MEMORANDUM

January 5, 2012

BY ELECTRONIC MAIL

TO: Mr. Hal Norris  
President  
ARC Medical, Inc.

FROM: Olsson Frank Weeda Terman Matz PC  

RE: Multiple Patient Use of Anesthesia Breathing Circuit Labeled for Single Patient Use –  
Practice of Medicine

Introduction

We have been asked to apply the Food and Drug Administration’s (FDA) practice of medicine (POM) exemption to the practice of a healthcare practitioner using an anesthesia breathing circuit (circuit) on multiple patients when it is labeled for single patient use, adding a new ARC Medical FilterFlo™ filter or ThermoFlo™ filter (both designated as “circuitGuard™” with an elbow) (hereinafter “filter”) to the circuit for each patient use.

Practice of Medicine Exemption Criteria

The POM exemption may be relied upon by a healthcare practitioner when all of the following four criteria are met:

1) The circuit is a legally marketed device;
2) Use is by the licensed healthcare practitioner;
3) An actual healthcare practitioner-patient relationship exists; and
4) The healthcare practitioner does not solicit patients for the “off-label” circuit use.

If multiple patient use of the circuit falls within the POM exemption, FDA is not authorized to interfere with legitimate “off-label” use by the healthcare practitioner.

Legally Marketed Device

If the circuit in question is labeled for single patient use, complies with applicable FDA requirements, and is not adulterated or misbranded under the Federal Food, Drug, and Cosmetic (FD&C) Act, it is legally marketable in the U.S. As such, the first criterion would be met.

Licensed Healthcare Professional

If the individual responsible for multiple patient use of the circuit is a duly licensed healthcare practitioner, the second criterion would be met.

Actual Physician-Patient Relationship

We understand that patients would present themselves for medical treatment or management to the licensed healthcare practitioner responsible for multiple patient use of the circuit on these patients. Each patient is presumably identified to and interviewed by the healthcare practitioner prior to treatment, having the patient’s medical information and the medical treatment/management information at his or her disposal, evidencing the bona fide nature of the healthcare practitioner-patient relationship. In short, the patient’s anesthesia needs are assessed. If this is the case, the third criterion would be met.

Solicitation for “Off-Label” Use

If the healthcare practitioner is not marketing or soliciting patients for purposes of using the circuit on multiple patients, and the “off-label” use is simply a medical decision by the healthcare practitioner, the fourth criterion would be met.
Application of the POM Exemption

If the four criteria for the POM exemption are satisfied, multiple patient use of the legally marketable circuit by the licensed healthcare practitioner is within the scope of his or her practice on a bona fide patient, who has not been solicited for such off-label use. Hence, multiple patient use of the circuit would fall outside the scope of FDA’s regulatory authority.

“On Label” Use of Filter

It is clear that use of the filter, whether the circuit is used on 1) one patient, or 2) multiple patients (where a new filter is used with each patient), is “on-label” use of the filter. The 510(k)-cleared indications for use for the filter read as follows:

FilterFlo™ filter is a breathing system filter which is designed to reduce possible airborne or liquid-borne cross-contamination with micro-organisms and particulate matter via anesthetic or ventilator breathing systems.

The FilterFlo™ filter may either be used on the patient side or on the device side of the ventilator/anesthetic device and is used as a hygienic measure alternatively to decontamination of breathing system and/or breathing gas conveying parts of the ventilator.

The ThermoFlo™ filter/HME is a breathing system filter and a Heat and Moisture Exchanger. The combination of a filter and a Heat and Moisture Exchanger offer the benefit of both product features. Heat and Moisture Exchangers are used as a conditioning system for mechanically ventilated patients whose upper airways are bypassed. In almost all cases of mechanical ventilation they are a fully valid alternative to heated humidifiers. The product is the only conditioning opportunity of breathing gases in cases of emergency ventilation or during transport since heated humidifiers are almost impossible to use. The ThermoFlo™ filter/HME should be used with patients who have a Tidal Volume between 250 – 1500 ml.

The products mentioned above are designed as disposable single patient use and should be changed at least every 24 hours.
See Indications for Use Statement for 510(k) Submission K090738. As such, the 510(k)-cleared indications for use for the filter contemplate use with anesthesia breathing circuits generally, whether the circuit is used on one or multiple patients.

Summary

The practice of a healthcare practitioner using a circuit, labeled for single patient use, on multiple patients is perfectly legal if the POM exemption criteria are met. The law expressly defers circuit off-label use to the discretion of the licensed healthcare practitioner acting within the scope of his or her practice. The FD&C Act specifically provides for this exemption from FDA regulation.

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