Kap 17.4 Steriltest av fyllnadsporten

I-Flow Disposable Elastomeric Infusion Pumps

Fill Port Sterility Testing

A one-way check valve is located in the fill port of all I-Flow disposable elastomeric pumps. The purpose of the check valve is to prevent the solution inside the pump from flowing back out of the fill port. A twist cap is designed to cover the fill port. Testing was conducted to determine whether the solution inside of the elastomeric pumps maintained sterility when the fill port cap was removed.

Background

Testing was performed by an independent laboratory on I-Flow elastomeric pumps.

The first test condition consisted of filling half the pumps with sterile fluid and storing for 14 days in a temperature controlled environment with the fill port caps removed. After 14 days of sterility testing, the fluid contents of the pumps were tested for sterility per standard lab specification.

The second test condition also consisted of filling the remaining pumps with sterile fluid and immediately submerging them into a highly contaminated broth of pseudomonas aeruginosa with the caps removed. The pumps were then stored for seven days in a temperature-controlled environment.

Results and Conclusions

Under each condition tested, the fluid contained inside the elastomeric pumps was found to be sterile. Because these elastomeric pumps were exposed to extremely harsh conditions, it has been determined that the I-Flow elastomeric pumps will adequately maintain sterility of the infusate when the fill port caps are removed.

Please contact the Clinical Services Department at 800.444.2728 or 949.206.2700 if you have any questions regarding this information.

1302575C