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CE 0120

ΕN

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

DESCRIPTION

The SurgiCase Planner 2.4 is a 3D environment software which allows the surgeon to accurately plan a joint replacement surgery based on MRI, CT or X-ray images of the patient. Based on this approved surgical plan, Materialise will manufacture patient-specific guides that will be used during the surgery, if ordered by the surgeon.

INDICATIONS

The SurgiCase Planner software is intended to be used for simulation of surgical interventions and the planning of preoperational interventions.

The SurgiCase Planner software used to assist in the positioning of orthopedic components.

CONTRAINDICATIONS

None.

WARNINGS

- The software should be operated by trained personnel, or the output should always be reviewed and approved by a qualified clinician.
- 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 using the medical device software.
- Patient specific guides are to be used by a trained clinician in the performance of surgery.
- Be aware that any patient-specific guides and/or anatomical models derived from a planning created in the software have been manufactured based on MRI/CT/X-ray images of the patient. If the patient's anatomy has changed significantly since the time of the MRI/CT/X-ray images, the guides or models should not be used.

PRECAUTIONS

 It is advised to use the guide or model within 6 months of performing the MRI/CT/X-ray images on which they are based. If the patient's anatomy has changed significantly since the time of the MRI/CT/X-ray images, the guide or model should not be used, even if the time period of 6 months has not expired.

INSTRUCTIONS FOR USE

<u>Install</u>

No installation is required to use the SurgiCase Planner. The SurgiCase Planner is a web based application and can be accessed through SurgiCase Online.

• <u>Start</u>

To open a case in the SurgiCase Planner, browse to the appropriate case in the SurgiCase Online Ordering System and click the link in the Case Details to open the SurgiCase Planner.

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

Browsers

Browser with WebGL support and WebGL enabled.

Following browsers are supported by the SurgiCase Viewer per operating system:

- Google Chrome on Windows, Mac OS X
- Microsoft IE on Windows OS desktop
- Microsoft Edge on Windows OS desktop
- Mozilla Firefox on Windows OS desktop
- 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

Please refer to the following list describing black/white lists for graphic cards:

https://www.khronos.org/webgl/wiki/BlacklistsAndW hitelists