1. General

Read this manual carefully.
You can then decide whether or not to participate in this follow-up.

Dear Patient,

You will be operated on [__/__/____] of the shoulder and you will be implanted with a shoulder prosthesis manufactured by FX Shoulder USA, Inc.

In this context, FX Shoulder USA, Inc. will provide the surgeon with software for planning and surgical simulation of the shoulder in 3-D (the software FX SPS Shoulder Positioning System). For this, some personal information will be sent to Pixee Medical to create the image for the planning. This data will be stored by Pixee Medical in complete security according to local laws and regulations.

2. GENERAL INFORMATION ABOUT FX SPS

2.1. 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 case 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 of building 3-D bone models of the patient's shoulder and positioning anatomic landmarks on it in the software. Once these data are generated, their accuracy 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 3-D reconstruction of the patient's shoulder. The surgeon will choose implants from a library of implants. Afterwards, they can move prosthesis components in all directions and select the size of the implant more suitable to the joint . Once the positioning of the implant is accepted by the surgeon, the planning is validated to generate a planning report.

During surgery, they will have a copy of the planning report comprised of the 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.

2.2. INTENDED USE / INDICATION FOR USE

The FX Shoulder Positioning System (SPS) software is intended to be used as an information tool to assist in the preoperative surgical planning and visualization of a total primary shoulder replacement.

2.3. INTENDED PATIENT POPULATION

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

2.4. 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.

2.5. 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.

2.6. 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.

2.7. POTENTIAL ADVERSE EFFECTS AND RESIDUAL RISKS

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

3. LEGISLATIVE FRAMEWORK

3.1. RETENTION OF YOUR DATA

Some of your data that will be sent to Pixee Medical will be kept on file as data collection for an indefinite period of time.

3.2. Planning framework

As part of your shoulder arthroplasty surgery, the surgeon will use planning software before your surgery. This software simulates the position of the prosthesis on your bone using CT images. To do this, information such as name, gender, date of birth, medical images, operated side and date of surgery will be sent to Pixee Medical to create the image for the planning.
This data will be stored by Pixee Medical in complete security according to local laws and regulations.
You can request at any time the correction or deletion of your data used in the FX SPS software.

3.3. Research framework

With your permission, Pixee Medical may use certain planning data for clinical research purposes only. Within the framework of this research, your personal clinical data will be collected in a strictly anonymous way (they will be coded, without mentioning your name).
The results of this research may be presented at scientific conferences or published in scientific journals with the aim of improving the health of patients.

If you wish to object to your data being used by Pixee Medical for clinical research purposes, you will continue to benefit from surgical planning with the FX SPS shoulder software and this will not affect the care you may require. You can refuse the use of your data for research in the §4.

3.4. YOUR RIGHTS

The purpose of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), or commonly called “the Privacy Rule” was to establish minimum Federal standards for safeguarding the privacy of individually identifiable health information (PHI). Covered entities, in this case your surgeon, may not use or disclose PHI except as permitted or required under the provisions of the Privacy Rule. The Rule confers certain rights on individuals, including rights to access and amend certain health information and to obtain a record of when and how their PHI has been shared with others for certain purposes.

The Privacy Rule recognizes that the research community has legitimate needs to use, access, and disclose individually identifiable health information to carry out a wide range of health research protocols and projects. In the course of conducting research, researchers may create, use, and/or disclose individually identifiable health information. The Privacy Rule protects the privacy of such information when held by a covered entity but also provides various ways in which researchers can access and use the information for research.

The Privacy Rule permits covered entities to use or disclose PHI for research purposes with an individual's specific written permission, termed an “Authorization,”

Your participation in this research is entirely voluntary, you will not be subjected to any additional visit or examination compared to the usual follow-up of your surgeon's usual practice and to your care.
If you wish not to participate or withdraw from it at any time, and for any reason, you will continue to benefit from medical follow-up and this will not affect your future monitoring.

An internal Data Protection Officer (DPO) has been appointed by Pixee Medical, who can be contacted at dpo@fxshouldersolutions.com.

4. CONSENT

I, the undersigned, _____

Certify that I have read the information in this consent form (or it has been read to me). I have been informed prior to my shoulder surgery, and have had the opportunity to ask questions about the use of my data and the use of FX SPS, and all of my questions have been answered.

Choose one below:

☐ Certify that I have been informed prior to my shoulder surgery and **authorize the use of my deidentified** health information for clinical research as described in this letter.

☐ Certify that I have been informed prior to my shoulder surgery and **DO NOT authorize the use of my deidentified** health information for clinical research as described in this letter.

_____

Printed Name of Patient

_____ _____

Signature Date