

### **SeptaVent Directions for Use and Disclaimers**

1. To use as a bioreactor with CHO cells use a Kuhner Model: ISF1-X incubator set at a minimum shake speed 225 RPM w-50mm throw and 10ml -35ml working volume

2. SeptaVent is intended for In-vitro use only and they are to be used in the vertical position, upright, to prevent leakage from tube through cap.

3. SeptaVent is available non-sterile but it is usually irradiated after assembly and packaging but is not intended to be marketed or identified as a "sterile" product. Dose mapping study data is available upon request and a fee based sterility validation may be performed by special request but a sterility validation is very costly i.e. \$35K or more and requires revalidation at 6mo. intervals.

4. Septavent should always be used under a laminar flow hood or biosafety cabinet, sterility may be momentarily compromised at insertion point of cannula, syringe or pipette through septum.

5. SeptaVent is an integral product as assembled. Its hinged septum is designed to withstand multiple penetrations while maintaining excellent resealing ability. The reseal-ability characteristics of the silicone septum and its ability to maintain a hermetic seal can be compromised by contaminating the septum with residual residue, debris or foreign matter. If care is taken to keep the surface of the septum clean the SeptaVent design allows for repeated penetrations by a cannula, pipette tip or other blunt objects without effecting the seal. As long as the tubes are used in their proper vertical orientation and mixing does not exceed the recommended speed SeptaVent will maintain its seal for a minimum of 40 - 50 insertions and retractions of a flat bottom cannula or small i.e. 1 or 2ml pipette tip.

6. The SeptaVent slitted septum is mechanically held in place, it is not bonded, thus it is important to wet the septum by swab or spray with IPA or sterile water prior to penetration with any object larger than 2.5mm in diameter. A wetting with IPA spray or swab will lubricate and ensure that the septum stays in place during insertion and removal provided the diameter of the inserted object is not too large. In a robotics application it is critical that the X - Y axis guiding the tips are aligned directly to target the center of each septum in the cap. Misalignment or targeting of the center of the septum may result in the full disengagement or displacement of the septum into the bottom of the tube.

7. Whenever a large object i.e. 1ml or 2ml pipette is inserted it is important to insert it slowly while twisting

gently and to withdraw it slowly while twisting gently to prevent detachment of the septum during insertion or withdrawal.

8. It is recommended that an experimental trial be performed verifying applicability or suitability and validation be conducted before SeptaVent is used for any critical application.

9. Please refer to tube and cap manufacturer i.e. Corning for a chemical compatibility chart to determine appropriateness prior to use for your application.

10. Working temperature range is -40C - 400C

11. Not recommended for centrifugation beyond 2500 RPM after one irradiation cycle, the post irradiation maximum centrifugation force must be determined via experimentation by end user if intending to centrifuge.

12. If centrifuging, a tube cushion may be required to support the conical bottom, see Corning for more information.

13. SeptaVent will maintain sterility when stationary or shaken and held in an upright position under normal cell culture operating conditions. If SeptaVent is inverted while holding a liquid it may result in leakage of its contents. A vented or non-vented SeptaVent in either 50ml or 15ml tube or SeptaVent adapted disposable container is vulnerable to leaking when a liquid is contained inside and it is turned upside down.

14. SeptaVent adapted containers are not intended to be used as an injectable drug or liquid device shipping container.

**CAUTION:** When centrifuging pathogenic organisms, clinical specimens known or suspected to be infectious, or any other potentially biohazardous materials, approved secondary safety containment systems should be used.

Should this product be used with infectious or otherwise hazardous materials those materials should be rendered harmless by sterilization or other suitable treatment prior to disposal.

Marin Scientific Development Co. or Optimum Processing Inc. do not recommend that you recycle products that have been used with hazardous materials, hazardous waste or biohazard items.

These tubes are intended for use by persons knowledgeable in safe laboratory practices only.

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