

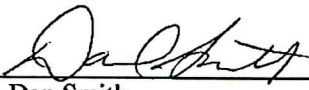

## MEMORANDUM

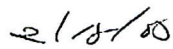
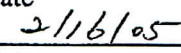
**DATE:** February 11, 2005  
**TO:** MDM Testing Program Group  
**FROM:** Dan Smith & Su-Syin Wu  
**RE:** Substantial Equivalency of STERRAD NX Sterilizer to the STERRAD 100S/50/200 Sterilizers

The intent of this memo is to document the equivalency of the STERRAD NX Sterilizer to other STERRAD 100S/50/200 Sterilizers. The STERRAD NX Sterilization System was designed to meet customer needs for a fast, compact, less-expensive sterilizer. The STERRAD NX Sterilizer is very similar to the current STERRAD 100S/50/200 Sterilizers. The major difference is that the STERRAD NX Sterilizer utilizes a new vaporization system with "Concentration Technology" – Water is removed from the 59% Hydrogen Peroxide before it is transferred to the sterilization chamber. The result is highly concentrated hydrogen peroxide, which allows for the sterilization of longer, narrower lumens without the need for Boosters.

During the product development and validation phases of the STERRAD NX Sterilizer, the sterilization efficacy, material compatibility, and device functionality studies were performed using the test methodology and protocols very similar to those used for the STERRAD 100S/50/200 Sterilizers. For the material compatibility of the STERRAD NX Sterilizer versus other STERRAD Sterilizers, a specially selected group of sensitive materials and medical devices were evaluated. The materials and devices tested are known to be sensitive to yet compatible with current STERRAD Sterilizers. Results of the testing indicate that medical devices that are compatible with current systems will also be compatible with the STERRAD NX Sterilizer as long as the medical devices are within claim limits of each system.

There was an exception during the surface sterilization study. Neoprene was found not to be equivalent, and therefore, it is not recommended for processing in the STERRAD NX Sterilizer.

  
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Dan Smith  
  
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Su-Syin Wu

  
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