



END USER LICENSE AGREEMENT

1 INTRODUCTION

This End-User License Agreement (hereinafter “Agreement”) is a legal agreement between you and FH ORTHO for the software that allow you to use **e-ORTHO** shoulder technology (hereinafter “**e-ORTHO** software”).

Please read this Agreement carefully and in its entirety. By clicking « *I certify I am surgeon and I accept terms and conditions of use* » option, accessing or otherwise using all or any portion of this **e-ORTHO** software, you have read, understand, and agree to be bound by all of the terms and conditions of Agreement, without limitation or qualification. You agree that this Agreement is like any written negotiated Agreement signed by yourself or on behalf of your entity. This Agreement is enforceable against yourself or your entity.

e-ORTHO software is provided as a shoulder surgery planning tool for informational purposes only. The chosen procedure is your responsibility. Prior to any shoulder surgery, you should evaluate the appropriateness of the procedure to the specific patient based on your medical training. Do not use **e-ORTHO** software for clinical diagnostic purposes.

e-ORTHO software is intended to carry out a surgical planning of an ARROW shoulder prosthesis by FH ORTHO.

2 LICENSE GRANT

The **e-ORTHO** software license is granted exclusively to orthopedic surgeons who have been approved by FH ORTHO.

Accordingly, you are only authorized to connect and access to **e-ORTHO** software after FH ORTHO’s approval. FH ORTHO reserves the right to grant, refuse or deactivate any license at any time, without prior notice.

The **e-ORTHO** software license is personal, non-exclusive, non-transferable and revocable. You will be entirely responsible for any use of **e-ORTHO** software under your license.

3 PASSWORD AND LOGIN INFORMATION

Access to **e-ORTHO** software is granted by the use of a password associated with you on a strictly personal basis. Under no circumstances you can share the password or allow third parties to use the password to access **e-ORTHO** software. Each password has a specified validity period. On his request, you will be enabled to reset his password at the expiration of the specified period. You can then use the **e-ORTHO** software for a new period.

4 RESTRICTION

FH ORTHO reserves all rights in and to the **e-ORTHO** software not expressly granted to you, and no other licenses or rights are granted by implication or otherwise.

In addition, and without limiting the foregoing reservation of rights, your use of the **e-ORTHO** software is subject to the following restrictions:

- you may not reverse engineer, decompile, disassemble or attempt to derive the source code of the **e-ORTHO** software, except to the extent the foregoing restriction is expressly prohibited by applicable law;
- you may not modify, adapt, alter, translate or create derivative works based upon the **e-ORTHO** software in whole or in part;
- you may not copy the **e-ORTHO** software;
- you may not remove any proprietary notices or labels on the **e-ORTHO** software;
- you may not permit other individuals to use the **e-ORTHO** software;
- you may not loan, rent, lease, sublicense, distribute, sell or otherwise transfer all or any portion of the **e-ORTHO** software to third parties;
- you may not merge the **e-ORTHO** software with any other software;

FH ORTHO permits you to use **e-ORTHO** software during congress communication, paper communication or free presentation as long as the intellectual property of the **e-ORTHO** software is respected. The brand logo of **e-ORTHO** software has to appear on each publication.

e-ORTHO software is not intended or designed to be used for the planning or consideration of procedures with devices other than those FH ORTHO devices specified in the **e-ORTHO** software. Any use of the software in connection with any other devices is not authorized by FH ORTHO and may, at FH ORTHO's sole discretion, result in having your access and use of the **e-ORTHO** software terminated.

You will comply with applicable laws, rules, regulations and orders and FH ORTHO's instructions regarding the use of the **e-ORTHO** software.

5 DATA

You hereby grant FH ORTHO a license to use this limited data sets (patient data and surgeon data) to generate the surgical planning set data requested by you in relation to your use of **e-ORTHO** software. FH

ORTHO could use anonymized data sets as needed for data's analysis and for research proposes under the patient's authorization.

FH ORTHO has implemented a strict data security solution to store all **e-ORTHO** software data (including users' and patients' data) in a web-based private cloud including a physical protection according to European regulations.

Regarding to patient data, before any use in **e-ORTHO** of the data of a new patient, you will need to have it signed a letter of information (hereinafter " The Patient Information Letter " **Appendix 1**), in which we inform the patient of the treatment in **e-ORTHO** of his personal data.

The signed Patient Information Letter should be kept by yourself, and you will be responsible of the conservation. You must be able to communicate this signed letter to FH ORTHO at any time without delay.

All users (including patients) can request FH ORTHO to delete all personal data stored on our servers at any time. In this case you have to send an email to e-ortho@fh-industrie.com indicating the UID of the patient in order FH ORTHO could delete without delay the patient data requested.

PRINT DATA: You are authorized to print the **e-ORTHO** software surgical report, only planning after validation can be recorded or printed in a report. The surgical report of **e-ORTHO** software are traced with you and patient information, you will be entirely responsible for the final use or lose of this report.

6 INTELLECTUAL PROPERTY

e-ORTHO software which may include associated user documentations are propriety of FH ORTHO and are protected under copyright law. FH ORTHO permits you to use or otherwise benefit from the functionality or intellectual property of this software only in accordance with the terms of this Agreement.

You acknowledge and agree that, as between FH ORTHO and you, FH ORTHO owns all right, title and interest in and to the **e-ORTHO** software, including all intellectual property rights therein or appurtenant thereto. You further acknowledge and agree that the **e-ORTHO** software contains the valuable trade secrets of FH ORTHO and third parties. You will not acquire any right, title or interest in the **e-ORTHO** software or any portion or component thereof pursuant to this Agreement, other than the right to access and use the **e-ORTHO** software as expressly granted in this Agreement, subject to the terms and conditions of this Agreement. You may not modify or create a derivative device based upon **e-ORTHO** software.

7 e-ORTHO SOFTWARE MODIFICATIONS BY FH-INDUSTRIE

FH ORTHO reserves the right, in its sole and absolute discretion, to modify the operation mode and/or any functionality of **e-ORTHO** software without prior notice. Therefore FH ORTHO will inform all user about the modifications.

8 TERMS AND CONDITIONS

The term of this Agreement will begin on the date you accept this Agreement and, continue as long as you have authorized access to e-Ortho. Unauthorized access is prohibited by FH ORTHO.

Termination:

- FH ORTHO may, at its sole discretion, terminate this Agreement at any time:
 - (1) if you are in breach of this Agreement, or
 - (2) if you use the **e-ORTHO** software other than as permitted in this Agreement, including by using this software in connection with procedures involving any implantable device not specified in the **e-ORTHO** software.

- FH ORTHO may terminate this Agreement at any time upon written notice to you, if FH ORTHO is ceasing generally to provide the **e-ORTHO** software to end users.

Your obligations upon termination: Upon the expiration or termination of this Agreement for any reason, you will cease immediately all use of the **e-ORTHO** software.

9 POWER OF JURISDICTION

If no amicable settlement can be reached, disputes relating to the interpretation and performance of this Agreement shall be referred to the Courts of the city of Mulhouse, France.

Appendix 1

PATIENT INFORMATION AND CONSENT LETTER

For using the **e-Ortho® software** from **FH ORTHO**
Read this letter carefully and ask all the questions that you think will be useful.
Then you can decide to accept or not

Dear Sir, Madam,

You will undergo a primary total shoulder replacement the [____ / __ / __] using an Arrow prosthesis, made by FH ORTHO and distributed by FH ORTHOPEDICS, 68990 Heimsbrunn.

In this context, FH ORTHO could provide the surgeon with a 3-D surgical simulation and planning software (**e-Ortho** shoulder software). For this, a part of your clinical record, including your medical images and personal data (Name, Sex, Birthday, Date of surgery and Surgical center) will be sent to FH ORTHO for the pre-treatment needed in order to carry out the surgical planning. FH ORTHO will store this data safely according to the applicable European laws. You can request, at any time, the correction or the elimination of your data used in **e-Ortho** software system.

LEGISLATIVE FRAMEWORK

• DATA CONSERVATION

A part of your clinical record will be transmitted to FH ORTHO. Consequently, FH ORTHO will save your data in the information systems for an indefinite period.

• YOUR RIGHTS

In accordance with the Law No. 78-17 of January 6, 1978, known as "Information and Freedoms" as amended and Regulation 2016/679 of the European Parliament and of the Council of April 27, 2016, applicable from May 25, 2018, you have the following rights:

- The right to request access, rectification, erasure or limitation of your data used in surgical planning. You can also access directly or through a doctor of your choice, all your medical files in application of the provisions of Article L. 1111-7 of the Public Health Code;
- The right to oppose the collection and transmission of your data covered by medical confidentiality;
- The right to recover all the data concerning you in order to transmit them to another controller (right to portability);

- The right to remove, at any time, your agreement for the use of your data. This will not affect the medical-care you might benefit.

You also have the right to lodge a complaint with the “Commission Nationale de l’Informatique et des Libertés” - CNIL (French authority for the control of personal data).

Your participation is entirely voluntary, you will not be subjected to further visits or examinations differently of the surgical routine follow-up established by your surgeon.

If you do not wish to attend or withdraw your participation at any time and for any reason, you will continue to receive the same medical follow-up and this will not affect your future monitoring.

In accordance with Regulation 2016/679 (RGPD), an internal Data Protection Officer (DPO) has been appointed by FH ORTHO, who can be contacted at dpo@fhortho.fr.

LEGISLATIVE FRAMEWORK FOR RESEARCH

Under your authorization, FH ORTHO may use a part of your data for clinical research purposes. As part of this research, **your data will be collected strictly anonymously** (it will be codified, without name or last name mention).

The results of this research may be presented at scientific conferences or published in scientific journals in order to improve patients’ healthcare.

If you wish to object to your data being used by FH ORTHO for clinical research purposes, you will continue to benefit from the surgical planning with the e-Ortho® shoulder software and this will not affect the medical care you might benefit.

Thank you for taking the time to read this PATIENT INFORMATION AND CONSENT LETTER

I, _____

Certify that I have been informed before my shoulder surgery and authorize the use of my health data for surgical planning purposes as described by e-Ortho® in this letter

Certify that I have been informed before my shoulder surgery and authorize the use of my anonymous health data for clinical research purposes as described in this letter

Signature and date