



# Corporate Presentation

(NASDAQ: CHFS)  
November 2017



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This presentation contains forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties. Various factors could cause actual results to differ materially from these statements including our ability to execute on our strategic realignment and to grow our Aquadex business, our post-market clinical data collection activities, benefits of our products to patients, our expectations with respect to product development and commercialization efforts, our ability to increase market and physician acceptance of our products, potentially competitive product offerings, intellectual property protection, our expectations regarding anticipated synergies with and benefits of the Aquadex business, and the other risks set forth under the caption "Risk Factors" and elsewhere in our periodic and other reports filed with the U.S. Securities and Exchange Commission, including our Annual Report or Form 10-K for the fiscal year ended December 31, 2016. We are providing this information as of the date of this presentation and do not undertake to update any forward-looking statements contained in this presentation as a result of new information, future events or otherwise.

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*We have filed a Registration Statement on Form S-1 with the SEC, including a preliminary prospectus dated October 18, 2017 (the "Preliminary Prospectus"), with respect to the offering of our securities to which this communication relates. Before you invest, you should read the Preliminary Prospectus (including the risk factors described therein) and, when available, the final prospectus relating to the offering, and the other documents filed with the SEC and incorporated by reference into the Preliminary Prospectus, for more complete information about us and the offering. You may obtain these documents, including the Preliminary Prospectus, for free by visiting EDGAR on the SEC website at <http://sec.gov>.*

*Alternatively, we or any underwriter participating in the offering will arrange to send you the prospectus if you request it by contacting Ladenburg Thalmann & Co. Inc., 277 Park Avenue, 26th Floor, New York, NY 10172 or by email at [prospectus@ladenburg.com](mailto:prospectus@ladenburg.com).*

# Aquadex Business Overview

## Business and Market Overview

- Aquadex and its Aquapheresis therapy, a form of ultrafiltration to reduce fluid overload in patients, when diuretics fail
- Acquired from Baxter in August 2016
- FDA 510(k) market cleared and CE marked
- Installed base of 500+ consoles, in over 300 US hospitals and successfully used in over 60k patients
- There are an estimated 6.5 million people in the US with heart failure<sup>1</sup>
- There are approximately 1 million US hospital admissions per year for heart failure<sup>2</sup>
- **Approximately 90% of US hospitalizations admissions for heart failure are due to fluid overload<sup>3</sup>**

## Product Overview

- Removes nearly 40% more fluid in patients than conventional diuretic drug therapy over the same period of time<sup>4</sup>
- At 90 days, patients have a 53% reduction in the risk of rehospitalization than those treated solely with diuretics<sup>3</sup>
- Fewer re-hospitalization days due to cardiovascular event<sup>5</sup>
- Three large cardiology societies have published guidelines recommending ultrafiltration

1. Benjamin E, et al. *Circulation*. 2017 Jan 25; e379.
2. CMS Provider Utilization and Payment 100% Coverage IPPS.
3. Costanzo MR, et al. *J Am Coll Cardiol*. 2007 Feb 13; 49(6): 675-683.
4. Bart BA, et. al., *Am Coll Cardiol*, 2005;46:2043- 6
5. Costanzo MR, et. al., *J Am Coll Cardiol*, 2005;46:2047-51.

# Aquadex Product Overview

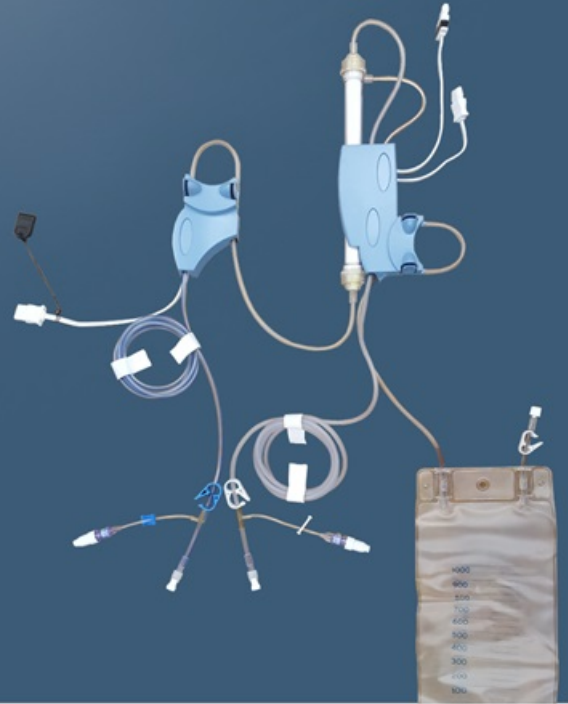
Aquadex Console



Venous Catheter



Blood Circuit Set



## Our Vision

To be the global market leader in the prediction,  
control, and prevention of hypervolemia.



# Fluid Management Today vs Tomorrow

## Device-based Therapy

**chf solutions™**

**Standard of care** therapy to prevent fluid overload. Used both in **In-Patient and Outpatient** settings

**Symptomatic**

**Preventative**

Managing symptoms mostly in In-Patient settings. Used after diuretic failure in very sick patients.

**Pharmacologic Therapy**

# Fluid Overload

## The Predominant Cause of Heart Failure Hospitalization

### Heart Failure

A weakening of the heart's pumping ability causing fluid retention in the body.

### A Significant Burden on our Healthcare System

- 1 million people in the US are admitted annually to the hospital for heart failure<sup>1</sup>
- 90% of these admissions are because of fluid overload<sup>2</sup>
- US congestive heart failure projected cost increase from \$31 billion in 2012 to \$70 billion in 2030<sup>3</sup>

1. CMS Provider Utilization and Payment 100% Coverage IPPS.  
2. Costanzo MR, et al. *J Am Coll Cardiol*. 2007 Feb 13; 49(6): 675-683.  
3. Heidenreich PA, et al. *Circ Heart Fail*. 2013 May; 6(3): 606-619.

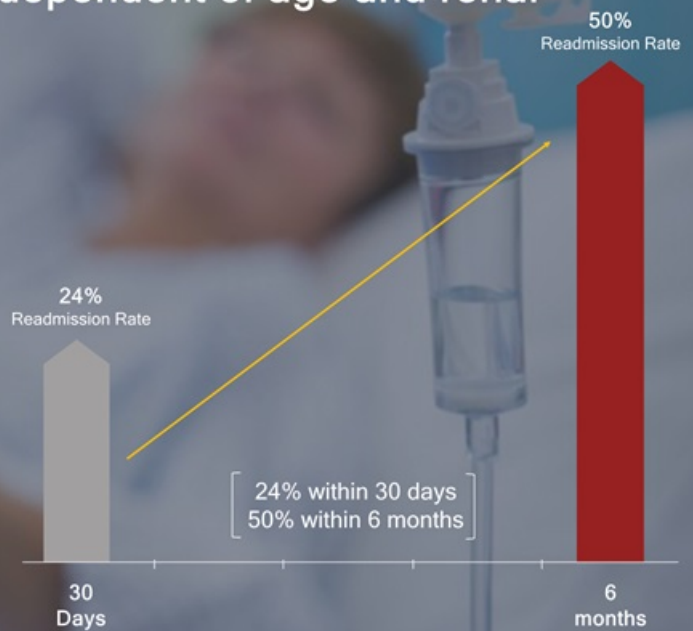


# Recurrent Fluid Overload

## An Alarming Problem

Recurrent fluid overload in heart failure has uniformly been associated with worse outcomes independent of age and renal function

- 24% of patients are readmitted within 30 days of hospital release
- 50% of patients are readmitted within 6 months of hospital release



Sources: Ross JS, et al. *Circ Heart Fail.* 2010 Jan; 3(1): 97-103.  
Desai AS, Stevenson LW. *Circulation.* 2012 Jul 24; 126(4): 501-506

# Diuretics

## The Current First-line Standard of Care

### Symptoms of Fluid Overload\*

- Difficulty in breathing and shortness of breath
- Swelling in legs, arms, abdomen, and fluid in lungs
- Limitations in daily life, decrease in patient's quality of life

### Treatment

- Lasix and Furosemide
- The body develops natural resistance; treatment goals are not met; patients discharged still fluid overloaded
- Unresolved congestion leads to further cardiovascular morbidities

### Limitations

- Diuretic effectiveness can become unpredictable; unique to the patient and disease progression
- Longer exposure to diuretics can lead to Acute Kidney Injury, Cardio Renal Syndrome and non-responsiveness

\*Granado and Mehta, BMC Nephrology (2016) 17:109.

# Diuretics

## The Current First-line Standard of Care

In a large subset of patients, Diuretics fail to provide optimal patient outcomes due to:

- Diuretic resistance, which leads to ineffective removal of fluid from patients
- Residual fluid excess at the time of discharge accounts for nearly half of hospitalized patients with heart failure
- Worsening heart failure with increased mortality after discharge
- Insufficient symptom relief, such as persistent congestion
- Increase in re-hospitalization rates
- Risk of electrolyte imbalance (i.e. low magnesium and low potassium)

Costanzo MR, et al., J Am Coll Cardiol., 2017; 69: 2428-45

# Indications for Use

The Aquadex FlexFlow® System is indicated for:

- Temporary (up to 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy
- Extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization

*All treatments must be administered by a healthcare provider, under physician prescription, both of whom having received training in extracorporeal therapies.*

*Use in pediatric patients has not been validated and is not recommended.*



# Aquadex Ultrafiltration System

## How it Works

An FDA cleared, ultrafiltration system that is a safe and effective way to remove excess salt and water from the body

- The device is connected to a catheter to withdraw blood containing excess fluid from the interstitial space
- The blood then passes through a special filter in the device
- The filter separates excess salt and water from the blood
- The blood is returned to the patient's body via the catheter



# Aquadex FlexFlow® System

## Controlling Fluid Reduction. Restoring Balance.

### Clinical and Economic Advantages of the Aquadex System:

- Simple to use, highly automated, and provides precise control of rate and amount of fluid removed
- Extracts more sodium than diuretic therapy while sparing potassium and magnesium<sup>1</sup>
- Restores diuretic responsiveness<sup>2</sup>
- Sustained benefits of early and adjustable ultrafiltration<sup>2</sup>
- At 90 days, patients have a 53% reduction in the risk of rehospitalization than those treated solely with diuretics<sup>3</sup>
- Reduced unscheduled ER visits<sup>3</sup>
- Fewer rehospitalization days due to cardiovascular event<sup>4</sup>
- Aquadex provides for efficient patient to nurse workflow



1. Ali SS, et al. Congest Heart Fail. 2009; 15(1):1-4.

2. Costanzo MR, et al., J Am Coll Cardiol., 2017; 69: 2428-45.

3. Costanzo MR, et al. (UNLOAD) J Am Coll Cardiol. 2007 Feb 13; 49(6): 675-683

4. Costanzo, et al. (AVOID-HF) Am Heart J 2015;170: 471-82.

## Extracorporeal Ultrafiltration for Fluid Overload in Heart Failure

### Unmet Clinical Need:

- The foremost goal in managing acutely decompensated heart failure is to effectively resolve fluid overload
- Diuretic agents become increasingly ineffective with disease progression due to the development of unresponsiveness in a significant sub-set of patients
- Nearly 50% of hospitalized patients are discharged with residual fluid after receiving conventional diuretic therapies

### The Clinical Solution:

- Ultrafiltration can restore diuretic agent responsiveness
- Clinical benefits of ultrafiltration can persist beyond the index heart failure hospitalization up to 90 days
- Precise control of rate and amount of fluid removal
- No effect on plasma concentration of potassium and magnesium
- More effective decongestion and fewer heart failure events compared to diuretics
- Efficacy, and improved outcomes can be seen with ultrafiltration

Costanzo MR, et al., J Am Coll Cardiol., 2017; 69: 2428-45

# Aquadex FlexFlow® Ultrafiltration System

## Significant Clinical Evidence

Study Name	Study Design	# of Patients	Study Patient / Patients Group	Date	Key Findings
<b>SAFE</b>	Multi-center, prospective, single-arm	21	IDE for 510k	2003 JCF	<ul style="list-style-type: none"> <li>Extracellular and intravascular fluid volume excess can be safely achieved via peripherally inserted UF</li> <li>Fluid removal endpoint achieved in 92% of patients</li> </ul>
<b>RAPID-HF</b>	Multi-center RCT	40 20 UF/20 SC	Early UF vs Diuretics	2005 JACC	<ul style="list-style-type: none"> <li>Early use of UF in CHF patients resulted in significant weight loss and fluid removal.</li> <li>Dyspnea and CHF symptoms were significantly improved in the UF group at 48 hours.</li> </ul>
<b>EUPHORIA</b>	Single-center, prospective single-arm	19	Early UF in diuretic resistance	2005 JACC	<ul style="list-style-type: none"> <li>UF before IV diuretics effectively and safely decreases length of stay and readmissions.</li> <li>60% of patients discharged in ≤3 days</li> </ul>
<b>UNLOAD</b>	Multi-center RCT	200 100 UF/100 SC	UF vs SC	2007 JACC	<ul style="list-style-type: none"> <li>UF produces greater weight loss than IV diuretics</li> <li>UF produced greater fluid loss than IV diuretics</li> <li>At 90-days, UF had fewer patients rehospitalizations</li> </ul>
<b>CARRESS-HF</b>	Multi-center RCT	188 94 UF/94 SC	UF vs SC patients with cardiorenal syndrome	2012 NEJM	Stepped pharmacologic therapy algorithm was superior to a strategy of ultrafiltration for the preservation of renal function at 96 hours, with a similar amount of weight loss with the two approaches.
<b>AVOID-HF</b>	Multi-center RCT	224 110 UF/114 SC (810 planned)	UF vs SC to evaluate readmissions	2015 JACC:HF	Ultrafiltration group trended towards a longer time to first HF event within 90 days and fewer HF and cardiovascular events.



# Clinical Guidelines Support Aquapheresis Use

## **HFSA - Heart Failure Society Of America**

Ultrafiltration may be considered in lieu of diuretics

## **ESC / HFA - European Society of Cardiology and Heart Failure Association**

Venovenous isolated ultrafiltration is sometimes used to remove fluid in patients with HF, although is usually reserved for those unresponsive or resistant to diuretics

## **CCS - Canadian Cardiovascular Society**

Patients with persistent congestion despite diuretic therapy, with or without impaired renal function, may, under experienced supervision, receive continuous venovenous ultrafiltration

1. HFSA 2010 Comprehensive Heart Failure Practice Guidelines: Lindenfeld J, et al. J Card Fail. 2010 Jun; 16(6): 475 – 539.
2. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: McMurray JJ, et al. Eur Heart J. 2012 Jul; 33(14): 1787 – 1847.
3. 2012 Canadian Cardiovascular Society Heart Failure Management Guidelines Update: McKelvie RS, et al. Can J Cardiol. 2013 Feb; 29(2): 168 – 181.

# 80% of Hospital Readmissions Due to Heart Failure

In response, on October 1, 2012 the Affordable Care Act instituted the Hospital Readmission Reduction Program (HRRP)<sup>†</sup>

- **Requirement:** CMS to reduce payments to hospitals with excess readmissions
- **Penalty:** hospitals can lose  $\leq 3\%$  of Medicare reimbursement

<sup>†</sup>Readmissions Reduction Program (HRRP). Centers for Medicare & Medicaid Services website. Updated April 18, 2016. Accessed May 25, 2016.  
<https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html>

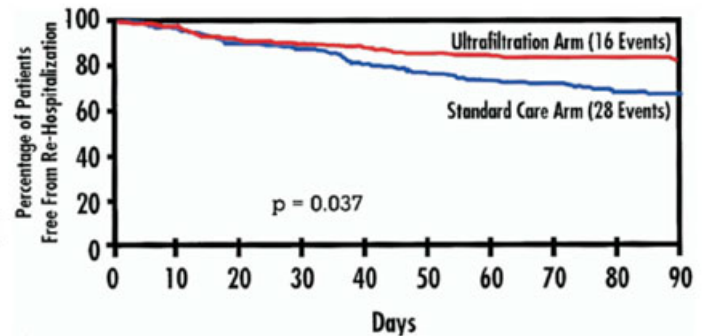
# Ultrafiltration vs. Intravenous Diuretics for Patients Hospitalized for Acute Decompensated CHF (UNLOAD Study)<sup>1</sup>

## Multicenter, prospective, randomized clinical study

- 100 patients UF vs. 100 patients standard of care (diuretics)

## Ultrafiltration 90-day Outcomes

- 44% reduction in patients re-hospitalized for heart failure
- 63% reduction in re-hospitalized days (1.4 vs. 3.8 p = 0.022)
- >50% reduction in unscheduled clinic / ER visits (21% vs. 44%; p=0.009)



<sup>1</sup>Costanzo MR, et. al., *J Am Coll Cardiol.*, 2007;49:675-83

# Today's Healthcare Environment

## Aquapheresis in a Clinical Setting Good Samaritan Hospital: A Single Center Experience

### Independent study on 67 heart failure patients who received Aquapheresis:

- No 30-day readmits for volume overload
- Length of Stay when started within 24 hours was 2.2 days, compared to national average of 5.9 days
- Readmission rate from before Aquapheresis down from 12% to 4% the year prior
- Average of 5.7 liters removed per patient

\*Data presented at the National Teaching Institute & Critical Care Exposition (NTI) in Chicago, IL on May 5-8, 2008. Results may vary.

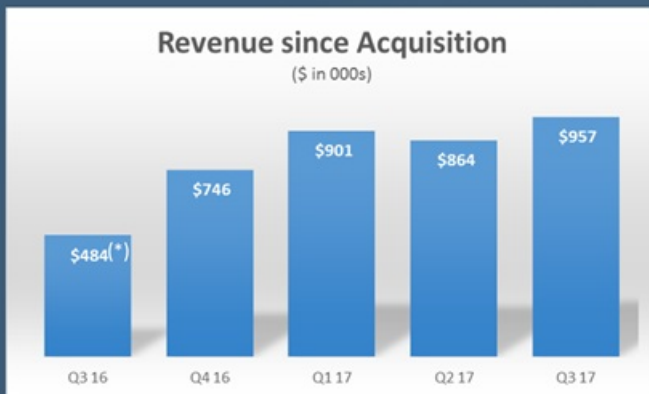
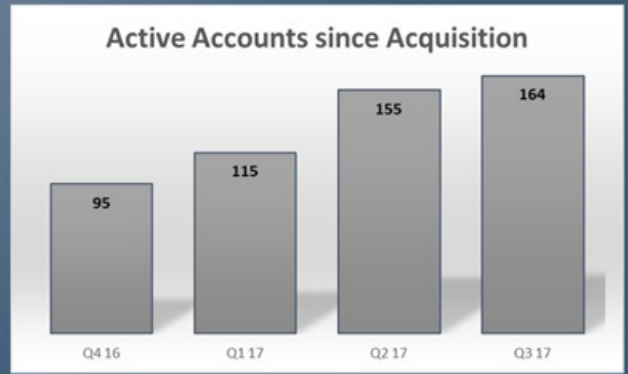
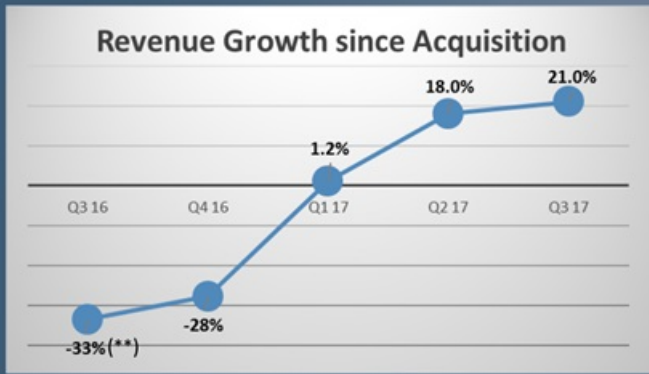


# Recent Developments

- Revenue increased 21% compared to the same period in 2016 on a pro forma basis
- Expanded sales footprint to 10 territories by adding 6 additional sales professionals
- Distribution commenced in United Kingdom
- Completed Scientific Advisory Board (SAB) meeting with 6 physician Key Opinion Leaders
- Clinical research protocols underway
- Transitioned Aquadex manufacturing from Baxter to in-house operations
- Current number of customers continues to increase (Currently at 164)



# Performance Metrics



(\*) Represents revenue since acquisition date, August 6, 2016  
 (\*\*) Calculated on a pro forma basis

# Capitalization Table

Instrument	Shares
Common Shares (Nasdaq: CHFS)	625,791
Warrants (WAEP \$26.10; Exp 2021-2025)	496,468
Options (WAEP: \$90.70)	36,868
RSUs	297
<b>Total</b>	<b>1,159,424</b>

# Growth Opportunities

## Aquadex Growth Drivers

- 1 Established Customer Base**  
Opportunity to expand utilization in current base of over 300 US hospital customers who currently own over 500 consoles
- 2 Underpenetrated Inpatient Market**  
1 million annual HF admissions for fluid overload, 30% whom are resistant to diuretics provide an inpatient opportunity of  $\geq 315,000$  patients/year
- 3 Untapped Outpatient Market**  
Medicare penalties for early readmissions is driving a growing outpatient market with  $\approx 300K$  treatments per year in U.S. alone
- 4 OUS Growth Opportunity**  
OUS market largely untapped to date, offering long-term growth potential
- 5 Multiple Clinical Applications**  
Aquadex removes excess fluid in diuretic resistant patients with a variety of volume overloaded conditions
- 6 Alignment with Market Dynamics**  
Readmission and length of stay benefits of Aquadex are in line with the market shift toward value-based technology
- 7 Dedicated Reimbursement Opportunity**  
Producing clinical data or assimilating existing data can achieve dedicated outpatient codes and drive market uptake



# Executive Leadership Team



**Megan Brandt**  
Senior VP Operations

- 15 Years medical device/pharma experience
- Veteran regulatory & quality professional with provide track record
- B.S. in Biochemistry & Microbiology



**Jim Breidenstein**  
Chief Commercial Officer

- 15 years Executive Leadership (President/COO/GM) Experience
- Commercial and Operations Sr Level Leadership
- Paradigm changing technology development -Baxter, Kyphon, Neuronetics, CSI.



**Claudia Napal Drayton**  
Chief Financial Officer

- 15 year finance career with Medtronic in United States and Europe
- 20+ years finance/accounting experience
- CPA, MBA Finance and Strategy University of Minnesota



**David Lerner**  
Senior VP R&D

- 25+ years of medical device development experience
- Founder of several vascular diagnostic device firms
- Graduate degrees in Medical Physics and Technology Management



**Sandra Eays**  
VP Human Resources

- 20 years experience in human resources with medical device experience with Boston Scientific and St. Jude Medical
- B.A. degree in Business Administration from the University of Wisconsin



**Gordon Weber**  
VP General Counsel

- 19 year legal career, 6 in medical devices, 13 in corporate law
- 12 years finance/accounting experience
- B.A. in Accounting, Valedictorian of William Mitchell College of Law class of 1997

# Board of Directors

**John Erb**

Chief Executive Officer, Chairman

- 40+ years experience in medical devices
- CEO of 4 med-tech start-up companies
- Chairman of 3 public boards
- BA in Business Administration from California State University, Fullerton

**Jon Salvesson**

Non-Executive Member

- Investment Banking and Chairman of the Healthcare Investment Banking Group at Piper Jaffray, focus on the medical device industry
- B.A. in Chemistry from St. Olaf College and an M.M.M. in Finance from the Kellogg Graduate School of Management at Northwestern University

**Warren Watson**

Non-Executive Member

- 35+ years of medical device experience
- 33 years of experience at Medtronic in CRM, HF, Cardiac Ablation, and Cardiology
- Undergraduate and graduate degrees in Engineering from the University of MN

**Greg Waller**

Non-Executive Member

- 40+ years of financial management experience
- Current and past Board member for multiple medical device companies
- 30 years experience as CFO
- MBA in Accounting from California State University at Fullerton

**Matthew Likens**

Non-Executive Member

- President and CEO of Ulthera, Inc. from 2006 to 2016
- President of GMP Wireless Medicine from 2001 to 2006
- Baxter Healthcare Corporation from 1978 to 2001, President of Baxter's Renal U.S.
- B.B.A. in Marketing, Kent State University

**Steve Brandt**

Non-Executive Member

- 35+ years of experience in medical devices.
- VP, Global Sales and Marketing at Thoratec, 2004 to 2015
- VP Sales & Marketing, CHF Solutions 2002 to 2004
- VP of Global Marketing, Cardiovascular Surgery Division for St. Jude Medical, 2000 to 2002
- B.S. from Franklin Pierce College

## For More Information

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