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Instruction for Use
TPP TubeSpin® Bioreactor with Septum

The TubeSpin® Bioreactor with Septum integrates the proven design of the standard TubeSpin® Bioreactor (#87050) with the rigorous demands of laboratory automation. This specialized tube provides multiple access points for injection needles and pipette tips, streamlining automated workflows. It is engineered to facilitate the sterile exchange of media and solutions, as well as the precise sampling of cell-based products without compromising culture integrity.

The TubeSpin® Bioreactor features a cross-slit silicone septum (Fig. 1, #2), and a filter screw cap designed with integrated openings (Fig. 1, #1) positioned above a hydrophobic PTFE filter membrane. This configuration is available both with and without a Code 128 barcode for automated tracking.

The TubeSpin® Bioreactor is for single use only. Re-use disclaims all warranties.

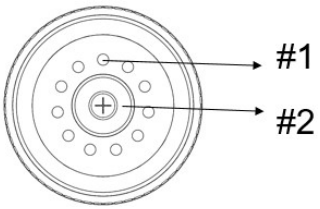

Figure 1. Cap with septum

Safety instructions

- Handling and Safety
  Handling of biological materials shall be performed in full compliance with all applicable national and international regulations. Activities must conform to the laboratory's assigned biological safety level, the relevant Safety Data Sheets (SDS), and the manufacturer's Instructions for Use (IFU).
  Appropriate personal protective equipment (PPE) shall be always worn during handling.
- Risk of Contamination
  All operations shall be conducted in accordance with aseptic techniques and established Good Laboratory Practices (GLP). Packaging shall be opened immediately prior to use. Only products that are visually intact and free from defects shall be utilized. Products exhibiting visible damage, contamination, or any other irregularities shall be disposed of in accordance with applicable regulations.
- Storage
  TPP products shall be stored under the following conditions:
  - Temperature: 10 °C to 30 °C (50 °F to 86 °F).
  - Light exposure: Products shall be protected from direct ultraviolet (UV) radiation.
  - Relative humidity: ≤ 60 %, with a recommended control range of 50 – 60 %.

  Storage conditions shall be monitored and recorded to ensure compliance with these requirements. Any deviations shall be documented, evaluated, and managed in accordance with the applicable quality.

Instructions

- Check the expiry date (EXP) on the label and packaging. Use only products with a valid EXP.
- Open the package in a sterile environment and remove a complete system for use.
- Inoculate the bioreactor by either removing the cap or utilizing the septum access port for aseptic transfer. Load the tube with media and inoculum following standard protocols, ensuring the volume remains within the recommended working range (see Technical Data). If the cap is removed, close it firmly and ensure it is properly seated back on the tube to maintain a sterile seal minimizing the risk of contamination.
- Continuous gas exchange takes place through the openings above the hydrophobic 0.22 µm membrane. Note: If the PTFE membrane becomes wet, gas exchange may be temporarily reduced.
- The cross-slit silicone septum is compatible with needles and pipette tips with a diameter of less than 2.1 mm. Perform filling operations according to your facility's established laboratory protocols.
- The septum supports multiple entries with needles and tips while maintaining aseptic integrity. While specific maximum entry limits have not been established, the design is optimized for repeated access within standard automated workflows.
- Shake the cells in an appropriate shaker.

Laboratory Automation

- Consult the manufacturer's operating instructions for system-specific integration. Adhere to the optimal working volume as specified in the technical data section to ensure proper performance
- Versions with a unique Code 128 barcode, enable high-efficiency automated tracking and sample management.

Incubator Shaker

- Always follow all safety instructions and the operating manual provided by the shaker manufacturer.
- Shaking speed (RPM) and fill volume (mL) are critical factors that influence cell growth and oxygen transfer. These parameters should be verified in advance to ensure optimal performance.
- The recommendations provided are not cell line specific. Optimal conditions must be determined through in-house testing.

Optimization of Suspension Cell Growth

For optimal proliferation and viability of suspension cultures, please adhere to the following guidelines:

- Cells shall be fully and gently resuspended to achieve a homogenous single-cell suspension. Residual aggregates (clumping) result in non-uniform nutrient distribution within the clusters and compromise process scalability and analytical reproducibility.
- Foam formation should be minimized during resuspension and seeding, as protein denaturation and the trapping of cells in foam bubbles lead to high shear stress and impair cell viability.
- Unlike adherent cultures, suspension cultures require continuous orbital agitation to prevent sedimentation. The shaking speed (RPM) shall be optimized to maintain cells in suspension while ensuring hydrodynamic shear forces remain below the threshold for cellular damage.
- Seeding density shall be selected according to validated, cell line specific protocols. Sub-optimal low densities may extend the lag phase due to insufficient autocrine factor concentrations, whereas excessively high densities lead to rapid substrate depletion, accumulation of inhibitory metabolites (e.g., lactate, ammonia), and oxygen transfer limitations.
- In high-density shaken bioreactor cultures, oxygen supply is frequently the rate-limiting factor. The Oxygen Transfer Rate (OTR) is significantly governed by the shaking diameter (throw, orbit) and agitation speed.
- Given the high volumetric cell densities in bioreactor systems, pH levels and critical substrate concentrations (e.g., glucose) shall be monitored to facilitate timely intervention, such as media exchange.
- While agitation is necessary for mass transfer, excessive mechanical shear shall be avoided.
- Cultures shall be maintained under controlled environmental conditions (temperature, humidity, and CO_2 concentration). Maintenance of high relative humidity is critical to prevent evaporative loss, which induces a detrimental increase in medium osmolarity.

Centrifugation Safety and Performance

To ensure operational safety and optimal performance, strictly adhere to the centrifuge manufacturer's instructions and use appropriate rotors and adapters.

- Ensure the centrifuge load is correctly balanced. Tubes must be positioned symmetrically relative to the rotational center and axis to maintain a horizontal orientation. Improper loading may result in uneven separation, vibration, or tube damage.
- Several factors influence the structural integrity of the tube during operation:
    - Tube shape and material composition.
    - Proper fit within the designated adapter.
    - Centrifugation parameters: Temperature, duration, and Relative Centrifugal Force (RCF).
    - Sample properties (density and viscosity).
    - Rotor type (fixed-angle vs. swing-out).
- RCF (g-force) ratings are determined at room temperature using water-filled tubes in a horizontal rotor for 5 minutes. Use in fixed-angle rotors or with unsupported tubes may significantly reduce mechanical performance.
- Perform a test run with the specific sample and settings before routine use to verify suitability for the intended application.

Sub-Zero Storage

- Polypropylene (PP) tubes exhibit reduced mechanical strength at temperatures below 0 °C (32 °F).
- For samples that need to be frozen or stored at low temperatures for long periods of time, transferring the contents to TPP cryotubes. These are specially validated to ensure integrity and safety under extreme thermal conditions.
- Do not expose these consumables to liquid nitrogen (LN_2). Contact with LN_2 can cause embrittlement, structural damage, or bursting during thawing.
- TPP does not guarantee the integrity or performance of centrifuge tubes or bioreactor vessels under sub-zero conditions.

The following information is provided for guidance only:

- If freezing samples in standard PP tubes is considered, the following precautions should be taken:
    - The freezing process must be controlled and proceed evenly from bottom to top.
    - Ensure sufficient space for the volume expansion of the freezing liquid (e.g., by using suitable racks or boxes).
    - Do not use highly insulated containers (e.g., Styrofoam). These lead to uneven freezing and significantly increase the risk of material failure and breakage.
- Perform a test run with the specific sample and settings before routine use to verify suitability for the intended application.

General Handling and Limitations

- Graduations are for reference only and serve as approximate guidelines for fill volume. For precise measurements, use calibrated pipettes or volumetric instruments.
- Avoid exposing the white labeling area to 90% alcohol in combination with mechanical stress (e.g., rubbing or wiping), as this may cause the ink to dissolve or smear.

Technical Data

Component	Material
Screw Cap	Polyethylene (PE)
Membrane	Polytetrafluoroethylene (PTFE)
Septum	Silicone
Tube	Polypropylene (PP)

Measurement	86050	186050
Volume grad. mL	50	50
Length mm	115	115
Diameter mm	30	30
Max. RCF x *g*	15‘500	15‘500
Form	Conical	Conical
Septa	Cross-slit	Cross-slit
Optimal fill volume mL	5 – 35	5 – 35
Shaker: Recom. Orbit / Shaking diameter mm	50	50
Shaker: Recom. speed RPM	180	180
Openings mm	11 x 2.0	11 x 2.0
Packaging	20 x Pouches	Single wrapped i.e. 1 x Blister

Additional Information

Instructions for use, chemical resistance lists, and quality certificates for individual products can be downloaded from the TPP website at www.tpp.ch.

Disclaimer

TPP products are intended for Research Use Only (RUO) and are not approved for clinical, diagnostic, or in vitro fertilization (IVF) applications. The full Terms & Conditions, including limitations of warranty and liability, intended use, and reseller obligations, are available at: https://www.tpp.ch/page/qualitaets_sicherung/index.php

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