

URGENT MEDICAL DEVICE RECALL NOTICE

RECALLED PRODUCT: 2.5 mm LifePort™ Adapters (Lot Number 22042320) for use with the LifePulse® High Frequency Ventilator

Bunnell Incorporated, the manufacturer and distributor of the LifePulse® High Frequency Ventilator is voluntarily recalling a limited number of 2.5 mm LifePort™ Adapters.

Some 2.5 mm LifePort™ Adapters in Lot Number **22042320** may have been packaged improperly, and they may deform at the tip prior to or during use with the LifePulse® High Frequency Ventilator.

A deformed tip on a 2.5 mm LifePort™ Adapter may impair the ability to pass a suction catheter or affect normal performance of the LifePulse® High Frequency Ventilator. While unlikely, a deformed LifePort Adapter may lead to hypercarbia, hypoxia, and gas trapping if a clinician fails to respond to ventilator alarms and changes in the patient's condition.

The affected 2.5 mm LifePort™ Adapters were packaged in these products:

Catalog #	Description	Lot Numbers*
Catalog # 9025	2.5 mm LifePort Adapters 10-pack	22042320
Catalog # 938	Patient Circuit Kits	22052381
	(Each package contains 2 Kits – each Kit	22052407
	contains one circuit, one 2.5 mm	22062431
	LifePort Adapter, and LifePort Adapters	22062458
	in other sizes)	22062478

* All 2.5 mm LifePort™ Adapters under recall are individually labelled with lot number **22042320**

All hospitals who received these products have been notified.

Customers should immediately check inventory to identify any 2.5 mm LifePort Adapters in lot number **22042320**. 2.5 mm LifePort Adapters from lot number **22042320** should be removed from Patient Circuit Kits (lot numbers listed above) and discarded.

- The remainder of the Patient Circuit Kit may be retained for future use.
- LifePort Adapters in other sizes and lot numbers are **not** affected and should **not** be discarded.

All affected LifePort Adapters from lot number **22042320** should be discarded immediately.

Bunnell will promptly replace any affected LifePort Adapters at no cost. As a reminder, customers may use a 3.0 mm LifePort Adapter (included in each Patient Circuit Kit) to connect to a 2.5 mm endotracheal tube if this is the only available product for patient care, per the instructions for use in the User Manual (model 204) and Operator's Manual (model 203).

If you have additional questions, please call 800-800-4358 or email info@bunl.com. If you have had any adverse events associated with recalled product, please contact Bunnell to report the information.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online (www.fda.gov/medwatch/report.htm), or by regular mail or by fax 1-800-332-1088 to request a Form.