

Demonstration of XCell™ ATF 2 and XCell™ ATF 6 Single-use Performance

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XCell™ ATF 2 Single-use System

Components

- XCell™ ATF Single-use device with 0.2um PES or 0.2um PS Filter
- Tubing set
- Reusable stand

Materials

- Housing & Aseptic Connectors: Polycarbonate
- Hollow Fiber: PES/PS, Polyurethane, & Polypropylene
- Adhesive: PMMA
- Diaphragm & Gaskets: Silicone
- Tubing: Silicone & Pure Weld



XCell™ ATF 6 Single-use System

Components

- XCell™ ATF Single-use device with 0.2um PES or 0.2um PS Filter
- Tubing set
- Reusable stand

Materials

- Housing & Aseptic Connectors: Polycarbonate
- Hollow Fiber: PES/PS, Polyurethane, & Polypropylene
- Port Adhesive: Cyanoacrylate
- Diaphragm & Gaskets: Silicone
- Inlet Elbow: Polyvinylidene fluoride

Features

- 0.2um Polyethersulfone/Polysulfone Hollow Fiber Filters
- Fitted with convenient aseptic connectors
- Supplied gamma sterilized & double bagged
- Compatible with existing C24 and C410 XCell™ ATF Controllers
- Same pump and diaphragm configurations as existing XCell™ ATF stainless steel systems
- Lightweight and stable

Benefits

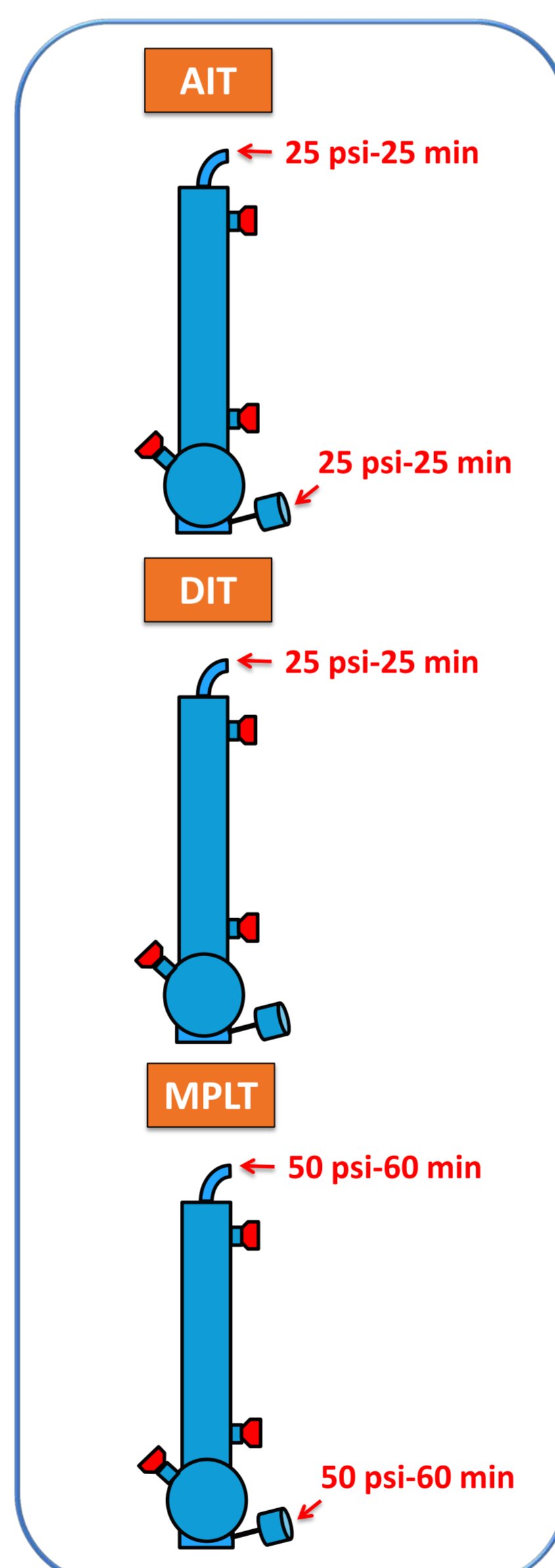
- Identical cell culture and cell retention performance to the stainless steel devices
- No autoclaving required - up to 80% faster implementation time
- Configurable for sterile wetting and pre-use integrity testing
- More portable than stainless steel systems
- Reduced preparation, cleaning and validation activities

Product Characterization Tests

Characterization Tests on XCell™ ATF SU Units

Test		Results	
		XCell™ ATF 2 Single-use	XCell™ ATF 6 Single-use
Visual Inspection	Appearance	Pass	Pass
Diaphragm Integrity Test (DIT)	25psi	Pass	Pass
Assembly Integrity Test (AIT)	25psi	Pass	Pass
Max Pressure Limit Test (MPLT)	50psi	Pass	Pass
Filter Integrity	Diffusion Test	Pass	Pass
Water Flux	@ 2, 4, 6 TMP	Pass	Pass
Assembly Cycle Test	100,000 or 2M* cycles	Pass	Pass
Sterility	Media Hold	Pass	Pass
Perfusion Culture	CHO cells	Pass	Pass

Note: All product characterization tests were performed on post gamma XCell™ ATF Single-use devices.
*Two XCell™ ATF 6 devices are evaluated up to 2M cycles (~100 days).

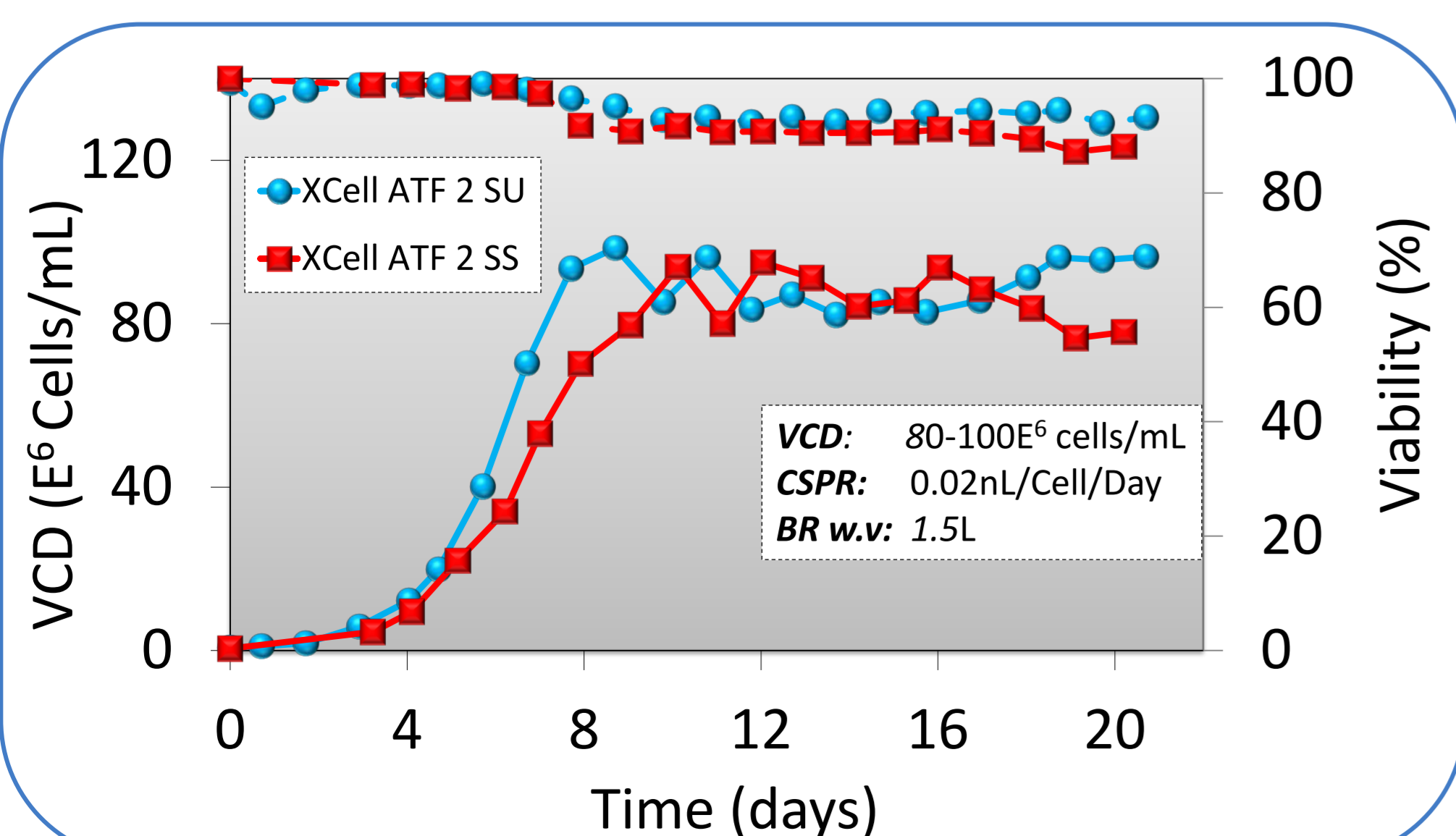


- **Extractable Study (Completed)**
 - Performed as per BPOG requirements
- **ISTA 2a Shipping Study (Completed)**
- **Sterility Assurance Level Study (In progress)**
 - Vdmax methodology per ISO 11137/AAMI TIR33
- **Shelf Life Stability Study (In progress)**
 - Real time study @ 22°C for 27 months
 - Accelerate temp. study @ 55°C for 12 weeks (Predicts to 27 months at RT)

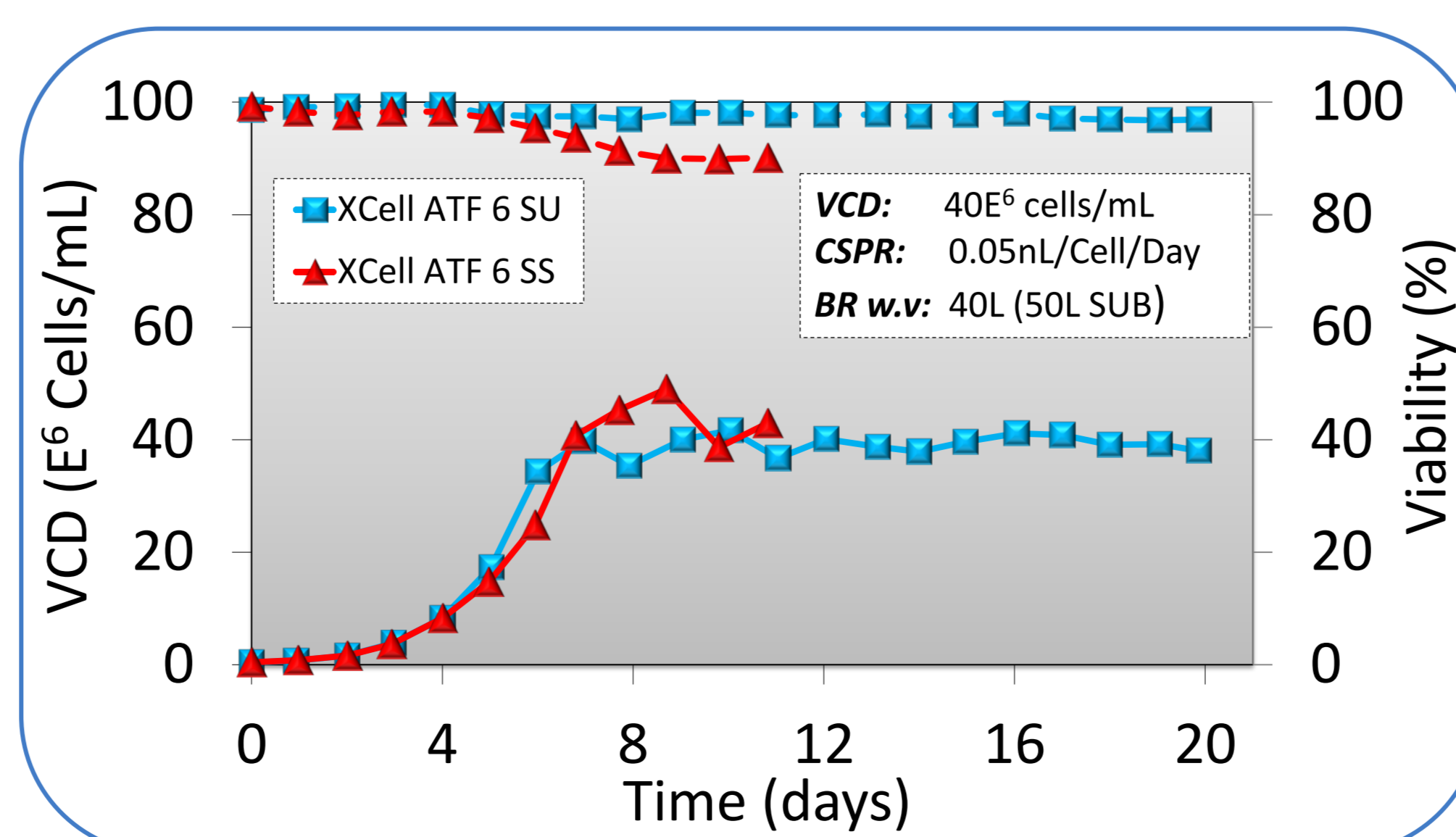
- All post gamma irradiated single-use devices passed all product characterization tests
- Visual Inspection, AIT and DIT will be tested on each unit as release criteria prior to gamma irradiation of XCell™ ATF 6 single-use devices

Perfusion Cell Culture Performance

XCell™ ATF 2 (VCD & Viability)



XCell™ ATF 6 (VCD & Viability)



SUMMARY

- XCell™ ATF 6 Single-use and XCell™ ATF 2 Single-use both exhibited similar cell growth, viability and cell specific productivity profiles compared to respective stainless steel versions. Data not shown for cell specific productivity.
- Both XCell™ ATF 6 single-use and stainless steel devices demonstrated compatibility with SUBs (Single Use Bioreactors)

ACKNOWLEDGEMENTS

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