# Table of Contents

- **Company Letter** 03
- **Managing Fluid Overload in Heart Failure Patients** 04
- **Product Information** 11
  - 11 Aquadex SmartFlow System Overview
  - 14 Product Resources
    - Therapy Guide Card
    - Quick Reference Guide
    - Console and Blood Set Brochure
    - Dual Lumen Extended Length Catheter
    - Venous Access Considerations
- **Additional Reading on Role of Ultrafiltration in the Treatment of Heart Failure Patients** 16
- **Patient Care Pathway** 17
- **Standing Orders Template** 19
- **Vendor Information** 22
Dear Physicians and Caregivers:

Every day, physicians and caregivers face the challenge of managing fluid balance in patients with Heart Failure (HF). HF is the leading cause of hospitalizations in patients >65 years of age in the US. Over 1 million HF related hospitalizations occur in the US and 90% of these hospitalizations are due to signs and symptoms of fluid overload. The average length of stay for these patients is nearly 5 days and this puts a tremendous strain on already scarce hospital resources.

Diuretics play a critical role in the management of fluid overload in HF patients. However, they are associated with mixed outcomes and adverse clinical events.

The Aquadex SmartFlow™ System is a simplified form of ultrafiltration that provides safe and predictable removal of isotonic fluid in HF patients with fluid overload. It has been clinically shown to:

- Have no significant changes to electrolytes
- Reduce neurohormonal stimulation (RAAS)
- Stabilize or improve cardiac hemodynamics
- Restore diuretic effectiveness in patients allowing for improved response to diuretic agents
- Decrease the risk of rehospitalization for HF compared to diuretics by 53%
- Re-establish euvolemia and decrease hospital length of stay when initiated early

Additional benefits include:

- Easy setup and management allows for 4:1 patient to nurse ratio
- Integrated diagnostics, including Hematocrit and SV02 monitoring
- Low 35 ml of extracorporeal blood volume in the circuit may help promote hemodynamic stability

I understand that you are busy, but a brief discussion may lead to a solution to your needs. Do you have a short window of time to talk this week or next?

Kind Regards,

CHF Solutions
MANAGING FLUID OVERLOAD IN HEART FAILURE PATIENTS USING ULTRAFILTRATION
Managing Fluid Overload in Heart Failure Patients Using Ultrafiltration

Fluid Overload in Heart Failure Patients

- Heart failure is the leading cause of hospitalizations among adults >65 years of age in the United States\(^1\)
  - >1 million HF hospitalizations occur annually in the US, and hypervolemia (fluid overload) is the predominant cause\(^2\)
- Average length of stay for HF hospitalization is ~5 days\(^3\)
  - HF hospitalizations are a strong predictor of mortality\(^4\)
- 24% of HF patients will be readmitted within 30 days and 50% of HF patients will be readmitted within 6 months\(^2\)
  - Since 2012, Medicare has levied penalties for hospitals with 30-day readmission rates above expected\(^5\)
  - Penalty: Hospitals can lose ≤3% of Medicare reimbursement for all admissions

Average length of stay for HF hospitalization is ~5 days\(^3\)

24%
of HF patients will be readmitted within 30 days and 50% of HF patients will be readmitted within 6 months\(^2\)

90%of heart failure hospitalizations due to signs and symptoms fluid overload\(^2\)

Sources:
### Use of Diuretics in Heart Failure Patients

Diuretics play a central role in the management of fluid overload in HF patients; however diuretics are associated with:

<table>
<thead>
<tr>
<th>MIXED OUTCOMES</th>
<th>ADVERSE CLINICAL EVENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The longer a patient is on diuretics, the less effective they become¹,²</td>
<td>• Increased risk of worsening renal failure/accelerated kidney function decline¹⁴,⁵,⁶</td>
</tr>
<tr>
<td>• High incidence of poor diuretic response: among HF patients, 40% showed poor diuretic response and 68% showed suboptimal response³</td>
<td>• Electrolyte imbalances and symptomatic hypotension⁴,⁵,⁶,⁷,¹⁰</td>
</tr>
<tr>
<td>• High risk of re-hospitalization (24% of HF patients readmitted within 30 days and 50% within 6 months)⁴</td>
<td>• Higher risk of mortality¹¹-¹⁷</td>
</tr>
</tbody>
</table>

### Diuretics VS. Ultrafiltration in Heart Failure Patients

<table>
<thead>
<tr>
<th>LOOP DIURETICS⁴ to eliminate hypotonic urine</th>
<th>ULTRAFILTRATION⁶ to remove isotonic plasma water</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚠ Unpredictable elimination of sodium and water</td>
<td>✅ Predictable removal of sodium and fluids</td>
</tr>
<tr>
<td>⚠ Development of diuretic resistance</td>
<td>✅ Restoration of diuretic responsiveness</td>
</tr>
<tr>
<td>⚠ Risk of hypokalemia (low potassium levels) and hypomagnesemia (low magnesium levels)</td>
<td>✅ No change in electrolytes, particularly potassium and magnesium</td>
</tr>
<tr>
<td>⚠ Insufficient symptom relief: Persistent congestion, failure to lower sodium levels</td>
<td>✅ More effective decongestion and fewer heart failure events compared to loop diuretics</td>
</tr>
<tr>
<td>⚠ Worsening heart failure, increased mortality after discharge, increase in re-hospitalization rates</td>
<td>✅ Improved glomerular filtration rate</td>
</tr>
<tr>
<td></td>
<td>✅ Efficacy, and improved outcomes</td>
</tr>
</tbody>
</table>

### Sources:

11. Cooper H.A et al, Circulation 1999, 00(12);1311-1315.
Clinical Evidence on Diuretics

**ADHERE Registry**¹ (Acute Decompensated Heart Failure National Registry)

- Out of > 50,000 pts nearly half of hospitalized HF patients are discharged with residual fluid excess after receiving diuretics.

**DOSE Trial**² (Diuretic Optimization Strategies Evaluation)

- Regardless of diuretic strategy, 42% of acutely decompensated HF pts reached the composite endpoint of death, rehospitalization, or ER visit at 60 days.

Sources:
Clinical Evidence on Ultrafiltration in Heart Failure Patients

**STUDY DESIGN**
- Single center, prospective, single-arm: 20 patients

**RESULTS**
Administration of early UF in acute decompensated HF patients with diuretic resistance
- Removed an average of 8.6 liters of fluid
- Hospitalizations:
  - When initiated early, average Length of Stay was 3.7 days
  - In the 3 months preceding ultrafiltration, 10 hospitalizations in 9 patients
  - After ultrafiltration, 1 patient was readmitted for ADHF within 30 days
- Improvement of volume overload after ultrafiltration persisted at 30 and 90 days

**CONCLUSION**
- HF patients with volume overload and diuretic resistance, *UF before IV diuretics effectively and safely decreases length of stay and readmissions*. Clinical benefits persist at three months.

# What We’ve Learned Since CARESS-HF

## OBJECTIVES AND FINDINGS

<table>
<thead>
<tr>
<th>2012</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CARRESS-HF Study Results</strong>&lt;sup&gt;1&lt;/sup&gt; (N=200)</td>
<td>**CARRESS-HF Per-protocol Study Conclusions&lt;sup&gt;2&lt;/sup&gt; and Counter Points&lt;sup&gt;3&lt;/sup&gt; (N=163)</td>
<td><strong>ADDITIONAL ANALYSES ON CARRESS DATA</strong>&lt;sup&gt;4&lt;/sup&gt; (N=105)</td>
</tr>
<tr>
<td>Compare ultrafiltration (UF) and stepped pharmacological therapy (SPT) in the treatment of patients with acute decompensated heart failure (ADHF)</td>
<td>Better understand the direct effects of UF in comparison to an aggressive, urine output-guided pharmacological protocol for decongestion in heart failure patients</td>
<td>Understand the impact of intensive volume removal in ADHF patients with preexisting worsening renal function and renal tubular injury</td>
</tr>
</tbody>
</table>
| • No significant difference between UF vs. SPT for weight loss at 96 h | • UF had higher serial cumulative fluid loss (p=0.003)<sup>*</sup>  
• UF had higher net fluid loss (p=0.001)<sup>*</sup>  
• UF had a greater relative reduction in weight over time (p=0.02)<sup>*</sup>  
• Although SCr levels increased in the UF arm, there was no significant difference in long-term outcomes | • Although intensive volume removal resulted in a further worsening of creatinine levels approximately half of the time in CARRESS-HF patients, decongestion and renal function recovery at 60 days were superior in patients with increased tubular injury markers |
| • UF group had a higher increase in serum creatinine (SCr) vs. SPT group | • 39% in the UF group received only diuretic agents or were given diuretic agents before the assessment of the primary endpoint at 96 h, which impairs adjudication of adverse events to one or the other therapy<sup>5</sup> | • The authors concluded “these data suggest that the benefits of decongestion may outweigh any modest or transient increases in serum creatinine or tubular injury markers that occur during intensive volume removal” |
| • SAEs: 72% (UF) vs. 57% (SPT) at 60-days | • All patients’ fluid removal rates were fixed at 200 ml/h and vasodilators or isotropic drugs were prohibited unless necessary for rescue therapy  
These results are consistent with data from other randomized, controlled studies for volume removal (RAPID-CHF<sup>4</sup> and UNLOAD<sup>5</sup>) | • Increase in renal tubular injury biomarker score was associated with a greater incidence of hemoconcentration and trends toward other metrics of superior decongestion |
| | | • Change in creatinine (i.e. transient increase creatinine) should not be the major factor to dissuade the use of UF where a therapeutic advantage may exist |

### Sources:
Ultrafiltration in Heart Failure Patients

- Shown to have no significant changes to electrolytes\(^1\)
- Reduces neurohormonal stimulation (RAAS)\(^2\)
- Stabilizes or improves cardiac hemodynamics\(^3\)
- Restored diuretic effectiveness in patients allowing for improved response to diuretic agents\(^4,5\)
- 53% reduction in the risk of rehospitalization for HF compared to diuretics\(^6\)
- Early initiation of UF in ADHF patients shown to re-establish euvolemia and may decrease hospital length of stay.\(^7\)

Sources:
Managing Fluid Overload in Heart Failure Patients Using Ultrafiltration

Aquadex’s Healthcare Economic Benefits

Analysis published in February 2019 Journal of Medical Economics1:

- Compared costs at the hospital level for treating fluid overload in HF patients when using ultrafiltration versus IV diuretics (DIUR-T) over a 90 day period
- Model in analysis used clinical data from published literature (i.e., UNLOAD) and hospital data from the Healthcare Cost and Utilization Project (HCUP) database
- The analysis demonstrated that despite higher up-front costs, ultrafiltration reduces hospital readmission rates and readmission duration of stay
- Data showed a cost savings of $3,975 per patient when using ultrafiltration versus diuretic therapy over 90 days

Background

- Heart failure is a common, serious disease in the United States and Europe.
- Patients with heart failure often require treatment for fluid overload resulting in costly inpatient visits.
- The first line of treatment for fluid overload is diuretic therapy (DIUR-T), but if DIUR-T fails alternative treatment options should be considered.
- Limited data exists on the costs (or cost savings) associated with the use of alternative therapies to treat patients with fluid overload.

Objective

The purpose of this study was to perform a cost analysis from the hospital perspective on ultrafiltration versus DIUR-T in the treatment of patients with heart failure related fluid overload.

Methods

- The cost-analysis model used a decision analytic framework to reflect treatment decisions, probabilistic outcomes, and associated costs for treating patients with heart failure and fluid overload with various ultrafiltration or intravenous DIUR-T (Figure 1).
- The model was informed by clinical data obtained from published literature and the Healthcare Cost and Utilization Project (HCUP) for the calendar year 2014.
- A 90-day timeframe was considered to account for hospital readmissions beyond 30 days.
- Sensitivity and scenario analyses were performed to gauge the robustness of the results.

Results

- Initial hospitalization costs were higher in the ultrafiltration arm due to the cost of the ultrafiltration system itself.
- Fluid removal by ultrafiltration lead to reduced hospital readmission days which resulted in a cost savings of $1,448 per patient.
- UF treatment showed a total cost savings of $3,975 or 14.4% ($2,363 for UF vs. $2,708 for DIUR-T).
- A one-way sensitivity analysis was performed that incorporated varied model input values that showed a greater cost savings for the ultrafiltration arm compared to DIUR-T (Figure 3).

Conclusion

Ultrafiltration is a viable alternative to DIUR-T when treating fluid overload in heart failure patients. Despite higher up-front costs, ultrafiltration substantially reduced hospital cost via readmission rates and durations, over a 90-day period compared to DIUR-T.

Aquadex SmartFlow™ System

The Aquadex SmartFlow System uses a simplified approach to ultrafiltration for the removal of salt and water in patients with hypervolemia, or fluid overload. Compared to renal replacement devices used for ultrafiltration, the Aquadex SmartFlow System is smaller and more portable. Physicians can specify and adjust the exact amount and rate of fluid to be removed from each patient, resulting in a gradual reduction that has been shown to have no significant clinical impact on blood pressure, heart rate, or the balance of electrolytes (e.g. sodium, potassium, etc.) in the body.\(^1\) Up to 500 mL per hour of excess fluid can be removed with no clinically significant impact on electrolyte balance.\(^1,2\)

Features & Benefits

**SIMPLE**
- Easy set-up and monitoring allows for up to 4:1 patient to nurse ratio
- Highly automated with only one setting required to begin
- Smart alarms/alerts prompt action when necessary

**FLEXIBLE**
- Perform therapy through peripheral or central venous access
- Portable system with small 35 ml extracorporeal volume meets patient needs in a multitude of clinical settings
- Customizable HCT monitor can be tailored to individual patient needs

**SMART**
- HCT sensor provides real time measurement of % blood volume change
- SvO2 monitoring provides insights into tissue oxygen delivery
- Filter Alert prompts action to extend filter life and reduce therapy time

Sources:
Simplified approach to ultrafiltration for the removal of isotonic fluid.

**Easy to Operate, Safe to Use**

- Controllable fluid reduction and individualized patient fluid removal
- Perform therapy through peripheral or central venous access
- Highly automated with only one setting required to begin
- Hematocrit sensor provides real time measurement of % blood volume change
- User defined hematocrit limit
- SvO2 monitoring provides insights into tissue oxygen delivery
Blood Circuit Set

Uniquely designed for the removal of isotonic fluid with a low extracorporeal blood volume of approximately 35 ml.

Aquadex System Fluid Path

Fully Integrated Blood Circuit Set

- Patented filter designed to reduce clotting
- Air and blood leak detectors to ensure correct operation
- Needleless access ports for aspiration or infusion of fluids
- Filter Resistance Alert prompts action to help extend circuit life
CHFS Resources

Click on the links below to access the complete product resource.

Therapy Guidelines Card

Dual Lumen Extended Length Catheter

Quick Reference Guide

Console and Blood Set Brochure

Venous Access Considerations
Additional Reading on Role of Ultrafiltration in the Treatment of Heart Failure Patients


https://academic.oup.com/eurheartjsupp/article/7/suppl_B/B13/603537


**Patient Care Pathway**

**Fluid Overload Patient Care Pathway with Aquadex SmartFlow™ System**

**Initiate Aquadex Therapy**

**Goal**
- Clinical Euvolema: JVP < 8 mmHg, absence of dyspnea, trace or no peripheral edema
- Reduction in NT proBNP by 30% or BNP by 45%

Evaluate transition to oral diuretics.

If oral diuretics indicated, consider lower home dose.

Follow GWTG or ACC transitional care guidelines

- Optional second dose of diuretics double previous dose or repeat FST

**Monitor**
- Continue to dose diuretics
- Stop diuretics*

**Patient Identification**

**Heart Failure**

**General Symptoms of Fluid Overload**

Fluid overload as indicated by at least 2 of the following:
- Patient weight 10 lbs. > dry weight or > 5 lbs. for pt weighing < 50 kg
- Patient admitted with fluid overload who are taking ≥ 80 mg furosemide (or equivalent) per day
- Low urine output (<100 cc/hr)
- JVD > 8 cm H2O
- Peripheral or sacral edema ≥ 2+
- Pulmonary rales
- Pulmonary edema or pleural effusions on CXR
- PND or orthopnea
- Respiratory rate ≥ 20 per minute
- Hypoxemia requiring supplemental oxygen
- LVEDP or PCWP > 20 mmHg

**Currently on Diuretics?**

- **YES**
  - IV diuretics at double the baseline oral dose or
  - Furosemide Stress Test (FST) 1.5 mg/kg IV bolus

- **NO**
  - Lasix 40 mg IV or
  - FST: 1 mg/kg IV bolus

**Monitor**

FST: 200 ml/hr urine output over 2 hours and/or spot urine sodium <50 mEq/L

- >200 ml in 2 hrs urine output
- <200 ml in 2 hrs urine output

- Optional second dose of diuretics double previous dose or repeat FST

**Monitor**

FST: 200 ml/hr urine output over 2 hours and/or spot urine sodium <50 mEq/L

- Continue to dose diuretics
- Stop diuretics*

**Initiate Aquadex Therapy**

---

*Consider stopping electrolyte replacement

---

**Expedites Fluid Removal Path**

- Outpatient diuretics uptritrated without adequate response
- Frequently present with fluid overload

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**References**

[1] CHF Solutions Medical advisory board meeting 2020 recommendations.

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**CHF Solutions Medical Advisory Board consultation was sought on the pathway.**
Patient Care Pathway

**INITIATE AQUADEX THERAPY**

**Obtain vascular access**

**Start anticoagulation unless contraindicated**

**Choose initial UF rate**

- SBP <100 mm Hg: 150 cc/h
- SBP 100-120 mm Hg: 200 cc/h
- SBP >120 mm Hg: 250 cc/h

Decrease initial UF rate by 50 ml/hr if any of the following:
- RV>LV dysfunction
- sCr increase 0.3 mg/dl above baseline
- Baseline sCr > 2.0 mg/dl
- Hx of instability with diuresis or UF in the past

**Monitored**

- Heart rate
- Blood pressure
- SCr level
- Urine output

**GOAL**

Clinical Euvolema: JVP < 8 mmHg, absence of dyspnea, trace or no peripheral edema, reduction in NT proBNP by 30% or BNP by 45%

Evaluate transition to oral diuretics. If oral diuretics indicated, consider lower home dose. Follow GWTG or ACC transitional care guidelines.

CHFS Medical Advisory Board consultation was sought on the pathway.

*Consider stopping electrolyte replacement*

---

[1] CHF Solutions Medical advisory board meeting 2020 recommendations.
1. **Indication:** The Aquadex SmartFlow System is indicated for: Continuous ultrafiltration therapy for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kilograms or more whose fluid overload is unresponsive to medical management, including diuretics. All treatments must be administered by a healthcare provider, within an outpatient or inpatient clinical setting, under physician prescription, both of whom having received training in extracorporeal therapies.

2. **Patient selection:**
   a. Fluid overload and two of the following
      i. ____ lbs/kg over dry weight (estimated)
      ii. IV Diuretic Dose > ____ mg furosemide or equivalent (1 mg bumetanide or 20 mg torsemide=40 mg furosemide)
      iii. Diuresis < _____ cc/hr, and/or > _____ mg/dl sCr rise
      iv. ___ hospitalizations in ______ days
      v. readmission

3. **Labs:**
   a. CBC prior to treatment and every_____hour_____days during treatment
   b. BMP prior to treatment and every_____hour_____days during treatment
   c. CMP prior to treatment and every_____hour_____days during treatment
   e. Other Labs:_______________________________________________________________

4. **Anticoagulation therapy (e.g. aPTT, PTT, INR, etc):**
   a. Keep the patient is contraindicated
   b. Labs: obtain anticoagulation level prior to treatment
      i. ___PT/INR, PTT now and every _____ hrs. Every _____ day
      ii. ___ACT now and every _____ hrs
      iii. ___AntiXa level and every _____ day(s)
      iv. follow PTT based on heparin protocol
   c. Therapy
      i. Heparin with DVT protocol dosing or
      ii. Alternative therapy
         _____ Continuous slow infusion of heparin (e.g. 500 units/hr)
         _____ ECMO Heparin protocols, narrower range of PTT (for example 40-60 sec general range)\(^2\)
         _____ Heparinized saline to prime/reprime the circuit (for example 5000 units in 500 ml normal saline or 5000 units in 1L normal saline)\(^3,4\)
         **Bolus of Heparin prior to initiation of therapy:**
         _____ Priming circuit with Heparin in saline 5000 Units/L in saline (9 mg/ml)\(^5\)
         _____ Weight based option: patient on Heparin gtt, with subtherapeutic PTT, bolus units/kg per Heparin protocol\(^6\)
ULTRAFILTRATION ORDERS USING THE AQUADEX SMARTFLOW

5. Venous access:
   a. ______ CHF 6Fr. dual, triple or quad lumen (with at least 2 lines 16ga or larger) Peripheral Extended Length Catheter (dELC), -- OR --
   b. ______ 7-8Fr. dual lumen central line (dual 14ga or dual 16ga). -- OR --
   c. ____________________________________________________
   d. Remove all extensions and needle-less systems from the lines when connecting blood circuit (e.g. hub to hub)

6. Before starting treatment:
   a. Diuretic and electrolyte replacement therapies may be discontinued for duration of Aquapheresis treatment.
   b. Ensure venous access is patent and can deliver required blood flow.
   c. Ensure blood circuit set is loaded properly (press the PRIME then HELP keys on device).
   d. Prime blood circuit with a minimum of 250 ml NS and ensure prime is successfully completed.

7. Treatment:
   a. Connect blood circuit to venous access.
   b. NET Fluid removal at a rate of ______ ml/hr (0-500 ml/hr) for _____ hours OR until _____ liters of fluid removed.
      i. Monitor patient for clinical signs of hypovolemia and hypotension as appropriate.
   c. Vital signs Q____ minutes or first ____ hour(s), then Q____ hour for duration of treatment and PRN patient status.
   e. IV drug therapy can be administered through the access ports on the blood circuit.
   f. For laboratory testing, blood can be removed through the access port on the withdrawal side of the blood circuit.

8. Monitoring
   a. Vital signs every ______ minutes for the first hour(s), then every ______ hr(s)
      i. Aline monitoring every ______ hr(s)
   b. Hemodynamic Monitoring
      i. CVP monitor every ___ hr(s)
      ii. PA monitoring every ______ hr(s)
      iii. CO/Cl every ______ hr(s)
   c. SVO2 Monitoring
      i. Keep the SVO2 monitor every ___ hr(s)
      ii. add contact provider for ______%
      iii. if SVO2 < _____% contact provider
      iv. if SVO2 < ____% set UF rate to 0 and contact provider
   d. Hematocrit Monitoring (if prescribed/available):
      i. To enable, place sensor clip on the blood set chamber and follow the onscreen instructions.
      ii. After baselining is complete, accept the default or set the prescribed Hct Limit:
         Accept the default Hct limit, or
         Set Hct limit to (%) _______
   e. Strict I& O record every _____ hr(s)
   f. Daily weight ________
   g. Fluid restriction ______ ml/24 hours
ULTRAFILTRATION ORDERS USING THE AQUADEX SMARTFLOW

9. Call the physician or provider if:
   a. SBP < ______ mm HG
   b. Heart rate > _____ and decreased UF rate by ______ ml/hr, or place at 0 ml/hr until stabilized.
      Once stable, Resume UF at lower rate (i.e. 50-100 ml/hr less that last rate)
   c. If the Hct Limit is consistently exceeded (e.g. at least ____ “Extended UF Pump Stoppage” alerts have occurred) and
      the patient is otherwise stable and obviously fluid overloaded, consider the following:
      i. Returning the patient to the baseline position.
      ii. Reducing the UF Rate by________ (e.g. 100 ml/hr)
      iii. Increasing Hct Limit to_________ (e.g. 34.5 to 35.5)
      iv. 50-100 ml/hr by reducing UF rate add increasing Hct limit by _____%

10. Post therapy:
   a. Maintain IV access per unit protocol ________________________________________________
   b. Discontinue anticoagulation as appropriate.
   c. Resume diuretics as appropriate.

Additional Orders

__________________________

__________________________

__________________________

__________________________

Physician signature

☐ Sent to pharmacy _______ (initials)

Date/Time

Printed physician name

RN Name

Vendor Information

Legal Name: CHF Solutions, Inc
Address: 12988 Valley View Rd, Eden Prairie, MN 55344
Tax ID: 68-0533453
Customer Service: 1-855-786-2778

To place an order:
• Email orders to: orders@chf-solutions.com
• Fax orders to: 952-500-8731
Remittance: Same as above
Payment method: Check/Credit Card/ACH

Electronic Funds Transfer:
Bank: JP Morgan Chase Bank, N.A.
Account: 878351183
ABA: 075000019
Terms: Net 30

Accounts Receivable Contact:
Chris Paulson
AR@chf-solutions.com
952-563-7039

Product Family:
The Aquadex SmartFlow™ Product Line