For more information, contact:

For Best Practices in Blood Management
**Reduced Activation:**

- **Minimizing blood exposure to foreign surface area and blood-air interface throughout the procedure reduces the incidence of SIRS**
- The inflammatory response to cardiopulmonary bypass causes by the blood-air interface and blood exposure to foreign surfaces has long been recognized as a major clinical issue that affects outcomes in cardiac surgery. Postoperative complications vary but can include renal, pulmonary, cardiac and central nervous system dysfunction. The ROCSafe system has the best activation rate available: 0% vs 3% for a conventional circuit.

**Blood Conservation:**

- **Reducing hemolysis by minimizing prime volume decreases the need for blood transfusions**
- The ROCSafe system has a prime volume of 665 mL, the lowest prime volume of any commercially available reduced prime circuit. The user can virtually eliminate prime volume by using retrograde autologous priming (RAP) techniques.
- Table 1: Impact of Priming Volume on Hematocrit Levels. The calculations show how reducing the prime volume decreases the hematocrit for an 85 kg patient with a starting hematocrit of 35.

**No Added Heparin:**

- **Polymer-based surface coating is safe for heparin-intolerant patients**
- The ROCSafe™ Hybrid Perfusion System is coated with XCoating™, Terumo’s own biopassive polymer surface coating that reduces platelet activation and protein denaturing. Studies have shown that using XCoating helps reduce bleeding and SIRS in cardiac surgery patients undergoing cardiopulmonary bypass.

**Reduced Prime:***

- The ROCSafe system has 45% less surface area than a conventional circuit. Should the clinical team need to add a reservoir — during any time during a procedure. The core configuration of the ROCSafe system has 45% less surface area than a conventional circuit. The user can virtually eliminate prime volume by using retrograde autologous priming (RAP) techniques.
- Table 1: Impact of Priming Volume on Hematocrit Levels. The calculations show how reducing the prime volume decreases the hematocrit for an 85 kg patient with a starting hematocrit of 35.

**Reduced Risk of Gaseous Microemboli:**

- **Safety features prevent air from reaching patient**
- As the cardiac surgery community continues to focus on blood management strategies, the ROCSafe system is designed to offer frequent circuit changes during any cardiopulmonary bypass procedure:
  - **Baseline CAVI**
  - **CAVI valve combinations**
  - **Perfusion-assisted beating heart**
  - **Complex vascular procedures**

- The ROCSafe system features anti-embolism safety features of the Terumo® Advanced Perfusion System 1 to actively trap GME as they enter the circuit, preventing them from reaching the patient.

**Air Removal:**

- The ROCSafe™ Hybrid Perfusion System uses a centrifugal pump to engage Coast® Response System 1.
- Air bubble detector sends a signal to centrifugal pump to engage Coast® Response System 1.
- Air bubble detector detects venous air bubble trap.
- Venous occluder closes.
- Centrifugal pump slows to 1500 rpm and the core configuration.
- Clinician removes air from venous bubble trap.
- Venous line.
- Reservoir accessory kit.
- Optional flexible roller pump.

**Reservoir Accessory Kit:**

- Optional hardshell reservoir accessory kit.

**Impact of Priming Volume on Hematocrit Levels**

<table>
<thead>
<tr>
<th>Prime Volume (mL)</th>
<th>Hgt Ft</th>
<th>End Fluids</th>
<th>Primed Ht</th>
<th>Scrubbing Time</th>
<th>Restricted BC</th>
</tr>
</thead>
<tbody>
<tr>
<td>2500</td>
<td>40%</td>
<td>40%</td>
<td>27%</td>
<td>55%</td>
<td>40%</td>
</tr>
<tr>
<td>1500</td>
<td>40%</td>
<td>40%</td>
<td>27%</td>
<td>55%</td>
<td>40%</td>
</tr>
<tr>
<td>1000</td>
<td>40%</td>
<td>40%</td>
<td>27%</td>
<td>55%</td>
<td>40%</td>
</tr>
<tr>
<td>750</td>
<td>40%</td>
<td>40%</td>
<td>27%</td>
<td>55%</td>
<td>40%</td>
</tr>
<tr>
<td>500</td>
<td>40%</td>
<td>40%</td>
<td>27%</td>
<td>55%</td>
<td>40%</td>
</tr>
<tr>
<td>250</td>
<td>40%</td>
<td>40%</td>
<td>27%</td>
<td>55%</td>
<td>40%</td>
</tr>
</tbody>
</table>

**No Added Heparin:**

- Today, the majority of cardiac centers choose polymer-based coating over heparin-based coatings because polymer coatings have shown to provide the same or better benefits without the risk of a patient heparin reaction.
- The ROCSafe™ Hybrid Perfusion System is coated with XCoating™, Terumo’s own biopassive polymer surface coating that reduces platelet activation and protein denaturing. Studies have shown that using XCoating helps reduce bleeding and SIRS in cardiac surgery patients undergoing cardiopulmonary bypass.
A successful hybrid blends the best features of two separate technologies. It extends what is possible.

Think of the hybrid engine that switches between gas and electric power to reduce emissions and improve mileage — while maintaining performance.

Now imagine a perfusion system that seamlessly switches between circuit configurations during a case to reduce the potential complications of cardiopulmonary bypass while maintaining safe and reliable perfusion.

That’s the ROCSafe™ Hybrid Perfusion System.

The ROCSafe system is an intuitively designed, ergonomic system that allows clinical teams to practice today’s best blood management strategies during any cardiopulmonary bypass procedures:

- Routine CABG
- CABG valve combinations
- Affinity-assisted bypass heart
- Complex vascular procedures
- Reoperations
- Elective protocols
- Evolving protocols
- Conditions requiring unique bypass strategies

As the cardiac surgery community continues to focus on blood management strategies, the ROCSafe system can assist to decrease activation, decrease hemodilution and reduce the need for blood transfusions. The ROCSafe system continues to provide the high level of safety that has been demonstrated when using Terumo® products.

Reduced Risk of Gaseous Microemboli: Safety features prevent air from reaching patient

Studies suggest that the presence of gaseous microemboli (GME) in the perfusion circuit is a clinical concern; some have documented an association between GME and neurological damage or other organ failures after cardiac surgery.1, 2

The ROCSafe system has proven more effective at trapping and removing air than a traditional perfusion circuit. It utilizes the exclusive safety features of the Terumo® Advanced Perfusion System 1 to actively trap GME as they enter the circuit, preventing them from reaching the patient.3

Reduced Prime:

The ROCSafe system has 45% less surface area than a conventional circuit. Should the clinical team need to add a reservoir — during any time during a procedure. The core configuration is a closed, reservoir-less system with 45% less surface area than a conventional circuit. The ROCSafe system allows clinical teams to minimize blood exposure to foreign surface area throughout the procedure reduces the incidence of SIRS.

The ROCSafe system continues to provide the high level of safety that has been demonstrated when using Terumo® products. Numerous studies have documented that reducing hemodilution during cardiopulmonary bypass reduces the need for blood transfusions and thereby reduces morbidity and mortality.4

Reduced Activation:

The ROCSafe system reduces activation during CPB by using retrograde autologous priming (RAP) techniques. The calculations show how reducing the prime volume decreases the hematocrit for an 85 kilogram patient with a starting hematocrit of 35.

Numerous studies have documented that reducing hemodilution during cardiopulmonary bypass reduces the need for blood transfusions and thereby reduces morbidity and mortality.5

No Added Heparin:

Because polymer coatings have shown to provide the same or better benefits without the risk of a patient heparin reaction.6 Polymer-based surface coating is safe for heparin intolerant patients.

X coating

Polymer-based surface coating is safe for heparin intolerant patients.

The ROCSafe system is coated with XCoating™ Terumo’s own heparin-free polymer surface coating that reduces platelet activation and protein denaturing. Studies have shown that using XCoating helps reduce bleeding and SIRS in cardiac surgery patients undergoing cardiopulmonary bypass.7

Reduced GME:

ROCSafe passes 40% fewer GME than conventional circuits.

The ROCSafe system has proven more effective at trapping and removing air than a traditional perfusion circuit. The ROCSafe system allows clinical teams to minimize blood exposure to foreign surface area at every time during procedures.

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Baseline Heparinization

750 IU/kg

Table 1

Impact of Priming Volume on Hematocrit Levels

<table>
<thead>
<tr>
<th>Prime Volume (mL)</th>
<th>High Exp</th>
<th>Low Exp</th>
<th>Priming Exp</th>
<th>Hematocrit Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>265</td>
<td>41%</td>
<td>40%</td>
<td>41%</td>
<td>35%</td>
</tr>
<tr>
<td>195</td>
<td>40%</td>
<td>41%</td>
<td>41%</td>
<td>35%</td>
</tr>
<tr>
<td>140</td>
<td>94%</td>
<td>92%</td>
<td>93%</td>
<td>35%</td>
</tr>
<tr>
<td>665</td>
<td>69%</td>
<td>69%</td>
<td>69%</td>
<td>35%</td>
</tr>
</tbody>
</table>

The calculations show how reducing prime volume decreases the hematocrit for an 85 kilogram patient with a starting hematocrit of 35.

Reduced Activation:

The ROCSafe system reduces activation during CPB by using retrograde autologous priming (RAP) techniques. The calculations show how reducing the prime volume decreases the hematocrit for an 85 kilogram patient with a starting hematocrit of 35.

ROCSafe™ Hybrid Perfusion System

- Air Removal
- Air bubble detector detects venous air
- Air bubble detector alerts user to check central venous to engage Cannüla® Heparinizer
- Central venous occlusion in 1000 amp needle valve and vena cava occluder
- Optional reservoir or air venous bypass trap
- Clinician vascular system

Reduced Activation:

Minimizing blood exposure to foreign surface area and blood-air interface throughout the procedure reduces the incidence of SIRS.

The inflammatory response to cardiopulmonary bypass caused by the blood-air interface and blood exposure to foreign surfaces has long been recognized as a major clinical issue that affects outcome in cardiac surgery. Post operative complications vary but can include renal, pulmonary, cardiac and central nervous system dysfunction that can lead to prolonged ICU stay, ventilation time, the need for additional inotropic support and the associated costs and risks.9

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The ROCSafe system is an intuitively designed, ergonomic system that allows clinical teams to practice today’s best blood management strategies during any cardiopulmonary bypass procedure:

- Routine CABG
- CABG/valve combinations
- Complete vascular procedures
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As the cardiac surgery community continues to focus on blood management strategies, the ROCSafe system can assist in decreasing activation, decreasing hemodilution and reducing the need for blood transfusions. The ROCSafe system continues to provide the highest level of safety that has been demonstrated when using Terumo® products.

Reduced Risk of Gaseous Microemboli:
Safety features prevent air from reaching patient

Studies suggest that the presence of gaseous microemboli (GME) in the perfusion circuit is a clinical concern, some have documented an association between GME and neurological damage or other organ failures after cardiac surgery.1 The ROCSafe system has proven more effective at trapping and removing air than a traditional perfusion circuit. It utilizes the exclusive safety features of the Terumo® Advanced Perfusion System 1 to actively trap GME as they enter the circuit, preventing them from reaching the patient.3

Reduced GME:
ROCSafe passes 40% fewer GME than conventional circuits.

Figure 1

Reduced Prime:
ROCSafe System Prime 665 mL

Typical Prime 2 L

Figure 3

Reduced Activation:
Minimizing blood exposure to foreign surface area and blood-air interface throughout the procedure reduces the incidence of SIRS.

The inflammatory response to cardiopulmonary bypass causes both the blood-air interface and blood exposure to foreign surfaces, which has long been recognized as a major clinical issue that affects outcome in cardiac surgery. Post operative complications vary but can include renal, pulmonary, cardiac and central nervous system dysfunction that can lead to prolonged ICU stay, ventilation time, the need for additional inotropic support and the associated costs and risks.4

The ROCSafe system allows clinical teams to minimize blood exposure to foreign surface area at every time during bypass.

The core configuration is a closed, oxygenator-less system with 6% less surface area than a conventional circuit. Should the clinical team need to add a reservoir — during any time of the procedure such as a cardioplegia trigger for instance — it can be done with a simple click.

Blood Conservation:
Reducing hematocrit by minimizing prime volume decreases the need for blood transfusions

Impact of Priming Volume on Hematocrit Levels

<table>
<thead>
<tr>
<th>Prime Volume (mL)</th>
<th>Hgb Vol (%)</th>
<th>Red Cell Vol/Ph (Liters)</th>
<th>Starting Hct</th>
<th>Target Hct</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 L</td>
<td>40%</td>
<td>0.4</td>
<td>37%</td>
<td>27%</td>
</tr>
<tr>
<td>1.6 L</td>
<td>40%</td>
<td>0.3</td>
<td>41%</td>
<td>31%</td>
</tr>
<tr>
<td>1.4 L</td>
<td>40%</td>
<td>0.3</td>
<td>42%</td>
<td>32%</td>
</tr>
<tr>
<td>1.2 L</td>
<td>40%</td>
<td>0.2</td>
<td>43%</td>
<td>34%</td>
</tr>
<tr>
<td>1 L</td>
<td>40%</td>
<td>0.2</td>
<td>44%</td>
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The calculations show how reducing the prime volume decreases the hematocrit level by using retrograde autologous priming (RAP) techniques.

Numerous studies have documented that reducing hemodilution during cardiopulmonary bypass reduces the need for blood transfusions and thusly reduces morbidity and mortality.5

The core configuration of the ROCSafe system has a prime volume of 665 mL, the lowest prime volume of any commercially available reduced prime circuit. The user can virtually eliminate prime volume by using autologous or autologous priming (RAP) techniques.

No Added Heparin:
Polymer-based surface coating is safe for heparin intolerant patients

Today, the majority of cardiac centers choose polymer-based coating over heparin-based coatings because polymer coatings have shown to provide the same or better benefits without the risk of a patient heparin reaction.

The ROCSafe system is coated with XCoating™, Terumo’s own biocompatible polymer coating which reduces platelet activation and protein denaturing. Studies have shown that using XCoating helps reduce bleeding and SIRS in cardiac surgery patients undergoing cardiopulmonary bypass.6

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Polymer-based surface coating is safe for heparin intolerant patients

Table 1

Section

1. Air bubble detector detects venous air
2. Air bubble detector sends a signal to centrifugal pump to engage Centifuge® Impeller
3. Centrifugal pump in 1800 rpm and venous bubble trap
4. Optional accessory kit per air traps
5. Optional accessory kit per air traps

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<td>32%</td>
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<td>0.2</td>
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The ROCSafe™ Hybrid Perfusion System

Thoughtful Design and Expert Support:
Developed by the global leader in cardiopulmonary bypass

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In the U.S., Terumo perfusion products are used by surgeons at the country’s top heart hospitals. Terumo heart-lung machines, intraoperative monitoring systems, cannulae, and oxygenators are each the best in their classes.

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734 663 4145 phone

Terumo’s expert Clinical Support team is available to provide a custom training experience, including one-on-one in-service and advanced perfusion simulation training.

Training

Terumo’s expert Clinical Support team is available to provide a custom training experience, including one-on-one in-service and advanced perfusion simulation training.

Safe doesn’t need a definition.

Exclusive air handling features

The ROCSafe system is designed exclusively for use with the Terumo® Advanced Perfusion System 1; the combined platforms efficiently prevent air from traveling beyond the venous filter through the circuit. A separate two-chamber air bubble detector automatically engages the Core™ Response of the centrifugal pump to temporarily suspend blood flow and simultaneously exclude the venous line allowing the clinician to review the air.

Adaptability

The ROCSafe system seamlessly switches configurations during a case to reduce the potential complications of cardiopulmonary bypass. The user can add sections of the circuit as needed, whether converting from complete cardiopulmonary bypass to partial cardiopulmonary support, or choosing regular or select use of a chamberless reservoir.

Ease of use

The ROCSafe system is a pre-connected circuit designed for simplicity. The entire circuit mounts on its bracket and is easy for priming with a simple click. Optional accessory packs are available for adding a hardshell reservoir or flexible cardiotomy reservoir for volume management. These can be added at any time, before or during the procedure.

For best practices in blood management, Terumo’s expert Clinical Support team is available to provide a custom training experience, including one-on-one in-service and advanced perfusion simulation training.

Adhesion and protein denaturation to prevent activation and blood reactions to foreign surfaces. The blood contact areas of the circuit are coated with Terumo’s own XCoating™, shown to reduce platelet activation and protein denaturation.

The total surface area of the ROCSafe system’s core configuration is only 1.9 m2. This represents a surface area reduction of approximately 50% compared to a conventional circuit.

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adhesion and protein denaturation to prevent activation and blood reactions to foreign surfaces. The blood contact areas of the circuit are coated with Terumo’s own XCoating™, shown to reduce platelet reduction of approximately 50% compared to a conventional circuit.

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The ROCSafe system is designed exclusively for use with the Terumo® Advanced Perfusion System 1; the combined platforms effectively prevent air from traveling beyond the venous filter through the circuit. A venous line ultrasonic air bubble detector automatically engages the Coast™ Response of the centrifugal pump to temporarily suspend blood flow and simultaneously occlude the venous line allowing the clinician to remove the air.

Adaptability

The ROCSafe system seamlessly switches configurations during a case to reduce the potential complications of cardiopulmonary bypass. The user can add sections of the circuit as needed, whether converting from complete cardiopulmonary bypass to temporarily suspend blood flow and simultaneously occlude the venous line ultrasonic air bubble detector automatically engages the Coast™ Response of the centrifugal pump to temporarily suspend blood flow and simultaneously occlude the venous line allowing the clinician to remove the air.

Ease of use

The ROCSafe system is a pre-constructed circuit designed for simplicity. The entire circuit resides on its bracket and is ready for priming with a single click. Optional accessory packs are available for adding a heat exchanger or filter to the circuit as needed, without compromising safety or ease of use.

Training

Terumo’s expert Clinical Support team is available to provide a custom training experience, including one-on-one in-service and advanced perfusion simulation training.