# Expand Outside the Hood: Mycap® CCX Cell Expansion System

Simplifying Progress

SARTORIUS

# Mycap® CCX Cell Expansion System – Revolutionizing Cell Expansion

Mycap® CCX brings closed processing and aseptic technique to cell culture expansion. Now you can passage cultures comfortably and confidently outside the a biosafety cabinet.

**Mycap® CCX Gas Exchange Cartridge**
The Mycap® CCX gas exchange cartridge is a three-dimensional component featuring two 0.2 µm hydrophobic filter membranes.

The alignment of the cartridge in the cap ideally positions and protects the membranes. The stadium-like shape saves space and opens an unobstructed pathway for gas exchange across the membrane.

**Enabled by Mycap® Technology**
Mycap® CCX is the next advance made possible by Sartorius' patented Mycap® bottle closure system. Our novel manufacturing process brings new possibilities to bottle closure design.

Mycap® CCX features the high-performance, plasticizer-free silicone seal and integral tubing like other Mycap® closures with the addition of the Mycap® CCX Gas Exchange Cartridge.

**Aseptic Fluid Transfer**
Good aseptic technique is critical in upstream operations where preserving axenic, or monoculture, conditions is compulsory.

Integral tubing in the cap and the most trusted aseptic connection technologies facilitate aseptic technique and eliminate the risk of contamination.

**Mycap® CCX Has it All**
- Gas exchange cartridge supports cell growth
- Integral tubing for aseptic transfer of media and culture
- Aseptic sample collection
- Quickseal® for trouble-free aseptic disconnection
- Pre-assembled and ready to use on 125mL to 3000mL Erlenmeyer flasks

**Your Benefits**
- Feed media, inoculate and transfer from flasks, collect samples outside the biosafety cabinet
- Avoid contamination: Never open a flask. Never change and cap
- Improve ergonomics and process efficiency by avoiding the biosafety cabinet and eliminating liquid transfer by manual pipettes

Mycap® CCX Gas Exchange Cartridge


1000mL
900
800
700
600
500
400
300

# Cell Culture Expansion From Vial to Bioreactor in the Open Space of Your Workbench

**Enjoy the freedom of working outside the biosafety cabinet (BSC):**

- Cut BSC maintenance and use costs
- Eliminate BSC pre-use decontamination and environmental monitoring
- Eliminate wasteful back-up passages
- Save operators from cumbersome hood work

# Automate Passages With Cubis® II QApp

Leverage the power of Cubis® II with the Mycap® CCX Cell Passaging QApp. Enter batch-specific information at the Cubis® II touchscreen and allow the balance to control the peristaltic pump, precisely transferring media and culture to a pre-programmed targeted cell density and volume. The Cubis® can report batch information via a connected thermal printer or digitally.

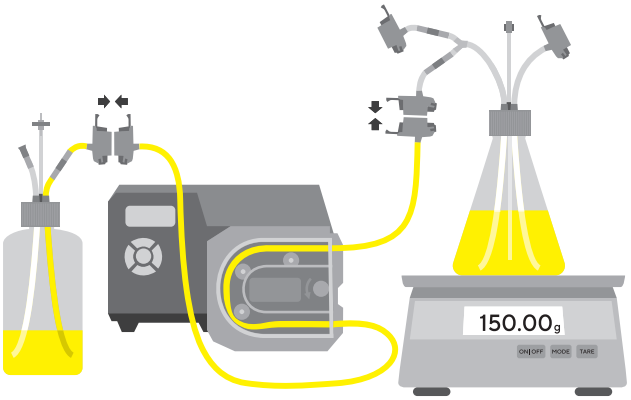
# Mycap® CCX Process Overview

The Mycap® CCX product family uses familiar and easy-to-use equipment and components.

### 1. Pump Media into Flask

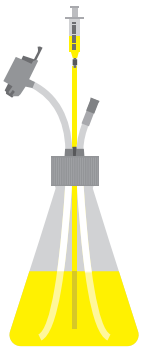
Aseptic Connections by:
- Aseptic Connector
- Tube Weld

Aseptic Disconnection by:
- Quickseal®




Sartorius Cubis® II Balance

### 4. Collect Samples for Cell Viability, Density, etc.

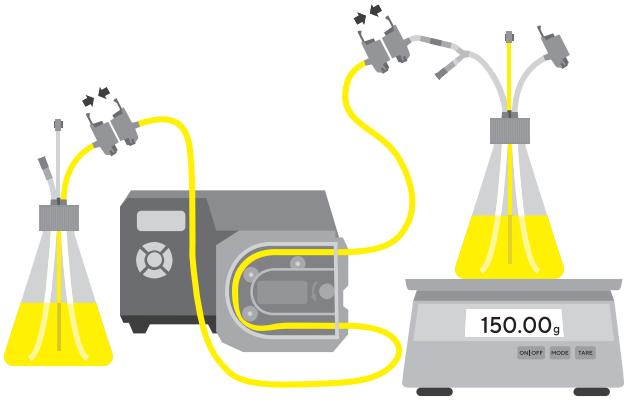


Sampling by Syringe
Connected to Benchmark™

## 2. Inoculate Flask with Cell Culture

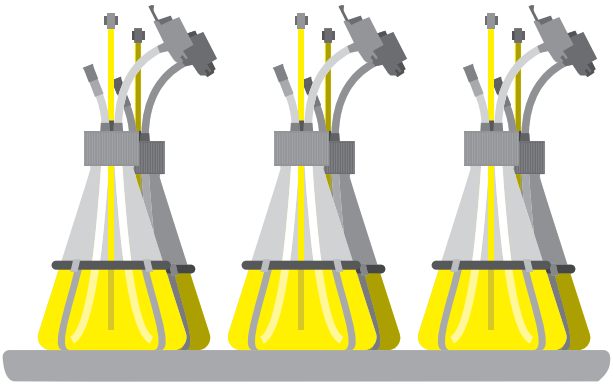
Aseptic Connections by:
- Aseptic Connector
- Tube Weld

Aseptic Disconnection by:
- Quickseal®



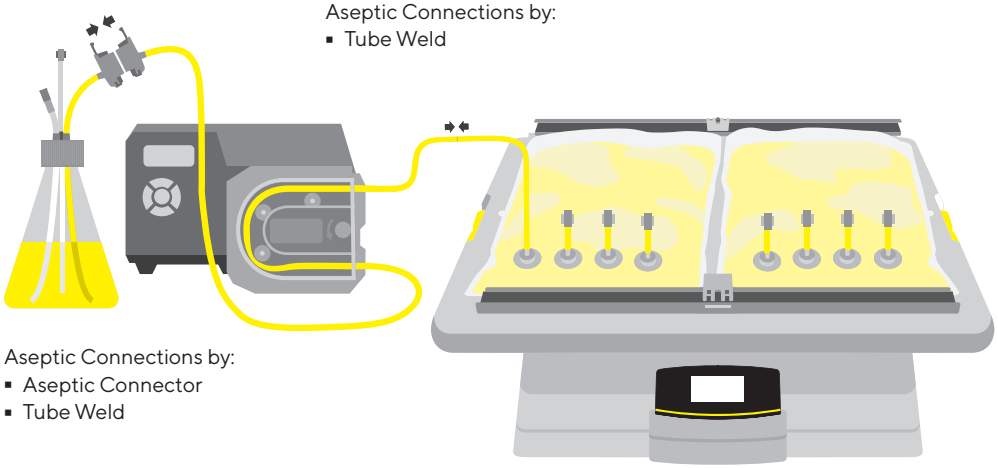

Sartorius Cubis® II Balance

## 3. Grow Culture in Incubator

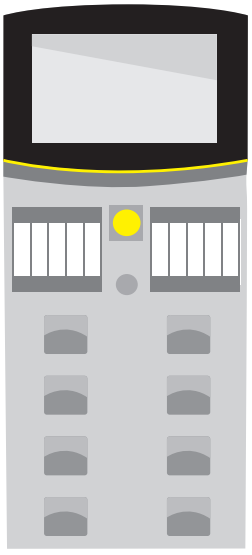


## 5. Transfer to Next Flask or Seed Reactor

Aseptic Connections by:
- Tube Weld



Aseptic Connections by:
- Aseptic Connector
- Tube Weld



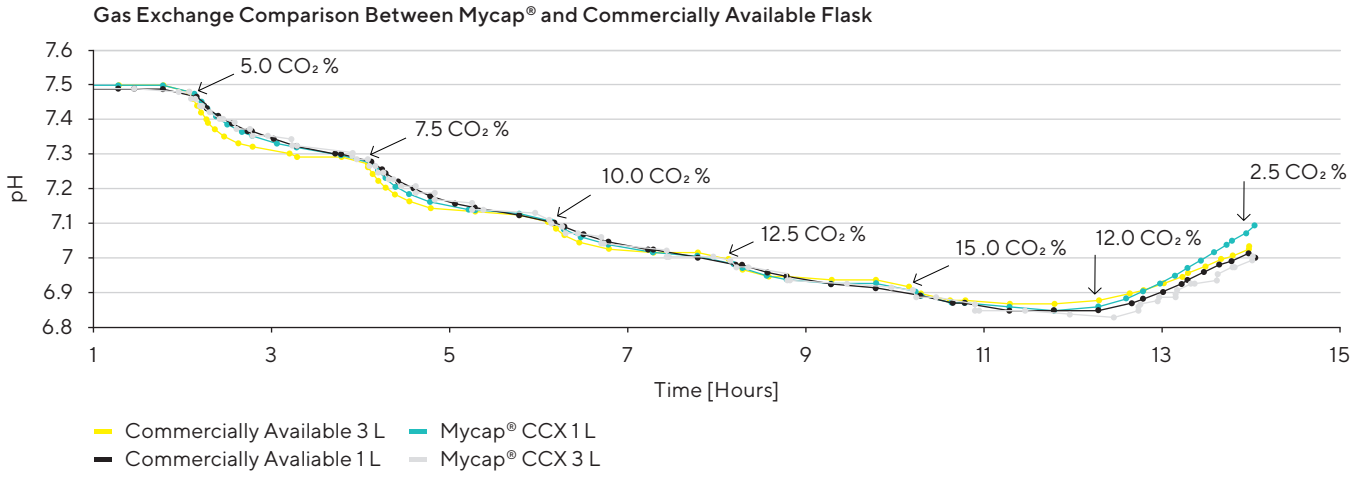
Biostat® RM | Biostat® A

# Proven Performance

## Exceptional Gas Exchange

Exchange of $O_2$ and $CO_2$ across a filter membrane is critical to cell growth. During cellular respiration, oxygen is consumed and carbon dioxide is produced. Cultures starved of $O_2$ will not expand; an overabundance of $CO_2$ increases acidity and harms cell viability.

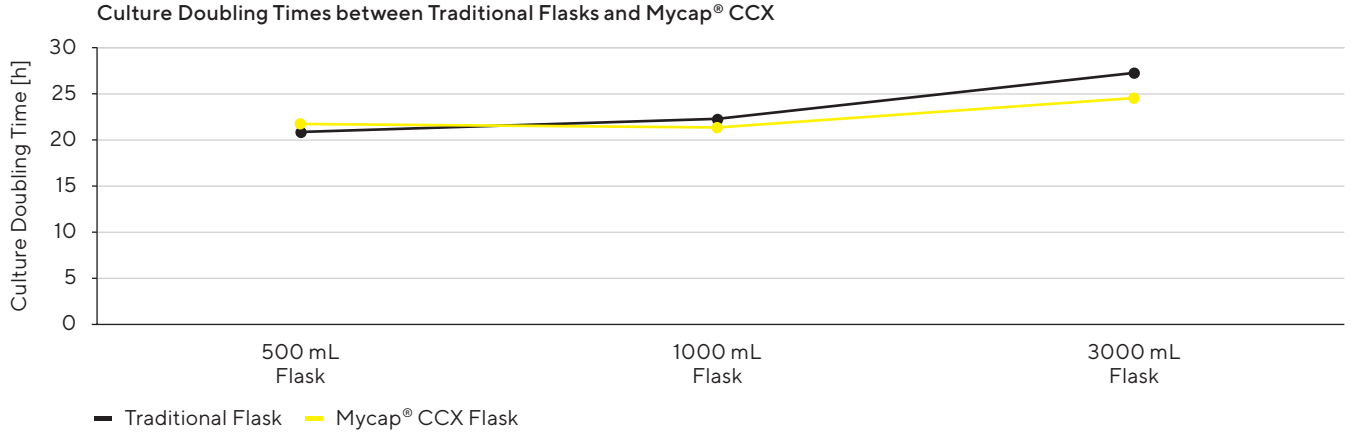
Gas exchange in the incubator is passive. A large filtration area with unrestricted air flow is required for adequate gas exchange. A study of the change in pH of a solution in response to a change of $CO_2$ in an incubator showed equivalent response between Mycap® CCX and traditional Erlenmeyer flasks.




## Proven Cell Growth

Cell expansion passage endpoints are typically measured by cell culture doublings. The Mycap® CCX Cell Expansion System has been studied to confirm that it reaches critical endpoints, and the findings of these studies have been independently verified.

Sartorius compared experimental cell expansion passages from 500 mL through 3 L Erlenmeyer flasks with Mycap® CCX and traditional vented caps. There were no discernible differences in cell culture doubling times between Mycap® CCX and traditional flasks.



**Simple Implementation**
Thorough product validation and careful selection of materials make it simple to implement Mycap® CCX in your expansion process. It has been validated for compliance with the following regulations and standards:

- USP Class VI biocompatibility
- USP 85 Bacterial Endotoxins Test
- USP 788 Particulate Matter in Injections
- ISO 11137-2 Sterilization of Health Care Products – sterility
- Extractables | Leachables Acc. to 21 CFR 177.2600 (Rubber Articles Intended for Repeated Use) and USP 381 (Elastomeric Closures)
- Container closure validation

**Use our Mycap® CCX Validation Template to guide you through validation and implemention**

- Experimental design
- Data capture
- Analysis of results (charts, T-test)

Please contact your sales representative for further information.

# Mycap® CCX Product Family

**Growth and Transfer Systems**
Assembled and ready-to-use. Transfer media and inoculum, collect samples and grow cells all in one system without opening a cap or ever using a biosafety cabinet.

| Article Number | Description | Aseptic Connection Method |
|---|---|---|
| MCX02500204TG | Mycap® CCX 250mL Flask | Tube Welding, ⅛" ID × ¼" OD Tuflux® TPE |
| MCX050002040204T | Mycap® CCX 500 mL Flask | Tube Welding, ⅛" ID × ¼" OD Tuflux® TPE |
| MCX100002040204T | Mycap® CCX 1,000 mL Flask | Tube Welding, ⅛" ID × ¼" OD Tuflux® TPE |
| MCX200002040204T | Mycap® CCX 2,000 mL Flask | Tube Welding, ⅛" ID × ¼" OD Tuflux® TPE |
| MCX300002040204T | Mycap® CCX 3,000 mL Flask | Tube Welding, ⅛" ID × ¼" OD Tuflux® TPE |
| MCX02500204AG | Mycap® CCX 250mL Flask | Aseptiquik® |
| MCX050002040204A | Mycap® CCX 500 mL Flask | Aseptiquik® |
| MCX100002040204A | Mycap® CCX 1,000 mL Flask | Aseptiquik® |
| MCX200002040204A | Mycap® CCX 2,000 mL Flask | Aseptiquik® |
| MCX300002040204A | Mycap® CCX 3,000 mL Flask | Aseptiquik® |

Contact your local Sartorius office for more tubing and connector combinations.

**Mycap® CCX Flask Stands**
The Mycap® CCX Flask Stand is a reusable accessory which accepts Mycap® CCX flasks. The stand has a wide base and has tacky silicone feet. Place the stand with flask on the balance pan or workbench to stabilize containers during cell passaging.

## Transfer Assemblies

Connect flasks to media container, flasks to bioreactors for aseptic transfer via peristaltic pump.

| Article Number | Description | Aseptic Connection Method |
|---|---|---|
| X020412T020412T | ⅛" ID × ¼" OD (Size 16) | Tube Welding, ⅛" ID × ¼" OD Tuflux® TPE |
| X020436AA | ⅛" ID × ¼" OD (Size 16) | Aseptiquik® S |
| X020412T040712T | ⅛" ID × ¼" OD (Size 16) | Tube Welding, ⅛" ID × ¼" OD Tuflux® TPE<br>Tube Welding, ¼" ID × 7/16" OD Tuflux® TPE |
| X040712T020418A | ⅛" ID × ¼" OD (Size 16) | Aseptiquik® S<br>Tube Welding, ¼" ID × 7/16" OD Tuflux® TPE |
| XY020418T | 2-Way Splitter | Tube Welding, ⅛" ID × ¼" OD Tuflux® TPE |
| XY020403A | 2-Way Splitter | Aseptiquik® S |

Contact your local Sartorius office for more tubing and connector combinations.

## Accessories

| | |
|---|---|
| QSCUTTERSD | Small Diameter Quickseal® Cutting Tool |
| QSCAP04SILNT | Quickseal® Protective Cap for ¼" OD Quickseal® Collar |
| MCX0250STDCRN | Mycap® CCX Flask Stand; 250mL Corning Flask |
| MCX0500STDCRN | Mycap® CCX Flask Stand; 500mL Corning Flask |
| MCX1000STDCRN | Mycap® CCX Flask Stand; 1000mL Corning Flask |



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