Customize V1.2 – Instructions for Software Use – Shoulder Arthroplasty E-DND-30-03. Version of 14 March 2022.

This document contains the basic 'Instructions for Use' of Customize Shoulder Arthroplasty.
Detailed instructions can be found in the 'User Manual' E-DND-32 For Shoulder Arthroplasty.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

1. Indications for Use

Customize for shoulder arthroplasty is intended to be used as a software interface to assist in:

- Visualization, modification, validation of the planning of shoulder arthroplasty;
- communication of treatment options;
- segmentation of CT-scan data;
- 3D CAD models generation;
- managing timeline and cases

Customize is not intended to be used for:

- spine surgeries;
- implant and instrument design

Experience in usage and a clinical assessment are necessary for a proper use of the software. It is to be used for adult patients only and should not be used for diagnostic purposes.

No potential side effects nor complications associated with the use of Customize have been identified through the development process.

2. Warning and precautions

Customize should only be used by trained medical professionals.

Inputs provided to the software are not evaluated by a medical specialist. This implies that the surgeon is responsible for the quality of the inputs provided to the software, such as medical images, and is responsible to decide if those inputs are proper for a segmentation or surgery planning.

The output of the (semi)-automatic segmentation functionality in Customize should always be evaluated by the design engineers or medical professionals before being used for any purpose. Output of distances between bone and implants are proposed in the planning functionality in Customize. These outputs, expressed in percentage or millimeter are display as approximate estimate only and medical decision cannot be solely based on this information.

Only surgeons are allowed to take medical decisions and to approve a pre-operative planning.

3. Instructions for Use

To access the platform, go on the following URL : xxxx.3d-customize.com, where xxxx is referring to a subdomain name such as a company name.

Hardware Requirements
• Video Graphics Card which supports WebGL
• RAM > 4 Go
• 25Go free hard disk space*
• Powerful internet connection

Software Requirements
• Web browser supporting WebGL** and having the related option enabled.
• Compatible browsers versions and more recent releases: Google Chrome 33, Edge 12, Firefox 29, Safari 7.1.
• JavaScript should not be blocked. All settings*** (including cache system) should not be altered compared to the default behavior of the browser.

Medical images
• DICOM image format only

*Depending on the functionalities of Customize used by the customer.

**Once the download and install of Customize are completed, please visit this page to ensure the main component is active: https://get.webgl.org/. If you do not see a spinning cube, please contact the manufacturer.

*** In case of a display problem (text, task numbers, …) on Customize, it is advised to clear the cache on the browser using the site https://clear-my-cache.com/detect.html.

It is recommended to use or software within a hardware and/or a network environment in which cybersecurity controls have been implemented including anti-virus and use of firewall.

This IFU can be opened from the footer of Customize interface. The IFU language opened via those links depends on the language applied to the customer Customize interface. To find all versions and all available languages of Customize IFU please refer to 3D-Side website (https://www.3dside.com/ifu-customize). You have the right to request a paper version of this IFU without any additional cost; it will be delivered the latest 7 days after your request is received. For any questions or to request a paper version of this IFU, please send an-email to the manufacturer.

4. Manufacturers Contact Details

Manufactured in July 2021 by

3D-Side
5 Rue André Dumont
1435 Mont-Saint-Guibert, Belgium
support@3dside.eu