

## ***STERRAD® Sterilization Systems Statement for Gyrus ACMI Rigid Products***

Gyrus ACMI has tested certain Gyrus ACMI rigid telescopes in the STERRAD® Sterilization Systems supplied by Advanced Sterilization Products (ASP). The purpose of this testing program was to determine the compatibility of Gyrus ACMI device materials with the STERRAD® Sterilization Systems. In addition, ASP has conducted an evaluation to confirm the sterilization efficacy of the STERRAD® NX Sterilization System with these Gyrus ACMI devices.

The table below lists the results of the compatibility testing and the sterilization efficacy of STERRAD® Sterilization Systems. Gyrus ACMI devices listed in the table have been determined to be “compatible,” and Gyrus ACMI endorses the processing of that particular model of rigid telescope with the STERRAD® 50, 100S, 200 and NX Sterilization Systems.

Gyrus ACMI intends to continue compatibility testing with our current and future product offerings to confirm that our devices may be satisfactorily processed in STERRAD® Sterilization Systems. The table below will be updated by Gyrus ACMI as the appropriate testing data is established. In addition, devices that have successfully completed both compatibility and efficacy testing\evaluation will also be listed on ASP’s Sterility Guide. In order to access this information, go to <http://www.sterradsterilityguide.com/>. Please note you will need the serial number of a current STERRAD® unit in order to access the Sterility Guide.

The results below are based on the completion of a minimum number of sterilization cycles, and may not be representative of actual use. No assurance can be given that you will have the same results or that additional cycles will not adversely affect the device and materials. Cosmetic and/or functional damage may yet occur in the STERRAD® Sterilization Systems. For example, the engraving process used to mark Gyrus ACMI instrumentation may be damaged by the STERRAD® NX Sterilization System. Although this is generally defined as cosmetic, the engraving detail may be removed by the sterilization process.

Functional damage to Gyrus ACMI instruments which is deemed to have been caused by use of STERRAD® NX Sterilization System **will** be covered under Gyrus ACMI’s Limited Express Warranty when such damage has been identified.

<b>Device</b>	<b>Product Description</b>
M3-0A	M3 - Gold Autoclavable Direct Telescope, yellow, 0°
M3-12A	M3 - Gold Autoclavable Direct Telescope, green, 12°
M3-30A	M3 - Gold Autoclavable Direct Telescope, white, 30°
M3-70A	M3 - Gold Autoclavable Direct Telescope, blue, 70°

Please note that the references above apply to the STERRAD® 50, 100S, 200 and NX Sterilization Systems only, and do not apply to the STERRAD® 100NX Sterilization System.