ANESTHESIA BREATHING CIRCUITS & KITS

HISTORY OF ANESTHESIA

- History of Surgical Anesthesia Research on modern techniques to reduce surgical pain began when an English scientist **Joseph Priestley** (1733-1804) discovered that inhalation of nitrous oxide might relieve pain. Others followed suit and dug up other gases like carbon dioxide which produced similar effects.

HISTORY OF ANESTHESIA

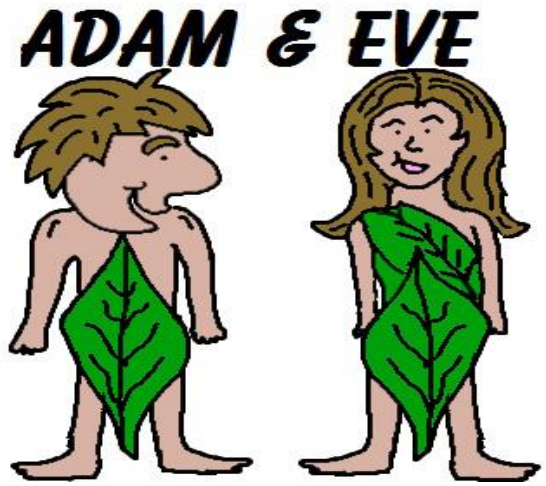
HISTORY OF ANESTHESIA

- Until the discovery of general anesthesia in the middle of the 19th century, surgery was performed only as a last and desperate resort. Conscious and without pain relief, it was beset with unimaginable terror, unspeakable agony and considerable risk.

HISTORY OF ANESTHESIA

HISTORY OF ANESTHESIA

- Actually, the use of anesthesia has been around since the beginning of time. If you have read the Bible, it states that when God created Man, he put Adam under a deep sleep, to remove one of his ribs to create his companion Eve! Who knew?!



HISTORY OF ANESTHESIA

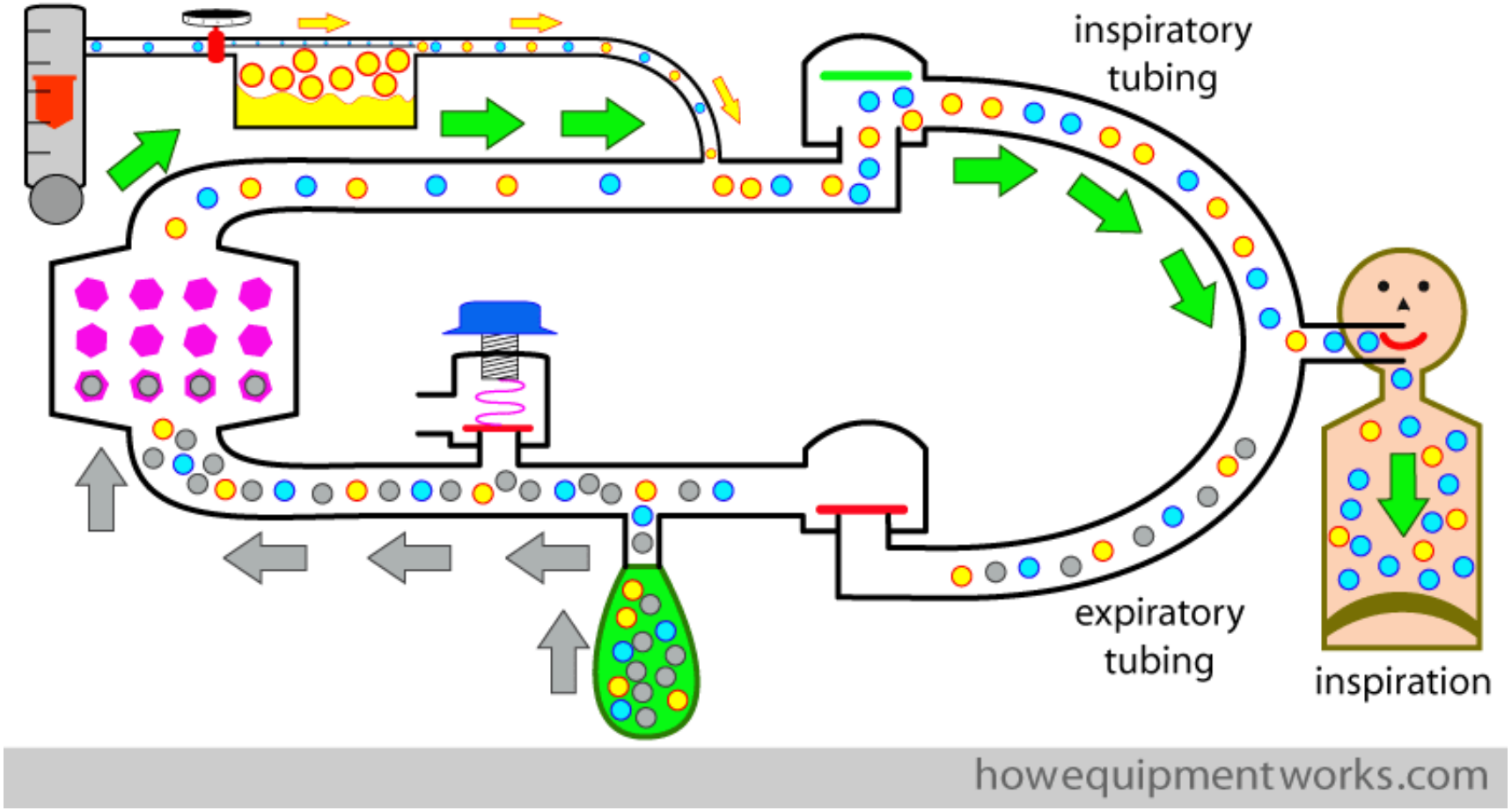
- The practice of general anesthesia has now evolved to the point that it is among the safest of all major routine medical procedures. For around 300,000 fit and healthy people having elective medical procedures, one person dies due to anesthesia.

PRINCIPLES OF THE ANESTHESIA MACHINE

- The anesthesia machine dispenses the gases that are necessary to induce sleep and prevent pain during surgical procedures.
- This is critical, since room pollution with anesthetic gases may lead to health problems in humans.

DELIVERY OF GAS TO PATIENTS

- During delivery of anesthetic gas to the patient, O2 flows through the vaporizer and picks up the anesthetic vapors.
- The anesthetic/O2 mix then flows through the breathing circuit and into the patient's lungs usually by spontaneous ventilation.
- Most common anesthetic gases are Sevoflourane, Isoflourane and Desflourane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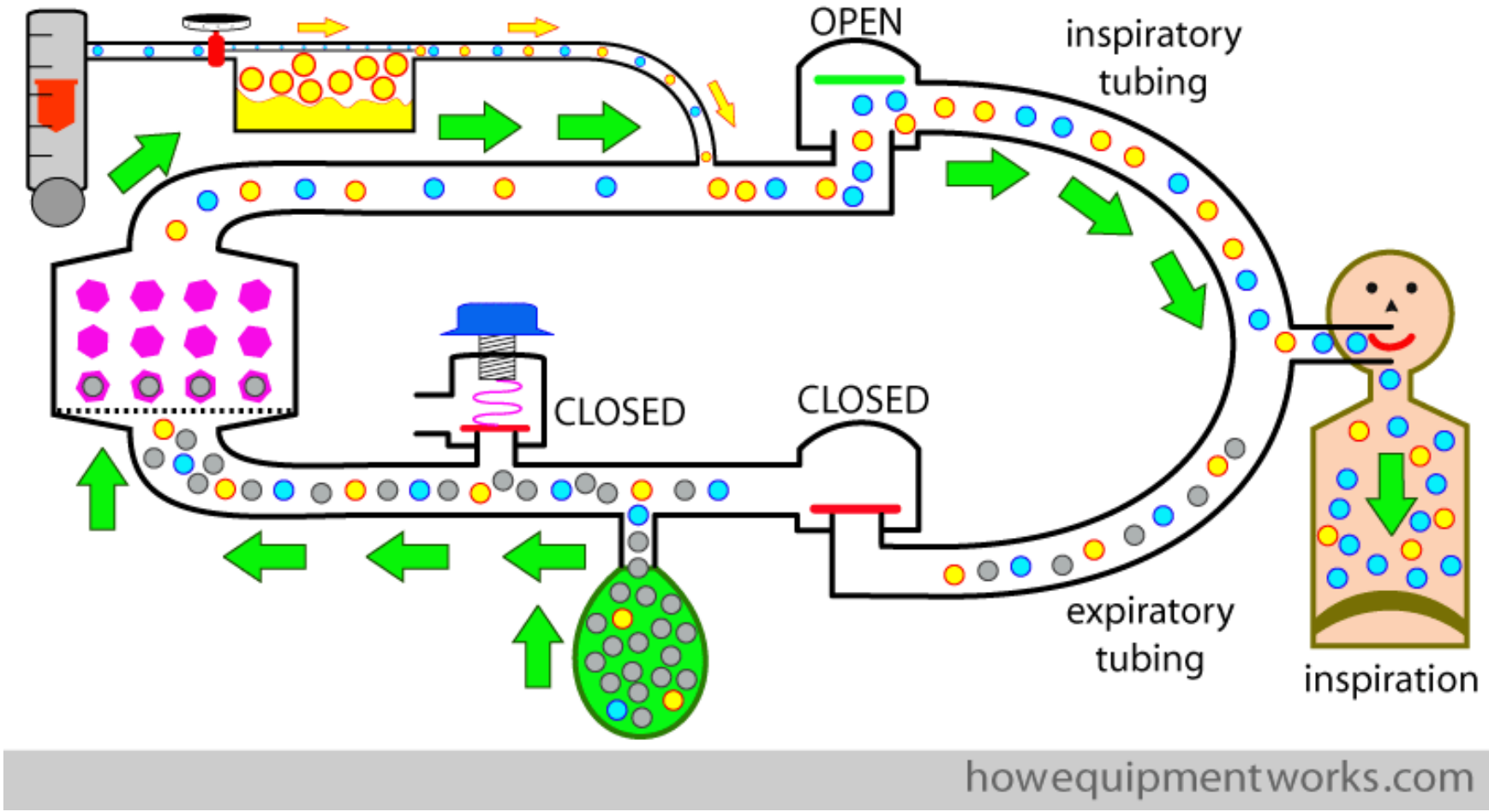
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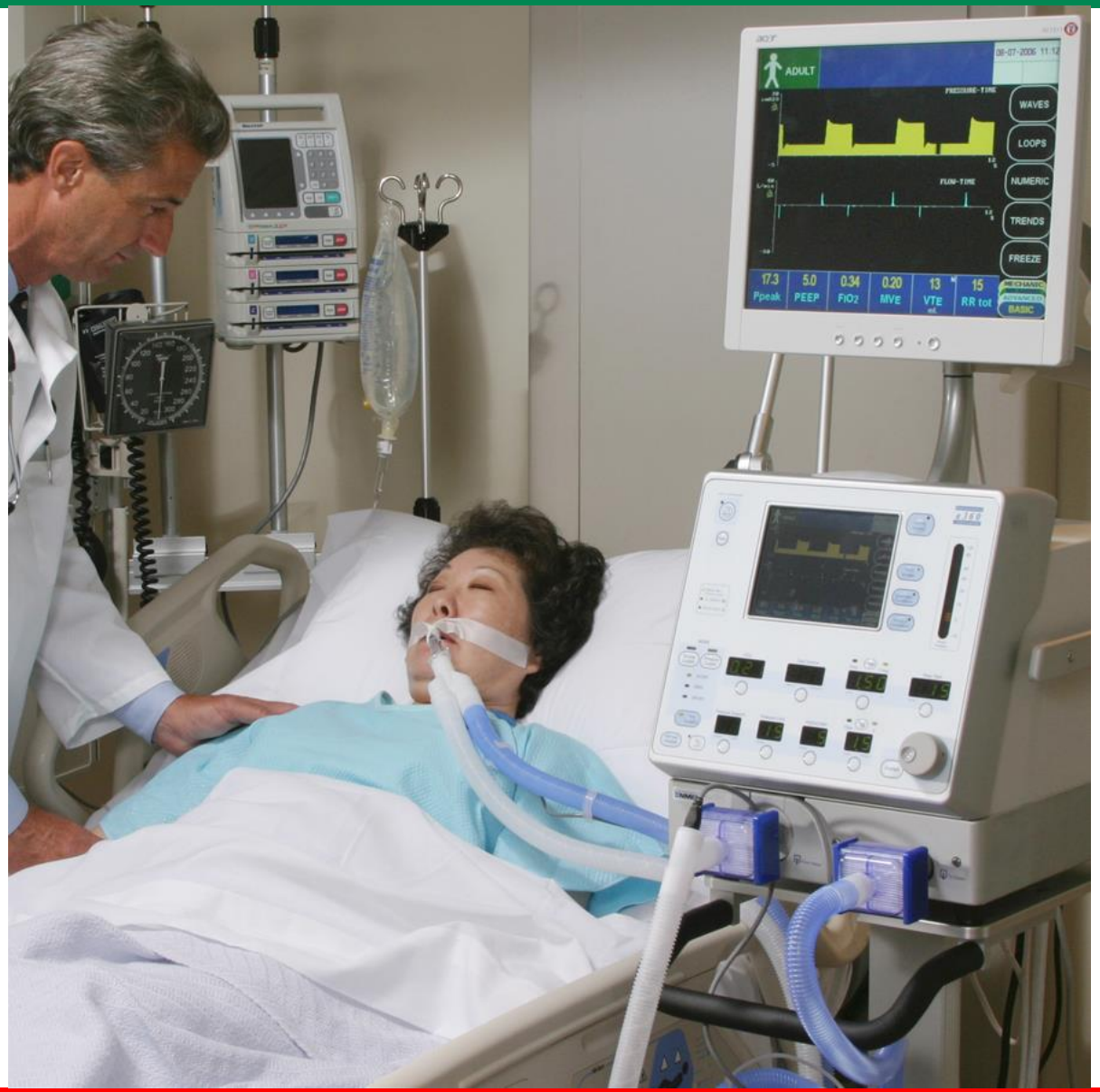
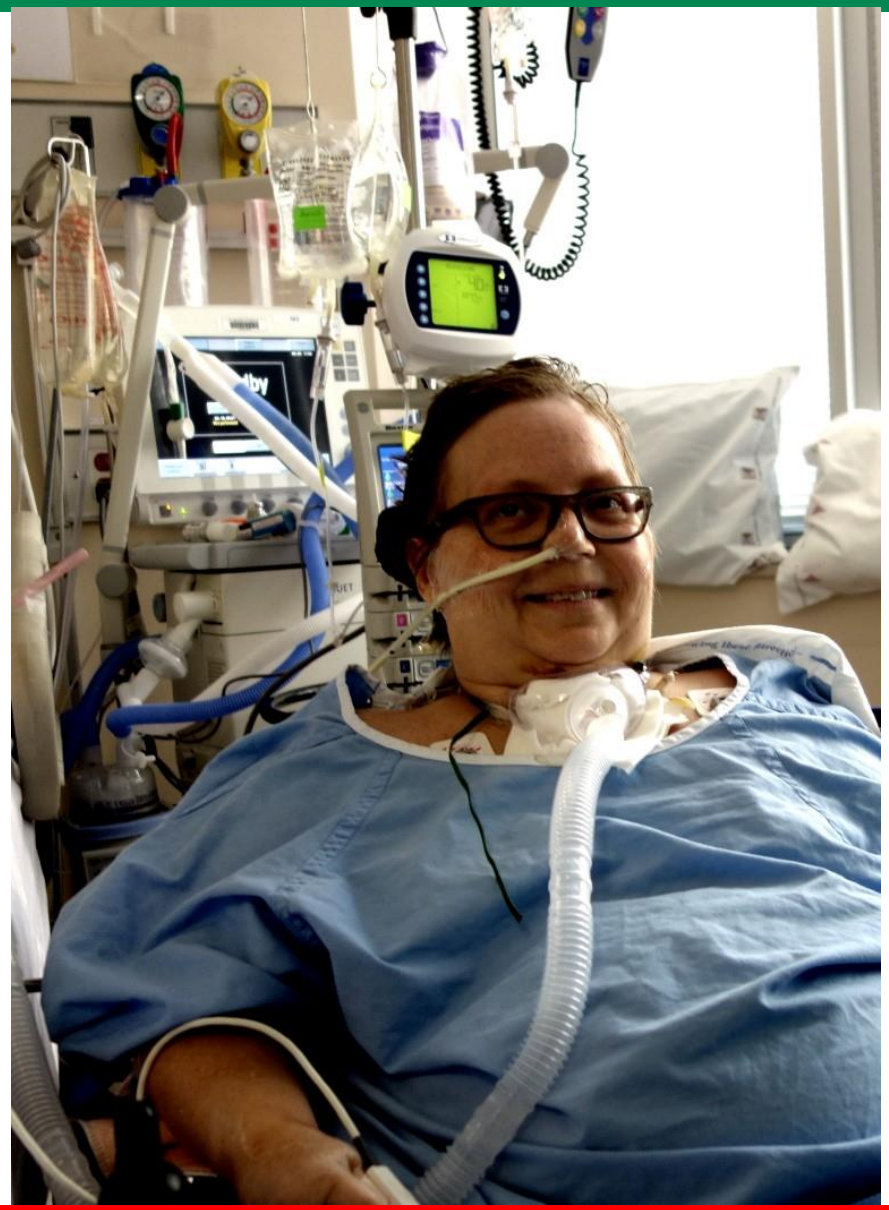
VENTILATORS



VENTILATORS



PATIENT BREATHING CIRCUIT

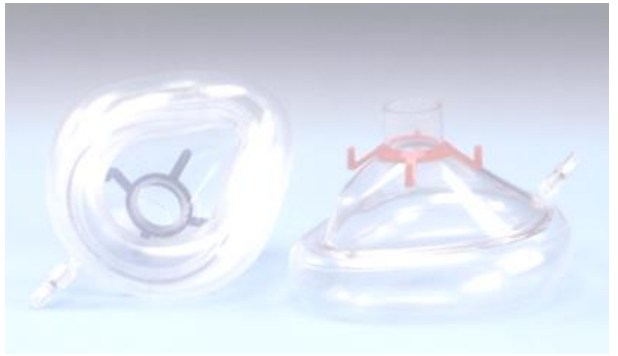
- The patient breathing circuit is the highway for anesthetic gas delivery to the patient. The goals of the circuit are:
- Deliver O2 to the patient
- Deliver anesthetic to the patient
- Remove CO2 that is produced by the patient
- Provide a method of controlled ventilation

PRESENTATION OUTLINE

- Re-breathing circuits (Circle Systems)
  - Dual limb circuits
  - Single limb systems
- Non-rebreathing systems
  - Jackson-Rees
  - Mapleson D
  - Coaxial non-rebreathing circuit (bains-type)
- Multi-Use Breathing Systems

GENERAL PRODUCT OVERVIEW

- Adult & pediatric circle anesthesia breathing systems
- Adult/Pediatric single limb (Coaxial)
- Complete breathing circuit kits and procedure packs
- Multi-Use Breathing Systems



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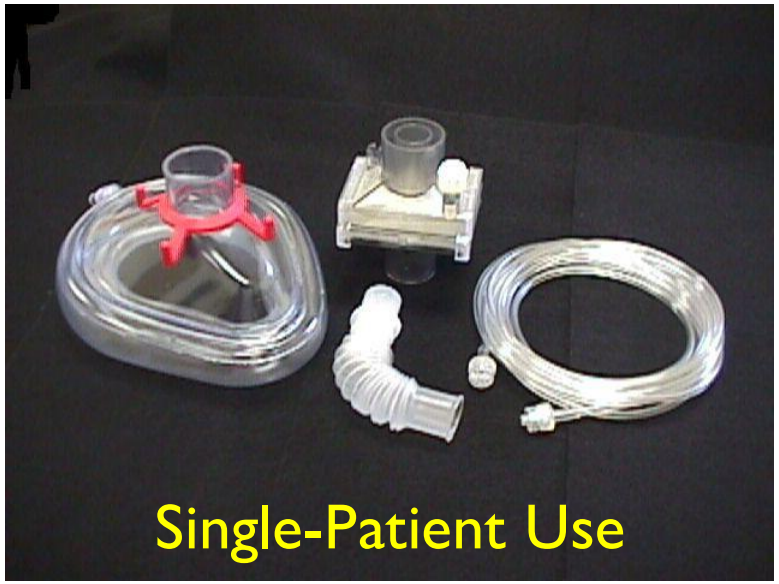
GENERAL PRODUCT OVERVIEW

- Specialty Anesthesia Breathing Circuits
  - Modified Jackson Rees circuits
  - Mapleson D non-rebreathing circuits
  - Bains-type breathing circuits

MULTI-USE BREATHING SYSTEMS

- Alternative to disposable anesthesia breathing circuits:

+



THE BREATHING CIRCUIT

THE BREATHING CIRCUIT

What is the breathing circuit?

- The breathing circuit is, basically, the plumbing through which gases are routed to the patient and back to the machine.
- Gases can either be routed in a continuous circle, between the anesthesia machine and the patient (rebreathing systems), or
- Gases can be routed to the patient and then out to the atmosphere, without recirculation (non-rebreathing systems).

REQUIREMENTS OF A BREATHING SYSTEM

- It must maintain potency of gas flow, with minimal flow resistance;
- It must have secure, leak-resistant connectors;
- It must present minimum pull or torque on the patient's tracheal tube;
- It must function, as intended, for the entire duration of its use;
- It must be simple, safe, and reliable in use;
- Minimize dead space.

CIRCLE (RE-BREATHING) SYSTEMS

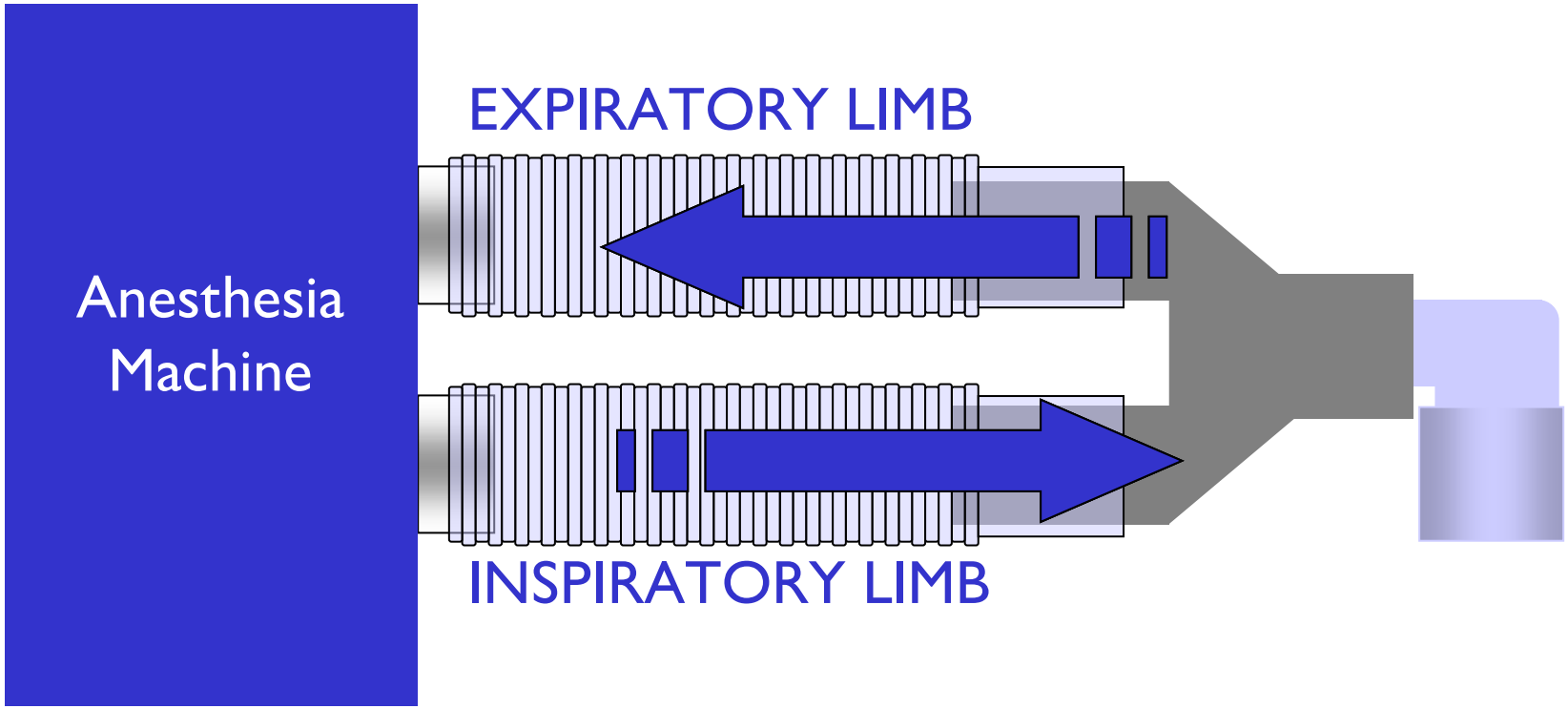
- Circle systems are the most common in use today.
  - All circle systems are used in conjunction with carbon dioxide absorbers.
  - Circle systems can function over a wide range of flows.
  - They're especially useful in low-flow anesthesia, which has been gaining popularity in recent years.

CIRCLE BREATHING SYSTEMS

- In its most basic form, the circle breathing circuit consists of a wye, two tubes, and a breathing bag.

CIRCLE BREATHING SYSTEMS

- How do they work?



CIRCLE BREATHING SYSTEMS

- Who uses circle systems and why?
  - Just about everyone uses them.
  - They're economical.
  - Everyone knows how they work.
- How do circle systems differ?
  - Tubing diameter (adult 22mm, pediatric 15mm)
  - New Universal L.I.C. (19mm Universal)
  - Tubing type (i.e. fixed length, expandable)
  - Wye Configuration

CIRCLE BREATHING SYSTEMS

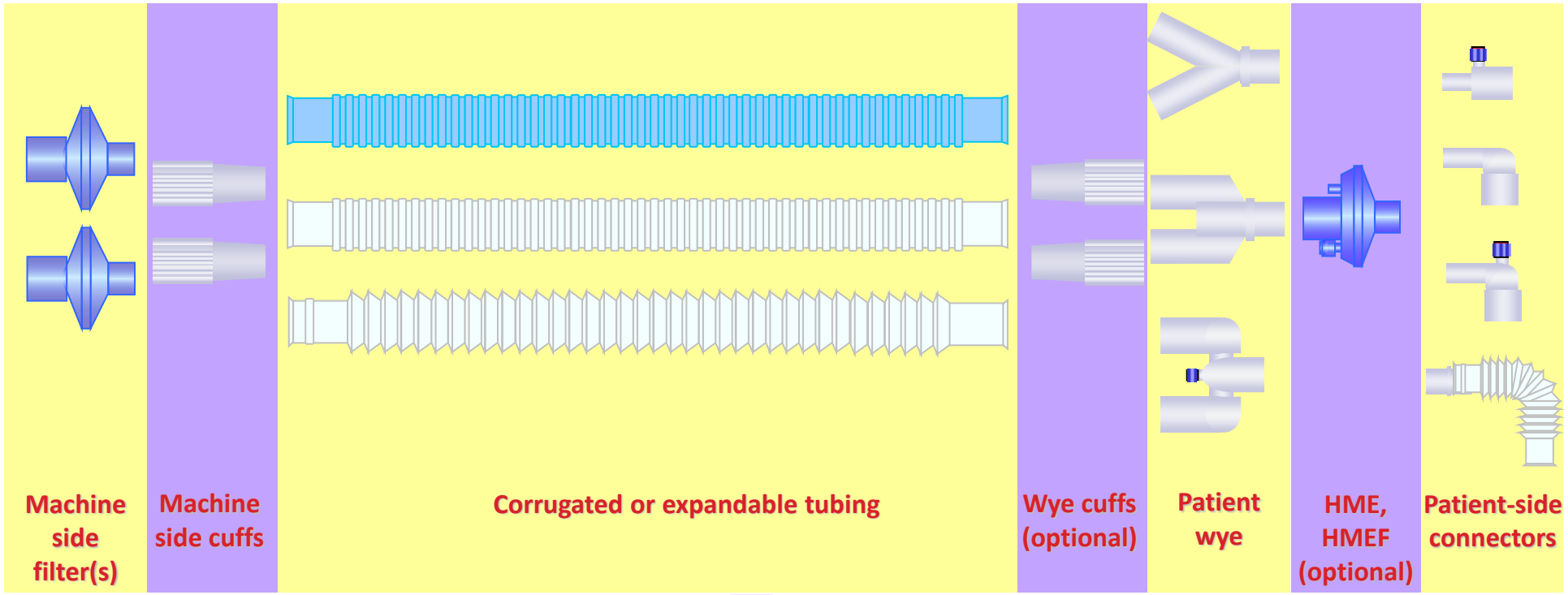
- In what other ways can a circle system differ?

  Does it have a gas monitoring port? location?

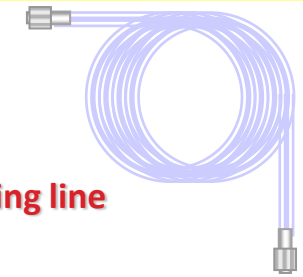
  Does the circuit have a filter or an HMEF? Location?

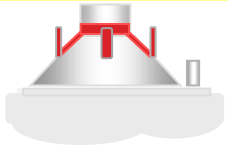
  Does the circuit kit contain latex? We are latex free

COMPONENTS OF A CIRCLE SYSTEM



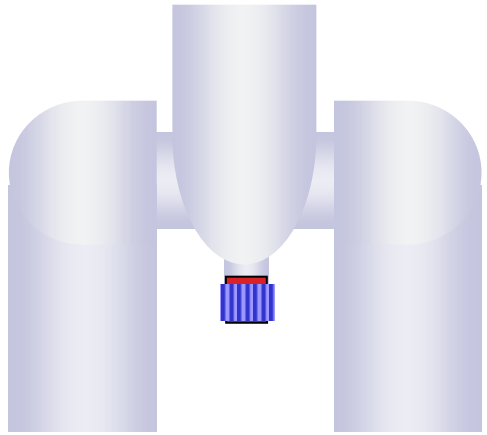
Other items





WYE'S

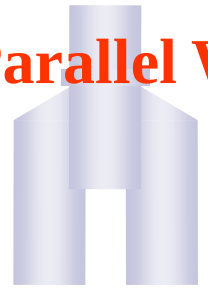
Bifurcated Wye



Swivel Wye

Parallel Wye

PATIENT WYE CHART

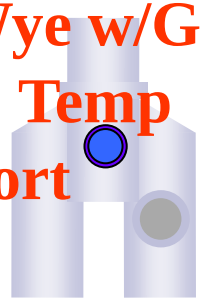


Parallel Wye

Bifurcated Wye

Swivel Wye

Wye w/GSP



Wye w/GSP & Temp Port

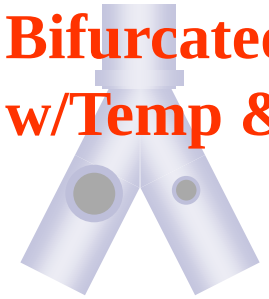
Bifurcated Wye w/GSP

Swivel Wye w/GSP

Pediatric Wye

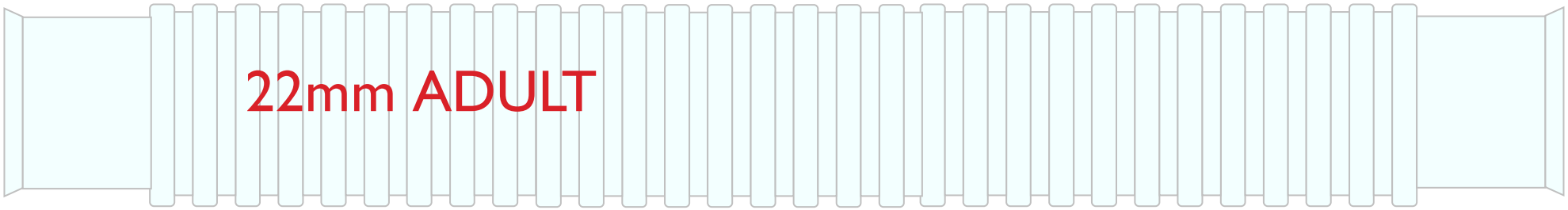
Parallel wye w/GSP & Press

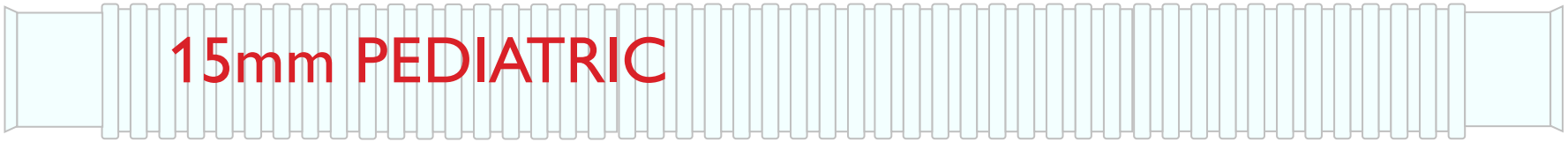
Bifurcated Wye & Temp port



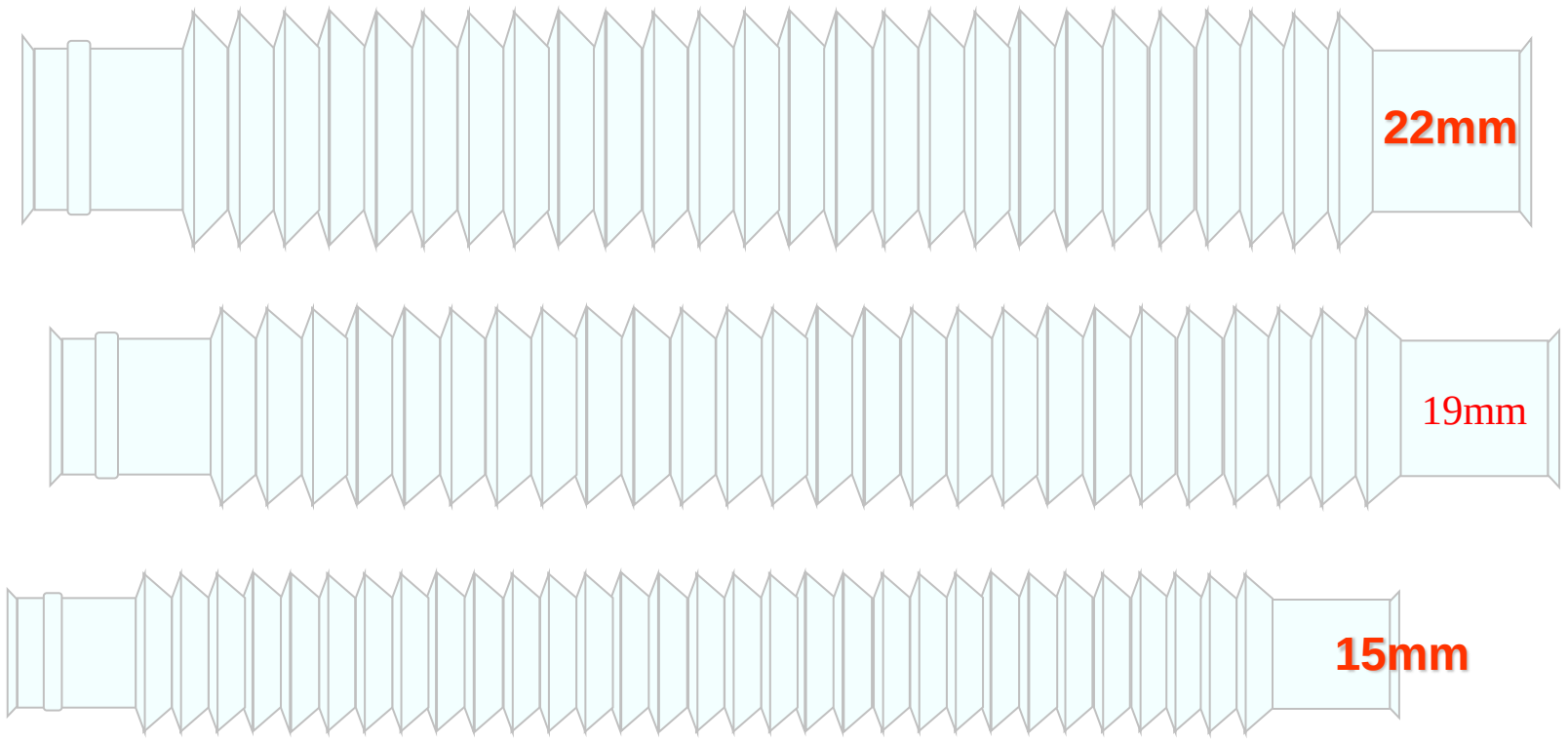
Bifurcated wye w/Temp & Press

TUBING SIZES – FIXED-LENGTH, CORRUGATED STYLE





TUBING SIZES – EXPANDABLE (CUFFS REQUIRED)



CIRCLE BREATHING SYSTEMS

- What advantages does the Westmed circle system offer?
  - ISO tapered fittings for secure, leak-resistant connections.
  - Excellent tubing drapability
  - Improved feel.
  - More options for your customer (lengths, diameters, ports, accessories, etc.)

COMPETITION

COMPETITION

- In the disposable circuits and kits business, Westmed has four major competitors:
  - Vital Signs (Now BD)
  - Medline
  - Smith's
  - King Systems (Now Ambu)
- The collective market share of these four players is ~ 90%.

BASIS OF COMPETITION

- Successful product differentiation comes through:
- Proven improvements in patient outcomes,
- Demonstrable improvements in ease of use and/or time savings for the end-user.
- Availability of Custom Configurations
- Ability to Standardize to one supplier

BASIS OF COMPETITION

- Marketing Strategies of Major Competitors:
  - Low-price, limited offering:
    - Smith's, Medline
  - Broad product range, highly customized offering sold at a premium:
    - Vital Signs (Now Vyaire)
    - King Systems (Now Ambu)

COMPETITION

- Vital Signs (Now Vyaire)
  - Perennial market leader
  - Large national sales force
  - Solid base of contract business
  - Face mask
  - Custom Kits

VITAL SIGNS (NOW VYAIRE)

- Most distinguishing features:
  - Hard, blue cuffs
  - Machine side filter has a very flat profile
  - Ribbed elbow
  - Limbo

COMPETITION

- Smith's
  - Solid market position
  - Large national sales force
  - Solid base of contract business

SMITH'S

- Most distinguishing features:
  - Clear , ribbed patient elbow
  - "Swivel" tubing connections at the wye
  - Nearly opaque filter housing

COMPETITION

- King Systems (Now Ambu)
  - Solid market position
  - Very high product quality
  - Innovative product offering
  - Popular mask offering, including scented masks
  - Some GPO contracts

KING (NOW AMBU) SYSTEMS

- Most distinguishing features:
  - Clean, well-engineered construction
  - Clear wye and patient elbow
  - Color-coded pediatric bag option

COMPETITION

- Medline
  - Unparalleled bundling power
  - Large national sales force
  - Narrow product offering sold at very aggressive pricing
  - Co-holder of Premier contract
  - Gaining strength with National Contracts

OTHER COMPETITION

- Teleflex
  - Well-known entity in the respiratory business
  - Minimal broad product offering
  - Strong dealer relationships w/General Line Distribution
  - Large national sales force

BASIS OF COMPETITION

- How does Westmed now fit into the market?
  - As a manufacturer of high-quality anesthesia circuits, kits, and accessories that offers a broad product range sold through the customer's preferred route of distribution.
- What advantage does Westmed have?

  Breadth of Product Line

  Custom Kits

  National Contracts

  Distribution

SALES PROSPECTING – CIRCLE BREATHING SYSTEMS AND KITS

Positioning and Niche Identification

CIRCLE BREATHING SYSTEMS

- Macro Strategy:
  - Always attempt to change the ground rules for competition.
  - Focus on our advantages!
    - Best face mask offering
    - Most flexible, drapable breathing tubes
    - Full customization capabilities
    - All Latex Free!

CIRCLE BREATHING SYSTEMS

- What not to do:
- Do not try to simply duplicate what someone is already buying
- Duplication encourages simple price competition.
- If at all possible, *change the basis of competition.*

SINGLE LIMB COAXIAL SYSTEMS

COAXIAL BREATHING SYSTEMS

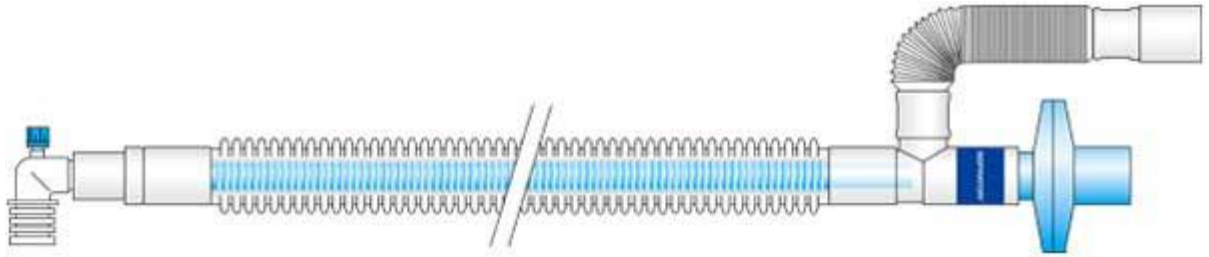
Are there advantages to the Coaxial Circle System?

- Yes
  - More streamlined.
  - Less waste
  - Better heat and moisture retention characteristics than a plain circuit

COAXIAL CIRCLE BREATHING SYSTEMS

King Systems F-Circuit®

Smith's



KING SYSTEMS (NOW AMBU)

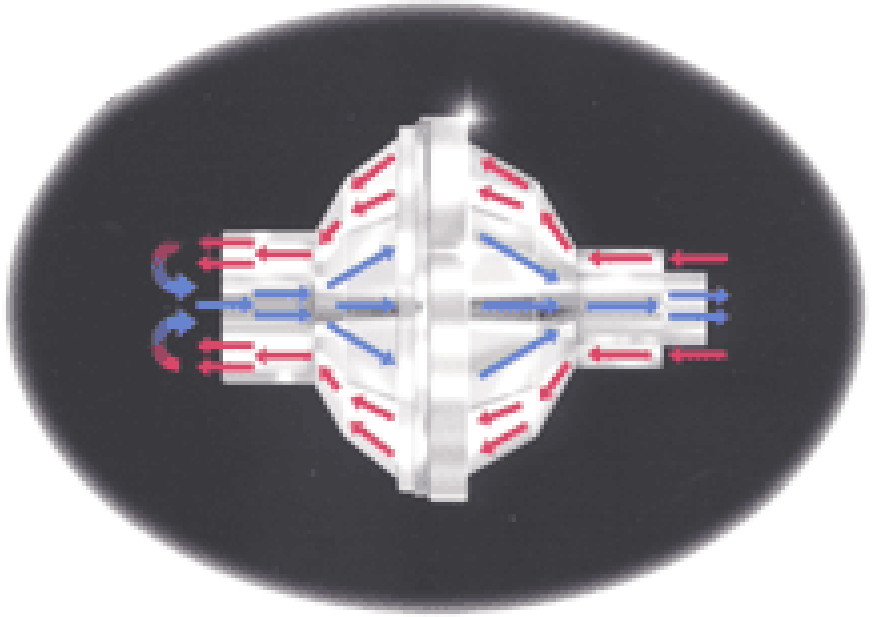
- King F-Circuit
  - The original single-limb circle system
  - High product quality
  - Premium pricing
- Disadvantages
  - High cost to produce

KING SYSTEMS (NOW AMBU)

- King F2 Circuit
  - Disposable circuit with reusable manifold
  - Adult & Ped versions
  - Product quality
  - Premium pricing
- Disadvantages
  - High cost to produce

KING SYSTEMS (NOW AMBU)

- King F2 Circuit
  - Special coaxial breathing filter separates inspiratory and expiratory gases
  - Standard filters cannot be used in this application
  - Strong patent coverage

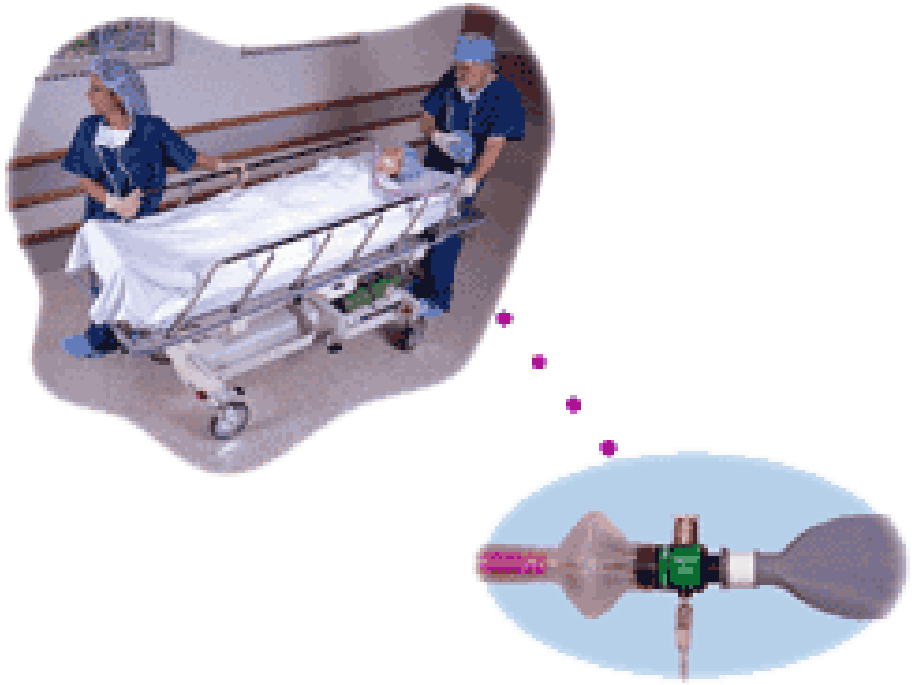


KING SYSTEMS (NOW AMBU)

- F-Circuit Transport Capability
  - Customer makes post-operative use of F Circuit and breathing bag
  - Add-on valve completes the transport system

KING SYSTEMS (NOW AMBU)

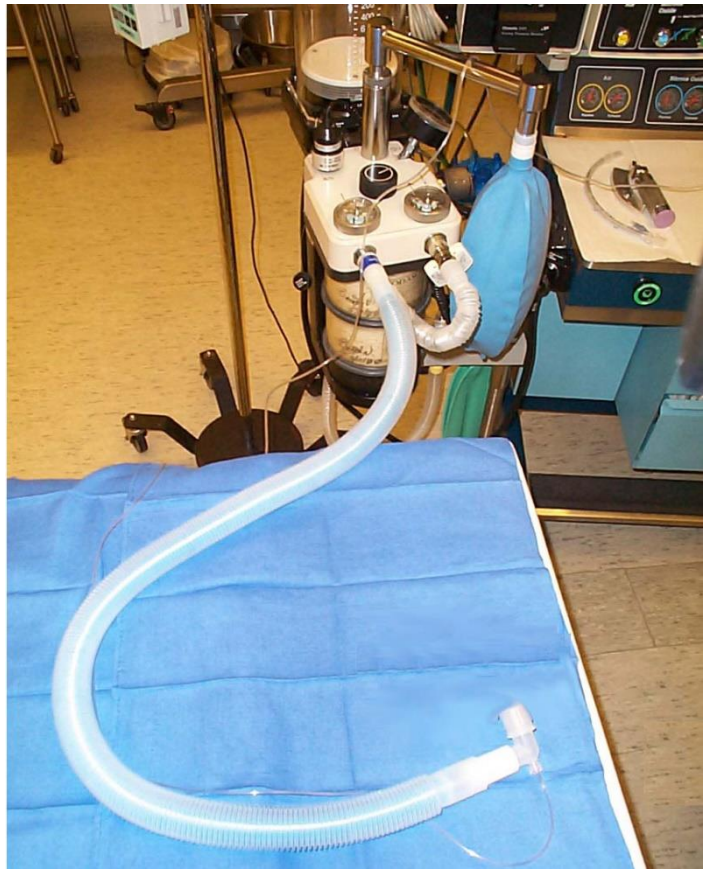
- F2 Transport System
  - Customer makes post-operative use of the F2 circuit and the breathing bag
  - Add-on valve completes the system
  - No better solution than the F-Circuit transport system



SMITH'S

- Smith's Nexus Circuit
  - Swivel patient end-connector
  - Internal tube fixed at both ends
  - Patented pressure-check system
  - "Economical" alternative

SMITH'S

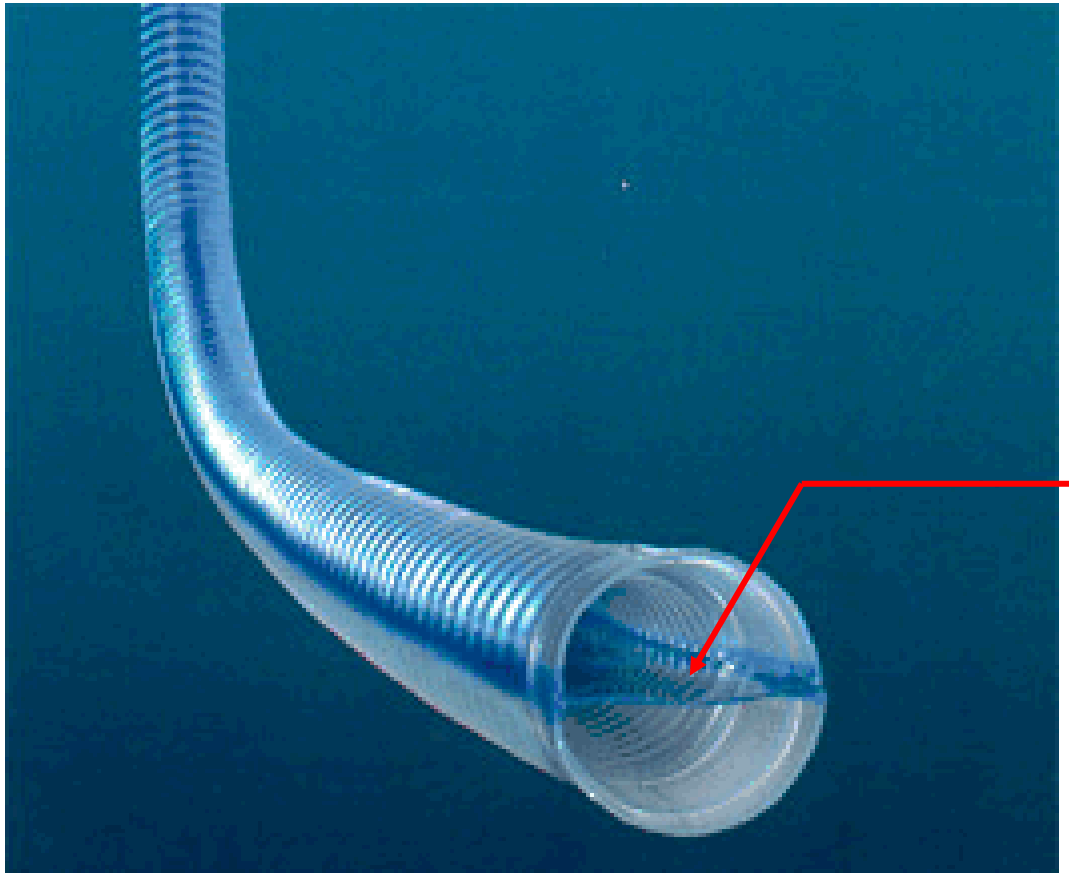


- Smith's Nexus Circuit
  - Adult & pediatric versions
  - Internal gas sampling line option

SINGLE LIMB BREATHING SYSTEMS

- What about Vital Signs' *Limb-O* circuit?
  - Less bulky than a standard circle system, but…
  - Costly to produce,
  - More difficult to detect flaws in the septum
  - Limited Drapability

VITAL SIGNS (NOW VYAIRE) LIMB-O™ CIRCUIT



Not a true coaxial circuit (not a tube-within-a-tube design).

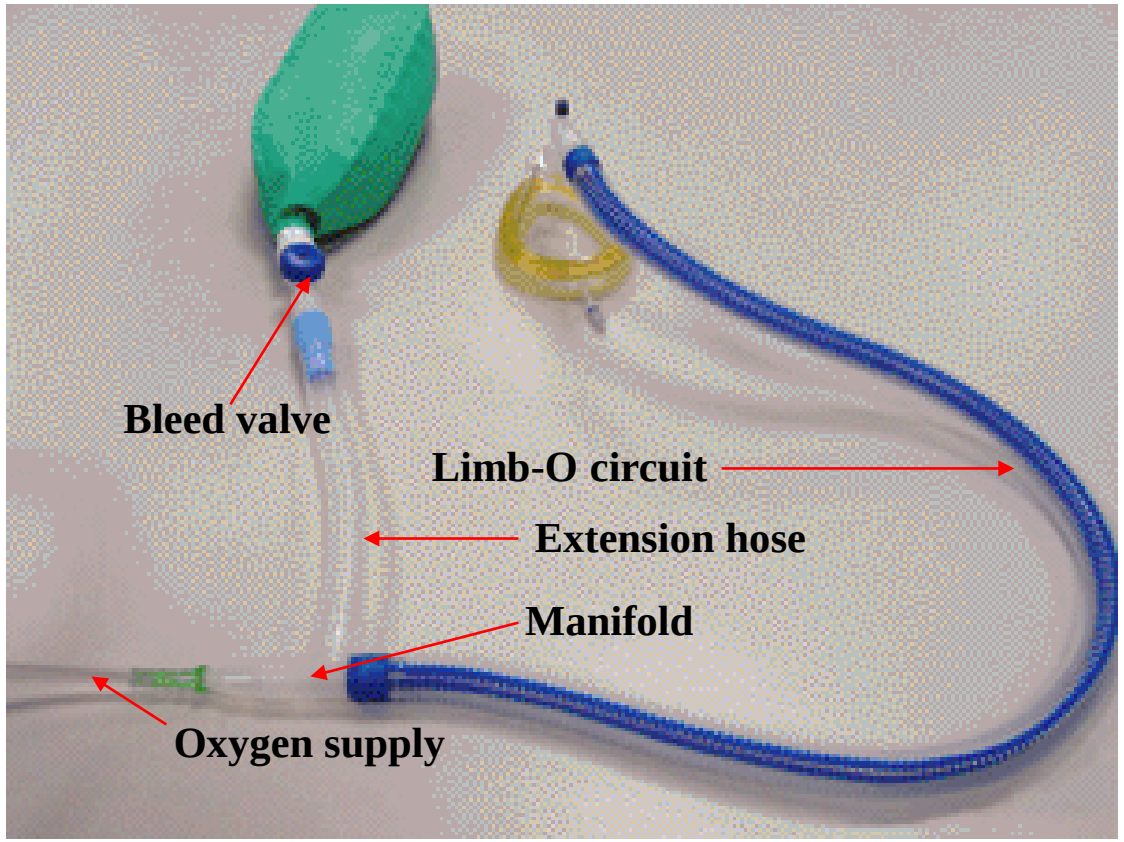
A septum separates inspiratory from expiratory flows.

VITAL SIGNS (NOW VYAIRE) LIMB – O™ CIRCUIT

Shown here as an ICU vent circuit

Note position of septum and curvature of the tubing

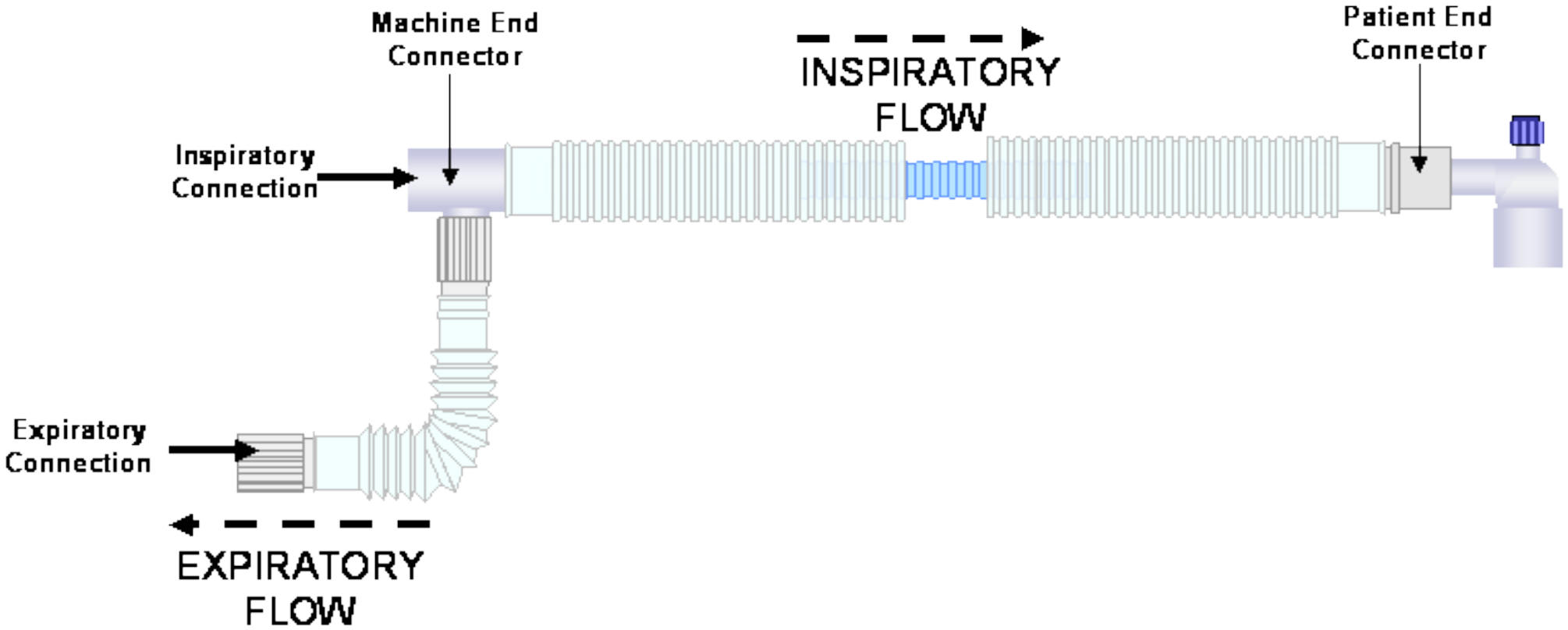
VITAL SIGNS LIMBO-O CIRCUIT



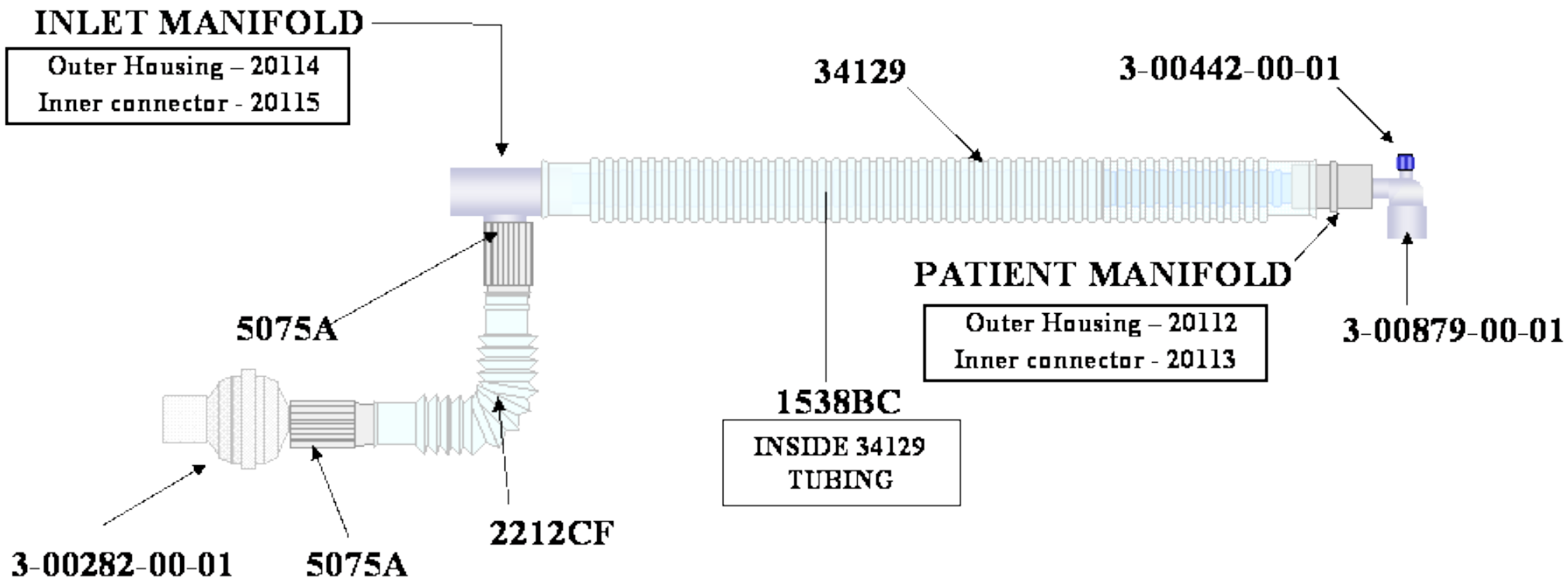
Shown here as a transport system

WESTMED'S COAXIAL CIRCUIT

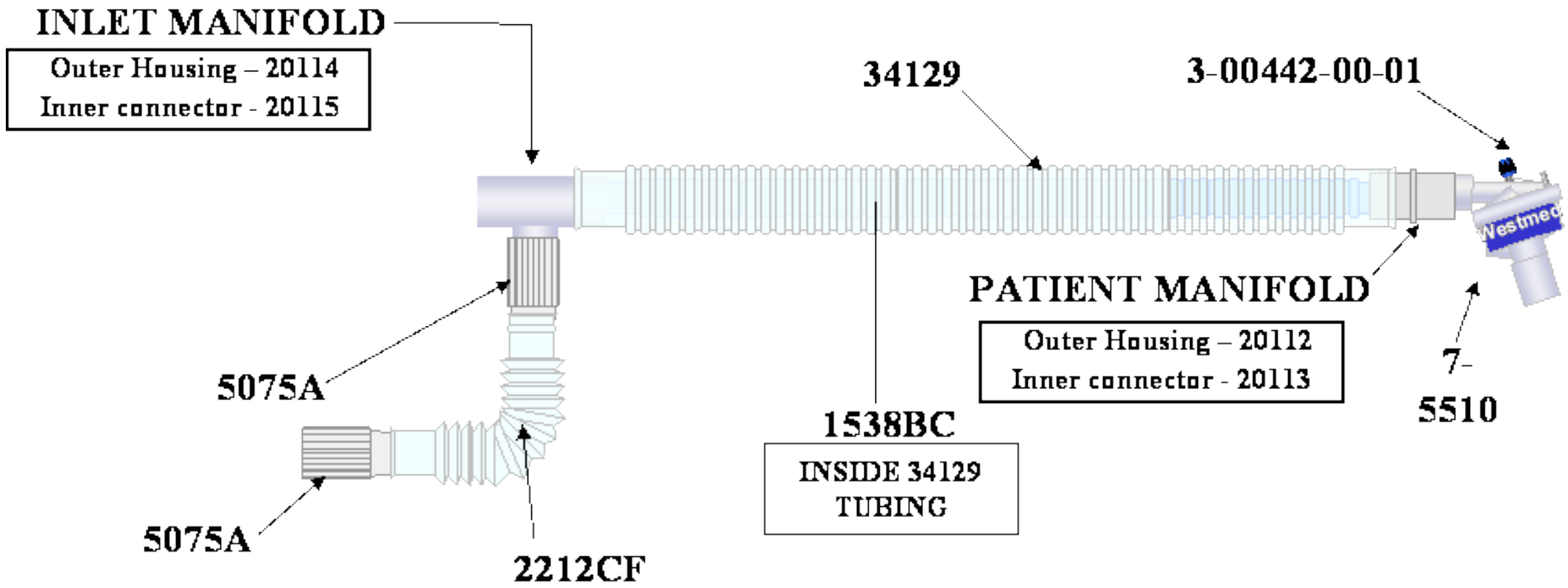
THE UNI-LIM™


Machine End
Connector
INSPIRATORY
FLOW
Patient End
Connector
Inspiratory
Connection
Expiratory
Connection
EXPIRATORY
FLOW

UNI-LIM™ WITH FILTER



UNI-LIM™ WITH HMEF



UNI-LIM™ FEATURES & BENEFITS

- Conventional dual limb circuits may twist between the inspiratory & expiratory limbs. The Uni-Lim® eliminates this as an issue.
- Conventional Circuit's take up more of the OR space than single limb, especially on head and neck cases.
- Mean inspired humidity will rise faster and reach a higher level of humidity in a single limb. Both humidity and temperature of inspired gas will be greater.
- Elimination of the wye at the patient interface.

UNI-LIM™ FEATURES & BENEFITS (CONT.)

- No disconnects of the inner tubing or mixing of gases to increase dead space, therefore no rebreathing of gases.
- No swivel at patient interface to cause leaking of trace gases into Operating Room.
- Uni-Lim is available with an internal Gas Sampling Line (custom) that will allow an even more streamlined anesthesia breathing circuit.

UNI-LIM™ FEATURES & BENEFITS (CONT.)

- Uni-Lim is available in standard Latex Free configurations.

- Uni-Lim can be customized to meet your customer's needs (same custom process and accessories are available as are with the circle anesthesia breathing circuits).

Q & A'S

- *"Our King circuit has a patented coaxial filter. What can you offer me that is comparable?"*

  - King has a patent on a coaxial machine-side filter for its F2 circuit. If you're using the F-Circuit, you can use any machine-side filter affecting the functionality. We recommend a patient-side filter for bi-directional filtration.

Q & A'S

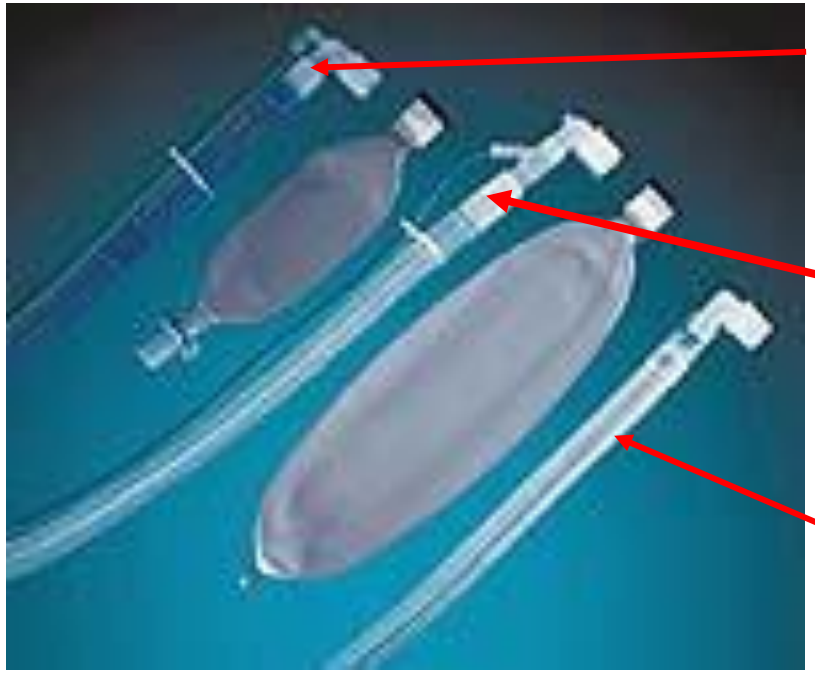
- *"I've got to show a 10% reduction in operating expenses this year. If you can't show me at least this much, even though my circuits are very basic, then we don't have anything to talk about."*
  - Westmed can help you meet your budgetary goals. These saving can come in a variety of forms, including:
    - Fewer SKUs
    - Fewer purchase orders
    - Less time spent modifying equipment
    - Lower disposal costs
    - Lower acquisition costs

NON-REBREATHING SYSTEMS

NON-REBREATHING SYSTEMS

- What's a non-rebreathing system?
  - Non-rebreathing systems have one thing in common: fresh gas is delivered to the patient, then drawn out of the breathing system through the scavenging system.
- Examples?
  - Mapleson D
  - Jackson Rees
  - Coaxial (bains-type)

NON-REBREATHING SYSTEMS

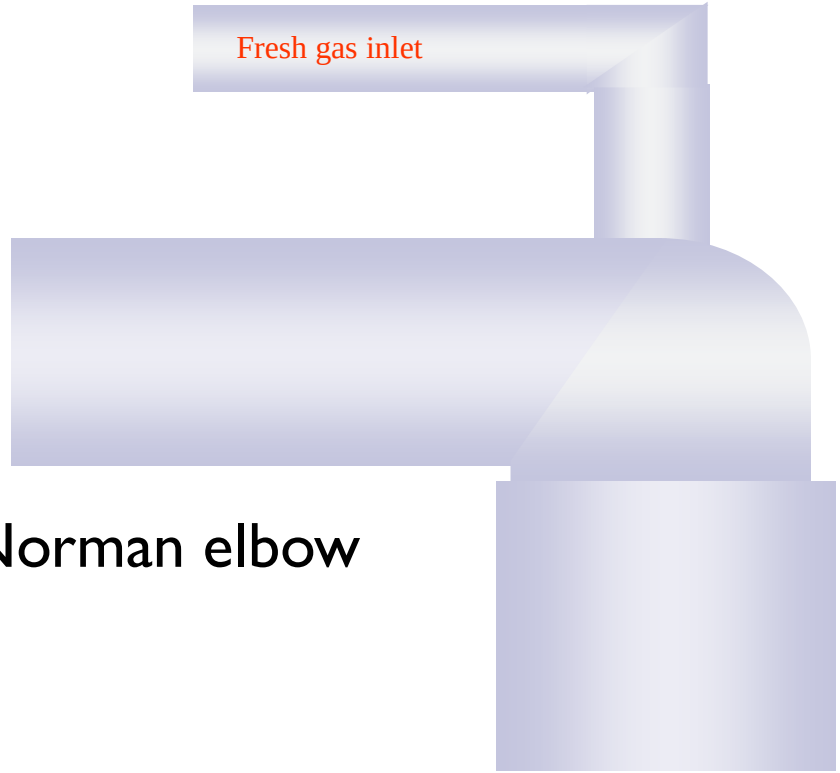


Modified Jackson Rees

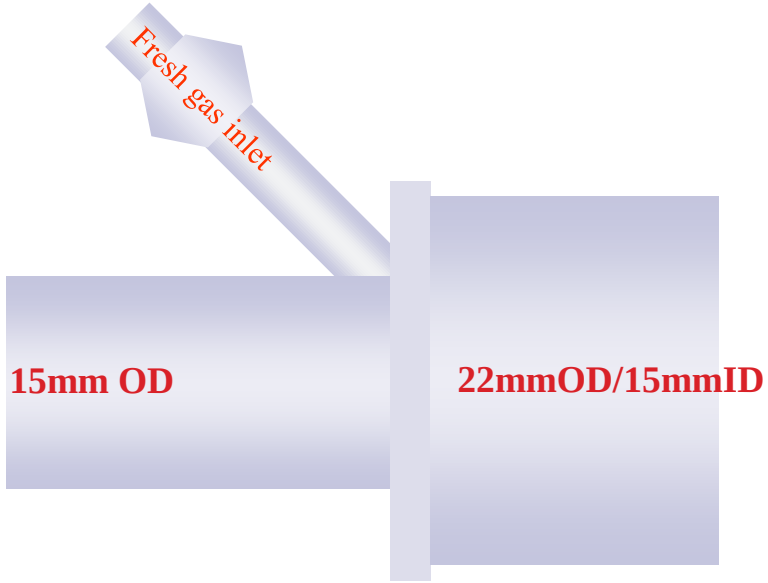
Mapleson D

Coaxial (Bains-type circuit)

BASIC MAPLESON D AND JACKSON REES COMPONENTS

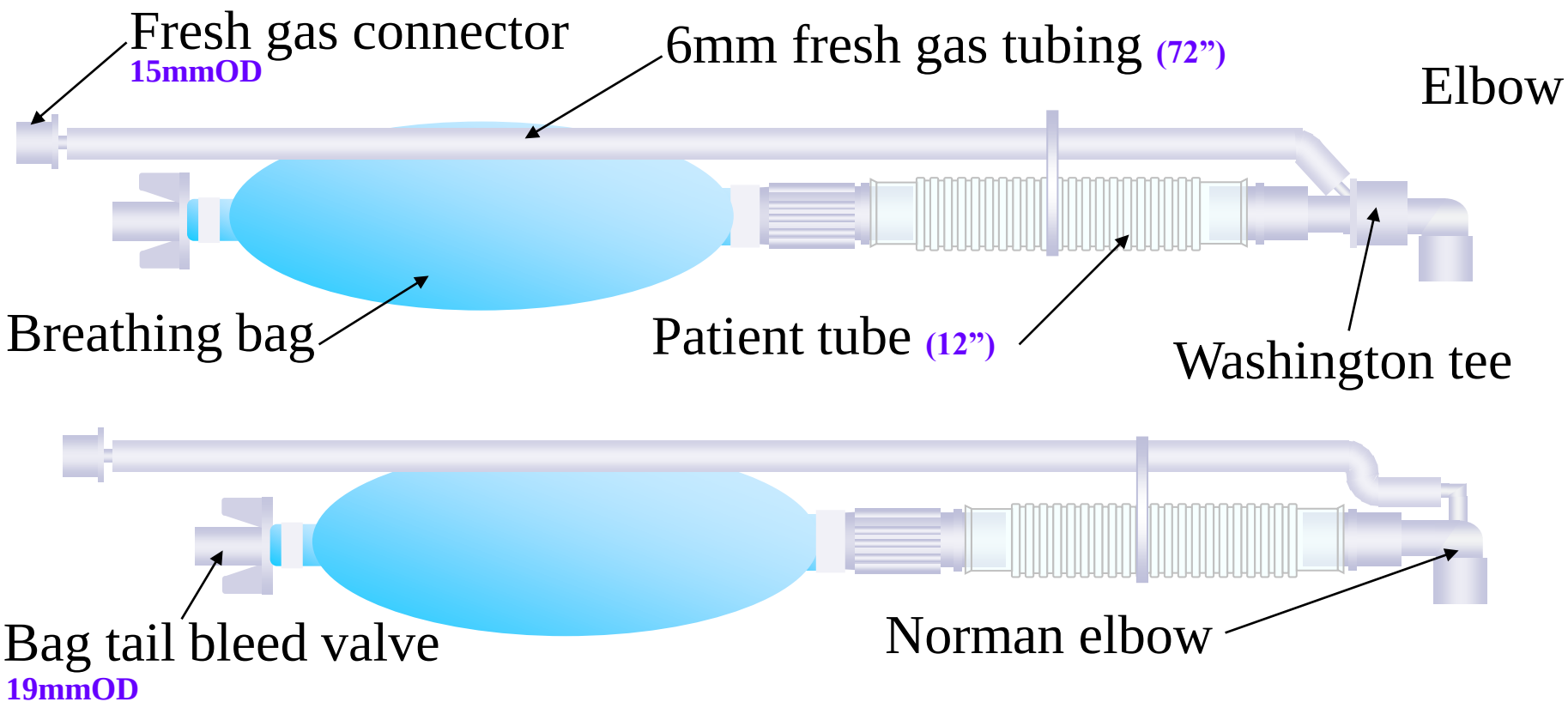


Norman elbow



Washington tee

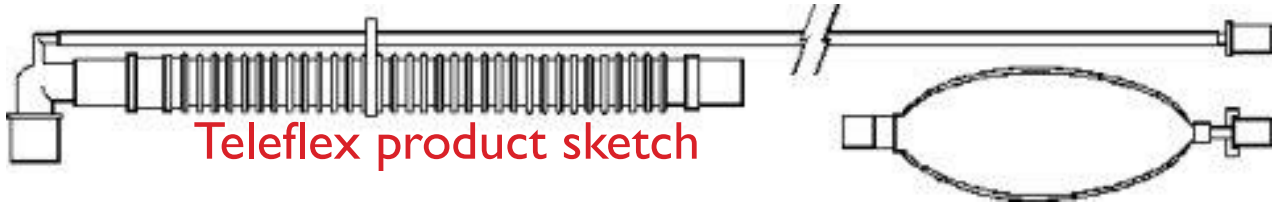
MODIFIED JACKSON REES



MODIFIED JACKSON REES

- What's it used for and why?
  - In anesthesia, it's usually used with children.
    - Better control of inspired gas mixture
    - Better control of dead space
  - Post-operatively, it can be used as an oxygen-powered resuscitation/ventilation device.

COMPETITIVE MODIFIED JACKSON REES SYSTEMS



Teleflex product sketch

King Systems' web site photo

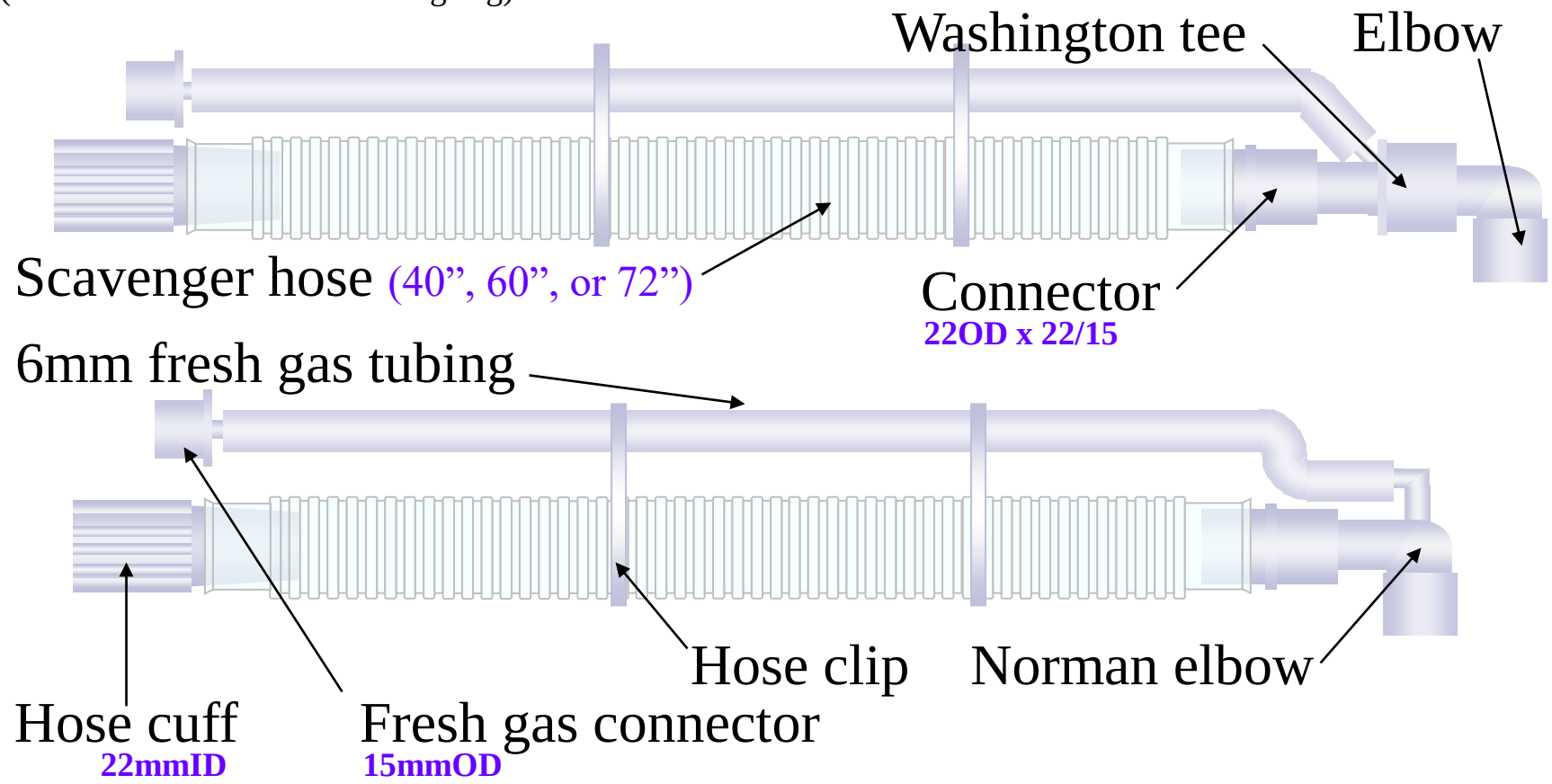
Note proprietary bleed valve with scavenger hose

MAPLESON D

- What's it used for and why?
  - In anesthesia, this system is mainly used with spontaneous respiration
    - At normal (low) flow rates this system creates high rebreathing if the patient has a short expiratory pause or no expiratory pause (i.e. infants)
    - Flows of 2-4 times minute volume are required in controlled or assisted ventilation
    - No patient-machine cross contamination

MAPLESON D

(Circuit shown without breathing bag)

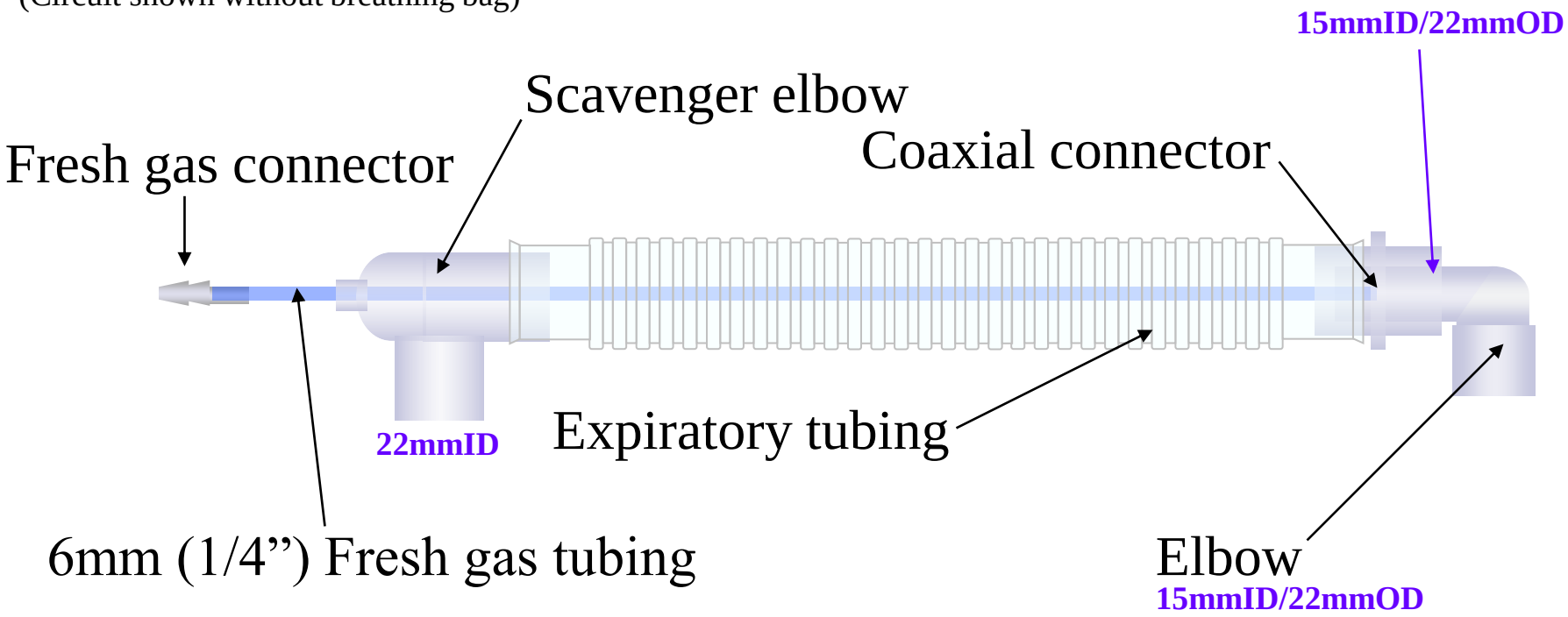


"MAPLESON C" CIRCUIT?

- King Systems offers a Mapleson C circuit, which is also known as a:
  - Waters bag, or
  - ***Hyperinflation*** bag
- It is used for manual ventilation, not for anesthetic gas delivery

COAXIAL (BAINS-TYPE) NONREBREATHING CIRCUIT

(Circuit shown without breathing bag)



COAXIAL (BAINS-TYPE) CIRCUIT

- How is this system used?
  - It is used in exactly the same way as a Mapleson D circuit
  - In fact, the bains-type circuit is nothing more than a Mapleson D circuit with the fresh gas tube run through the inside rather than on the outside.

NON-REBREATHING SYSTEMS

- Advantages
  - Known inspired gas concentrations
  - No soda lime to change
  - Negligible deadspace
  - Almost no resistance
- Disadvantages
  - Expensive to buy & use
  - Environmental pollution
  - Loss of water vapor
  - Loss of body heat

NON-REBREATHING SYSTEMS

- Why wouldn't someone want a filter or an HME on a non-rebreathing circuit? After all, doesn't the patient tend to lose more heat and moisture?
  1 *Gas only travels to the patient -- it doesn't come back to the machine.*
  2 *Yes, more heat and moisture are lost due to higher flows, but an HME isn't going to provide much help, if any.*

SALES PROSPECTING – NON RE-BREATHING (SPECIALTY) CIRCUITS & KITS

Positioning and Niche identification

MAPLESON D

Besides the circuit and anesthesia machine, what else is used during the inhalation of general anesthetic?

Consider the actions that are required by standard.

ASA STANDARDS OF CARE - STANDARD I -

"Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics, and monitored anesthesia care."

ASA STANDARDS OF CARE - STANDARD II -

"During all anesthetics, the patient's oxygenation, ventilation, circulation, and temperature shall be continually evaluated."

Oxygenation = Monitoring with an oxygen analyzer.

Ventilation = Monitoring qualitative clinical signs may be adequate, but quantitative measurement is encouraged.

Circulation = Constant ECG monitoring, BP every 5 minutes. At least one other method must be used: chest auscultation, intra-arterial pressure tracing, ultrasound peripheral pulse monitoring, or pulse oximetry.

Temperature = A means of continuous monitoring must be readily available.

ASA STANDARDS OF CARE

- What does all of this mean?

Opportunity

The requirement to monitor all of these conditions means that other consumables, in addition to the breathing circuit, will be needed by the anesthesia clinician.

ASA STANDARDS OF CARE

- What kinds of consumables might be needed, besides the circuit?
  - Arterial blood gas syringes **(Ventilation)**
  - End tidal CO2 lines **(Ventilation)**
  - Disposable BP cuffs **(Circulation)**
  - ECG electrodes **(Circulation)**
  - Pulse oximeter probes **(Circulation)**
  - Esophageal temp probes **(Temperature)**
  - Forehead temp strips **(Temperature)**

ANESTHESIA ACCESSORIES

- How do I know what to include in a kit?

  Observe.

  - Watch what the clinicians use, then determine what would be the best combination of products to meet the majority of their needs.

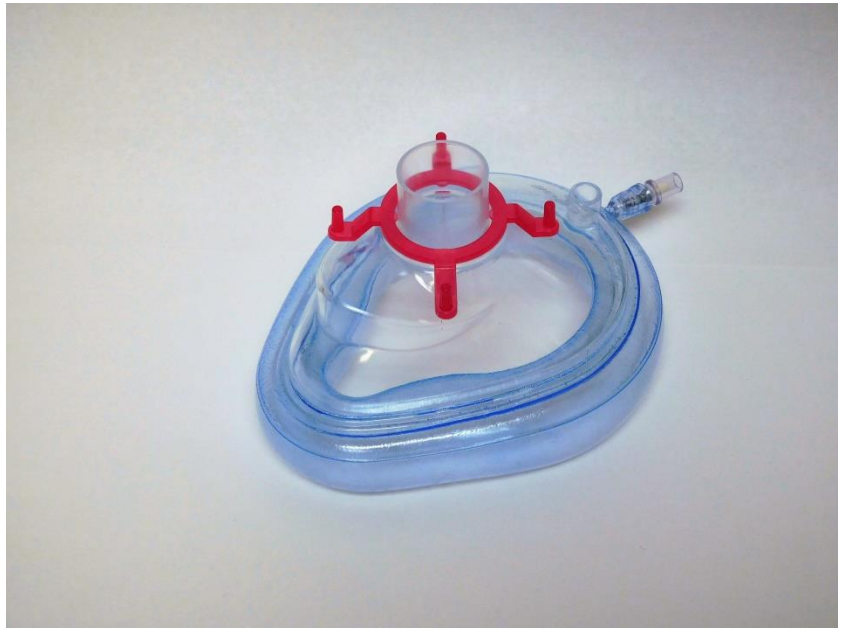
ANESTHESIA ACCESSORIES

- Sold as part of an anesthesia circuit kit or as a stand-alone, packaged item:
  - Face masks
  - Filters and HMEs
  - Breathing bags
  - Sampling/Monitoring lines
  - Flex extenders
  - Oral airways

ANESTHESIA ACCESSORIES

Disposable Face Masks

- 7700-Series (Replaces 9700 Series)
  - Blow molded cushion for soft, highly-elastic feel.
  - Exceptional low-pressure seal.
  - Clear faceplate for unobstructed patient visualization



CE

ANESTHESIA ACCESSORIES

CE

Disposable Face Masks

- 800-Series (No Valve)
  - Soft, blow-molded cushion for highly economical, all-purpose use throughout the hospital.
  - Crystal-clear face plate
  - High nose clearance

ANESTHESIA ACCESSORIES

900 Series Face Masks

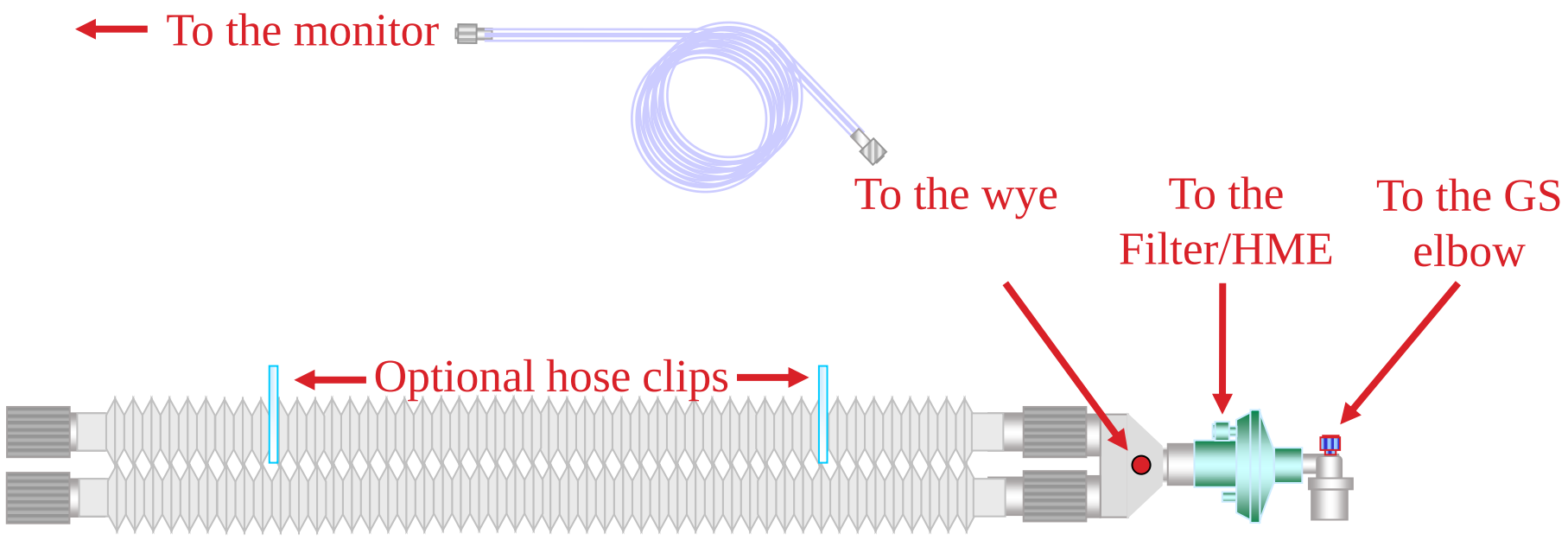
Disposable Face Masks

- 900-Series
  - Soft thin light blue bladder which is pliable and forms a perfect seal

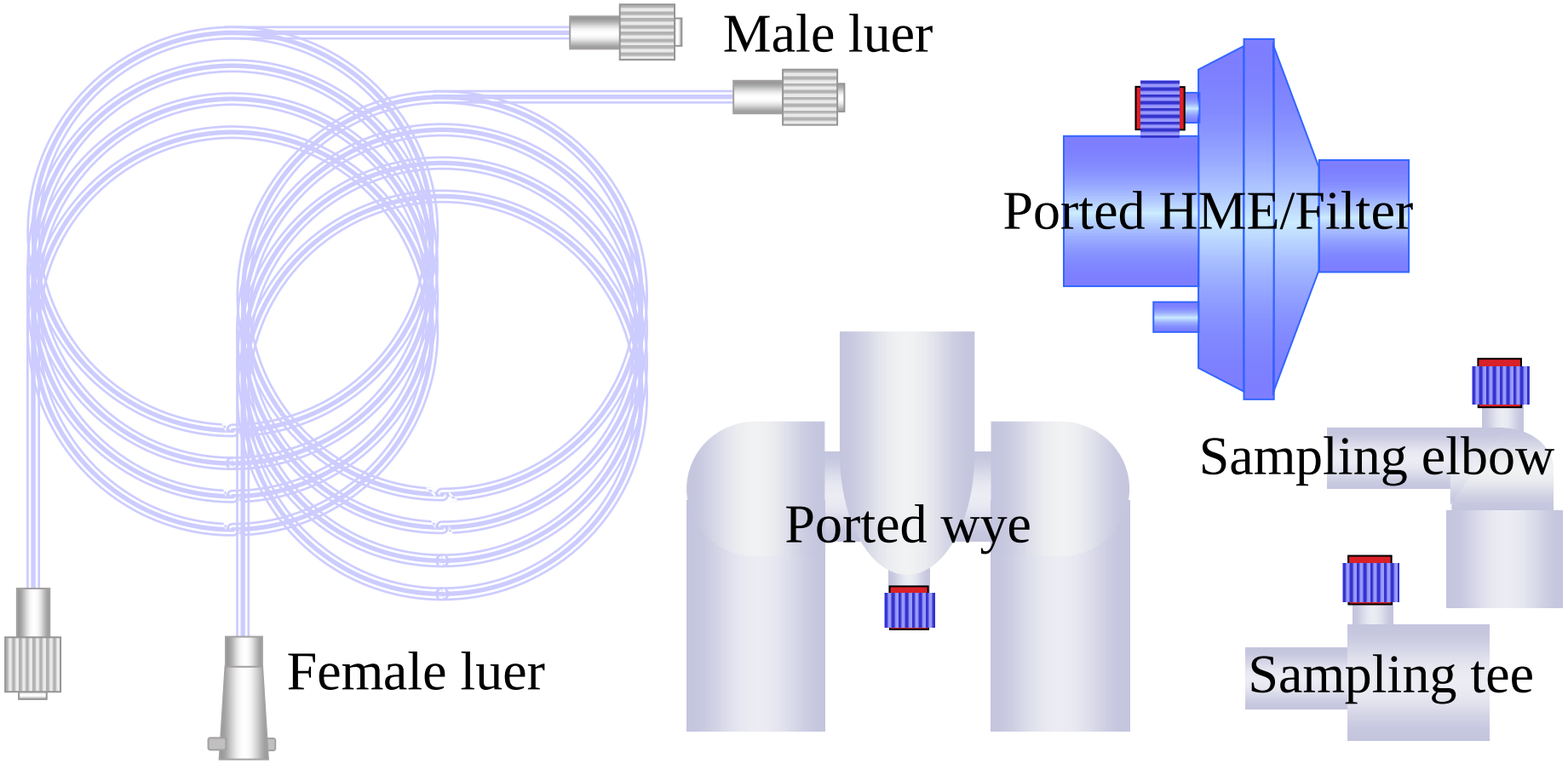
GAS SAMPLING LINES

- Things to know about gas monitoring lines
  - Different monitors can require different line specifications:
    - Male x Male luer
    - Female x Male luer
    - Inner diameters; 0.060” 0.050” 0.047” 0.040”
  - Multi-Gas monitors often require *co-extruded* (PE, PVC) monitoring lines.

CONVENTIONAL SAMPLING LINE ATTACHMENT



GAS SAMPLING OPTIONS



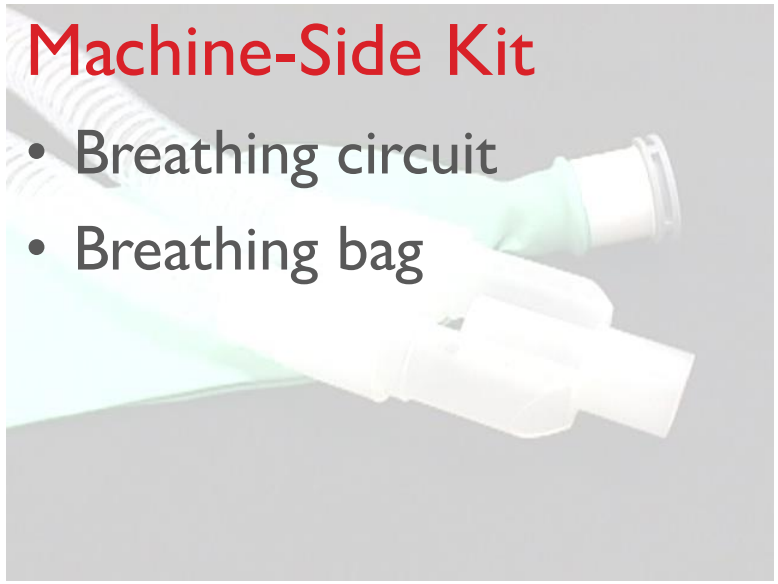
MULTI-USE BREATHING CIRCUITS

MULTI-USE BREATHING SYSTEMS

What does a Multi-Use System Include?

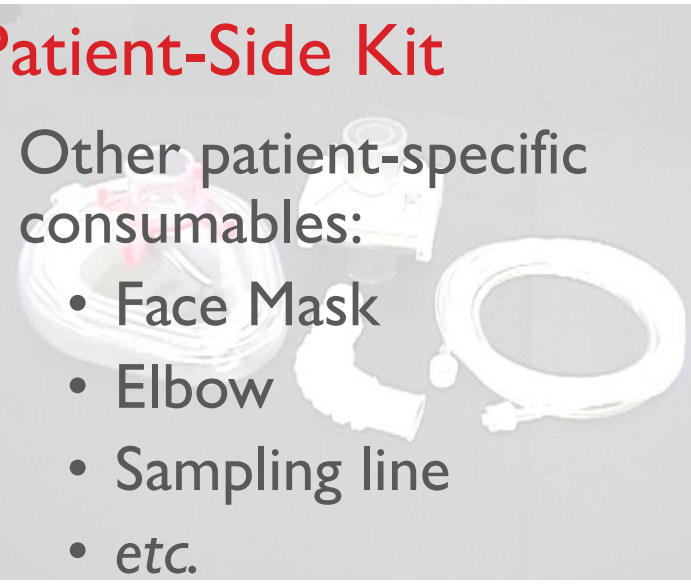
Machine-Side Kit

- Breathing circuit
- Breathing bag



Patient-Side Kit

- Other patient-specific consumables:
  - Face Mask
  - Elbow
  - Sampling line
  - *etc.*

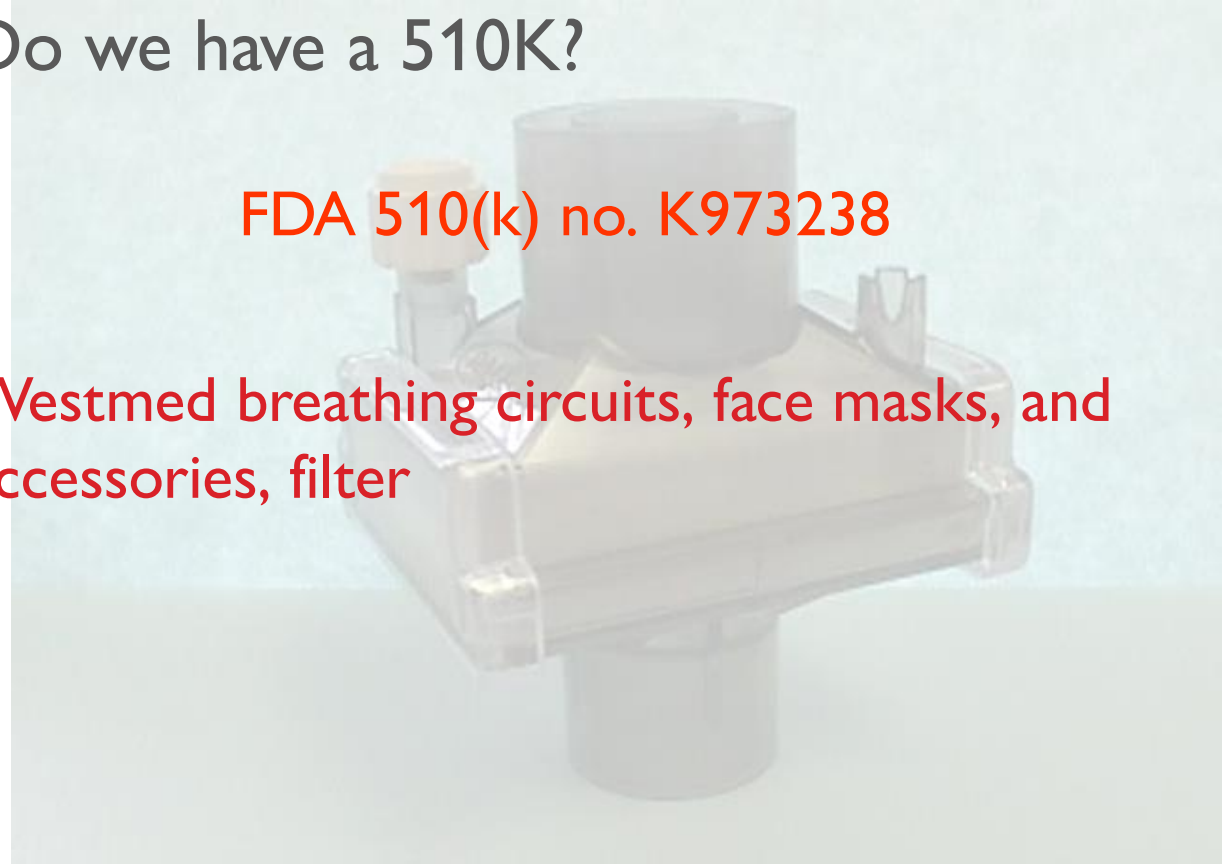


MULTI-USE BREATHING SYSTEMS

- How does the system work?
  - One machine-side kit is used for up to 24 hours.
  - Patient-side kits are changed out between cases.
- What's in the machine-side kit?
  - Wye, tubing, and breathing bag.
- What's in the patient-side kit?
  - Filter
  - Anything else the customer wants.

MULTI-USE BREATHING SYSTEMS

- Do we have a 510K?



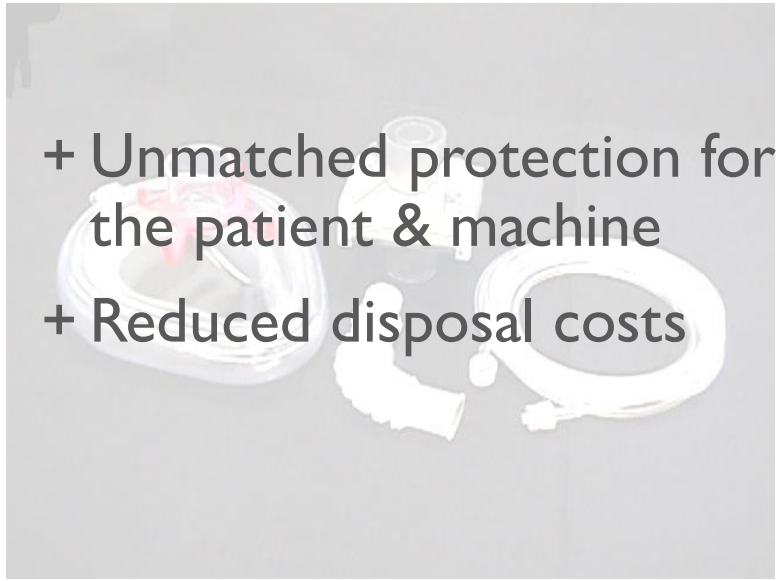
FDA 510(k) no. K973238

Westmed breathing circuits, face masks, and accessories, filter

MULTI-USE BREATHING SYSTEMS

What are the advantages of the Multi-Use System?

+ No need to reprocess circuits or accessories
+ Lower per-patient costs
+ Reduced inventory space requirements

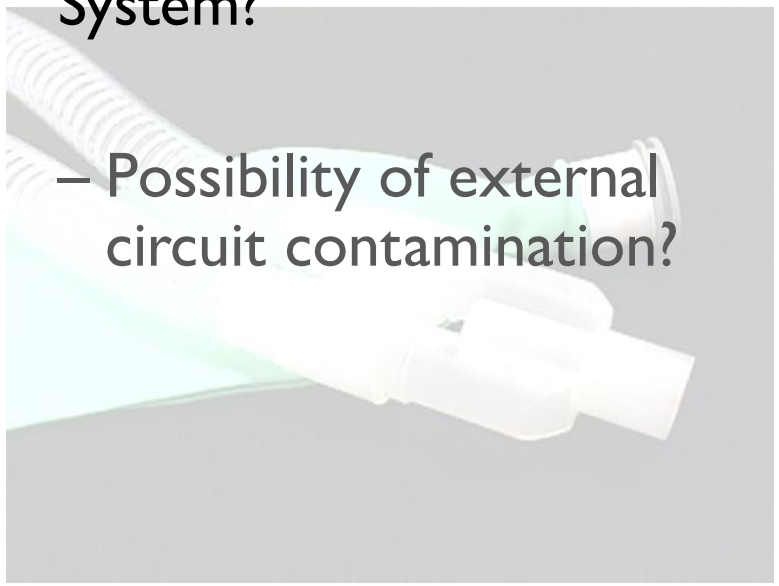


+ Unmatched protection for the patient & machine
+ Reduced disposal costs

MULTI-USE BREATHING SYSTEMS

What are the potential disadvantages of a Multi-Use System?

– Possibility of external circuit contamination?



HOW DO I GET CUSTOM CIRCUITS?

- Customs done through Build a Circuit
- All Build a Circuit Samples processed through Paula Lynch in Tucson. All new product code requests come to Kim Reisenauer.
- Always include as much information as possible

LET'S BUILD A CUSTOM CIRCUIT

WHAT HAPPENS WHEN MY CUSTOMER IS READY TO PURCHASE A CUSTOM CIRCUIT?

- All custom circuits require a $2000 minimum order
- An agreement must be signed by the customer in order for Westmed to stock a custom circuit
- All circuits require a customer signature prior to a part number being assigned

CUSTOM PRODUCT AGREEMENT

- Distributors are required to sign agreement
  - Opportunity to uncover new business
  - Must have current distributors sign agreement
- Minimize inventory issues
  - Westmed is exposed to inventory that is custom to a particular customer…unable to sell to anyone else
  - Custom products mean higher production costs

SPECIAL PRICING

- Master, General and List Pricing will be entered for all custom product
    - Makes product available to everyone
    - Expands product line
- You must submit special pricing for any pricing lower then Master Distributor