Introduction

With looming industry-wide changes in reimbursement, dialysis providers are under great pressure to deliver improved treatment outcomes while improving costs. Over the last four decades, providers have not looked to bloodlines for opportunities to improve dialysis efficiency. Instead, bloodlines have been considered simple tools to deliver blood to and from the patient, with multiple blood-air exposures. Conventional understanding and years of clinical experience suggested that “a bloodline is a bloodline.”

After more than seven years of research and development, Medisystems® has introduced its latest innovation – the Streamline® bloodline. Streamline is a revolutionary airless bloodline designed to improve treatment efficiency from a clinical, operational, and financial perspective.

This primer outlines the technological advances of Streamline. It also presents the clinical, operational, and financial experiences of multiple dialysis providers who have performed over one million treatments with Streamline. Finally, it summarizes important tools created by Medisystems to help providers maximize the benefits of Streamline.

Medisystems has prepared this document as an introduction; it does not address all topics critical for selecting and managing a bloodline. It is always the physician’s responsibility to ensure the appropriate prescription, therapy, and care plan for an individual patient.
Airless Components

One of the most significant innovations in Streamline is the elimination of air-blood contact. Conventional bloodlines use drip chambers with an air gap at the top for pressure monitoring. Potential splashing and foaming at this air-blood interface in conventional tubing can contribute to clotting and microbubble formation with resulting compromises in clinical outcomes (see Section Two).

Streamline replaces the conventional devices for pressure measurement with a novel airless arterial and venous pressure “POD” (Pressure Oscillating Diaphragm, Figure 1). As blood enters the POD, it displaces an internal flexible diaphragm, which transmits pressure to the machine sensors through a monitor line. No transducer protectors are required in this setup, as the internal diaphragm acts as an impermeable blood barrier.

Streamline also replaces the conventional venous chamber with a patented airless venous “vortex” chamber (Figure 2). Unlike conventional chambers that require air gaps for pressure measurement, the vortex chamber runs completely filled with blood. To prevent splashing and the formation of stagnant blood compartments along the sides, blood enters into the chamber in a horizontal “vortex” flow. The vortex chamber also contains a venous bubble-trap filter (Figure 3) with 50% less surface area than most conventional venous filters – designed to reduce clotting. The vortex chamber otherwise functions similarly to a conventional chamber in allowing venous air bubble detection.

Together, these components are designed to transport blood without air-blood interfaces, resulting in meaningful clinical and operational benefits (Section Two and Section Three) for the dialysis provider.

Simplified Tubing Design

Streamline is optimized for tubing length, eliminating most of the “spaghetti” loops of conventional tubing while remaining compatible with existing dialysis machines (Figure 4: Fresenius® 2008K; see APPENDIX A for B. Braun®). All the functions of a conventional bloodline are maintained with Streamline, but with reductions in extracorporeal blood volume, weight, packing density, and number of bond joints.3

<table>
<thead>
<tr>
<th>Conventional Bloodline Layout</th>
<th>Streamline Layout Change</th>
<th>Clinical and Operational Impact</th>
</tr>
</thead>
</table>
| Extracorporeal Blood Volume: 143-165 mL | 15-35% lower (108-118 mL) | • Less blood exposure to plastic  
• Lower saline priming volume  
• Less “spaghetti” designed for easier setup, teardown and troubleshooting |
| Set Weight: 0.64-0.70 lb | 35% lower (0.46 lb) | • Designed for lower disposal costs, less landfill usage, lower incineration pollutants  
• Fewer red bags to close and discard |
| Packaging Volume: 24 sets/case | 33-50% lower (32-36 sets/case) | • Lower storage space requirements  
• Reduced packaging waste |
| 31-36 bond joints | 35% lower (21 bond joints) | • Designed to lower blood flow resistance and improve pressures |
Needleless Access

Conventional bloodlines require the use of a needle and syringe for blood draws and medication delivery, which is associated with the risk of needlestick injuries. Typical needlestick injuries result in reduced staff morale, significant healthcare costs for the dialysis provider (at least $1,000 per incident), and risk of future legal costs.

Streamline employs Medisystems’ proprietary LockSite® needleless access ports (Figure 5) to minimize needle usage and reduce the risk of needlesticks. With its unique locking system, the syringe may be left on the circuit during treatment for medication delivery as well as for simple blood and saline draws.

Section Two: Impacting Clinical Outcomes

As described above, the novel airless components and tubing enhancements of Streamline are designed to reduce blood turbulence, flow resistance, clotting, and air bubble formation. Through different pathways, these improvements are designed to impact clinical outcomes.

Heparin Reduction

Most dialysis treatments require the administration of anti-coagulants, primarily in the form of unfractionated heparin. However, the use of unfractionated heparin has been associated with undesired side effects such as heparin-induced thrombocytopenia, allergies, osteoporosis, hyperlipidemia, and excessive bleeding. In addition, recent heparin manufacturing quality issues in 2008 have contributed to serious patient injury as a result of contaminated heparin.

To alleviate the potential clinical consequences of heparin use, Streamline is designed to lower heparin use under most circumstances:

1) For treatments where heparin is administered intravenously by bolus or hourly, priming of the Streamline heparin line requires only 0.27 mL, a savings of 0.75-1.75 mL as compared to typical priming volumes.

2) Providers have reported 33% reduction in heparin usage during treatment due to reduced clotting and improved rinsebacks.
Air Bubble Reduction

The majority of dialysis treatments may result in infusion of micro-air bubbles directly into patients’ bloodstreams. Recent evidence suggests that infusion of microbubbles during treatment poses a clinically significant risk of inflammation, air embolism, and lung damage. Pending further research, the elimination of air-blood contact and reduction in turbulence, foaming, and splashing with Streamline may help to reduce the incidence of micro-air bubble formation and patient infusion.

Arterial Pressure and Blood Flow Increase

Arterial pressure is a critical element of the dialysis treatment. Typical dialysis wisdom mandates that arterial pressure can only be improved by changes to the patient’s vascular access, or by lowering blood flow when using a conventional bloodline. Unlike with conventional bloodlines, Streamline is unique in that it has been reported to run at a lower arterial pressure (Figure 6).

This initial drop in arterial pressure is likely the result of improved hemodynamics and lower turbulence in the Streamline blood pathway. As reported by Streamline users, the drop in pressure provides the opportunity to raise blood flows by 50-100 mL/min from the same patient access without subjecting it to additional stress (Figure 7).

Kt/V Impact

Industry-accepted NKF-KDOQITM guidelines require measurement of dose by a minimum treatment urea ratio (Kt/V), typically set at 1.2. Maintaining adequate Kt/Vs is a critical goal for physicians, nurses, and clinic administrators to improve the clinical health of their patient population. Recent announcements on bundled dialysis reimbursement further emphasize the importance of dialysis dose, with reimbursement penalties proposed for those dialysis providers who fail to meet minimum KDOQI standards.

Basic dialysis kinetics establish Kt/V for a given patient as a function of dialysate flow, dialyzer size, and treatment time. With increased blood flows, Streamline has been reported to provide the clinician the opportunity to prescribe higher dialysis doses. Other approaches to raising Kt/V exist, but they are more costly and logistically complex alternatives:

<table>
<thead>
<tr>
<th>Typical Approaches to Increase Dose (Kt/V)</th>
<th>Incremental Cost per Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase dialysis treatment time</td>
<td>• 30-60 minutes of staff time (labor cost)</td>
</tr>
<tr>
<td></td>
<td>• Shift disturbances</td>
</tr>
<tr>
<td></td>
<td>• 30-60 minutes of patient time</td>
</tr>
<tr>
<td>Set Weight: 0.64-0.70 lb</td>
<td>• $0.75 to $3.50 cost per dialyzer</td>
</tr>
<tr>
<td>Increase dialyzer size</td>
<td>• $1.00 or more in fresh water, acid, bicarb and RO costs</td>
</tr>
<tr>
<td></td>
<td>• Increased environmental impact of fresh water usage</td>
</tr>
</tbody>
</table>

Unlike the above alternatives, Streamline can increase dose while simultaneously lowering treatment costs (see Section Three).
Section Three: Smart Economics

Dialysate and Dialyzer Size Reductions

In addition to blood flows, Kt/V for a given patient is also a function of dialysate flow, dialyzer size, and treatment time. Dialysis providers expend considerable effort in optimizing these inputs without compromising Kt/V. Streamline aids providers in these efforts to optimize the use of dialysate, dialyzers, and treatment time (Figure 8).

These improvements in treatment costs are possible due to the potential to increase blood flows (see APPENDIX D) without corresponding increases in arterial pressure.

Other Supply Savings

In 2008, a major manufacturer and supplier of heparin exited the market, leading to rising heparin prices. As the cost of heparin reached $0.20/mL in 2009, dialysis providers began searching for ways to lower their usage of the drug safely. As mentioned in Section Two, Streamline is designed to reduce clotting and thereby requires less heparin in priming and in treatment.

In addition to heparin, Streamline has been reported to reduce the need for saline. The reduction is due to the 15-30% smaller blood volume of Streamline and reported improved rinseback. Saline is primarily administered for priming and rinseback through one-liter bags that often cost upwards of $1.00 each. As such, dialysis providers who tend to use more than one bag of saline per treatment have reported savings.

Transducer Protectors and Easier CMS/OSHA Compliance

As mentioned in Section One, the non-permeable pressure POD design (Figure 1) of Streamline avoids the need for transducer protectors to prevent blood and serum from contaminating the dialysis machine. While the general incidence of contamination is not fully understood, regulatory authorities place increasing emphasis on vigilance and immediate action if a contamination is suspected:

“If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the machine after the treatment is completed and check for contamination. This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. If contamination has occurred, the machine must be taken out of service and disinfected…”

(Actual language from 2008 Centers for Medicare and Medicaid Services Conditions of Coverage).

When a transducer protector fails, the mandated removal of a dialysis machine for servicing and disinfection is an expensive and inconvenient procedure. It can also force providers to invest greater capital in replacement machines.
Section Four: Provider Experience

In addition to published clinical data, several million treatments have been performed to date with Streamline. These include several large evaluations by national dialysis providers across diverse facilities (urban vs. rural, single-use vs. reuse dialyzers, high-performing vs. low-performing, academic vs. other). Please contact Medisystems or your clinical educator for specific information pertaining to a user’s experience or to contact an existing user directly.

Staff Satisfaction with Setup, Teardown, and Treatment Alarms

Nowhere is the impact of Streamline more pronounced than on staff satisfaction. The simplified layout of Streamline, as evident from its shorter length, lighter weight, and fewer bond joints, is designed for quick and easy setup and teardown with fewer treatment interruptions. In addition, Streamline does not require constant management of chamber levels, a common source of treatment alarms with conventional bloodlines.

Published staff surveys reported significant staff preference for Streamline due to significantly lower alarms (Figure 9) during treatment and easier setup and teardown. As a result, the dialysis floor can be quieter, and treatments may have fewer alarm interruptions that potentially disrupt shift schedules or consume staff time devoted to patient care and vital administrative tasks. Studies have shown that treatment floors with calmer environments and lower ambient noise may enhance patient wellbeing and comfort.

Clinical Improvements

These large evaluations have reported clinical improvements in Kt/V, blood flow, and arterial pressure that mirror in-vitro studies of Streamline:

<table>
<thead>
<tr>
<th>Evaluation 1</th>
<th>Evaluation 2</th>
<th>Evaluation 3</th>
<th>Published Customer Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Patients</td>
<td>575+</td>
<td>275+</td>
<td>525+</td>
</tr>
<tr>
<td>Blood Flow with Streamline</td>
<td>426 mL/min</td>
<td>441 mL/min</td>
<td>412 mL/min</td>
</tr>
<tr>
<td>% of Patients with Kt/V ≥ 1.4</td>
<td>87% (+6%)</td>
<td>79% (+4%)</td>
<td>85% (+20%)</td>
</tr>
</tbody>
</table>

Operational Improvements

Similarly, these large evaluations have also reported noticeable cost savings from a variety of sources:

<table>
<thead>
<tr>
<th>Average Savings Reported Per Treatment</th>
<th>Published Customer Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dialysate</td>
<td>$0.31</td>
</tr>
<tr>
<td>Dialyzer Size</td>
<td>$0.28</td>
</tr>
<tr>
<td>Medical Waste</td>
<td>$0.16</td>
</tr>
<tr>
<td>Saline</td>
<td>$0.15</td>
</tr>
<tr>
<td>Heparin</td>
<td>$0.32</td>
</tr>
<tr>
<td>TPs</td>
<td>$0.03</td>
</tr>
<tr>
<td>Labor</td>
<td>$1.32</td>
</tr>
<tr>
<td>TOTAL SAVINGS</td>
<td>$1.24</td>
</tr>
</tbody>
</table>
Section Five: Proprietary Streamline Optimization Services

Physicians can modify prescriptions with Streamline according to their specific goals to maximize Kt/V, while providers optimize operational costs. In addition to providing the services of a highly trained and experienced clinical education staff, Medisystems has created and validated a series of proprietary tools and services to help physicians and facilities pursue these goals.

The Streamline Optimization Algorithm (Figure 10) is a unique service similar in concept to existing algorithms that optimize ESA (erythropoiesis stimulating agent) dose to maximize treatment outcomes and costs. The Streamline Optimization Algorithm service uses proprietary patent-pending software that incorporates:

1) Actual customer and in-vitro experience with Streamline;\(^\text{19}\)
2) Advanced dialysis kinetics;\(^\text{20}\)
3) Customized cost factors and clinical goals of the provider; and
4) Treatment and monthly lab data from the provider for each patient.

Clinical data required for the service to provide accurate guidance are: patient values for Kt/V, blood flow (delivered), arterial pressure, dialyzer, dialysate flow, and treatment time.

Basic operational data required to customize the service are treatment costs due to dialysate use and relative cost of dialyzers in the provider’s formulary. Sensitive cost data is not required for these calculations.

With the data in figure 10, Medisystems is able to provide powerful reporting to the customer in the form of prescription guidelines customized for each patient (APPENDIX E). Customers have successfully used these guidelines to realize improvements in Kt/V while lowering treatment costs.

Other tools available to providers include frameworks to gather useful treatment data to aid in heparin prescription as well as reference guides to supplement product Instructions for Use. Note that all tools and services provide data for informational purposes only. These tools do not address all topics critical to a patient’s dialysis prescription or clinical wellbeing. It is always the physician’s responsibility to ensure the appropriate prescription therapy and care plan for an individual patient.

For more information on the use of the Streamline Optimization Service and other tools, please contact Medisystems or your Medisystems clinical educator.

Conclusion

Streamline, with its unique design and reported positive impact on clinical outcomes, operational costs, and staff experience, has demonstrated benefits for all stakeholders in the clinic:

1) Patients have been shown to experience quieter centers with fewer interruptions and to receive better Kt/Vs, fewer long (>4 hour) treatments, and lower heparin intake.
2) Nurse and technician staff report reduced alarms and interventions, which allows them to focus more on patient care, and easier compliance with surveyor requirements pertaining to transducer protectors.
3) Physicians are allowed greater prescription flexibility and report reduced heparin usage.\(^\text{18}\)
4) Administrators report reduced overall treatment costs, improved clinical performance, higher staff satisfaction, and easier compliance with surveyor requirements.
Appendix

A) Conventional Dialog® bloodline (left) versus Streamline (right) on B. Braun® machine

B) Arterial Pressure Reductions by Clinic (each pair of bars represents one clinic)
C) Blood Flow Reductions by Clinic (each pair of bars represents one clinic)

```
<table>
<thead>
<tr>
<th>Clinic</th>
<th>Conventional</th>
<th>Streamline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic 1</td>
<td>459</td>
<td>444</td>
</tr>
<tr>
<td>Clinic 2</td>
<td>483</td>
<td>441</td>
</tr>
<tr>
<td>Clinic 3</td>
<td>457</td>
<td>459</td>
</tr>
<tr>
<td>Average Blood Flow per Clinic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conventional</td>
<td>425</td>
<td>Streamline</td>
</tr>
</tbody>
</table>
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D) Dialysate Flow and Dialyzer Curves

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Qd = 800 mL
Qd = 600 mL
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E) Sample Streamline Optimization Algorithm Results

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Current Prescription | New Prescription
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID</td>
<td>Dialyzer</td>
</tr>
<tr>
<td>-----------</td>
<td>---------</td>
</tr>
<tr>
<td>110487</td>
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<tr>
<td>9003208</td>
<td>PD120A</td>
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</tbody>
</table>
```
References


3. As compared to conventional bloodlines such as Medisystems ReadySet®, Fresenius CombiSet® and NiproSet®. Data on file.


18. Data provided to Medisystems by customers as part of Streamline evaluation. Conventional includes ReadySet and other non-Streamline bloodlines.

