

HELIX[®] OSCILLATING BIOMIXER TECHNICAL GUIDE



www.lifecyclebio.com

Introducing the

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The Helix® Oscillating Biomixer is a highly versatile container with multiple uses. Designed as a 50L self-mixing, closed system by manufacturers for manufacturers, the Helix® Biomixer can support your production needs in so many ways:

- ❖ Requires no inserted mixer, minimizing contamination risks when used with its Turn-Table
- ❖ Unique mixing platforms that can be fully programmed to deliver the desired amount of shear
- ❖ Closed system design to prevent microbial and non-viable contamination
- ❖ Manufactured with USP Class VI Polypropylene
- ❖ Fully recyclable but designed for years of work
- ❖ Cost Effective
- ❖ Produced under cGMPs in an ISO9001 facility



Helix® Advantage

Manufactured in the USA using Class VI polypropylene in compliance with Bioprocess Engineering ASME standards in a manufacturing facility under ISO:9001 QMS control.



- ▶ Light Weight, Leak Proof and Shatter Proof
- ▶ Reference gradation markings for both gallons and liters molded in the plastic
- ▶ Screw threads compatible with other 3rd party cap systems
- ▶ Can be sterilized by Autoclave, ETO or chemical sanitization
- ▶ Wide range of available accessories

The Helix® is the ideal solution for all areas of Life Sciences, such as:

- ✓ **Process Scientists** needing a faster, cleaner and more gentle mixing system
- ✓ **Manufacturers** needing an easier and more secure liquid storage vessel
- ✓ **Cell Biologists** need a cost effective bioreactor for supporting cell growth with superior and constant distribution of nutrients
- ✓ **Supply Chain Professionals** needing to diversify and simplify their cost controlled vessel programs

Helix[®] Uses

The patented Helix[®] Oscillating Biomixer is so versatile and unique, we can't stop finding new uses for it. Imagine the possibilities:

As a Mixer

The Helix[®] has dynamic radial fins molded into the bottle itself that move material upward when rotated in one direction and downward when oppositely rotated, thus the oscillation creates a unique mixing pattern. When used with our programmable Turn-Table, any mixing profile can be applied depending on the raw material characteristics. Low-shear, sensitive cellular work is possible with one program and difficult powder can be accomplished with another, all with the same equipment.



Suggested Applications

- Cost-effective Bioreactor
- Media Manufacturing
- Chemical Blending
- Tissue Cleaning



Suggested Applications

- Wet Powder Size Reduction
- Cell Disruption

As a Horizontal Jar Mill

The Helix[®] was designed to be compact and rugged with good handling characteristics. When used with a roller mill, the radial fins provide another cascade angle that can reduce milling time with compatible media.

As a Carboy

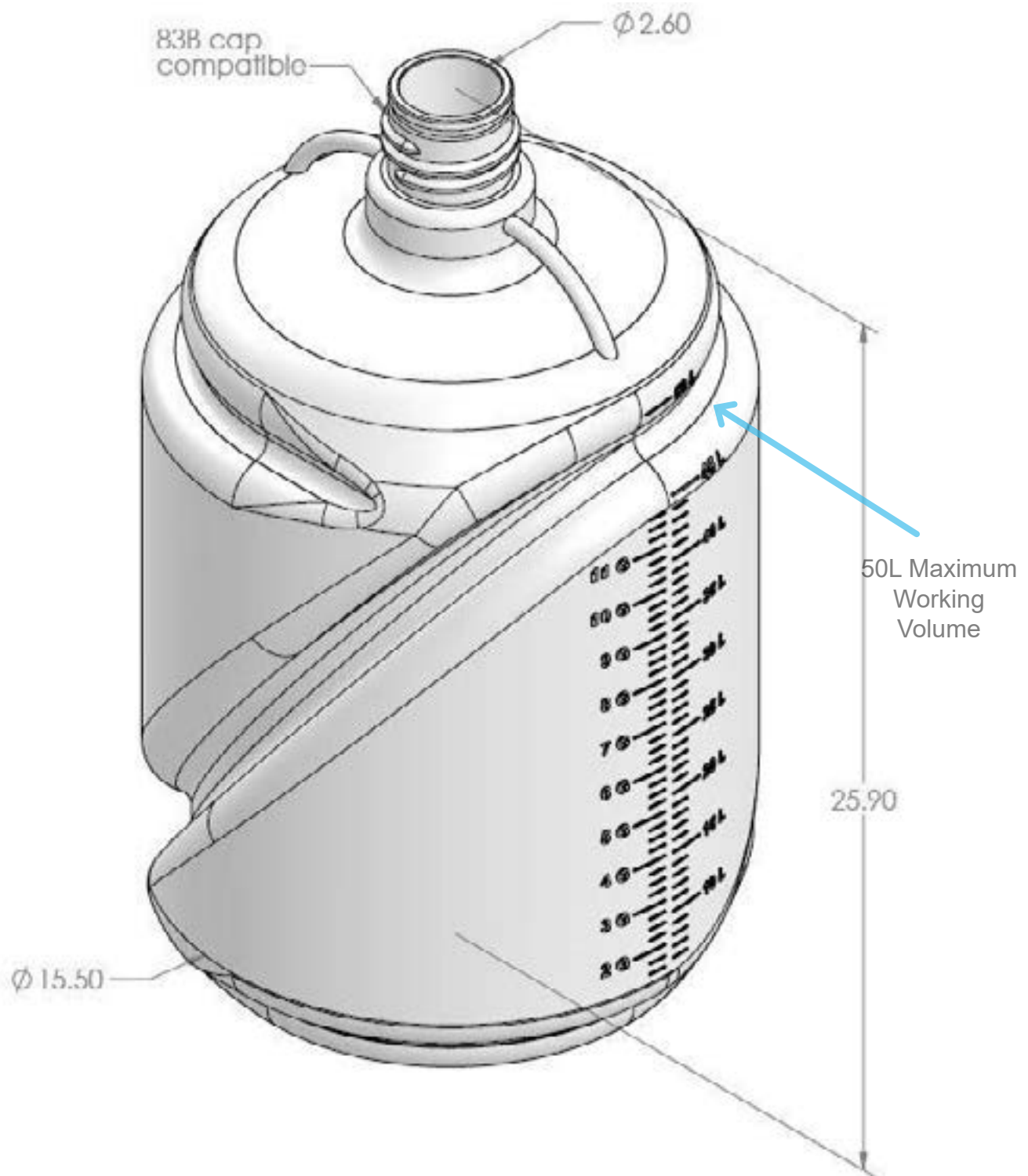
In its most basic form, the Helix[®] can be used to hold or transport solutions or cells at temperature ranges from 0°C to 121°C. As a carboy, it's rugged, volume indicating, sterilizable and can maintain your product isolated from environmental contamination. When its time to use the solution, you can even put it back on the Turn-Table for a quick mix just before use.



Suggested Applications

- Filler Staging
- Chemical and Cell Storage
- Pre-blends Holding
- Tissue Cleaning

Dimensions




Chemical Resistance and Physical Properties

In general, polypropylene has excellent compatibility with most Life Sciences ingredients. The table below is only a guideline and chemicals should be evaluated for incompatibility.

GOOD Suitable for use and storage
Acids, dilute and concentrated Alcohols Aldehydes Bases, dilute and concentrated Esters
Fair Suitable for immediate use
Oxidizing Agents
NOT RECOMMENDED May cause softening or deformation
Aromatic hydrocarbons Aromatic ketones Halogenated hydrocarbons

Physical Properties of Polypropylene

Maximum Use Temp	121°C
Brittleness Temp	0°C
Transparency	Translucent
Flexibility	Rigid
WVTR	3.9 g-mm/m2/day at 25°C & 90% RH
Cytotoxicity	Resin has been found non-cytotoxic by USP biocompatibility standards
Recyclability	5 PP 

Sterilization

Our recommended method to sterilize empty Helix® Biomixers prior to use is by autoclave. We have tested the Helix® up to 10 autoclave cycles without evidence of deformation, discoloration, cracking, or crazing.

- Slow exhaust cycle of 121°C, 15 psig for 20 minutes
- Ensure no obstruction over the container exists. Loosely place cap, cover with surgical wrap or use our sterile vented cap for sterilization
- Other suitable methods are Ethylene/Propylene Oxide, Microwave or Chemical sanitization with alcohol

We do not recommend dry heat or radiation sterilization methods as these methods may damage the carboys.



Product Quality

During production, parts are continually checked at specific intervals for the following criteria to ensure a high quality product is produced throughout the production run.

Test	Criteria
Visual	Physical defects / General appearance Molding integrity and completeness of threads
Dimensional	Weight and Wall thickness per specification Sealing ring dimension per specification
Leak testing	No water leaking while inverted for 2 minutes at 2 psig at specified closure torque



Helix[®] Care and Use

General Cleaning

In many cases, the Helix[®] Biomixer can be rinsed with water or a suitable solvent until clean. If additional mechanical action is necessary, we recommend our Simple Lifecycle Liquid Cleanse Detergent which was specifically formulated to clean plastic surfaces heavily soiled from difficult to remove residues such as oils and cellular debris. A 1% solution in water with mechanical action is usually sufficient. The detergent will not cause crazing, stress cracking or clouding when used as directed. This liquid detergent is for hand or machine use, it is biodegradable, not toxic, and low foaming.

Do not use abrasive cleaners or scouring pads on any plastic surface

Clean threads on carboys and closures to prevent build-up, which can cause leakage

Store the Biomixer at ambient temperatures, protected from contamination, until ready to use.

Dishwashers

Lab-ware washing machines can be used with Lifecycle carboys. Keep the dishwasher cycle time to a minimum and use a plastics cycle with a water temperature setpoint of 135°F (57°C) or lower. Remove the carboys as soon as possible after cooling is complete. Avoid excessive abrasion by covering metal spindles with soft material such as plastic tubing. Carboys should be weighted down and held in place with accessory racks.

Special Problems

If you are experiencing unexpected challenges cleaning your Lifecycle carboys, contact us so we can help at (817)840.7855, info@lifecyclebio.com, or at www.lifecyclebio.com.

Turn-Table and Other Accessories

The Turn-Table is what drives the Helix's® unique low-shear, oscillating action. Fully programmable for speed, revolutions and time, any profile can be easily and rapidly built for reproducibility. And, best of all, the Helix® can mix without introducing a mixer blade or magnet while in a sealed state.

Highlights:

- ▶ Easily programmable through interactive interface
- ▶ Low profile for easy loading
- ▶ Completely portable for movement around the facility
- ▶ 115V electrical requirements
- ▶ Wash-down compatible
- ▶ Cost effective
- ▶ Mixes while vessel is sealed
- ▶ Built in the USA



We stock a wide variety of accessories to give even more functionality to the Helix® and are regularly adding new ones. See updates at lifecyclebio.com.

Additional Sealing Cap, Part No. 100142A

Sealing cap with vent filter, Part No. 100175A

Sealing cap with Dual Ports, Part No. 100176A

Helix Funnel, Part No. 100180A

Simple Lifecycle Liquid Cleanse Detergent, Part No. 472906

Helix® Cleaning Brush, Part No. 100190A



Regulatory Support

We understand the critical importance to many of our partners that Lifecycle containers are manufactured in compliance with documented quality systems from controlled and traceable high quality materials.

We are committed to implementing effective procedures and measures to ensure product conformance to meet partner's needs while adhering to applicable regulations. Using strong quality programs, our knowledgeable team is developing innovative ideas to continually improve our partner service while maintaining product quality and effectiveness of the quality management system. We accomplish this with:

- ▶ ISO 9001:2015 and cGMP certified manufacturing systems
- ▶ Resin and product validation data support
- ▶ Lot specific product certificates on demand
- ▶ Change control procedures
- ▶ Change notification services and support
- ▶ Partner on-site audits by appointment and with advanced notification





For more information about Lifecycle Biotechnologies, our products our manufacturing capabilities, please contact us.

LIFECYCLE BIOTECHNOLOGIES

info@lifecyclebio.com

817.840.7855

www.lifecyclebio.com

421 Marti Drive
Cleburne, Texas 76033