LifeAire Systems *Aire~LifeLine™* Maintenance Certificate | V4 9/3/2020

Instructions for the Use of the Aire~LifeLine[™] – Model # A~LL-1 Filter

PRECAUTIONS AND WARNINGS

- 1. Do not exceed a maximum inlet pressure to the filter of 50 PSI (3.45 bar). Adjust the gas supply pressure as required.
- Do not use Aire~LifeLine[™] filters with O2 concentrations above ambient levels (18-21% O2).
- Aire~LifeLine[™] filter installation hardware requires ¼"soft plastic gas line tubing suitable for medical grade culture conditions to complete installation. The filter must be mounted vertically for optimal gas purification and media life-expectancy.
- Inspect Aire~LifeLine[™] filters, quick-release connectors, and all gas lines for damage. Immediately replace if necessary. Confirm all connections are tight and free of pressure leaks.
- 5. As with ALL inline gas filters, Aire~LifeLine[™] filters require gas equilibration prior to use for gamete or embryo culture. Equilibration time is variable depending upon individual gas component concentrations, flow rate, pressure, temperature, and humidity. We recommend allowing 24 hrs of equilibration of the specified gas, followed by pH / CO2 ch 15 check. This will ensure enough time for the gas line system to purge the filter bed to ensure equilibrium for all gasses.
- a. Pure supply gases such as 100% CO2 or 100% N2 are rapidly absorbed by the Aire~LifeLine[™] filter material requiring only a few minutes to equilibrate but mixed supply gases such as 5-6% CO2, 5-20% O2, N2 require more time to adsorb the individual mixed gas components to reach a full state of equilibrium. Mixed gases must be constantly flowing under pressure until the filter is fully equilibrated and supply gas concentrations are equal to the Aire~LifeLine[™] product gas concentrations. Flowrates of 0.5-1.0 L/min may take up to 5-6

hours of constant gas flow to achieve full equilibration of a mixed gas.

- b. Aire~LifeLine[™] filters must remain under pressure to maintain gas equilibration and prevent desorption of mixed gas components.
- 7. It is recommended that mixed gas Aire~LifeLine[™] filter product gas concentrations are tested to confirm filter equilibrium is complete prior to using the incubator for embryo / gamete culture after filter installation. Gas supply should equal gas product concentration when fully equilibrated.
- 8. It is recommended that the pH of the embryo culture medium be measured prior to using the incubator for embryo/gamete culture after filter installation to verify filter equilibration and correct gas concentrations have been achieved. For proper pH equilibrium, we recommend at minimum 24 hrs of continuous flow through an empty incubator prior to use for embryo culture.

GENERAL INFORMATION

Indications for Use

The Aire~LifeLine[™] filters provide the most comprehensive defense in removing contaminants such as VOCs and other contaminants from incoming gas sources. Attach directly to the current incoming gas lines.

Storage and Shelf Life

Store Aire~LifeLine[™] filters in a temperature and humidity-controlled room. Do not remove from packaging until ready to install. Immediate connection to the gas tubing lines is recommended once packaging is opened.

INSTRUCTIONS FOR USE

Aire~LifeLine[™] Bracket Installation

The Aire~Lifeline bracket was designed specifically for the Aire~Lifeline filter. It has two options for mounting the filter: a) magnetic b) wall-mount

* Two strong magnets are installed into each bracket. Take precaution when applying the magnets.

Initial Aire~LifeLine Filter and Bracket Installation Instructions

- Remove all reproductive materials from incubator, shut down the incubator according to the manufacturer's instructions, close all valves supplying the incubator with gas, and vent gas lines to zero pressure.
- Consider the filter installation location and ensure enough gas line is available to mount the filter vertically. Using IVF suitable ¼" soft plastic gas line tubing, cut the gas line between the regulator and incubator or point of use / final valve where the filter is to be installed.
- Place the hose clamps loosely around each end of the gas lines. Insert male connector into the line coming from the gas source and the female connector toward the point of use.
- 4. Attach Aire~LifeLine[™] filter to the connector set, ensuring the correct gas flow direction as indicated on the filter housing. Once the filter connections are correctly attached, an audible 'click' should be heard.
- 5. Attach the filter vertically into the Aire~LifeLine[™] bracket. This bracket should only be used to mount the Aire~LifeLine[™] filters. It is designed specifically for the Aire~LifeLine[™] filter. It gives the option of using the magnets or wall mount. The unique design of the LifeAire bracket allows the user to remove the Aire~LifeLine[™] filter while the gas line tubing is still attached to allow quick installation between filter changes and minimize equilibration time.

- a. Magnetic Mount: Take precaution when placing bracket on the side of the incubator or a metal surface. Carefully place the bracket vertically. It is critical that the bracket / filter is installed vertically to ensure maximum capacity is achieved. The Aire~LifeLine[™] filter should rest securely inside the lower and upper arms of the bracket.
- b. Wall Mount: Investigate an appropriate location to ensure ease of future filter changes. The filter/bracket must be installed vertically to ensure maximum filtering capacity. Use appropriate wall mounting materials only. Dry-wall mounting screws and a stud finder is highly recommended to ensure the filter is securely supported.
- 6. Slowly turn on all valves supplying gas to the incubator.
- 7. Check for leaks according to standard lab protocol.
- * See Figure 1.

Replacement Filter Installation Instructions

- Remove all reproductive materials from incubator, shut down the incubator according to the manufacturer's instructions, close all valves supplying the incubator with gas, and vent gas lines to zero pressure. Remove all tube clamps.
- There are two methods to detach the Aire~LifeLine[™] filter during filter changes.
- a. While the filter is still mounted on the bracket, press the small metal tabs found on the connector sets located on each end of Aire~LifeLine[™] filter that is to replaced. An audible 'click' should be heard and the filter will be released.
- b. Remove filter from the bracket while the plastic tubing is still attached to the filter at both ends, slowly slide filter up until it clears the bracket arms. Once removed from the mounting bracket, press the small metal tabs found on the connectors as described above in 2a.
- c. Document the date of installation directly on the Aire~LifeLine[™] filter.
- 3. Discard the filter as pre-standard laboratory protocol and according to local regulations.
- 4. Immediately attach new Aire~LifeLine[™] filter to the

connector set, ensuring the correct gas flow direction as indicated on the filter housing / label. When securely attached, an audible 'click' will be heard. This can be done prior to or after the filter is mounted in the Aire~LifeLine[™] bracket.

- 5. Once the filter is mounted vertically on the bracket, it should be held securely inside the two upper and lower arms. The directional arrows should be pointing directly upward in the 12 o'clock position. Check that all connections are secure.
- 6. Slowly turn on all valves supplying gas to the incubator.
- 7. Check for leaks according to standard lab protocols.
- 8. Allow the gas to purge through the Aire~LifeLine filter and plastic tubing while connected to the incubator for at least 15 minutes. Depending on the incubator in use, this process may take longer. This will help ensure that the inline system is running at its highest capacity and life expectancy.

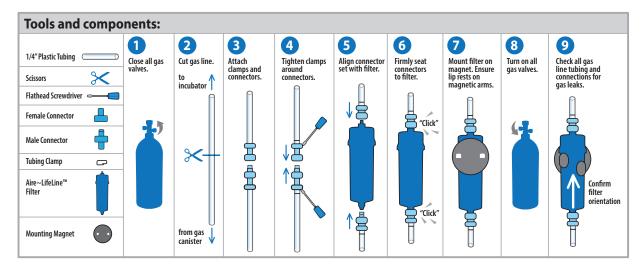


Figure 1: Tools / supplies and directions needed for proper installation of the Aire~LifeLine

Universal Quick-Release Connectors

You will need (1) male & (1) female per set. It will be also based on the size of the tubing they use but we recommend $\frac{1}{4}$ " tubing which is the standard size used by most programs.

40ACV-PB2-04 LinkTech 40AC Series Straight Male, Valved, 1/4" HB, Natural Acetal, Buna N.



40AC-S2-04 LinkTech 40AC Series Straight Female, Non-valved, 1/4" HB, Natural Acetal



40AC-S17-04 LinkTech 40AC Series Straight Female, Non-valved, 1/4" O.D. Push-In, Natural Acetal



40ACV-PB17-04 LinkTech 40AC Series Straight Male, Valved, 1/4" O.D. Push-In



In addition, our manufacture recommends this international distributor for the universal-connectors.

For 6 mm diameter hard tubing https://products.cpcworldwide.com/en_US/ProductsCat/GeneralPurpose/PLC1/PLCD13004

For 8 mm diameter soft tubing https://products.cpcworldwide.com/en_US/ProductsCat/GeneralPurpose/PLC1/PLCD17004

http://www.sparmed.dk/en/products/filters/as-852085/