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LETTER TO THE EDITOR

The configurations and the materials of the components of commercial coaxial or single-tube breathing circuits

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To the Editor:

Several types of coaxial breathing circuits have been developed and are currently used worldwide in clinical practice. Several articles have reported faults in the inner tube, including kinking, occlusion, or disconnection from the seat [1]. Despite this situation, no precise information is available on the properties of the materials or configurations of the circuits. The design and choice of the material used for breathing tubes depend entirely on the manufacturer. We selected four different commercially available coaxial or single-tube breathing circuits and compared their configurations and materials (Tables 1, 2).

The F breathing circuit (marketed by MERA Senko Medical Instrument Manufacturing Co., Ltd, Tokyo, Japan; manufactured by Merasenko Corporation, Cebu, Philippines) was originally developed from a lightweight, compact, and multipurpose coaxial circuit designed by Fukunaga in cooperation with Senko Medical (hence the "F," after the initial of the designer) [2]. This circuit can be applied to any conventional anesthesia system and has been used in circle systems and in rebreathing or nonrebreathing systems. Senko Medical filed for a patent in 1978 and the patent expired in 1998. The original noncorrugated inner tube was made of polyvinyl chloride, but it was rather heavy and rigid. Senko Medical replaced it with a hard, corrugated polyethylene tube. The outer tube is also a corrugated polyethylene tube that is designed for flexibility. The shape of the corrugation peak and the trough differs depending on the tube diameter. The outer tube is translucent while the inner tube is colored. The machine end of the inner tube is tightly attached to the connector of the socket, and the attachment is reinforced tightly by winding a metal wire. The latest product of Senko Medical is the newly designed "F Breathing Circuit Plus." The F Breathing Circuit Plus set includes a coaxial breathing circuit, an elbow connector, and a heat-moisture exchanger filter. The anesthesiologist can easily extract the removable inner tube from the preassembled circuit containing an integrated outer/inner tube unit, and he can make a careful visual inspection of the condition of the inner tube during pre-use checking. The newly designed elbow connector is equipped with a geared swivel that allows quick attachment and detachment and steadies the port of the connector at the patient end.

Universal F® (marketed by Acoma Medical Industry Co., Ltd., Tokyo, Japan; manufactured by King Systems Corporation, Noblesville, IN, USA) was launched in 1992. Again, "F" represents the initial of Fukunaga. The corrugated outer tube and the corrugated inner tube are both made of high-density polyester. The outer tube is translucent while the inner tube is colored. King Systems, the supplier, states that the colored inner tube is designed for easy identification of the type of breathing circuit (because they are color coded) as well as for the visual detection of defects through the translucent outer tube wall. However, the defects are undetectable on casual examination because the corrugated outer tube is translucent, and the corrugated

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Table 1 The configurations and the materials of the components of commercial breathing circuits

Circuit	Outer tube		Inner tube		Other parts
	Configuration	Material	Configuration	Material	Material
MERA Senko F anesthesia breathing circuit	Corrugated translucent	Polyethylene	Corrugated, colored, firm	Polyethylene	Socket: polyethylene or synthetic rubber Elbow connector: polycarbonate
Universal F2® anesthesia breathing circuit	Corrugated translucent	High-density polyethylene	Corrugated, colored, rough	High-density polyethylene	18″ reusable tubing: polyester elastomer
Triplex™ breathing circuit	Corrugated translucent	Polyethylene	Noncorrugated, smooth, transparent spiral string	Polyvinyl chloride	Expandable extension hose: polypropylene

	Single tube		Septum		Other parts
	Configuration	Material	Configuration	Material	Material
Limb-Θ™ single limb breathing circuit	Corrugated translucent	Low-density polyethylene/EVA	Smooth, colored	Low-density polyethylene/EVA	Elbow: polypropylene Expandable extension hose: polypropylene Cuff band: polyisoprene

Table 2 The characteristics of the commercial breathing circuits

MERA Senko F anesthesia breathing circuit	The corrugated outer tube is translucent, while the corrugated inner tube is colored
	The machine end of the inner tube is tightly attached to the connector of the socket
	The attachment is reinforced tightly by winding a metal wire
	Senko Medical supplies the newly designed "F Breathing Circuit Plus"
Universal F2® anesthesia breathing circuit	The corrugated, colored inner tube is designed for the visual detection of defects through the translucent outer tube wall
	The defects are undetectable on casual examination because the corrugated outer tube is translucent and casts circular shadows around the colored wall of the inner tube
	The machine end of the inner tube is tightly attached to the columnar connector in the seat assembly
Triplex™ breathing circuit	The corrugated outer tube has the lowest transparency among the four breathing circuits
	The wall of the noncorrugated transparent inner tube is reinforced by winding spirally with a string to prevent kinking or occlusion. Triplex™ is resistant to distortion
	The machine end of the inner tube is tightly attached to the columnar connector in the seat assembly
Limb-Θ™ single limb breathing circuit	The lightweight single tube is divided into two longitudinally by a flexible septum running the length of the tube
	The single tube has the highest transparency among the four breathing circuits
	The soft septum is tightly bound longitudinally to the corrugated inner wall of the single tube
	The machine end of the septum fits tightly into the slit of the hard septum in the elbow

outer tube casts circular shadows around the colored wall of the inner tube. King Systems has received a report of a damaged outer tube that was noticed when a brand new circuit was opened. This incident may have occurred during the transportation of the circuit. The company has not received any incidental reports regarding the disconnection, cracking, or the avulsion of the inner tube. The machine end of the inner tube is tightly attached to the columnar connector in the seat assembly.

The Triplex™ breathing circuit (marketed by Covidien Japan, Tokyo, Japan; manufactured by Mallinckrodt Dar S.R.L., Mirandola, Italy) was launched around 2002 in Japan. The patient-side corrugated outer tube and the machine-side extensible corrugated outer tube are made of polyethylene and polypropylene, respectively. This outer tube has the lowest transparency—which is similar to that of frosted glass—among the four breathing circuits. The noncorrugated inner tube is made of polyvinyl chloride and

the wall is reinforced by winding spirally with a polyvinyl chloride string to prevent kinking or occlusion. The Triplex™ circuit is resistant to distortion. The machine end of the inner tube is tightly attached to the columnar connector in the seat assembly. An aspiration line to measure the end-tidal CO_2 concentration is installed. The manufacturer did not disclose precise information on the materials used, but stated that they had received no incident reports regarding defects of the inner tube.

Unlike the abovementioned coaxial systems, the design of the Limb-Θ™ single limb breathing circuit (marketed by Tokibo Co., Ltd. Tokyo, Japan, manufactured by Vital Signs Inc., Totowa, NJ, USA) is a lightweight single tube divided in two longitudinally by a flexible septum running the length of the tube, such that the inspiratory and expiratory pathways are side by side in one tube [3]. It effectively transfers heat from the expiratory to the inspiratory side of the circuit. The corrugated tube and the septal wall are made of a composite of polyethylene/ethylene vinyl acetate, because it has excellent strength and flexibility and is easily molded into the required shape. This single tube has the highest transparency among the four breathing circuits. The soft septum is tightly bound longitudinally to the corrugated inner wall of the single tube. The machine end of the septum fits tightly into the slit of the hard septum in the elbow. Twisting this tube is liable to cause kinking or to obstruct both lumens. However, Vital Signs has not received any incident report regarding septal dislocation or defects for the past three years.

Regarding the material of the breathing tube, the International Organization for Standardization (ISO 5367:2000(E)) [4] and the JSA (JIS T 7201-4:2005) [5] list the following recommendations (see Annex G of ISO 5367:2000):

G1 Breathing tube should be made of materials that are compatible (i.e. resistant to deterioration and have low absorption and permeability) with substances that they may contact in the intended use.

G2 Unless designated and marked as being for single use, breathing tubes should be resistant to ordinary methods of cleaning, disinfection and sterilization recommended by the manufacturer. It is desirable that breathing tubes not intended for single use should withstand accepted methods of steam sterilization.

However, this international standard does not cover the coaxial or single-tube breathing circuit. In contrast, the manufacturers have carefully designed and improved coaxial or single-tube breathing circuits to prevent defects by the operator, even if it is for single use. The Minister of Health, Labour and Welfare (MHLW) of Japan notified the certification and approval standards for an anesthetic circuit set on September 27, 2010 (MHLW Ministerial Notification no. 112, Appendix Table, and no. 540). These standards apply to several components of the anesthetic circuit set, such as the breathing circuit, water trap, nebulizer, bacterial filter, face mask, pressure control valve, elbow connector, and reservoir bag. These devices are categorized as "Class 2: controlled medical devices, low risk to the human body." Sales agents and manufacturers are required to have these medical devices certified as conforming to the corresponding certification standards by a registered third-party certification body. For coaxial and single-tube breathing circuits that are outside the scope of JIS and ISO, these circuits are regarded as equivalent to "Class 3: specially controlled medical devices, medium risk to the human body." Sales agents and manufacturers are required to submit applications to the Pharmaceuticals and Medical Devices Agency (PMDA) to obtain the Minister's technical and marketing approval for these medical devices. The PMDA evaluates and objectively confirms the conformity of the devices to the technical requirements for performance, function, efficacy, and usefulness, which are determined based on standards such as JIS and ISO/International Electrotechnical Commission [6].

The manufacturers have carefully designed and improved coaxial or single-tube breathing circuits in order to prevent defects by the operator, even if it is for single use. Since anesthetists recognize that the inner tube is an important but hazardous component that may lead to the potential malfunctioning of the coaxial breathing circuit, they inspect it closely during the pre-use check of an anesthesia machine. However, the defects are undetectable, because the corrugated outer tube is translucent rather than transparent, and the outer tube casts circular shadows around the wall of the inner tube. We recommend that the manufacturers design an outer tube with a transparent material to allow easy detection of defects by the operator.

References

1. Garg R. Kinked inner tube of coaxial Bain circuit—need for corrugated inner tube. J Anesth. 2009;23:306.
2. Fukunaga A. A compact multipurpose breathing circuit: an application to the anesthesia circle system. Masui (Jpn J Anesthesiol) 1978;27:1113–7 (in Japanese with English abstract).
3. Vital Signs, Inc. LIMB-Θ™ single limbed circuit (webpage). http://www2.vital-signs.com/VSIHome/html/english/products/anesthesia/an_limbo.aspx. Accessed 26 Mar 2011.
4. International Organization for Standardization (ISO). Breathing tubes intended for use with anaesthetic apparatus and ventilators. 5367:2000 (E). Geneva, Switzerland: ISO; 2000.
5. Japanese Standards Association (JSA). JIS T 7201-4:2005 (J). Tokyo, Japan: JIS; 2005.
6. Pharmaceuticals and Medical Devices Agency. Regulatory system for medical devices in Japan (webpage). http://www.std.pmda.go.jp/stdDB/index_e.html. Accessed 26 March 2011.