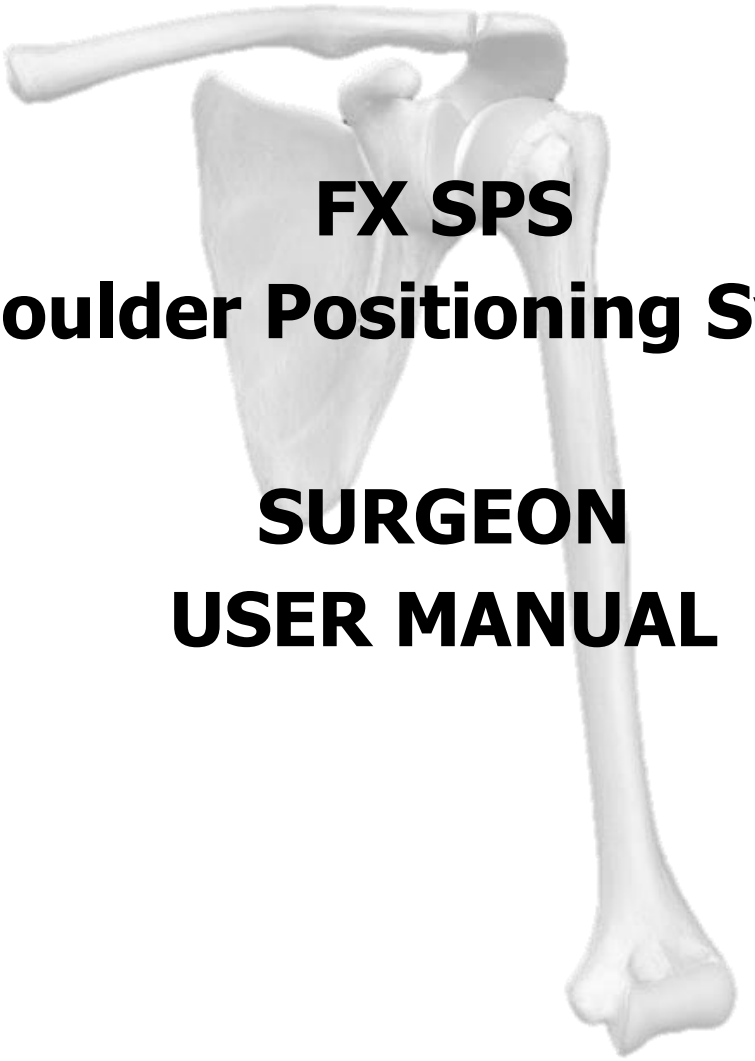
Shoulder Solutions



FX SPS
Shoulder Positioning System

SURGEON
USER MANUAL

pixee medical

Summary

Note: the names of the patients and surgeons appearing in the screen shots in this document are fictitious, as is the information concerning them.

Date of first marketing (Europe): May 2021
Date of publication: December 2021

1. Introduction

This user manual is an accompanying document to the FX Shoulder Positioning System (FX SPS) product, designed to assist the surgeon in preoperative planning for shoulder prosthesis placement.

1.1. Purpose of the manual

The purpose of this user's manual is to provide information on the safety of the FX SPS product, and to explain the basic operating instructions that are performed by the surgeon. This document is strictly for orthopaedic surgeons using the FX SPS solution.

1.2. Symbols description

Symbols	Description
	Manufactuer
	Manufacturing date
	Commercial product reference
	Consult the instructions for use
	Unique identifier
	Batch
	CE medical device
	RX ONLY
	Medical Device
	Warning

1.3. Software label

The label below is available in the help page of the software, it is accessible from the button located at the top right of the scheduling interface.

User manual		Download the user manual (FR, EN)
Patient information and consent		Download the patient consent (FR, EN)
Commercial Reference	REF	FXSPS001
Trade name		**FX SPS** **S**houlder **P**ositioning **S**ystem
Unique identifier	UDI	(01) 3760297030209 (10) vX.Y.Z-release-xxxxxxxx (11) YYMMDD
Batch code	LOT	vX.Y.Z-release-xxxxxxxx
Manufactured by		Pixee Medical 18 Rue Alain Savary 25000 Besançon, France
Manufacturing date		YYYY-MM-DD
Distributed by		FX Solutions 1663 Rue de Majornas, 01440 Viriat, France
European Conformity	CE	
Caution	Rx only	Federal law restricts the device to sale by or on the order of a physician
Medical device	MD	
Destination		Shoulder arthroplasty
Targeted users		Trained orthopedic surgeon

2. General

2.1. Pixee medical

Pixee Medical designs medical devices for orthopedic surgery. These devices are intended to assist surgeons in the preoperative preparation of a surgery or in the peroperative execution.

2.2. Medical device description

FX SPS is a preoperative standalone web-based medical software used for the planning of primary shoulder replacement from CT-images. It comprises a secure database which enables the patient's cases management and the access to the planning interface.

Preliminary to the planning, a manual segmentation needs to be performed from the patient's CT-images. The segmentation process consists in building 3D bone models of the patient's shoulder and positioning anatomic landmarks on it. Once these data are generated, their compliance is checked. They are then imported into the FX SPS's database making the planning available for the surgeon.

The planning step involves virtually positioning of the shoulder prosthesis on the 3D reconstruction of the patient's shoulder. On that purpose, the surgeon chooses implants from a library of implants. Afterwards, he selects the size of the implant more suitable to the joint and he can move prosthesis components in all directions. Once the positioning of the implant is satisfying, he validates the planning to generate a planning report.

During surgery, he will have at its disposal the planning report comprising preoperative and planned parameters.

The values displayed in the software are rounded to the millimeter (mm) and degree (°).

FX SPS is a planning information tool for shoulder prosthesis placement. The planning choices are the entire responsibility of the surgeon. FX SPS is not intended for diagnostic purposes.

2.3. Intended use / Indication for use

FX SPS is intended to be used as an information tool to assist in the preoperative surgical planning and visualization of a primary total shoulder replacement.

2.4. Intended patient population

FX SPS is indicated for patients with a planned total primary shoulder arthroplasty.

2.5. Target user group

FX SPS is intended to be used by qualified orthopaedic surgeons trained for the use of the device who are familiar with computer technologies.

2.6. Contraindications

FX SPS is contraindicated in the following cases:

- The patients' CT-scan acquisition protocol is not in compliance with the CT-scan acquisition protocol of Pixee Medical;
- For the planning of a revision surgery after total primary shoulder arthroplasty.

2.7. Expected benefits for patient

The clinical benefit for patient is indirect and consists in avoiding a time surgery lengthening. This benefit is induced by clinical performance which is to allow the choice of the right prosthesis size with plus or minus one size of difference.

2.8. Potential adverse effects and residual risks

The FX SPS product is intended for preoperative planning of a shoulder prosthesis and has no side effects.

2.9. Lifetime

The lifetime of the FX SPS software version 1.0 is 2 years. This lifetime may be reduced according to the evolution of the technologies used by the software (SOUP, browser, ...) and substantial modifications following the users' feedback.

2.10. Minimal configurations

- **Operating system:**
  - **Windows 10 Pro**
  - **Mac OS Catalina 10.15**
- **Browsers:**
  - **Google chrome version 90.0.**
  - **Mozilla firefox version 88.0.**
  - **Microsoft edge version 90.0.**
  - **Safari version 13.1 et plus**
- **Minimal resolution: 1920 x 1080**
  Be careful, if the minimum resolution is not respected, the impact will be the missing of some data in the display of the different views such as the version data. All the values are nevertheless present in the "Advanced" box on the right of the screen.

2.11. User profiles

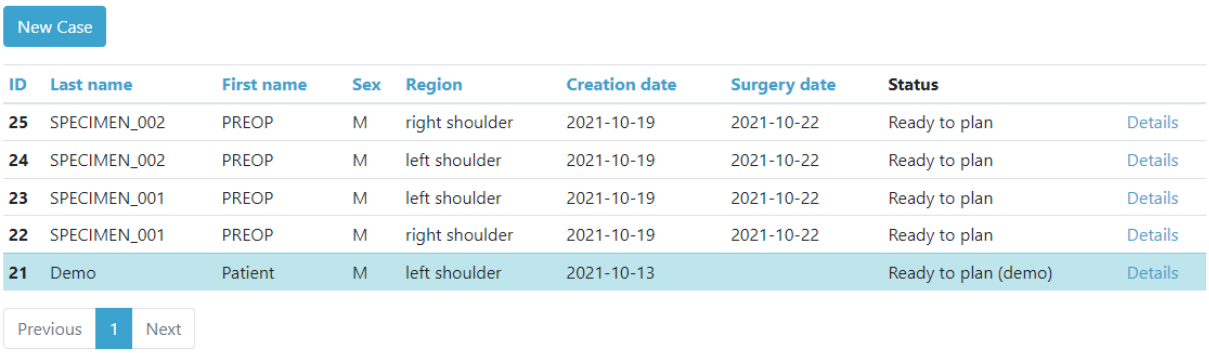
Two different profiles can have access to FX SPS:

- The surgeon: "surgeon";
- The sales person: "sales_rep".

The surgeon will have access to the whole process explained in paragraph 3.

The sales representative has a "Sales_rep" profile which gives him access to demonstration cases. Indeed, the "patient" information has been removed and it is possible to carry out planning on these cases to train surgeons or to present the software without having access to "patient" information.

The demonstration cases appear in blue as below.



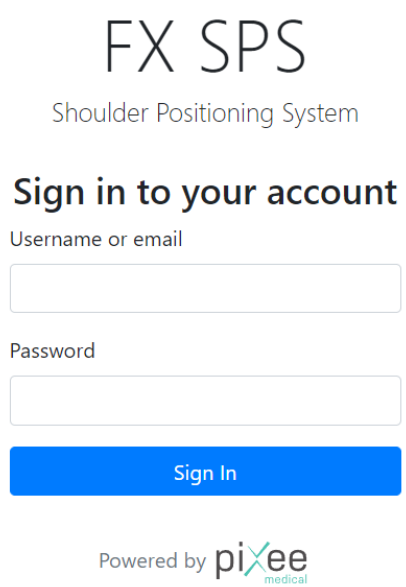
3. Planning

3.1. Login

To access the software, the surgeon must enter the following address in his internet browser:

- EUROPE server: https://fx-sps.pixee-medical.com/
- USA server: https://fx-sps-usa.pixee-medical.com/

A connection page is displayed, the surgeon enters his login and password.



- **The user account is unique and strictly personal, the user's name or the password must not be shared with colleagues or other people.**
- **Make sure your computer is protected with antivirus and anti-malware.**

3.2. Homepage

Once connected, the surgeon has access to the list of cases.

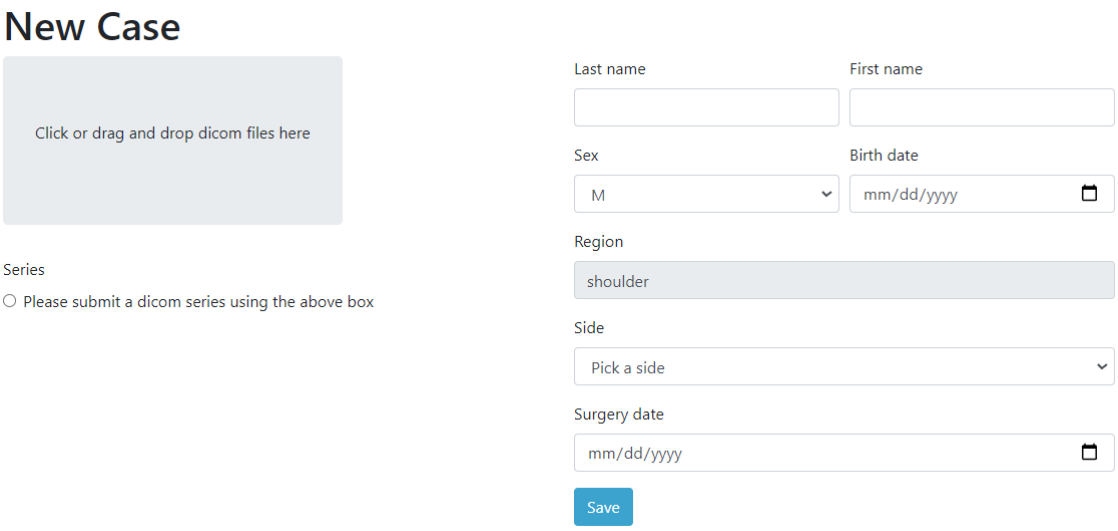
From the list of cases, the surgeon can create a new case and access the details of each case.

3.2.1. Create a new case

Before creating a new case on the FX SPS platform, make sure you have informed the patient and obtained the patient's agreement regarding the software use.

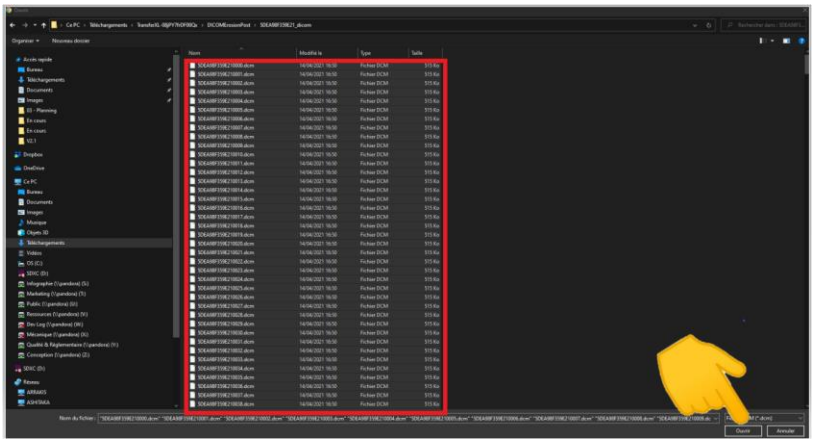
The information and consent letter is downloadable in the help section ? . If the patient opposes the use of their data, indicate it in the comment box or contact Pixee Medical.

To create a new case, click on the "New Case" button.
Click in the "New case" area to load the Dicom images.

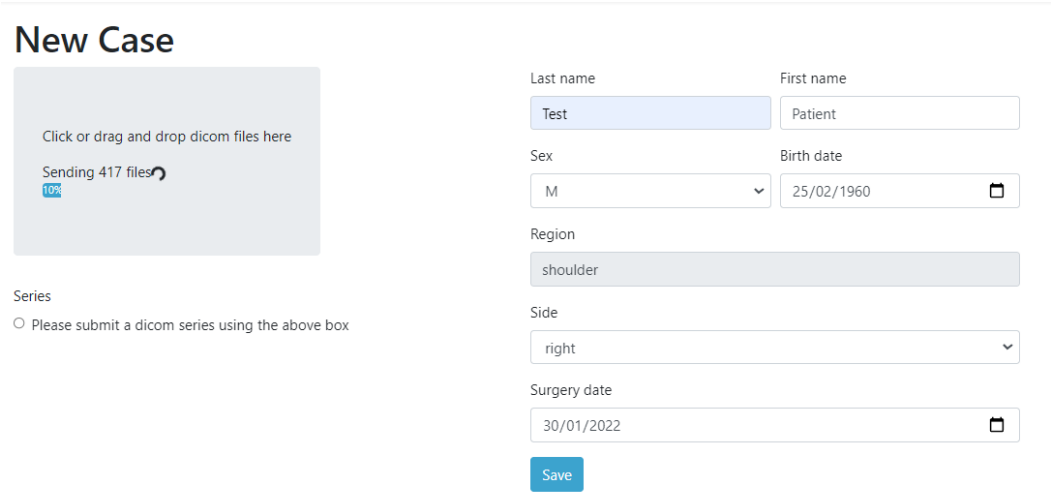


A page for selecting the Dicom images of the case to be planned is displayed:

- Select all Dicom files
- Click on the open button



Wait until the images are fully loaded.

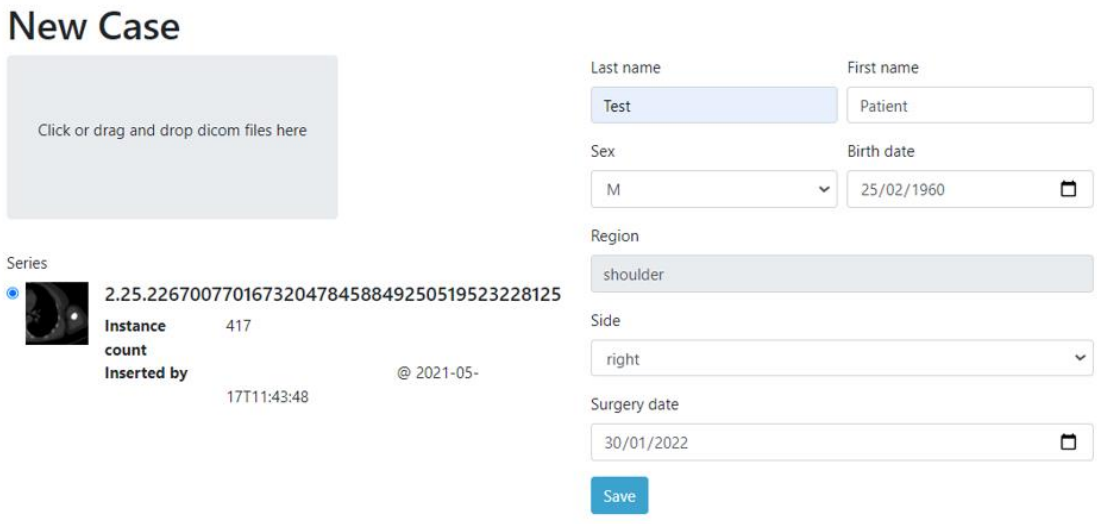


Fill in the case information and select the image series.

- **Always check that the number of images loaded is equal to the number of images in the patient folder**
- **During the loading of the DICOM images, do not close your browser.**

FX SPS must not be used:

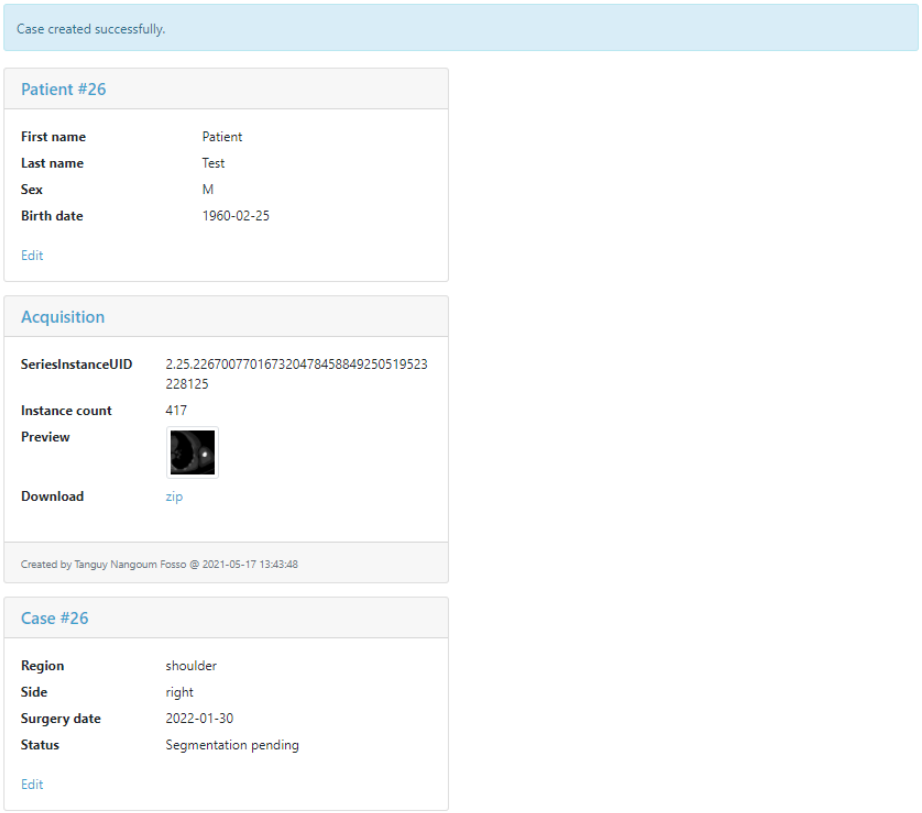
- **If the patient's anatomy has changed significantly since the images were acquired.**
- **If the period between the acquisition date of the images and the planning date is more than six months.**



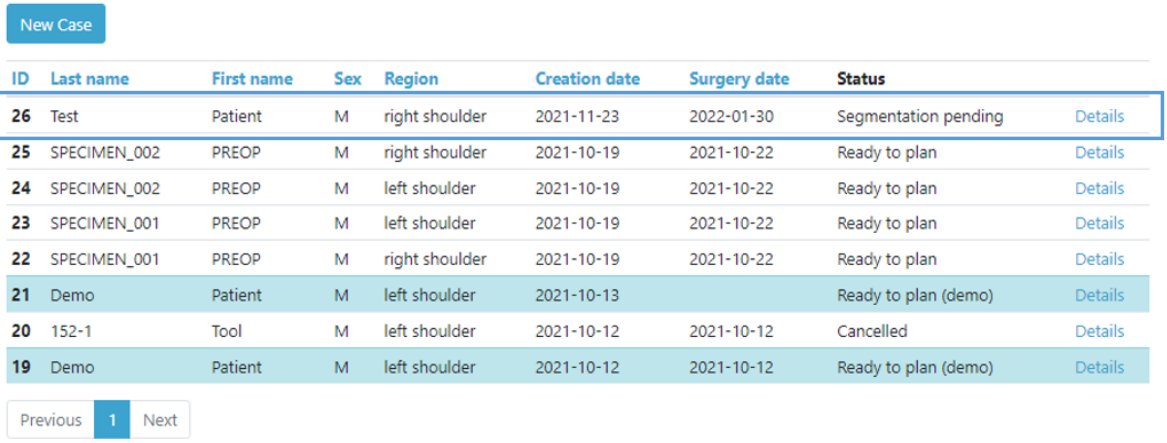
Click on the "**Save**" button to submit the case. You are automatically directed to the case details page.

3.2.2. Details of a case

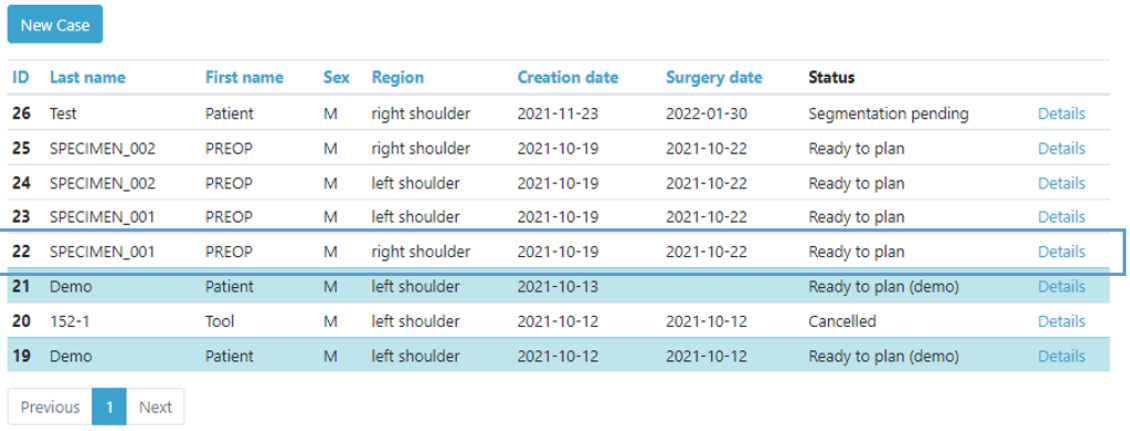
From the case details page, you have access to information about the case.
You can edit the information and download the case acquisitions.



The created case appears in the list of cases with the status "S**egmentation pending**".



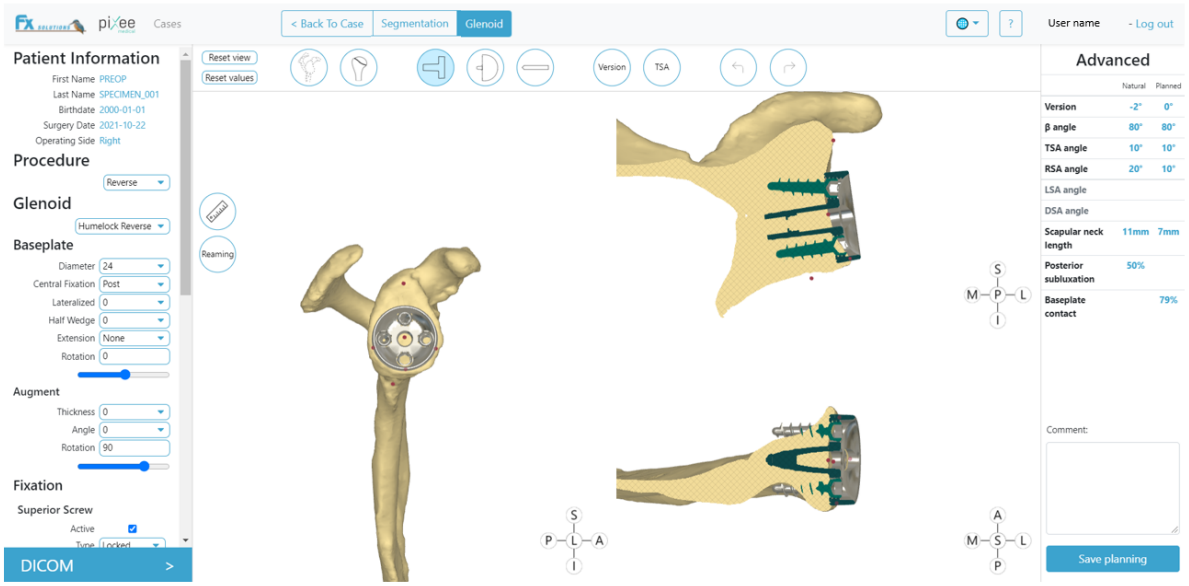
Once the segmentation has been completed, the patient case will change from "**Segmentation pending**" to "**Ready to Plan**" allowing you to plan the case.

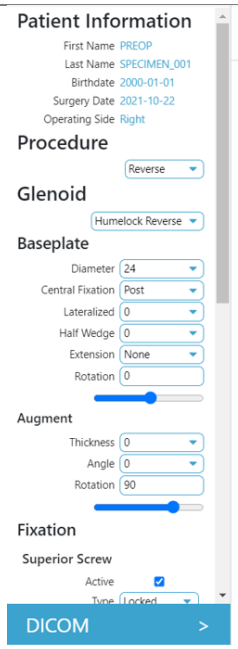


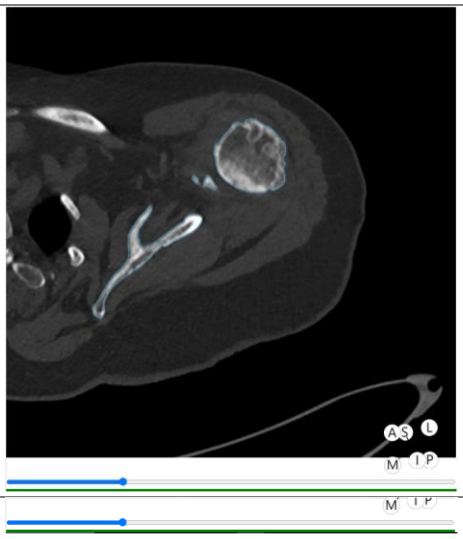
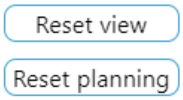
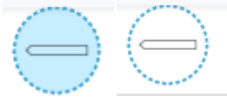
3.3. Planning

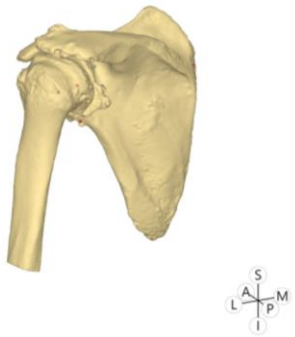
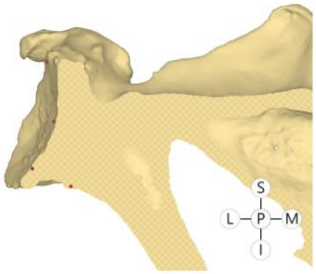
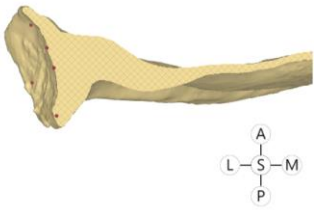
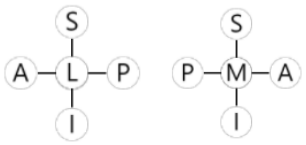
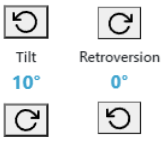
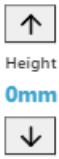
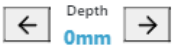
3.3.1. General description of planning elements

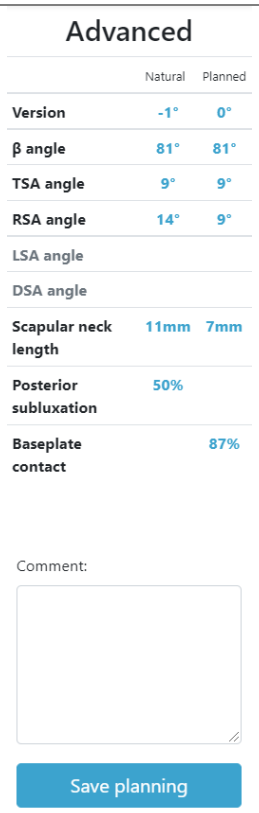
The interface consists of several elements allowing the surgeon to carry out his planning.



Interface	Description
	Buttons allowing to - Go to the case details page - To select the segmentation step - To select the glenoid planning step
	Located on the left side of the interface, this frame allows you to: - Display the patient's information - Select the type of prosthesis - Select the parameters of the prosthesis - Set up the augments - Select the screw positioning - View Dicom images
	Show/Hide Dicom images

	Dicom view
	Navigation slider in the Dicom view
	Buttons to - Reset the free 3D view to the initial state - Reset the planning parameters to the initial state
	Enable/Disable transparency of the scapula and humerus if the latter is enabled.
	Show/Hide humerus
	Show/hide the metaglene
	Show/hide the glenosphere
	Show/hide the drilling simulation pin
	Show/hide the natural version of the glenoid
	Show/hide the natural TSA and RSA glenoid inclinations
	Undo/Redo an action
	Display and calculate the distance between two points
	Show/hide the milling of the glenoid

	Free 3D view
	Front 2D view
	2D axial view
	Select the viewpoint and indicate the orientation A: Anterior, P: Posterior, S: Superior, I: Inferior, L: Lateral, M: Medial.
	Implant tilt/version adjustment button.
	Implant height/medialization adjustment button.
	Button for adjusting the milling depth



Located on the right side of the interface, this dial allows you to:

- Display the natural and planned clinical parameters
- Enter a comment
- Validate/Reject a segmentation
- Save a planning

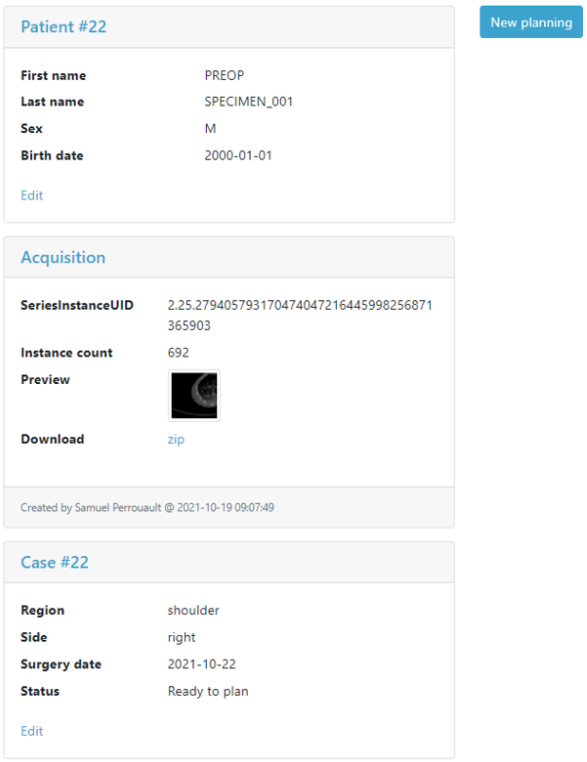
3.3.2. Planning

The planning of a patient case is done in two steps:

- Validation of the segmentation
- The realization of the planning

To schedule, go to the case list and click on the "**Details**" button. You are directed to the case details page.

Click on the "**New Schedule**" button to access the case schedule.

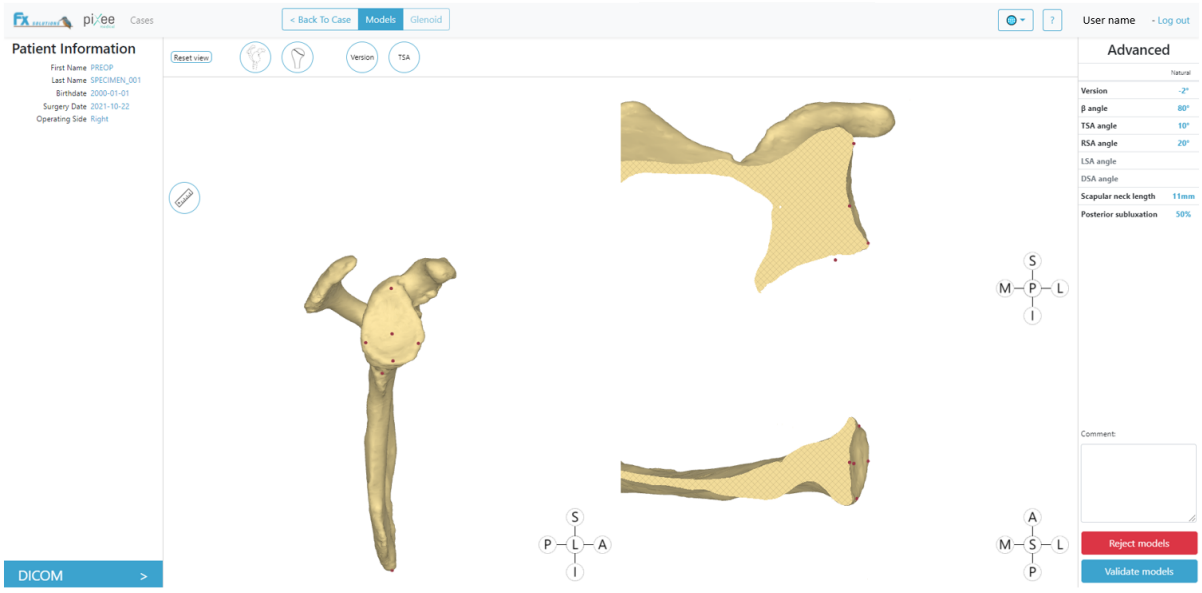


The planning page appears, you can carry out your planning.

3.3.2.1. Validation of the segmentation/models

The validation step of a segmentation is displayed at the first launch of a planning.
This step allows the surgeon to validate the conformity of the segmentation data:

- The positioning of the anatomical points;
- The 3D model of the scapula and humerus;
- The Dicom images.



Once the segmentation has been checked, you can validate or reject it by clicking on the "**Validate models**" or "**Reject models**" button located at the bottom right of the interface.

In the case of a rejection of the segmentation/models, a comment field allows you to enter the reason(s) for the rejection of the proposed segmentation.

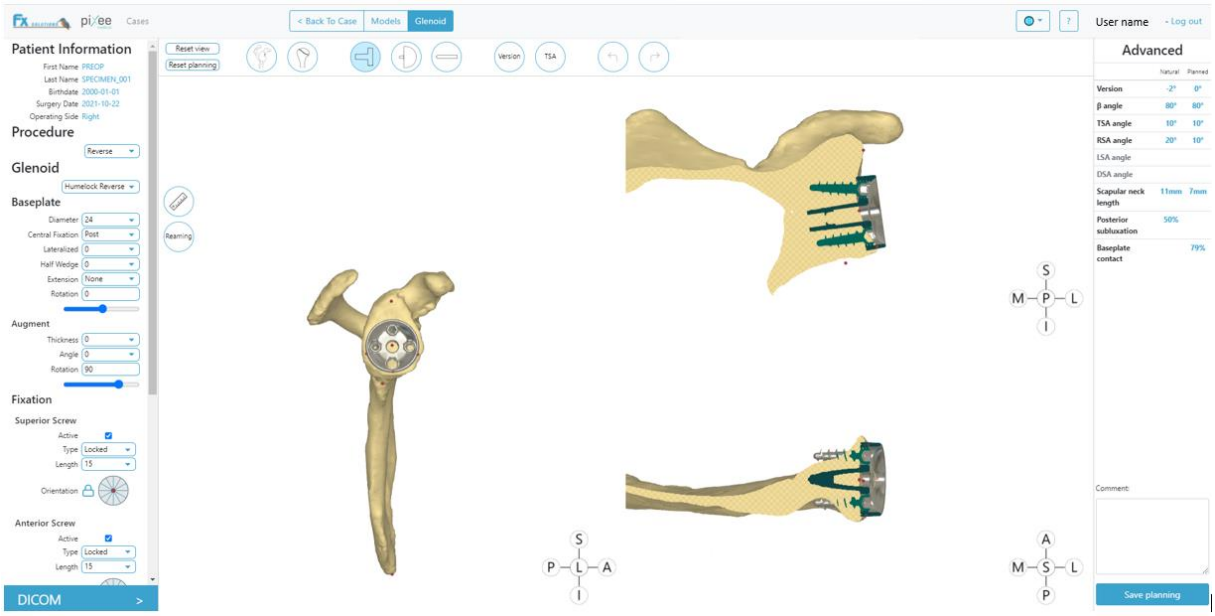
Once the segmentation has been validated, you will proceed to the planning stage of the glenoid.

3.3.2.2. Planning of the glenoid

This step allows the surgeon to plan the placement of a glenoid implant.

- **The planning parameters proposed by default by the software are not recommendations. The validation of the planning parameters is the surgeon's responsibility.**
- **Be careful, in the case of lateralized implants with a half-wedge, the "Metaglene contact" data is only calculated on the flat part.**

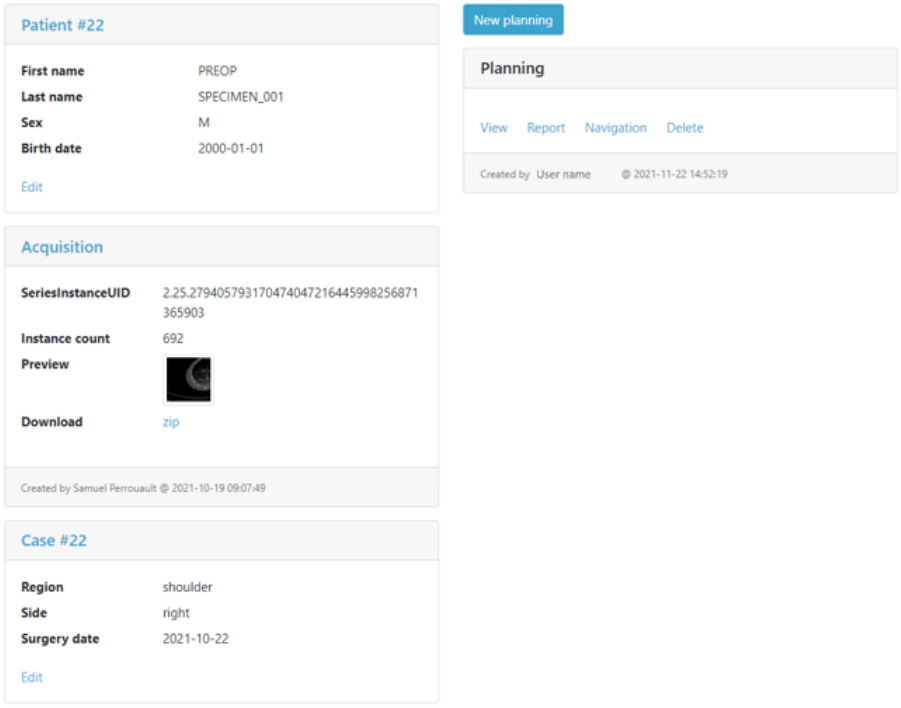
Once the planning is done, the surgeon saves his planning by clicking on the "**Save planning**" button.



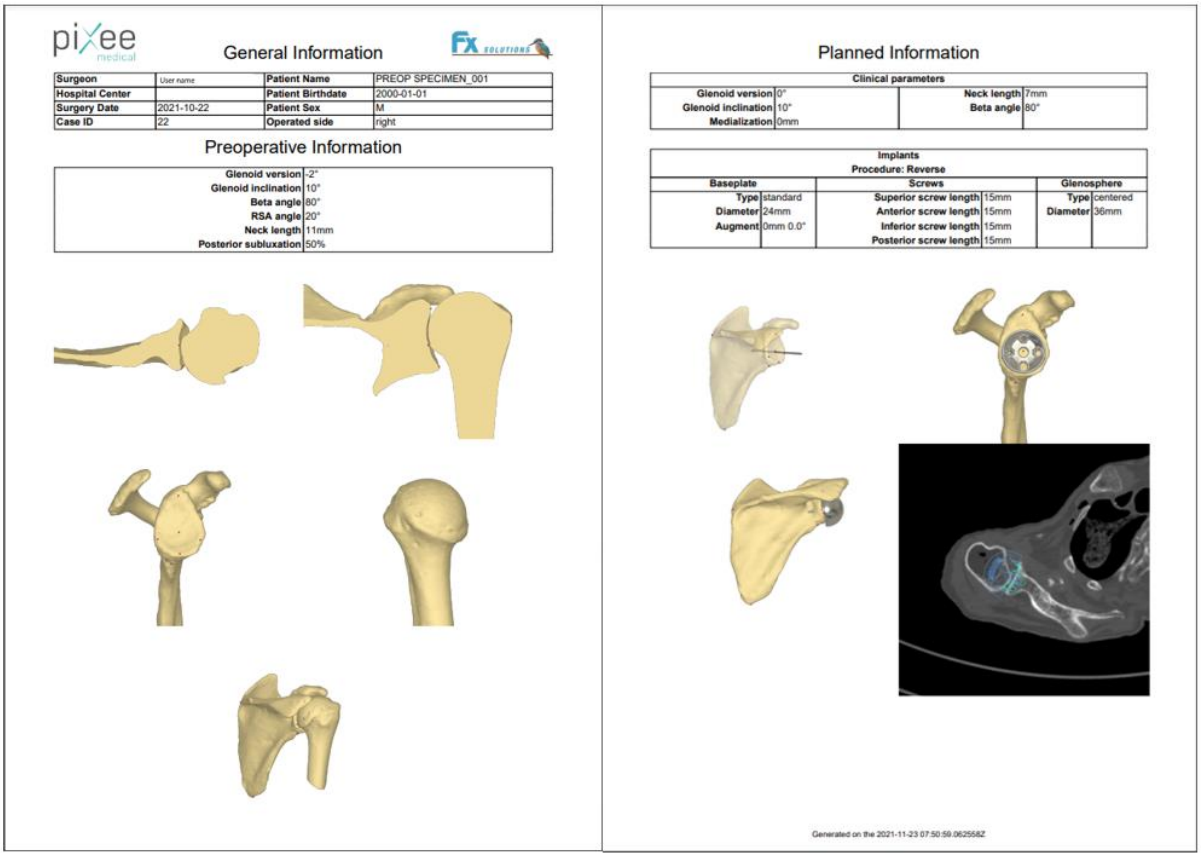
The surgeon can save several plans.

3.3.2.3. Planning report

Once the planning is saved by the surgeon, a planning report is generated.
To access the planning report, click on the "**Back to case**" button, then on the "**Report**" button.



The planning report is displayed in your browser.

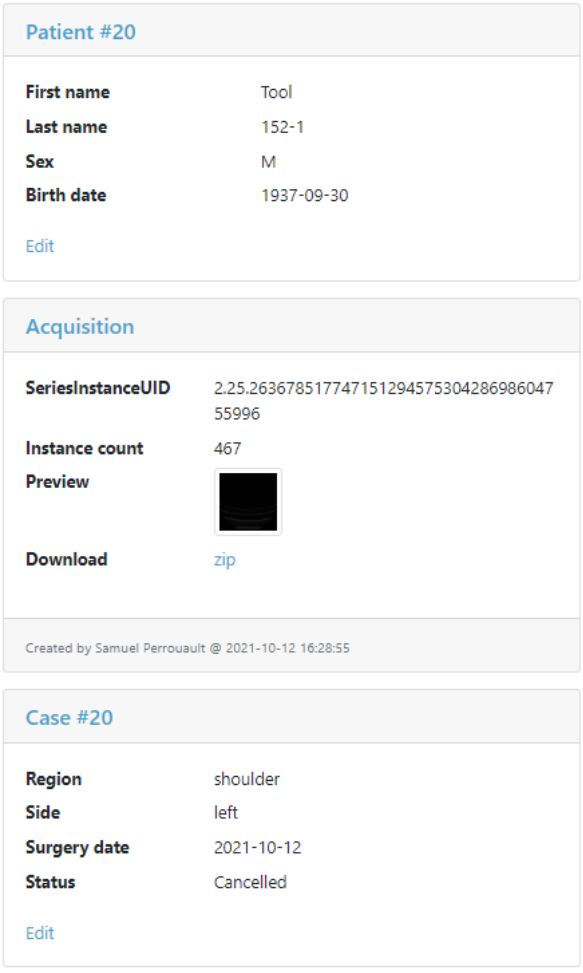


3.4. Particular cases

Cancelled case

When the DICOMs images are not compliance with the Pixee Medical acquisition protocol or the surgeon decides to cancel the surgery, the status of the case is changed to "Cancelled" with an explanation.

This information is sent directly to the surgeon by email. It is also possible to find the reason for this cancellation in the details of the patient case.



4. Support

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