



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 3.0 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 by browsing to the url of the case.

• <u>Start</u>

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

MINIMAL REQUIREMENTS

Browsers and Operating Systems

- Browser with WebGL support.
 - A list of browsers supporting WebGL can be found here:

http://en.wikipedia.org/wiki/WebGL#Support

You can check whether your browser supports WebGL by clicking this link:

https://get.webgl.org/

- Cookies support
- Following operating systems minimally:
 - o iOS 8.x
 - o MacOS 10.x
 - Windows[®] 7 Service Pack 1 (SP1) (32-bit or 64-bit)
- Internet Connection

Internet connection should be available

Graphic card

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

https://www.khronos.org/webgl/wiki/BlacklistsAndWhit elists

RECOMMENDED REQUIREMENTS

Browsers and Operating Systems

The software is recommended to be used in the following browser/OS combinations (with latest version of browser and used OS) – as these combinations are explicitly tested/supported:

On Windows 7 PC:

- Google Chrome
- Microsoft Internet Explorer
- Mozilla Firefox

MacOS:

- Safari
- Google Chrome

iPad iOS:

• Safari

Cookies support

Internet Connection Regular 4G (4Mbps, 20 ms RTT) Screen resolution WXGA or higher Graphic card Please refer to the following list describing black/white lists for graphic cards: https://www.khronos.org/webgl/wiki/BlacklistsAndWhit

<u>elists</u>