

STERRAD® NX Sterilization System Statement

Gyrus ACMI has tested certain Gyrus ACMI flexible endoscope devices in the STERRAD® NX Sterilization System 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® NX Sterilization System. In addition, ASP has conducted testing 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® NX Sterilization System. Gyrus ACMI devices listed in the table have been determined to be “compatible,” and Gyrus ACMI endorses the processing of that particular model of flexible endoscope with the STERRAD® NX Sterilization System.

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® NX Sterilization System. 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 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® NX Sterilization System. For example, the engraving fill material used to mark Gyrus ACMI instrumentation may be damaged by the STERRAD® NX Sterilization System. Although this is generally defined as cosmetic, the material 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.

Device	Product Description
DUR-D	INVISIO Flexible Ureteroscope
DUR-DBA	INVISIO Flexible Ureteroscope – Backwards Angle
DUR-8	Flexible Fiberoptic Ureteroscope
DUR-8BA	Flexible Fiberoptic Ureteroscope – Backwards Angle
DUR-8E	Elite Flexible Fiberoptic Ureteroscope
DUR-8EBA	Elite Flexible Fiberoptic Ureteroscope – Backwards Angle
DUR-8ULTRA	Ultra Flexible Fiberoptic Ureteroscope
DUR-8ULTRA-BA	Ultra Flexible Fiberoptic Ureteroscope – Backwards Angle
ACN-2T	Flexible CystoNephroscope
ACN-2TBA	Flexible CystoNephroscope – Backwards Angle
IPN-2505	INVISIO Smith Percutaneous Nephroscope System

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