K960556

510 (k) SUMMARY

Submitted by: Simon Johnston
SciTech Dental, Inc.,
562 First Avenue South, Suite 700
Seattle, WA 98104
FDA Establishment Registration No. 3027751
Owner/Operator I. D. 9011186
TEL # 800 524 6984 or 206 382 0880
FAX # 206 382 0823
e-mail 102477.2560 @ compuserve. com

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Trade Name of Device:

BACSTOP VALVE

Common Name of Device:

Daily disposable in-line Anti-retraction check valve

Classification name of Device:

Unknown

Legally Marketed Device to which BACSTOP is equivalent:

Aseptico Anti-retraction Valve for Dental Lines, from Aseptico, Inc., Kirkland, WA. This check valve was marketed prior to 1976.

Description of the device:

BACSTOP is a disposable, normally closed Anti-retraction check valve, consisting of a flat silastic rubber disc valve membrane in a housing made up of top and bottom parts, united by a sonically sealed joint. The two parts of the valve housing are made of clear Lexan 124R Polycarbonate, with the top (entry) port being in the form of a female Luer fitting, and the bottom (exit) port being in the form of a male Luer fitting, with locking collar. Total length of the device is 0.93 inches, width 0.5 inches. Nominal Cracking (Opening) pressure for the valve is 1.5 PSI.

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Intended use of the Device:

BACSTOP is intended for use in dental unit waterlines as a means of preventing the retraction of orally contaminated fluids into the coolant and irrigant water hoses. The unit is intended to be used for one day only, and is then to be discarded, and replaced daily.

Technical Comparison to Predicate Device:

BACSTOP is a polycarbonate device manufactured for SciTech Dental Inc. by B. Braun Medical Inc. It is commonly used as a backflow prevention component in I/V Infusion sets, and is cleared for marketing for medical use under K790062. It is "normally closed". When placed in-line in the dental water hose, it opens only under sufficient water pressure, equivalent to 1.5 PSI. The valve snaps closed and seals against backflow when the pressure drops below this point. The device is inserted by connection to luer mounts placed permanently in-line.

By comparison, the in-line Anti-retraction Valve sold by Aseptico Inc., has a plated brass housing surrounding a spring-controlled plunger with an O-ring seal at one end. As designed, the device is intended to fit "permanently" in-line by means of barbed hose mounts. The internal plunger and O-ring normally close an orifice through which water enters the central chamber of the housing, and then flows out through the exit barb. Water is permitted to pass only when sufficient pressure is applied against the spring--the "cracking pressure"--, to overcome its resistance. This pressure in the Aseptico device is 2.50 PSI.

Both valves remain open at working pressures up to 50 PSI or more, although normal working water pressures are in the 35-40 PSI range.

When newly inserted, the performance of the two devices is equivalent in preventing backflow of orally contaminated fluids into the dental irrigant and coolant hoses. However, no replacement schedule has been defined for the Aseptico valve, nor are there any limits established for its working life-span under normal conditions. It is considered to be appropriate for the Aseptico valve to allow the backflow of up to 45 microliters of fluid from the tip of the dental handpiece waterline, according to ANSI specification # 47, promulgated by the American Dental Association. Routine testing to ensure compliance with this standard is recommended, and deviations from it constitute grounds for Aseptico valve replacement. Failure to meet this standard may come about because of mechanical failure of moving parts, or because bacterial slime accumulation on the apposing surfaces of the valve prevents effective seal formation.

BACSTOP, by comparison, permits no backflow (zero microliters) during its normal working life (one day). Over this brief period, mechanical failure due to declining resilience of the silastic rubber valve disc does not occur, and there is insufficient time for

bacterial adherence and slime formation to interfere with the working of the valve surfaces.

Safety testing of the silastic rubber and polycarbonate polymer component parts of BACSTOP has included USP Class VI in vivo and in vitro biological reactivity testing, 24 Hour MEM elution test in vitro, hemolysis extract test, in vivo irritation, sensitisation, mutagenicity, and subchronic toxicity tests; all gave satisfactory results (see enclosed report).

Non-clinical Performance Testing for Substantial Equivalence:

Both devices were effective in preventing backflow of an aqueous suspension of a marker bacterium, *Chromobacterium* (ATCC # 553), into dental PVC hoses connected to either high speed handpieces or air/water syringes. Suction pressure of 3-5 PSI was applied upstream of the valves, which were placed in-line approximately 6 inches from the connection to the respective instrument, while the tip of each instrument was inserted into the bacterial suspension. After cessation of the suction pressure, the PVC tubing between the valve device and the instrument was removed and the entire contents flushed into a bacterial growth broth and incubated at 22 C for 3 days. If any bacteria had been drawn back up the waterline they should be detectable by their growth in this broth medium. No bacteria grew from water samples collected with either the Aseptico device or the BACSTOP valve in place. Under these conditions the devices were equivalent in performance.

Dental handpieces and air/water syringes are normally operated intermittently in a "pulsatile" pattern throughout the working day. Repeated on/off cycling of a backflow valve could cause exhaustion of the closure mechanism, and result in valve failure. In order to mimic these working conditions the experiment was repeated, but the efficacy challenge to each device was done only after a previous sequence of 250 five-second pulses of water flow at 35 PSI had been completed (intended to mimic air/water syringe use patterns), or after a sequence of 50 twenty-second pulses (intended to mimic handpiece use). Again, both devices were equivalent in completely preventing backflow of the challenge suspension of bacteria into the waterlines.

However, when the Aseptico valve was left in place in a dental waterline for 3 weeks with daily water flow, a layer of biofilm slime formed within the valve. These valves were challenged as before, and they were no longer effective in completely preventing retraction of bacteria into the waterline. BACSTOP valves were not challenged in these experiments because they are disposable and are to be discarded after each day's use; thus biofilm formation on the apposing surfaces does not take place. In this regard the two devices differ; BACSTOP has a defined use life-span. The Aseptico Anti-retraction valve has no defined life-span, and may fail whenever biofilm formation leads to interference with effective valve closure.

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Conclusions Drawn from the Non-clinical Laboratory Tests:

Freshly inserted, new valves of the BACSTOP and Aseptico types are substantially equivalent in preventing backflow of bacterially contaminated suspensions into dental waterlines connected to handpieces or air/water syringes, when negative pressures of 3-5 PSI are applied upstream of the valves. Both valves perform equally well after being subjected to repeated on/off cycling, intended to mimic one day's use in a dental operatory. Aseptico Anti-retraction valves fail when build up of biofilm slime occurs inside the valves, after continuous use in-line. BACSTOP valves are discarded daily, obviating this possibility.