To whom it may concern

Division/Dept.: CG-QM
Your contact: Juergen Kasprows, Director Quality Management

IMPORTANT SAFETY ALERT FOR ZEISS SURGICAL MICROSCOPES

Affected Microscopes with Navigation System Interface:
OPMI® Pentero®  OPMI® Pentero® C  OPMI® PENTERO® 900
OPMI® Vario / S8  OPMI® Vario / S88  OPMI® Neuro Multivision / NC4
OPMI® Vario / NC33  OPMI® Neuro / NC4  OPMI® Neuro / NC4 Ceiling Mount

RE: The Use of Third Party Drapes May Affect Third Party Navigation Systems Connected to Zeiss Surgical Microscopes

Dear Valued Carl Zeiss Customer:

We are writing to advise you that some third party surgical drapes have optically active protective lenses that could affect the Carl Zeiss surgical microscope position information that is passed on to third party navigation systems. Certain third party drapes (e.g. Microtek “Clearlens®”) may influence the accuracy of third party navigation systems due to an optical distortion caused by the convex shaped protective lens cover. Although there may be no perceptible impairment to the visual image quality observed through the microscope eyepieces (oculars), there is an imaging effect which displaces the microscope’s focal point displayed by the navigation software.

Due to this effect the focal point displayed by the navigation software may not be correctly aligned to the patient’s image information from the navigation system (i.e. the patient data set). Consequently the microscope-related reconstruction of the patient data set by the third party navigation system could display a wrong focal plane that does not comply with the real focal plane of your surgical microscope. In systems with such features, depending on the distortion caused by the lens, the object contours of a pre-planned anatomical structure displayed in the microscope video of the navigation software, or in the heads-up-display, may show an incorrect size and/or incorrect position in relation to the actual image in your surgical microscope.

If not noticed by the user, incorrectly displayed information could influence clinical decisions during a navigated surgery. Those clinical decisions could be incorrect and potentially result in ineffective treatment or in serious injury to the patient.
REQUIRED ACTIONS

- It is important to use surgical drapes compatible with Carl Zeiss surgical microscopes. Carl Zeiss offers a line of sterile drapes designed for use with Carl Zeiss surgical microscopes. If you choose to use a third party drape with the Carl Zeiss surgical microscopes in conjunction with a third party navigation system, please check with the drape manufacturer to ensure compatibility. The following Carl Zeiss drapes have been tested and verified to work with the calibration of the surgical microscope in conjunction with a partner navigation system.

<table>
<thead>
<tr>
<th>Carl Zeiss Drape with VisionGuard® Lens Technology</th>
<th>Carl Zeiss Part Number</th>
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<tbody>
<tr>
<td>Zeiss sterile drapes, type 25, pack of 5</td>
<td>306025-0000-000</td>
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<tr>
<td>Zeiss sterile drapes, type 26, pack of 5</td>
<td>306026-0000-000</td>
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<td>Zeiss sterile drapes, type 70, pack of 5</td>
<td>306070-0000-000</td>
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<tr>
<td>Zeiss sterile drapes, type 71, pack of 5</td>
<td>306071-0000-000</td>
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- Always follow the instructions for use of the third party navigation system manufacturer for calibration, calibration verification and operation.
- A supplement to your Carl Zeiss surgical microscope user documentation is provided that contains important information regarding the safe use of the Carl Zeiss surgical microscope with third party navigation systems. Please read this information and keep a copy of it with your Carl Zeiss surgical microscope user documentation. You may copy this supplement as needed if you have more than one Carl Zeiss surgical microscope.
- Enclosed please find an acknowledgement form for your completion indicating your receipt of this alert. Please sign and return the acknowledgement form to your local Carl Zeiss office (address information is provided on the form).

This Important Safety Alert is being performed with the knowledge of some local authorities.

Carl Zeiss appreciates your assistance in this matter. Should you have any questions about this Important Safety Alert, please contact us.

Carl Zeiss Meditec AG
Oberkochen Site

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