

ABSTRACT

5 METHOD OF TERMINAL STEAM STERILIZATION

 A method for terminal steam sterilization of a pre-filled plastic or glass syringe or cartridge is disclosed, said method comprising the steps of: maintaining a head space in the syringe
10 or cartridge of not exceeding about 10% volume; providing at least about 2%, preferably about 10%, leeway for the plunger therein to slide in response to pressure differential; and in the case of a plastic syringe or cartridge sterilizing the syringe or cartridge at an autoclave pressure that is less than the internal
15 pressure of the syringe or cartridge content; or in the case of a glass syringe or cartridge sterilizing the syringe or cartridge at an autoclave pressure that is less than, equal to or greater than the internal pressure of the syringe or cartridge content.

This Sheet Has Been Replaced
