



APR 15 1997

K962129

510(k) SUMMARY OF SAFETY and EFFECTIVENESS

Date of Summary: May 31, 1996

MERIT MEDICAL

Submitter's name: Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095-2415
(801) 253-1600

SYSTEMS, INC.

Contact Person: Dennis (Dan) Reigle

1600 WEST

Name of device: Continuous Flush Device

MERIT PARKWAY

Class: Class II

Classification name: The flush device is an accessory to an extravascular blood pressure transducer (product code 74DRS).

SOUTH JORDAN,

Predicate device: Predicate devices are flush device manufactured by:

UTAH 84095

Spectramed, Inc.
Critical Care Division
1900 Williams Blvd
Oxnard, CA 93030
(800) 235-5945
K873168

Baxter Healthcare Corporation
Edwards Critical Care Division
17221 Red Hill Avenue
Irvine, CA 92714
(800) 424-3278
K792141

801-253-1600

FAX 801-253-1651

INDICATIONS FOR USE

A continuous flush device is an accessory to a catheter-transducer system that permits a continuous flow to maintain catheter patency.

DEVICE DESCRIPTION

The flush device is comprised of seven small components which, when ultrasonically welded together, constitute the finished product. The device is supplied in two configurations; adult and neonate. The adult configuration differs from the neonate configuration by flow rate and color. The adult flow specification is a nominal 3 milliliters per hour (ml/hr) with a static head pressure of 250 millimeters of mercury (mmHg). The neonate flow specification is a nominal 30 ml/hr at 250 mmHg static head pressure.

The device has a fast flush feature which can be momentarily actuated by squeezing the tabs on either side of the device. The fast flush feature is used to aid in filling and debubbling the pressure monitoring lines.

The device has the capability of creating a momentary pressure spike to verify the frequency response of the pressure monitoring system. The pressure spike is created by pulling up and releasing (snapping) the pull tab on top of the device.

The device incorporates a pressure relief capability to provide over-pressure protection to the transducer. At pressures greater than 600 mmHg (11.6 psi), the silastic control component stretches and allows fluid to by-pass the flow restrictor thereby providing over-pressure protection.

SUBSTANTIAL EQUIVALENCE COMPARISON

Feature	Merit Flush Device	Spectramed Flush Device	Baxter Flush Device
Intended Use	For use in physiological pressure measurements which require continuous flow to maintain catheter patency.	For use in physiological pressure measurements which require continuous flow to maintain catheter patency.	For use in physiological pressure measurements which require continuous flow to maintain catheter patency.
Adult flow rate	3±1 ml/hr @ 250 mmHg pressure	3±1 cc/hr @ 300 mmHg	3±1 ml/hr (blue Snap-Tab™)
Neonate flow rate	30±10 ml/hr @ 250 mmHg pressure	30 cc/hr	30±10 ml/hr (yellow Snap-Tab™)
Fast flush mode	Yes	Yes	Yes
Bypass pressure	> 600 mmHg (11.6 psi)	Yes - unknown bypass pressure	Yes - > 500 mmHg (9.7 psi)
Sterilization	Ethylene Oxide Gas	Ethylene Oxide Gas	Ethylene Oxide Gas
Single Use	Yes	Yes	Yes
Pyrogen Free	Yes	Yes	Yes
Packaging	Tyvek™ pouch	Tyvek™ pouch	Tyvek™ pouch
Step response capability	Yes - via pull tab	Yes - by bouncing lever	Yes - via the Snap-Tab™
Adult Colors	Adult devices supplied with squeeze tabs in white, red, blue or green.	Different models for adults, neonate applications	Blue color
Neonate Colors	Neonate devices supplied with squeeze tabs in yellow color.	Different models for adults, neonate applications	Yellow color
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