

Microcarrier Delivery System

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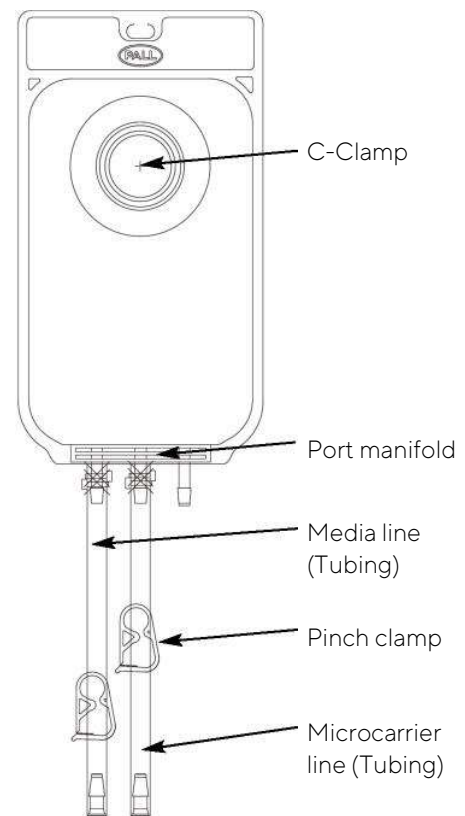
Introduction

Microcarrier Delivery Systems (MDS) are supplied sterilized by gamma irradiation. The ready-to-use format provides a convenient and easy method to transfer sterilized microcarriers into bioreactors. No additional time or effort is required to hydrating, washing or autoclaving the microcarriers prior to use, dramatically reducing the number of processing steps required prior to manufacturing. This coupled with eliminating the need for lengthy validations and routine checks of sterilization processes lead to significant reductions in overall costs. Importantly, the MDS allows for the transfer of microcarriers to bioreactors in a completely closed fashion, thereby significantly reducing contamination risk by removal of open-handling steps. It is very important that all instructions are carefully followed, and where appropriate, incorporated into the end user's standard operating procedures. If the recommended procedure does not suit your need, please consult SoloHill or your local Sartorius representative before using the system. Application of this product in a manner other than in accordance with SoloHill's current recommendations may lead to injury or loss of the product. Sartorius cannot accept liability for such injury or loss.

Receipt of the System

Please check the product label prior to use and ensure the part number corresponds to the relevant application. The gamma indicator "Dark Red" dot located on the right-hand side of the label indicates MDS exposure to gamma irradiation.

1. Store materials in clean, dry conditions between 0 and 30°C without exposure to irradiation sources such as direct sunlight, and wherever practical, in the packaging delivered.
2. Do not remove the product from inner packaging until just before installation.
3. Gamma-irradiated and sterilized MDS are doubled-bagged. Examine that the inner bag is undamaged before use.
4. In addition to the part number, each MDS is identified with a unique identification lot number.



Caution

- Do not open or tamper with the C-clamp located in front of the bio-container. Doing so will void sterility of contents in the MDS and may cause personal injury or harm.
- Ensure cutting tool does not damage any component of the MDS when opening the package.
- MDS are supplied gamma irradiated and must not re-irradiated or autoclaved.
- MDS are single-use and should not be re-used.

Materials and Equipment

- Cutting tool
- Tubing welder
- Tubing sealer
- Peristaltic pump

Method

1. Uncover pinch clamps by sliding off protective sleeves.
2. Open pinch clamps and invert the MDS by facing tubing in the upward direction.
3. Tap tubing to force microcarriers present in tubing back into the MDS.
4. Slide both tubing clamps as close to the port manifold as possible and close pinch clamps.
5. Place MDS flat in a horizontal position.
6. Sterile-weld microcarrier line tubing of MDS to the sample line of the bioreactor bag.
 - Any port present on the lower position of the bioreactor bag may be used to introduce microcarriers into the bioreactor bag. It is not recommended to add microcarriers through ports located on top of the bioreactor bag.
7. Sterile-weld medium line tubing of MDS to the cell culture medium source.
 - The medium source may be any sterile container with cell culture medium. (i.e., medium bag, medium bottle, bioreactor bag, etc.)
8. Position the tubing connecting cell culture medium source to the MDS bag into a peristaltic pump following the manufacturer's instructions.
9. Release pinch clamps located on the media line of the MDS as well as the line leading to the medium source and fill the MDS with the necessary volume of medium (at least 1.5 mL/gram of microcarriers).
 - The MDS bag may be filled with a higher medium volume to gram ratio if combined microcarrier and medium volume does not exceed the capacity of the MDS. It is not recommended to lower the medium volume to gram ratio as it can lead to clogging or pressurization of the system.
10. Stop the peristaltic pump and close pinch clamps located on the media line of MDS and the line leading to the medium source.
11. Gently mix medium and microcarriers in the MDS to form a free-flowing slurry without generating excessive bubbles or foam.
12. Position the tubing connecting MDS to the bioreactor sample line into a peristaltic pump following the manufacturer's instructions.
13. Quickly mix the microcarrier slurry in the MDS bag and open pinch clamps on the microcarrier line of the MDS as well as the bioreactor sample line.
14. Pump the microcarrier slurry from MDS to the bioreactor bag.
 - The MDS may be gently mixed as the slurry is pumped into the bioreactor to maintain a free-flowing state.

15. Stop the peristaltic pump and close pinch clamps on the microcarrier line and bioreactor sample line.
16. (Optional) Repeat the process from steps 8 to 15 with an additional volume of cell culture medium and rinse remaining microcarriers from the MDS bag.
17. Seal the tubing connecting MDS to the bioreactor bag and MDS to medium source using tubing sealer.
18. Disconnect and discard the MDS in accordance with Safety Data Sheet.

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