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This document contains general instructions for use for SurgiCase Viewer. For detailed instructions please refer to the user manual.

DESCRIPTION

SurgiCase Viewer provides functionality to allow visualization of 3D data and to perform measurements on these 3D data, which should allow a user to evaluate and communicate about treatment options.

SurgiCase Viewer is intended for use by people active in the medical sector. When used to review and validate treatment options, SurgiCase Viewer is intended to be used in conjunction with other diagnostic tools and expert clinical judgment.

The SurgiCase Viewer can be used by a medical device/service manufacturer/provider or hospital department to visualize 3D data during the manufacturing process of the product/service to the end-user who is ordering the device/service. This allows the end-user to evaluate and provide feedback on proposals or intermediate steps in the manufacturing of the device or service.

The SurgiCase Viewer is to be integrated with an online Medical Device Data System which is used to process the medical device or service and which is responsible for case management, user management, authorization, authentication, etc.

The data visualized in the SurgiCase Viewer is controlled by the medical device manufacturer using the SurgiCase Viewer in its process. The device manufacturer will create the 3D data to be visualized to the end-user and export it to one of the dedicated formats supported by the SurgiCase Viewer. Each of these formats describe the 3D data in STL format with additional meta-data on the 3D models. The SurgiCase Viewer does not alter the 3D data it imports and its functioning is independent of the specific medical indication/situation or product/service it is used for. It's the responsibility of the Medical device company using the SurgiCase Viewer to comply with the applicable medical device regulations.

INDICATIONS

SurgiCase Viewer is intended to be used as a software interface to assist in visualization and communication of treatment options.

CONTRAINDICATIONS

- SurgiCase Viewer can be used to visualize a medical device or service. The manufacturer of the said medical device or service is responsible to comply with the applicable medical device regulations.

WARNINGS

- The software should be operated by trained personnel, or the output should always be reviewed and approved by a qualified user.
- It is the clinician's ultimate obligation to exercise his/her professional judgment in any decision to follow or not follow the treatment plan made.
- It is the clinician's responsibility to only use the software on desktop or mobile devices satisfying the minimal requirements specified below.
- The SurgiCase Viewer is not responsible for the accuracy of the models it is displaying. Consult the medical device provider regarding the accuracy of the models. SurgiCase Viewer shows measurements with a precision of 0.1 mm/degree. Please note that the measurements are limited by the resolution of the models provided by the Medical Device Data System.

PRECAUTIONS

R_X only CAUTION: Federal law (USA) restricts this device to sale by or on the order of a Physician

INSTRUCTIONS FOR USE

- Install

No installation is required to use the SurgiCase Viewer. The SurgiCase Viewer is a web based application and can be accessed through the medical device data system it is integrated with.

- Start

To open a case in the SurgiCase Viewer, log in to the medical device data system, browse to the appropriate case and click the link to visualize the 3D data in the SurgiCase Viewer.

MINIMAL REQUIREMENTS

Operating Systems
Following operating systems are supported:

- Latest version of iOS
- Latest version of Mac OS
- Windows® 7 Service Pack 1 (SP1) (32-bit or 64-bit)
- Windows 10
- Android 6 Marshmallow and 7

Browsers

- Browser with WebGL support and WebGL enabled.
- Following browsers are supported per operating system:
    - Google Chrome on Windows, Mac OS X, Android OSs
    - Microsoft IE on Windows OS
    - Mozilla Firefox on Windows OS
    - Apple Safari on Mac OS X, iOS OSs
- Cookies support

Internet Connection

3G or higher

Application window resolution

WXGA or higher

Screen size

7 inches or more

Memory

2GB RAM or more

CPU

Dual Core processor or better

Graphic card

Refer to the following list:

https://www.khronos.org/webgl/wiki/BlacklistsAndWhitelists

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