18. Sterilization and Shelf Life

a. Sterilization Validation

After final assembly into the configuration described above in the 'Packaging' subsection of the 'Device Description' section, the product is sterilized via Ethylene Oxide (EO). Pursuant to the FDA guidance document entitled, "*Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*" (issued January 21, 2016) the following information is provided regarding the sterilization process:

Sterilization Method	Traditional Ethylene Oxide (EO) sterilization with devices in a fixed chamber.
Sterilization Validation Method	**ISO 11135:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices**
SAL	10^{-6}
Pyrogens	The product is not labeled "Pyrogen free".
Packaging Used to Maintain Sterility (not including packaging integrity test data)	See Packaging Section

Maximum levels of residuals of EO and ethylene chlorohydrin that remain on the device (based on replicate measurements/cycling):

Cycle	Contact Duration	EO (mg per device)	ECH
3 days 1X	Limited Use		
	24 Hour		
	30 Days		
5 days 1X	Limited Use		
	24 Hour		
	30 Days		
7 days 2X	Limited Use		
	24 Hour		
	30 Days		