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FILTERTEK
An ITW Medical Company

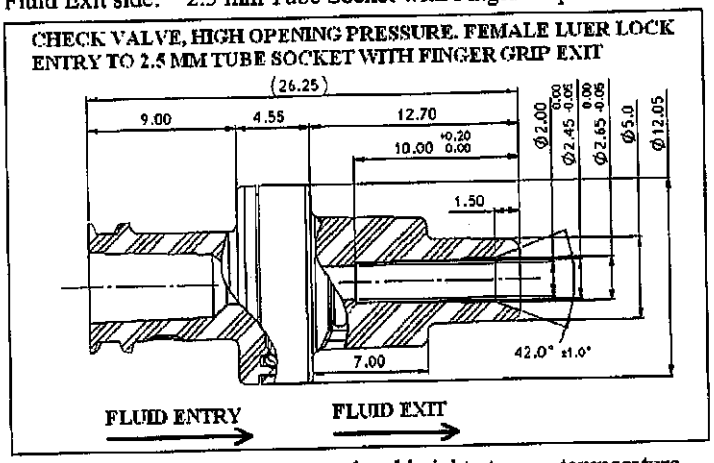
Sheet No: IPS-063	Ref Proc: 5/023	Date: 29/06/12	Rev: 004
Title: Internal Product Specification for Part Number 8922504 - Check Valve, High Opening Pressure, Female Luer Lock Entry to 2.5 mm Tube Socket with Finger Grip Exit.			Page: 1 of 1

SPECIFICATION DETAILS

1) Part number: 8922504 (Rev 003).

2) Part description: Check Valve, High Opening Pressure.

3) Connections:
a) Fluid Entry side: Female Luer Lock to ISO 594.
b) Fluid Exit side: 2.5 mm Tube Socket with Finger Grip.



Written/Revised by C. Carmody 29/06/12
Approved P.P. Gerard Hearn 29/6/12
Approved Brian O'Connell 27/6/12

4) Backflow: < 0.1 ml/hour of water at 1 metre head height at room temperature.

5) Opening pressure: 100 – 345 mbar (1.5 – 5.0 psi) with water.

6) Typical vol. flow rate[1]: 500 ml/min @ 690 mbar (10 psi), 2,000 ml/min @ 3,100 mbar (45 psi), with water.

7) Housing burst pressure: ≥ 55.2 bar (800 psi).

8) Housing working pressure: ≤ 29.3 bar (425 psi) recommended.

9) Void volume: 0.2 ml typical.

10) Materials:
a) Latex free.
b) Housing: Lipid Resistant Polycarbonate - Bayer Makrolon Rx 1805. USP Class VI (plastics) approved. Entry masterbatch - None. Exit masterbatch - None. Material has a natural purple tint.
c) Diaphragm: Silicone rubber. Meets biological requirements according to ISO 10993-1, under 'body contact-blood path, indirect; contact duration - prolonged'. These tests are cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity and haemocompatability.

11) Sterilisation: Check Valve materials of construction are compatible with Autoclaving, EtO and Gamma methods.

12) Supplied: Packaged in bulk and non-sterile.

13) Applications: For intravenous administration sets requiring a back check and/or anti siphon function.

14) Manufactured by: Filtertek, Newcastle West, Co. Limerick, Ireland.

15) Accredited to: I.S./EN ISO 13485:2003.

Specifications are for pre-sterilisation products and are subject to change. Colour change may be possible, post-sterilisation. Results in specific applications may vary. Users must confirm suitability for their individual applications. Filtertek can assist in a development programme on receipt of the application and test protocol. Patents granted.

1. Tested on valve without tubing, catheter or other restrictions on the exit side of the valve.