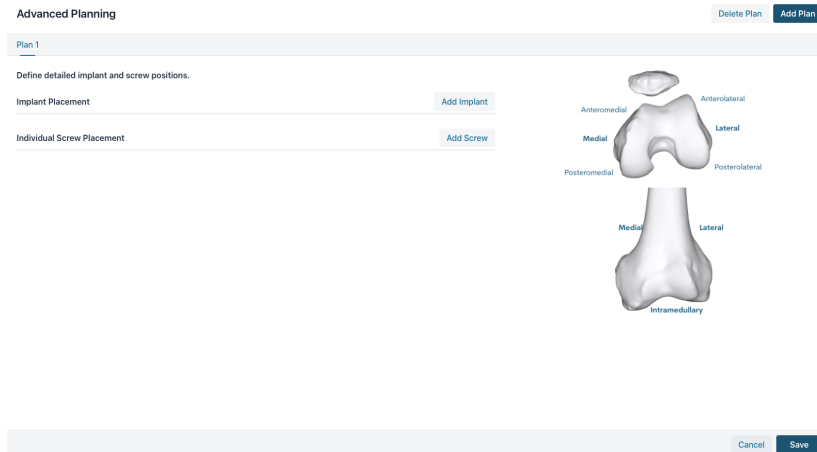


Figure 6 Advanced Planning Editor.

15.5.9.1 Implants:

15.5.9.2 You can add an implant by clicking the “Add Implant” button. This will make a new implant row appear, where you can select the implant position and the implant manufacturer / model. Once an implant manufacturer / model is selected the “Set Screws” button will become enabled, and you can select which screws you would like to place for that implant in your surgical plan.

15.5.9.2.1 To add a valid implant, you need to specify either the implant position or the implant manufacturer / model. Specifying the screws to be used is optional.

15.5.9.2.2 The “Set Screws” button will open a pop-up window showing you an image of the selected implant with labelled screw holes. You can select which screws should be used by using the provided checkboxes corresponding to the screw holes (see Figure 8). The screw holes you can select in this pop-up are only for screws in the articular region of the implant (e.g. above the slot). You cannot select the length of the implant in the surgical plan. For any specifications on the length of the implant please use the comment field.

15.5.9.2.3 You can delete an added implant by using the “Delete” button on the corresponding row of the implant.

15.5.9.3 In the *Advanced Plan* you can select more detailed implant positions compared to the *Simple Plan*. The possible positions are indicated to you in the image on the right side of the editor (see Figure 6).

Define detailed implant and screw positions.

Implant Placement

Add Implant

Implant	Position e.g. AL1	Manufacturer, Model Manufacturer, Model, Med	0 screws	Set Screws	Delete
Implant	Anterior	e.g. Manufacturer, Model, Position	0 screws	Set Screws	Delete

Individual Screw Placement

Add Screw

Screw	Screw trajectory e.g. Medial: A-P	Delete
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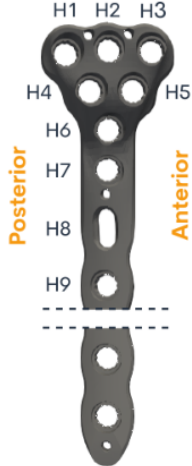
Figure 7 Implant Section.

Implant Screw Selection

Med Manufacturer, Model

Select screw holes to be used:

☐ H 1
☐ H 2
☐ H 3
☐ H 4
☐ H 5
☐ H 6
☐ H 7
☐ H 8
☐ H 9



Cancel

Save

Figure 8 Example of an implant pop-up showing the screw holes to select.

15.5.9.4 Individual Screws:

15.5.9.5 You can add an individual screw by clicking the “Add Screw” button. This will make a new individual screw row appear, where you can select the screw trajectory.



- 15.5.9.5.1 To add a valid individual screw, you need to select a screw trajectory to be used.
- 15.5.9.5.2 You can delete an individual screw after you added it by using the “Delete” button next to the selected screw trajectory.
- 15.5.9.5.3 The possible individual screw trajectories are directly depicted in the dropdown of each screw and their wording was purposely selected to be clinically meaningful (for example you can select a Medial A-P screw, an anterior-posterior screw on the medial plateau).
- 15.5.10 Once you have completed *Advanced Planning*, you must click “Save” at the bottom right to save your plans. This will bring you back to the main upload form and you will see a summary of your plans instead of the *Simple Plan* display (see Figure 9). To go back to Simple Plan, you must delete all advanced planning details, and the Simple Plan will re-appear (e.g. you cannot choose both simple plan and advanced planning).
- 15.5.10.1 If you reopen the *Advanced Planning* editor again, after having already saved an *Advanced Plan*, you will be able to continue working on your *Advanced Plans* from where you left off. This functionality to save your previous progress only works if you keep the browser tab open, as soon as you close the tab or reload the window, your progress will be lost.
- 15.5.11 After completing either, a *Simple Plan* or an *Advanced Plan* you can submit your files to CustomSurg to receive a surgical plan visualization according to your specifications by clicking the button “Send files to CustomSurg” on the lower right of the page.

Hello Example Surgeon,

Upload patient info and imaging files to create a new case.

Patient Data

Imaging Files

Upload Files... Drop files here.

✓ DICOM_scan.zip

Anticipated surgery date • 11/22/2024

Anatomy • Proximal Tibia

Year of Birth • 1965

Sex • Male

Body weight (e.g. 65lbs) • 75 lbs

Body height (e.g. 5'11") • 5'4"

Additional info (optional)

Any relevant details about patient, injury or planned surgery

Surgical Planning

Advanced Planning

Plan 1 Proximal Tibia 2 Implants, 1 Screw

Send files to CustomSurg

Figure 9 Upload Form showing a summary of the Advanced Plan.



15.6 Surgical Plan Visualization

- 15.6.1 Upon completion of your surgical plan submission, you will receive a personalized link via your registered e-mail that will let you access CustomSurg OrthoPlanner for visualizing your submitted plan. You can open this link using your laptop browser or your mobile phone. The link will open the landing page of CustomSurg OrthoPlanner, and you will be prompted to accept a Disclaimer and some case details used for you to identify the case (see Figure 10).
- 15.6.1.1 The pop-up will show the case ID generated by CustomSurg, the year of birth and the gender of the patient (e.g. no Protected Health Information according to HIPPA). This data should help you identify the correct patient associated with this link.
- 15.6.1.2 The link to your surgical plan is personalized and should not be shared with unauthorized individuals. The surgical plan link is case-specific and if you submit a new case, you will receive a new link.
- 15.6.1.3 You must read and “Confirm” the disclaimer to see your surgical plan visualization. If you do not “Confirm” the disclaimer, you will not see your surgical plan.

A screenshot of a dark blue pop-up window titled "Disclaimer". The window contains a table with patient information, a paragraph of disclaimer text, and two buttons at the bottom.

Please confirm the patient data and case ID.	
Year of Birth	1965
Sex	F
Case ID	fa5b-1fac

Planning supported by CustomSurg OrthoPlanner is a feature designed for surgeons to visualize surgical plans in 3D and is not to be considered medical advice. Provided is solely a 3D representation of the surgical plan and must be reviewed by a trained surgeon in conjunction with diagnostic tools (e.g. CT). Surgeons should use their clinical judgement for final patient management decisions; not to expect a completely safe and effective outcome with the use of the device in all cases.

For complete information on device features, limitations, and intended use, please refer to the product labeling and instructions for use.

Cancel Confirm

Figure 10 Pop-up window shown upon opening the personalized viewer link. The case details shown in this screenshot are placeholder values, only for visualization.



- 15.6.2 Attached to the e-mail where you receive the personalized link to the visualization of the surgical plan, you will also receive a PDF document with details of your surgical plan, suitable for print-out.
- 15.6.3 The surgical plan cannot be directly modified in the CustomSurg OrthoPlanner and any changes you apply to the visualization settings or materials are not permanent. To request changes to the surgical plan, please contact support@customsurg.com.

15.7 Explanations of all Visualizations shown in CustomSurg OrthoPlanner

- 15.7.1 All views in CustomSurg OrthoPlanner have the same user interface setup. You will have the 3D viewport and two panels on either side.
 - 15.7.1.1 **3D Viewport:** The whole area in the center of the screen where you will see the 3D visualization of your surgical plan and can interact with it using zooming, rotation and panning. On a computer you can left-click and drag to rotate the models, right-click and drag to pan the models and scroll to zoom in or out on the models. On mobile you can drag to rotate the models, drag with two fingers to pan the models and pinch to zoom in or out on the models.
 - 15.7.1.2 **Object Panel:** In the left side panel or object panel, you will see a list of the objects shown in the center viewport and by clicking the eye icon you can hide or show them.
 - 15.7.1.3 **Material Panel:** In the right-side panel or material panel, you will see available materials for each object category available in the object panel.
 - 15.7.1.3.1 The materials available in the material panel will change the visualization settings for a certain type of objects. For example, you will be able to display the fragment 3D models either by showing a separate color per fragment ("Colorcoded" material) or by showing the Hounsfield unit values of the CT scan ("Grayscale" material).
- 15.7.2 You can hide both panels by clicking the small arrow at the top of the panels or by clicking anywhere in the 3D viewport.
- 15.7.3 At the top right of the viewport, you can access the instructions panel or reset the view to its original position. The instructions will show you how to interact with the 3D models for zoom, rotation and panning.
- 15.7.4 In the header bar you can always see the details of your case, that were shown in the disclaimer. Directly next to the case details you can access software information through the "About" button. From there you can also access this Instructions for Use (IFU) document.
- 15.7.5 In the bottom center of the viewport, you can see which view of the surgical plan you are currently in and navigate back and forth between different views.
- 15.7.6 **Segmentation View**

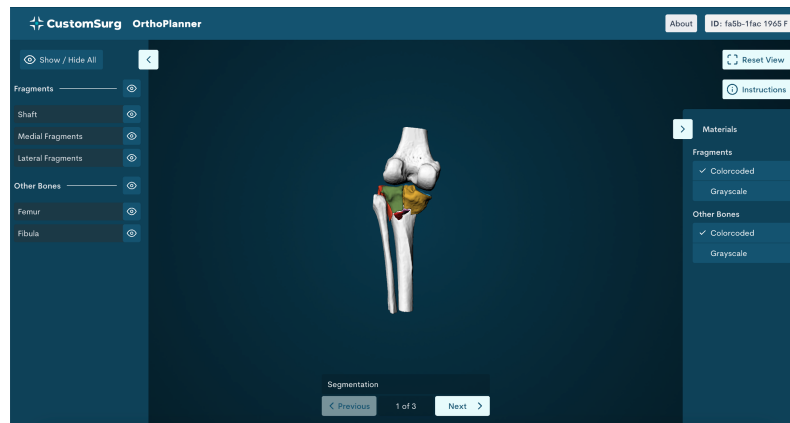


Figure 11 Segmentation View of CustomSurg OrthoPlanner.

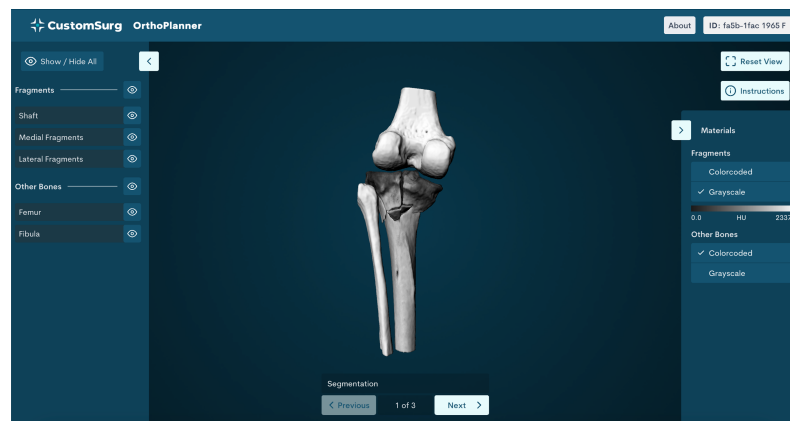


Figure 12 Segmentation View showing the Grayscale visualization.

- 15.7.6.1 The segmentation view is the first visualization you will see after you confirm the disclaimer. This view shows you a segmentation of your case, including additional relevant bone models, directly matching the CT scan (see Figure 11).
- 15.7.6.2 To visualize the Grayscale of the bone fragments and the other bones shown as Hounsfield Units (HU) directly matching the CT scan, you can toggle between “Colorcoded” and “Grayscale” materials in the material panel (see Figure 12).
- 15.7.6.3 To better visualize the fracture region, you can hide the entire category of “Other Bones” in the object panel or also hide individual groups of fragments using the buttons with the eye icon.

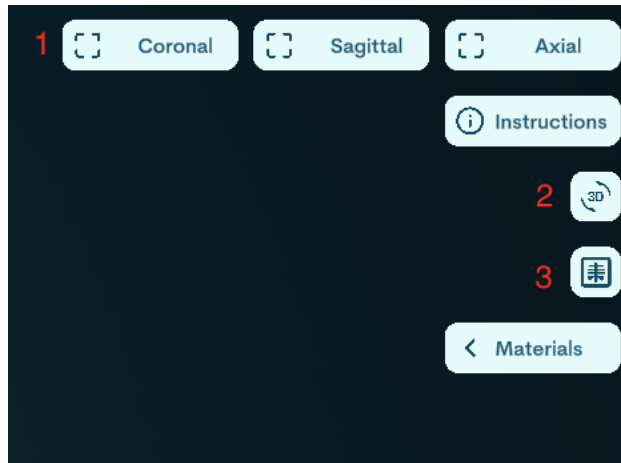


Figure 13 UI buttons

15.7.7 FLUROVISION view

- 15.7.7.1 You can toggle the FLUROVISION view through the button (3) on the right side of the UI. This enables these changes the render mode and let you have a gray scale

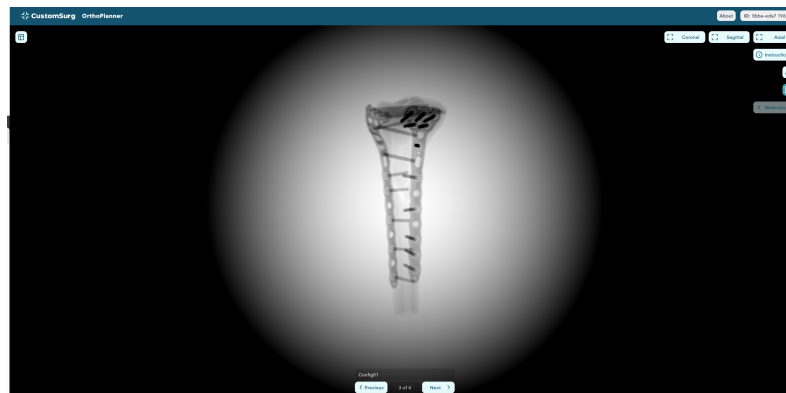


Figure 14 FLUROVISION view

15.7.8 360 Orbit view

- 15.7.8.1 You can toggle the orbit view through the button (2) on the right side of the UI. This will automatically spin the model continuously until you disable this mode again.

15.7.9 Pre-defined viewpoints

- 15.7.9.1 Through buttons (1) you can select pre-configured view positions. This depends on which anatomy is opened in the viewer.

15.7.10 Reduction View

- 15.7.10.1 The reduction view is the second visualization after the segmentation view. With the navigation panel at the bottom of the

screen you can step back and forth between the segmentation and reduction view to see an animation of the fragments between their fractured and reduced states. This will illustrate the anatomical reduction of the bone fragments.

15.7.10.2 To give a better visualization of the fracture region, the additional bones shown in the segmentation view, will be hidden by default in the reduction view. This will allow you to see the fractured region in more detail during the animation. If you wish to see the other bones again, you can toggle them back on using the object panel.

15.7.11 Plan Views

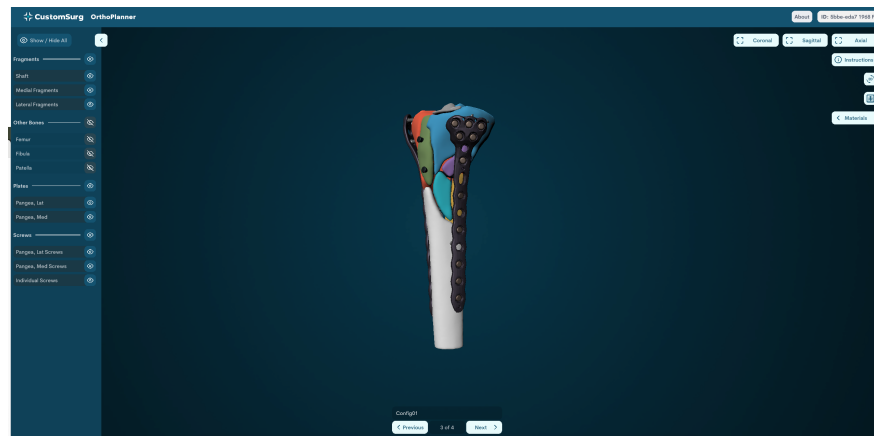


Figure 15 Plan View of the CustomSurg OrthoPlanner.



Figure 16 Plan View of the CustomSurg OrthoPlanner with transparent bone fragments, to visualize the planned implants and screws

15.7.11.1 The final visualization in CustomSurg OrthoPlanner is the visualization with the planned implants and screws. If you requested multiple surgical plans during submission of the case, you would have multiple plan views for visualization.



15.7.11.2 Using the material panel you can select “Transparent” visualization, in addition to the previous “Colorcoded” and “Grayscale” visualizations. This will allow you to view the bone fragments as transparent objects to see the screw trajectories through the fragments. Fragments that are not fixed by any hardware are shown in dark gray.

15.7.11.3 In the object panel you will see additional categories for Implants and Screws, that you can interact with in the same way as with the fragments.

15.7.11.3.1 The name of the implant will be the implant model, followed by its position.

15.8 PDF Version of Surgical Plan

15.8.1 Together with the personalized link to the CustomSurg OrthoPlanner visualization explained above, you will also receive a PDF with details of your surgical plan. The PDF will provide a similar view to the Plan Views in the CustomSurg OrthoPlanner, however it will provide some supplementary information, like “Measured Screw Length”.

15.8.1.1 Caution: Actual measurements specifications may vary. This document is for informational purposes only!

15.8.1.2 The measured screw lengths are accurate within $\pm 3\text{mm}$ when acquired from imaging data that meets the supported resolution specifications.

15.8.2 Each page in the provided PDF will also have an indication of which case this PDF belongs to and which of the requested plans it is referring to. This information will be shown as the title of each page.

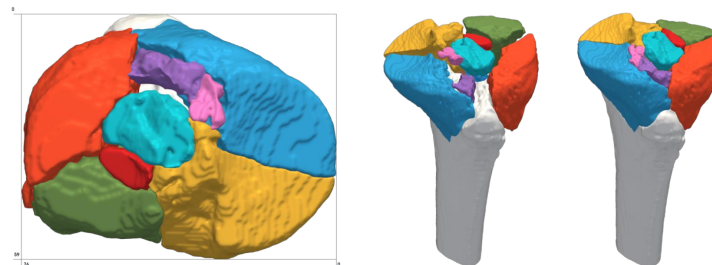
15.8.3 The PDF you will receive consists of four main sections for each surgical plan you requested:

Warning: Actual measurements and specifications may vary.
This document should always be used in conjunction with clinical judgement.



fac5b-1fac

Name	Value
Sex	M
Year of Birth	1967
Body Side	left



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15.8.4 An overview page with case information such as patient sex, year of birth and body side. An implant details page for each implant added to the plan, showing you an image of the implant and a table of measured screw lengths in millimeters for each screw that was placed. The measured screw length is the measured length of the digital screw and does not directly indicate which screw should be used given by the manufacturer.

Warning: Actual measurements and specifications may vary.
This document should always be used in conjunction with clinical judgement.

fac5b-1fac: Plan1

Pangea, Med

Screw Position	Measured Screw Length
H1	45
H2	77
H3	67
H4	64
H5	70
H6	54
H7	48
H8	45
H9	36
H11	29
H13	28



Figure 17 Example of an implant details page.

15.8.5 A fracture details page showing you a medial, lateral, anterior and posterior view of your fracture including the implants and screws.

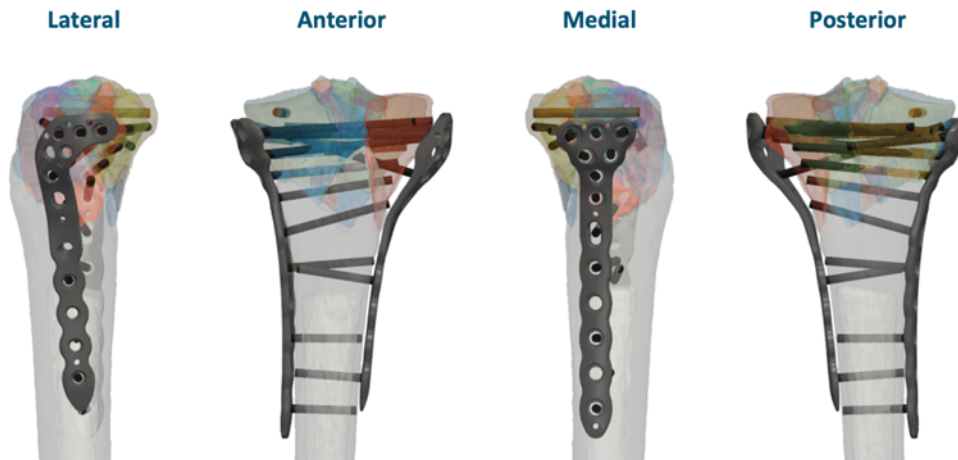


Figure 18 Example of a Fracture details page.

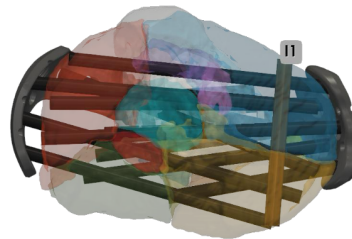
- 15.8.6 An individual screw details page showing you a top view of your fracture and a table of measured screw lengths for each added individual screw.
- 15.8.7 The top view of the fracture also shows a representation of the dimensions of your fracture in millimeters. In the example shown in Figure 19 the grid shows an anterior-posterior distance of 59 mm and a medio-lateral distance of 76 mm.

Warning: Actual measurements and specifications may vary.
This document should always be used in conjunction with clinical judgement.

fac5b-1fac: Plan1

Individual Screws

Screw Position	Measured Screw Length
I1	43



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Figure 19 Example of an individual screw details page.

16. DATA PROTECTION AND RESPONSE TO CYBERSECURITY THREATS

- 16.1** All data transfer and data at rest are encrypted, and the upload and visualization interface can only be accessed through HTTPS connections.
- 16.2** When creating a case through the upload interface or opening a surgical plan in the visualization interface the source IP address, the operating system and the browser version are logged and this data will only be used to track potential cybersecurity threats.
- 16.3** In case a cybersecurity threat is registered that affects the user, you will be notified via your registered e-mail address and receive instructions on recommended actions. CustomSurg will assess the criticality of the event and respond within 2-3 business days



17. Performance Characteristics and Validation Scope

- 17.1** CustomSurg OrthoPlanner has been validated for use as software for preoperative planning, using radiological images in DICOM format. Validation activities included verification of geometric measurement accuracy, data integrity, and system functionality under defined operating conditions.
- 17.2** The information on implant dimensions such as screw length is not intended to influence implant or screw selection or surgical preparation.
- 17.3** The software does not perform autonomous diagnosis, does not automatically select implants, and does not generate definitive treatment decisions. All outputs (visualizations) must be reviewed and clinically verified by a surgeon.
- 17.4** The performance of the device may be affected by:
 - 17.4.1 Poor image quality
 - 17.4.2 Incorrect image calibration
 - 17.4.3 Corrupted or incomplete DICOM data
 - 17.4.4 Internet connectivity interruptions
 - 17.4.5 Browser incompatibility outside validated configurations

18. Measures to Prevent Misuse

- 18.1** To minimize the risk of misuse:
 - 18.1.1 The system is restricted to surgeons.
 - 18.1.2 Surgeon review before surgical plans are considered finalized.
 - 18.1.3 Implant templates are not automatically applied without user selection.
- 18.2** Users must ensure:
 - 18.2.1 Images are acquired according to standard radiological practice.
 - 18.2.2 Planning outputs are reviewed in full before clinical use.
- 18.3** Use outside the intended purpose or by untrained personnel may result in inaccurate planning outcomes.

19. Residual Risk

- 19.1** CustomSurg OrthoPlanner has been developed in accordance with a documented risk management process. Identified risks have been reduced as far as possible through design controls, verification and validation testing, and implementation of user confirmation steps. However, certain residual risks remain inherent to the nature of image-based pre-operative planning software.
- 19.2** Despite implementation of risk control measures, residual risks related to image quality variability, segmentation limitations, measurement accuracy, and user-



dependent planning decisions remain inherent to digital pre-operative planning systems. These risks are mitigated through professional clinical oversight and adherence to standard radiological and surgical practices.

- 19.3** Residual risks associated with incorrect measurements or implant templating are mitigated through user verification and professional clinical judgment. The surgeon is responsible for confirming all planning outputs prior to surgical application.
- 19.4** The three-dimensional (3D) visualization is intended for reference only. The actual appearance, geometry, dimensions, and configuration of the hardware may vary depending on the specific size, design variant, or manufacturing revision of the hardware. Surgeons and healthcare professionals should not rely solely on the 3D representations when making clinical decisions.

20. PRODUCT LABEL



Manufacturer



Unique Device Identification Number



Instructions for Use (IFU)



Medical Device

Rx Only

Caution: Federal law restricts this device to use by qualified surgeons only.



Authorized Representative in the European Union



CE Marking 2443

21. SOFTWARE UPDATES

- 21.1** When a new software update with relevant features is available, you will be notified via your registered e-mail address, and you will receive a copy of the release notes.

22. Previous versions of the Instructions for Use

- 22.1** Contact support@customsurg.com to request previous versions of the Instruction for Use in electronic form.

Version	Document Name	Date
2	IFU-001	Jan 31, 2025



3	IFU-001	May 29, 2025
4	IFU-001	Oct 15, 2025
5	IFU-001	Nov 28, 2025
12	IFU-001	June 25, 2025

23. ADDITIONAL INFORMATION

The Instruction for use will only be made available in electronic form. If you require a hard copy of the Instructions for Use, please contact support@customsurg.com with your shipping details and a copy will be sent to you. Your request will be processed within 3 business days and depending on the country of destination shipping time might vary.

For any additional information, please contact customer service at CustomSurg:

 support@customsurg.com



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Approved By:
[\(CO-121\) OrthoPlanner 2.0](#)

Description
Changer Order for the release OrthoPlanner 2.0.

Justification
New software release requires change control

Assigned To:	Initiated By:	Priority:	Impact:
Iwein Bau	Iwein Bau	Medium	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Iwein Bau	July 1, 2026 5:00 PM CEST	CO-121	12	Published
Lara Zamboni	June 24, 2026 5:38 PM CEST	CO-119	11	Superseded
Thomas Zumbrunn	May 13, 2026 10:41 AM CEST	CO-118	10	Superseded
Thomas Zumbrunn	May 1, 2026 11:45 AM CEST	CO-115	9	Superseded
Iwein Bau	March 30, 2026 8:25 AM CEST	CO-108	8	Superseded
Iwein Bau	March 27, 2026 8:24 AM CET	CO-103	7	Superseded
Lara Zamboni	February 27, 2026 1:24 PM CET	CO-92	6	Superseded
Lara Zamboni	November 28, 2025 11:01 AM CET	CO-52	5	Superseded
Iwein Bau	October 15, 2025 8:59 AM CEST	CO-41	4	Superseded
Lara Zamboni	May 29, 2025 7:54 AM CEST	CO-35	3	Superseded
Lara Zamboni	January 31, 2025 2:33 PM CET	CO-28	2	Superseded
Lara Zamboni	January 27, 2025 4:05 PM CET	CO-25	1	Superseded
Sarah Lacey Robbins	December 19, 2024 9:22 AM CET	CO-18	0	Superseded