

# ***Pre-Assembled Cardiopulmonary Bypass Circuits — An Innovative Utilization of Evolving Technology***

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## ***Abstract***

With the recent Federal Drug Administration approval of preassembled circuits for percutaneous bypass, a new era of safety, cost effectiveness and time management has become possible.

By utilizing this new technology in a traditional heart/lung circuit, it is now possible to have a cardiopulmonary bypass circuit available for pre set up that meets long term sterility requirements, reduces the opportunity of contamination, addresses the situation of cancelled procedures, and allows for the heart/lung machine to be "ready" more expeditiously.

All of this is achieved with a cost factor of less than the individual components of a bypass circuit.

## ***History***

For 38 years the use of CPB has been used to support patients undergoing cardiothoracic surgical procedures. The materials and techniques first used by Gibbon in 1953<sup>1</sup> are vastly different from the standards of today.

During this period of time many advances have been achieved. Some of which were the development of PVC type tubing, antifoam agents for reusable oxygenators (filming and bubble) disposable bubbler oxygenators, disposable connectors, improved filtration devices, and improved gas flow meters and oxygen/air blenders.

During the development of these materials techniques were also in a constant state of change and indeed demanded many of these material improvements to be made.

Also the concept of custom tubing packs was developed and has now become the accepted standard of care. Commercial assembly of tubing packs offers the perfusionist many benefits, including a custom pack developed especially for an individual cardiac center, proper sterility of components, inventory control, less man hours required, therefore resulting in cost effectiveness, and ease of assembly of the complete circuit.

Further developments have been sought and achieved

due to emergent situations. One such product was developed to be utilized in emergency femoral-femoral bypass procedures.<sup>2,3,4</sup> (CPS® is a Registered Trademark of C.R. Bard, Inc.)

This product was developed to aid assisted circulation and became known as CPS®.<sup>5</sup> This system utilizes an assembly of components which includes: tubing, connectors, accessories, and an oxygenator. A very important aspect of this product is the concept of pre-assembly and unit sterilization of the components.

## ***Discussion***

Sterile products supplied by FDA approved manufacturing facilities must meet extremely stringent requirement. The certainty of sterilization capability must be less than 1 / 1,000,000 probability of bacterial survival.<sup>6</sup> The products that are utilized in an extracorporeal circuit have the following statement attached "contents sterile unless package is opened or damaged." The preconnected extracorporeal circuit further protects the continued integrity of the circuit by the following:

- (1) All connections (except three {3}) are pre-assembled. This does not allow room air to enter the system.
- (2) Connections are solvent bonded therefore reducing the possibility of separation during use.
- (3) The "up" packs continue to remain sterile for up to 21 days<sup>7,8</sup> after removal from outside plastic package.
- (4) Reduces probability of contamination during assembly of extracorporeal circuit.

### ***Advantages:***

- (1) Initiation of bypass time reduced
- (2) Reduced probability of contamination
- (3) Increased safety of assembly
- (4) Eliminates "waste of circuit" if procedure is not performed
- (5) Guarantees proper assembly of circuit by unfamiliar perfusion personnel (outside perfusion coverage)

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## Summary

By continuing the evolution of perfusion techniques we have expanded the original concept of a pre-assembled bypass circuit.

By further development of this initial principle, we have created a total body extracorporeal circuit which can be utilized for cardiovascular surgical procedures.

We find this circuit to be especially useful in the anticipation of standby or other emergent procedures.

The circuit can be processed from "standby" to "activation" in approximately five (5) minutes, including a three (3) minutes "CO<sub>2</sub> flush."

The final sequence consists of:

- (1) Connect cardiotomy reservoir outlet to venous bag inlet
- (2) Insert the Biohead
- (3) Insert O<sub>2</sub> line from oxygenator to gas source
- (4) Attach purge lines
- (5) Attach blood gas monitoring lines
- (6) Place appropriate tubing clamps
- (7) Attach and begin CO<sub>2</sub> flush
- (8) Apply priming solution and medications to cardiotomy reservoir
- (9) Attach H<sub>2</sub>O to heat exchanger and recirculate
- (10) End CO<sub>2</sub> flush, disconnect
- (11) Remove O<sub>2</sub> outlet cap from oxygenator
- (12) Remove appropriate tubing clamps
- (13) Recirculate priming solution Additional items (cardioplegia, cooling device, etc) can be added after initiation of cardiopulmonary bypass if needed.

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8. Perkins JJ: *Principles and methods of sterilization in health sciences*, ed. 2, 1982, Springfield, IL, Charles C. Thomas, Publisher.

**FIGURE 1**

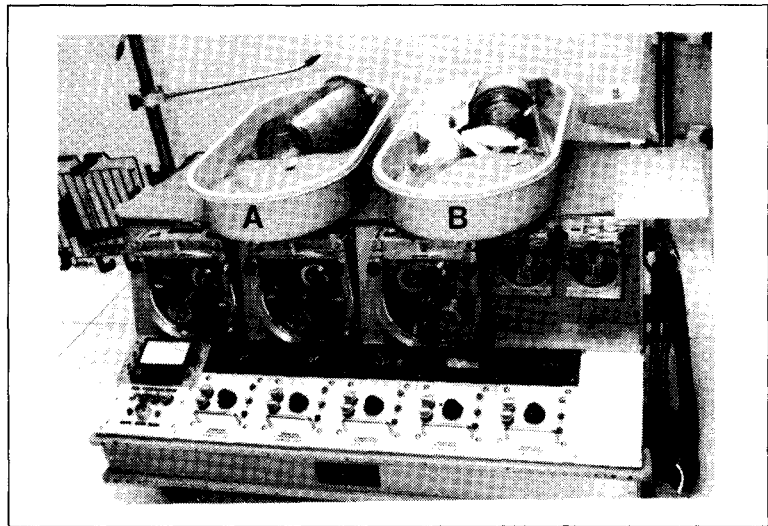
The pre-assembled circuit consists of two (2) tubing pack trays<sup>a</sup>. Tray A (Right) and Tray B (Left). Tray A consists of the vent and sucker lines of which the "up" portion is double sash wrapped with the exiting tubing securely attached to the wrap with tape. The vent and sucker lines are attached to the cardiotomy reservoir<sup>b</sup>.

Tray B consists of the A/V loop, venous reservoir bag<sup>c</sup>, oxygenator<sup>d</sup>, arterial filter<sup>e</sup>, and all other tubing<sup>f</sup> necessary to complete the extracorporeal circuit.

a-d Bentley Laboratories, Inc., Irvine, California

e Pall Biomedical Products, East Hills, New York

f Norton-Performance Plastics, Akron, Ohio



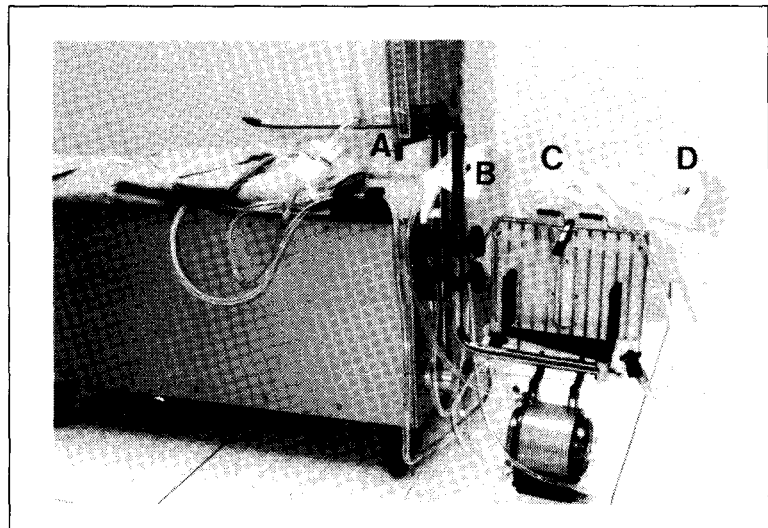
**FIGURE 2**

The extracorporeal circuit is placed in the appropriate positions on the heart/lung machine.

The internal surfaces and the "up" portions remain sterile (double sash wrapped).

The connection point of the cardiotomy reservoir remains capped and sterile (A). The connecting tubing (cardiotomy reservoir outlet (B), Biohead<sup>g</sup> inlet (C) and outlet (D) remains sterile in sealed packages.

g Medtronic Blood Systems, Inc., Anaheim, California



**FIGURE 3**

The connections of the cardiotomy reservoir (A) and the Biohead inlet (B), outlet (C) are completed. Auxillary items are then incorporated into the extracorporeal circuit - purge lines<sup>h</sup> (D), blood gas monitoring lines<sup>i</sup> (E), heat exchanger water inlet<sup>j</sup> (F) and outlet (G), cardioplegia circuit<sup>k</sup> (H), and topical cooling device<sup>l</sup> (I).

h Medtronic Blood System, Inc., Anaheim, California

i Mallinckrodt Sensor Systems, Ann Arbor, Michigan

j Cincinnati Sub Zero, Cincinnati, Ohio

k Shiley, Inc., Irvine, California

l Cobe Laboratories, Arvada, Colorado

