



# Company, Technology and Market Overview Presentation

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This presentation includes devices, systems and methods contained within pending, allowed and / or issued patents

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# Business Model

- Early and Broad IP Coverage
  - ◆ IP filing priority dates prior to company formation
- Minimal Cash Burn = Minimal Investment Required
  - ◆ Low overhead, Limited capital equipment
  - ◆ Utilization of consultants
- Limited Number of Outstanding Shares
- Focus on Increasing Company Value by Achieving Significant Milestones
- Rapid and Efficient Product Development
  - ◆ Functional prototypes in days, not weeks



# Summary

- Privately-held company with a family of vascular access closure systems designed to be safer, easier to use, perform better and cost less;
- Strong, early (pre 2001) and enabling IP position with two issued and eight pending patents;
- Scalable designs to accommodate a wide range of sizes, including large diameter access sites (< 16 Fr. to > 22 Fr.);
- Removable, permanent and bioabsorbable access closure solutions.



# What is a Vascular Access Closure Device?

- A device used to close the puncture in the vessel (typically the femoral artery) after a percutaneous transluminal diagnostic or therapeutic, cardiovascular catheterization procedure.
- Common designs include
  - Suture based,
  - Reabsorbable materials,
  - Nitinol clips.
- The estimated number of endovascular procedures requiring percutaneous access in 2006 was 8.5 M, growing to 11.1 MM by 2011.



## Why is their use important?

- Quickly stop bleeding at the puncture site (especially important with the increased use of anticoagulation drugs such as Plavix, etc.).
- Reduce time to ambulation and discharge (from multiple hours to minutes).
- Reduce the potential of serious procedure related complications, such as:
  - Femoral artery thrombosis,
  - The formation of a pseudoaneurysm,
  - Femoral artery laceration,
  - Hematoma,
  - AV fistula.



# What Problems Do We Solve?

- Current Systems Difficult to Use
  - Our System
    - Easy to use, only two system components,
    - System utilizes the already existing introducer to guide the sealing element to the puncture site.
- Current Systems Are Expensive - \$250. to over \$300. per set
  - Our Bioabsorbable Plug System (Nitinol Clip System)

Our system est. price:	< \$150.	(< \$150.)
Estimated COGS:	< \$25. per set.	(< \$50.)
- Limited Product Solutions
  - Our System
    - Multiple sealing element options available,
    - Removable, temporary use,
    - Permanent implant,
    - Size range from 6 Fr. to > 20 Fr.

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# Competitive System Prices

	<u>Average System Price</u>	<u>Est. Current Yearly Sales</u>
St. Jude Medical Angio-Seal	\$225.	\$368 MM
Abbott Vascular Perclose A-T	\$220.	\$120 MM
Abbott Vascular StarClose	\$225.	\$45 MM
AccessClosure Mynx	\$245.	\$32 MM
Our Nitinol Clip System	< \$150.	
Est. Cost of Goods Sold (COGS)	< \$50.	
Our Bioabsorbable Plug System	< \$150.	
Est. Cost of Goods Sold (COGS)	< \$25.	

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# Our Vascular Access Closure System Technologies

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# Vascular Access Closure System Versions

Covered by the Company's Intellectual Property

- **Bioabsorbable Plug (Single Piece)**
  - Non collagen sealing element is absorbed by the body within 60 to 90 days, leaving nothing behind;
  - Extravascular version design also – no foreign material inside vessel.
  
- **Swellable, Bioabsorbable Tubular Plug**
  - Extravascular – no foreign material inside vessel;
  - Sealing element is absorbed by the body within 60 to 90 days, leaving nothing behind.
  
- **Nitinol Clip (Self-Closing)**
  - Removable and Permanent Versions;
  - Extravascular – no foreign material inside vessel.
  
- **Thermal Closure**
  - Extravascular – no foreign material inside vessel;
  - Acute hemostasis – Patient leaves the hospital with nothing left behind in the body.

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# The Vascular Access Closure Market

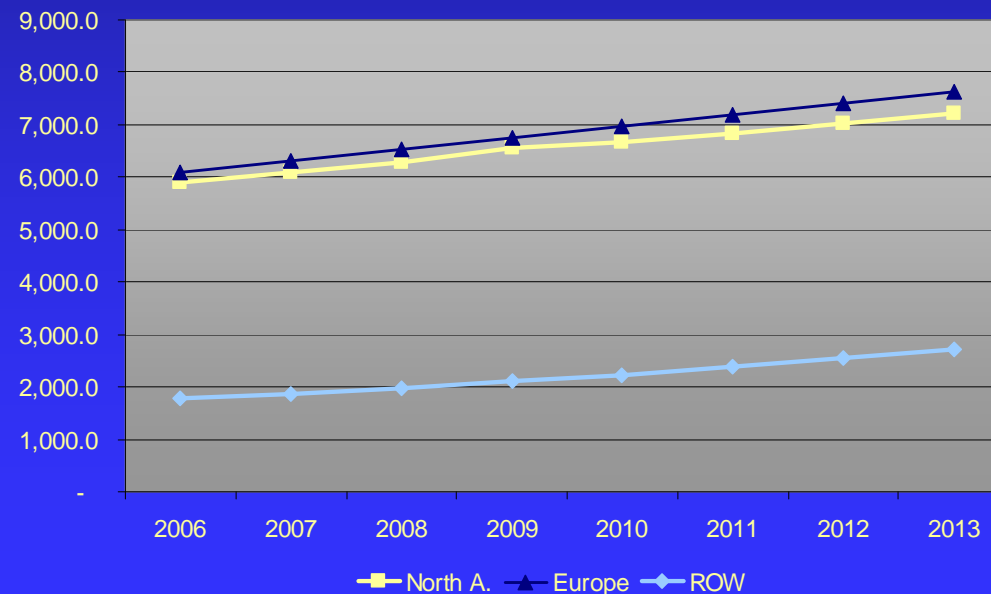
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# The Percutaneous Cardiovascular Procedure Market

- The Percutaneous Cardiovascular Market includes cardiac and peripheral vascular procedures performed using catheters inserted into the body via the femoral, brachial or radial artery
- An estimated 11,791,000 (range 8.7 – 14.1 million) cardiovascular procedures are to be performed in 2008 with an expected CAGR of at 2.6% (range 1.7-3.5%) per year through 2013

**Catheterization Procedures Requiring Vascular Closure  
2006-2013**



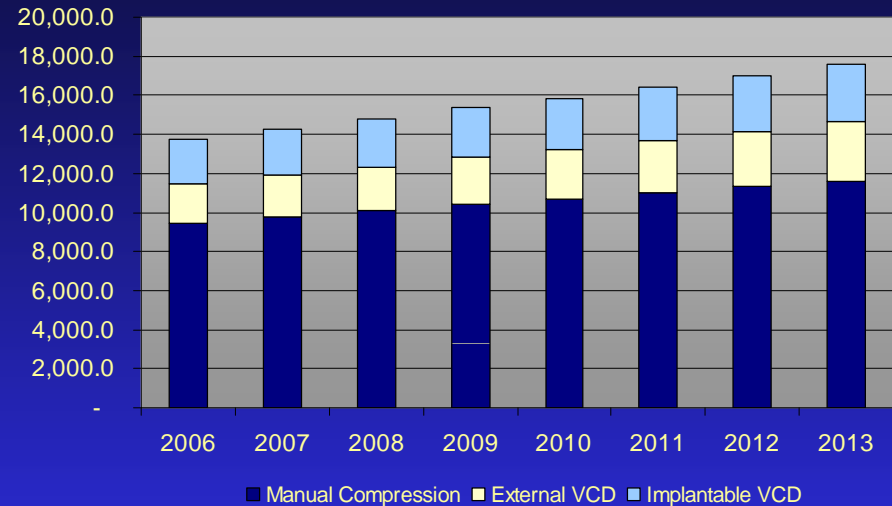
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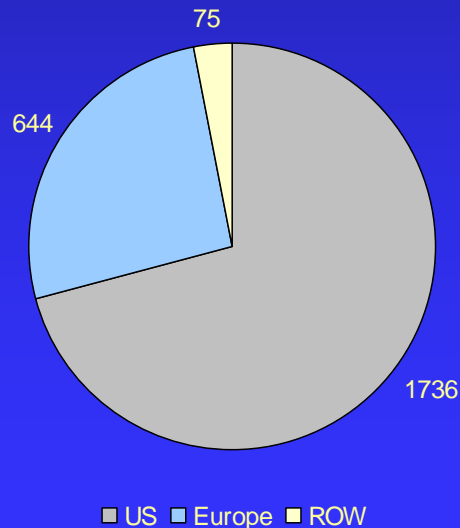
# The Opportunity

- The total market penetration for the VCD market is 31.9% (2008), with 16.6% of the market being served by implantable devices
- The US represents 2/3 of the global Implantable VCD market driven by the demand for reduced time to discharge and incremental cases

Global Utilization of Vascular Closure Methods 2006-2013



Implantable VCD Market by Procedures (000's)



- Implantable VCDs reduce time to hemostasis and time to ambulation that translates into 6 additional procedures per day in the typical lab setting, creating an **incremental margin of \$8,874 per day** at average US reimbursement rates.

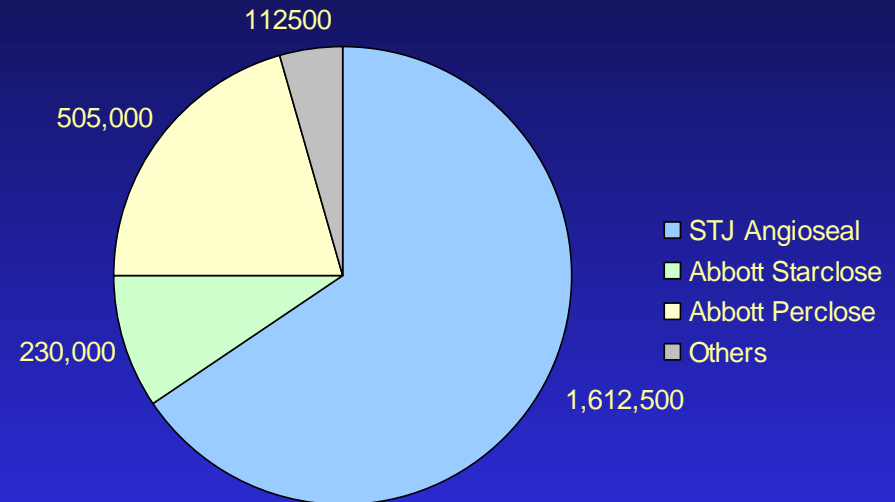
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# Competitive Landscape

- The market is dominated by St. Jude Medical and Abbott Vascular
- Key factors influencing choice of VCD system include fast, easy deployment with positive vessel localization and a fail-safe deployment and a low learning curve

2008 Global Implantable VCD Market Share



Implantable VCD Market Leaders - 2007				
Company	Device	Units	Revenue	ASP
St. Jude	Angioseal	1,612,500	\$350,000,000	\$ 217
Abbott	Starclose	230,000	\$ 45,000,000	\$ 196
Abbott	Perclose	505,000	\$120,000,000	\$ 238

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# Market Segmentation

- The market can be segmented by users:
  - ◆ Interventional cardiologists
  - ◆ Interventional radiologists
- The endovascular, arterial access market can also be segmented by procedures into two areas:
  - ◆ Coronary procedures
  - ◆ Peripheral procedures
- An emerging market is appearing in the percutaneous valvular repair / replacement market where large (16 Fr. to 22 Fr.) introducer sheaths are required;
- Our technology could also be used as a non-surgical method to quickly and easily close hemodialysis access sites that are no longer patent – huge potential market.

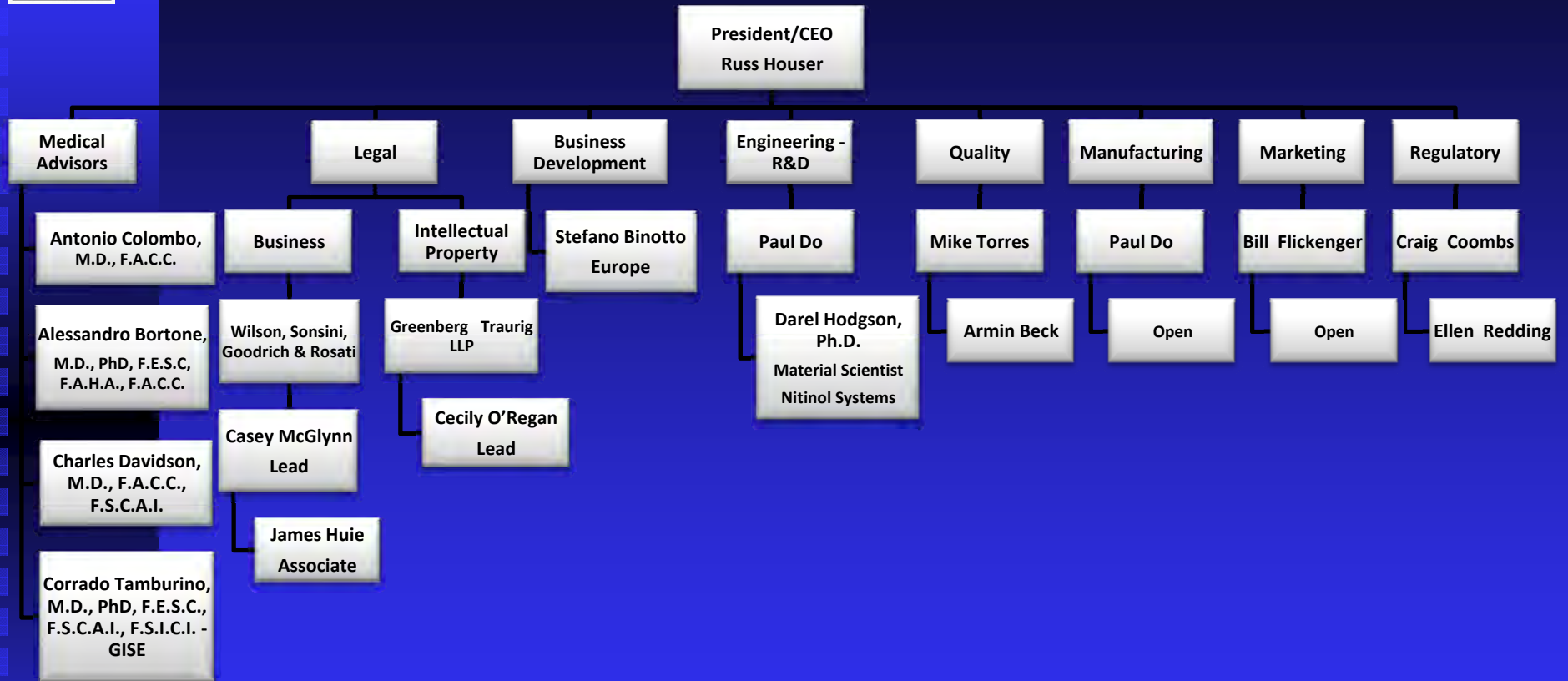


# Company Organization Chart and Group Bios

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# Company Organization Chart



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# Medical Advisors

- Alessandro Bortone, M.D., PhD, F.E.S.C., F.A.H.A., F.A.C.C.
  - Chief of Interventional Laboratory, Institute of Cardiac Surgery, Policlinico di Bari. University of Bari School of Medicine (IT);
  - Over 28 years experience in interventional cardiology and minimally invasive cardiovascular techniques;
  - Member of the council on clinical cardiology and cardiovascular and radiology intervention for the American Heart Association (AHA).
  
- Antonio Colombo, M.D., F.A.C.C.
  - Director of the Cardiac Catheterization Laboratory at EMO Centro Cuore Columbus Hospital, Milano (IT) and Chief of Invasive Cardiology at San Raffaele Hospital, Milano (IT) and is currently visiting professor at Columbia University School of Medicine (New York) NY.
  
- Charles J. Davidson, M.D., F.A.C.C., F.S.C.A.I.
  - Director of Interventional Cardiology Program, Professor of Medicine, Northwestern University Medical School;
  - Chief, Cardiac Catheterization Laboratories, Northwestern Memorial Hospital, Chicago.

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## Medical Advisors (continued)

- Corrado Tamburino, M.D., PhD, F.E.S.C., F.S.C.A.I., F.S.I.C.I. – GISE
  - Director of the Postgraduate School of Cardiology;
  - Chief of the Cardiovascular Department at Ferrarotto Hospital, Catania University (IT);
  
- Carlo Pappone - M.D., PhD, F.A.C.C.
  - Director, Department of Cardiology, Electrophysiology and Cardiac Pacing Unit, San Raffaele Scientific Institute, San Raffaele University Hospital, Milano (IT).



# Team Bios

- Russ Houser – CEO / Chairman
  - 20 years medical device development experience
  - 18 + commercialized product lines
  - Over 115 issued and pending medical device patents
  - 80% interventional cardiology, 20% cardiac surgery projects
  
- Darel Hodgson, Ph.D. – Material Scientist Consultant
  - President, Nitinol Technology, Inc.
  - Dr. Hodgson is a recognized authority on properties, fabrication and device issues regarding Nitinol alloys.
  - Chairman of the ASM Strategic Planning Committee involved with meeting the materials needs of the medical community.
  - Founded Shape Memory Applications (SMA) which was later sold to Johnson Matthey, Inc.
  - Dr. Hodgson is a founding member of the International Organization on Shape Memory and Superelastic Technologies (SMST) and served as Secretariat of the first SMST Conference in 1994 and as Chairman of SMST '97.

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## Team Bios (Continued)

- **Bill Flickinger – Marketing Consultant**
  - 19 years of domestic and international medical device sales and marketing experience;
  - Experience with interventional, long-term implantable devices, and capital equipment; working for start-ups and multi-billion dollar, multinational companies.
  
- **Craig Coombs – Regulatory Consultant**
  - Proven successful track record, specializing in start-ups, turn-arounds & facilitating company acquisitions/IPO's;
  - Strategies, negotiations & submissions: CE Mark, PMA, 510(k), IDE, ELA, Shonin.
  
- **Casey McGlynn (Partner, WSG&R - Palo Alto, Ca) - Lead Attorney**
  - Recognized in the 2006, 2007, 2008 and 2009 editions of *Chambers USA: America's Leading Business Lawyers*, most recently in the top tier of California life sciences attorneys;
  - Selected for inclusion in the 2007 edition of *The Legal 500 US*;
  - Named in 2006, 2007, 2008 and 2009 as a Northern California "Super Lawyer" by *Law & Politics* magazine;
  - Selected for inclusion in the 2006, 2007, 2008, 2009 and 2010 editions of *Best Lawyers in America*.

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# Clinical Procedure

## Permanent and Temporary (Removable) Nitinol Clip System

The Full Animation is Available to View at the Following Link:

<http://vclosure.com/nitinolclip.php>

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## Clinical Procedure

# Swellable, Bioabsorbable Tubular Plug Version

The Full Animation is Available to View at the Following Link:  
<http://vclosure.com/swellable.php>

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## Pre-Clinical Bench Tests

# Bioabsorbable Plug System

The Videos are Available to View at the Following Links:

<http://vclosure.com/fastsealpressurized.php>

<http://vclosure.com/VClosure6Ftestdeployment.php>

<http://vclosure.com/VClosure8Ftestdeployment.php>

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## Pre-Clinical *In Vivo* Study

# Bioabsorbable Plug System

The Video is Available to View at the Following Link:

<http://vclosure.com/fastsealpreclinical.php>

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# Intellectual Property

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# Intellectual Property

- IP Summary
  - Patent Filing Dates: April 2001
    - Priority date significantly earlier.
  - Two Issued Patents
    - 7,025,776 - Arteriotomy Closure Device and Techniques
      - IDS included over 50 patents
        - Including patents from Core Medical, Inc., Medical Technology Group, Inc., Datascope, Ethicon, Vascular Solutions, Sub-Q, Inc., Boston Scientific Corp, etc.
    - 6,726,696 - Patches and Collars for Medical Applications and Methods of Use
  - More Than Thirteen Additional Pending Patents
    - Including Continuation and CIP cases, using the issued patents as priority documents (enabling IP filing date priority to pre 2001)



# Intellectual Property

## ■ IP Summary (Continued)

### ■ Published US Patent Applications

<u>Application Number</u>	<u>Date Published</u>	<u>Filing Priority Date</u>	<u>Claims Focus</u>
20090143808	6/04/09	4/24/01	Guided, Slidable Tissue Cutter
20090143789	6/04/09	12/03/07	Nitinol Clips
20090005777	1/01/09	4/24/01	Thermal Closure
20080114394	5/15/08	4/24/01	Nitinol Clips
20080109030	5/08/08	4/24/01	Swellable, Bioabsorbable Tubular Plug

### ■ Claims Focus of Currently Unpublished Patent Applications

- Bioabsorbable Plug
- Nitinol Clips (PCT)
- Nitinol Clips

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# Intellectual Property

- IP Summary (Continued)
  - Key patents (issued and pending) reviewed in detail
    - Independent claim analysis performed on all relevant IP
  - Strong patent position – including when compared to
    - Integrated Vascular Systems, Inc.  
(Acquired by Abbott Vascular for \$65 million +)
      - Nitinol Clip Technology
    - Core Medical, Inc. / Ensure Medical, Inc.  
(Acquired by Cordis for \$52 million +)
      - Swellable Plug Technology
      - Both companies listed above were acquired without US regulatory approval
    - AccessClosure, Inc.  
(Published valuation: \$103 million)
      - Swellable Tubular Plug Technology

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## Additional Technology Covered by the IP and Available to the Company to License

- The Intellectual Property (IP) also covers devices, systems and methods for minimally invasive Patent Foramen Ovale (PFO) closure - About 40 percent of patients who have an ischemic stroke have no known cause (called cryptogenic stroke). PFO is present and associated with an increase in stroke in about 40 percent of cases. Also, migraine headaches are more common in patients with PFO. This additional application of our technology provides significant added value for the company.



# Competitive Closure Systems and Company Comparables

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# Competitive Landscape – Vascular Access Closure Devices

<u>Company Name</u>	<u>Product Name</u>	<u>Device Type</u>
Abbott Vascular	Perclose A-T Clincher ProGlide StarClose SE	Suture Suture Suture Nitinol Clip -Vessel Penetrating
Access Closure	Mynx	Swellable / Absorbable Plug
Cardiva Medical	Boomerang Wire	Interior Vessel Arteriotomy Compression
Cordis	ExoSeal	Bioabsorbable Plug
Datascope	Safeguard	External Tissue Compression Patch
Medtronic (AngioLink)	EVS	Titanium Staple
St. Jude Medical	Angio-Seal Evolution	Absorbable Inner Vessel Anchor and External Collagen Seal
Vascular Solutions	Duett Pro	Injectable, Flowable Procoagulant

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# Issues with Current Vascular Access Closure Devices

<u>Type</u>	<u>Method Deficiency (partial list)</u>
Localized Compression	Time (a half hour to several hours), method requires the patient to remain immobilized for a period of time, and is kept at the hospital for observation, potential for clot (at puncture site) to be dislodged. Amount of time can be significantly increased depending upon how much heparin, glycoprotein IIb/IIA antagonists, or other was used during the procedure.
Suture / Staple / Clip	Multiple required components, cost, separate deployment device required, some systems require a second insertion into the puncture site.
Collagen Plugs	Procedure variability, time to secure to vessel, cost, separate deployment device required (as well as second insertion into puncture site) and the potential of the plug becoming dislodged.
Adhesives, Gels, Foams, etc.	Cost, complicated deployment process, procedure variability, risk of closure material being injected into the vessel, separate deployment device required (as well as second insertion into puncture site).

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# Vascular Access Closure Company Acquisitions / Valuation

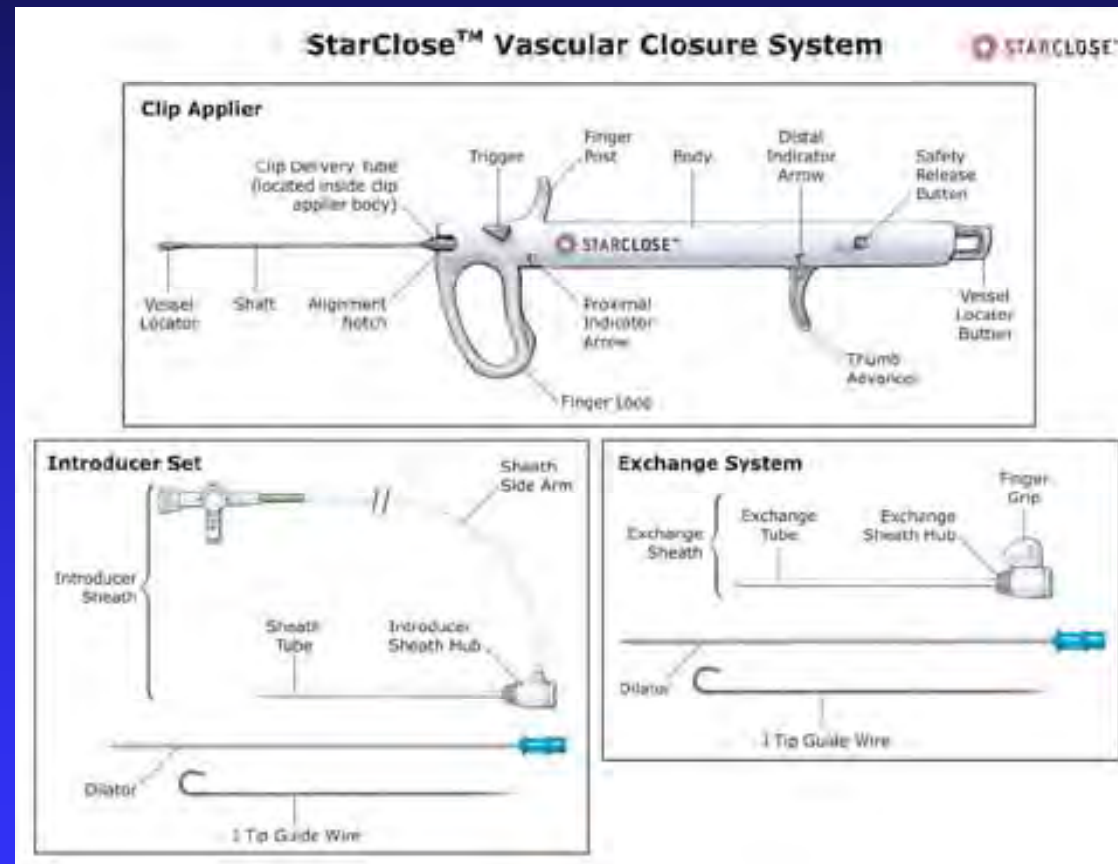
<u>Company</u>	<u>Stage When Acquired</u>	<u>Valuation</u>	<u>Acquiring Company</u>
AccessClosure	N/A	\$103 M	N/A
AngioLink	PMA Received	\$45 M +	Medtronic (Nov '04)
Ensure Medical	Pre FDA Approval	\$52M+	Cordis (July '06)
Integrated Vascular	Pre FDA Approval	\$63M+	Abbott (Sept '03)

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# Competitive Systems

## Abbott Vascular StarClose System



Multiple required system components – Multiple deployment steps

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## Abbott Announces Acquisition of Integrated Vascular Systems, Inc.

ABBOTT PARK, Ill., Sep 26, 2003 - Abbott Laboratories (ABT) today announced the acquisition of Integrated Vascular Systems, Inc. (IVS), based in Sunnyvale, Calif., a developer of a novel vessel closure technology. Under the terms of the agreement, Abbott acquired all of the equity of IVS, a privately held company, for approximately **\$65 million** in cash plus an additional milestone payment if agreed-upon targets are met. This transaction will not have an impact on the results of Abbott's 2003 ongoing operations, but will result in a one-time charge for in-process research and development. Additional financial terms of the agreement were not disclosed.

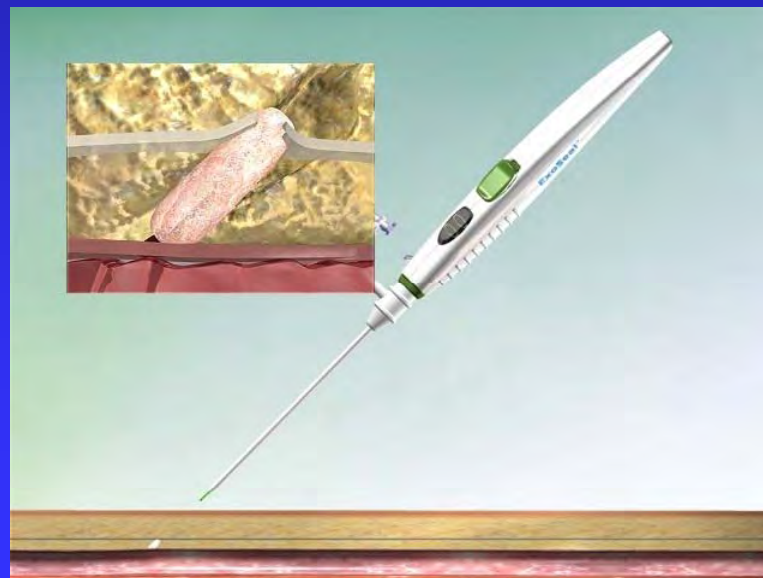
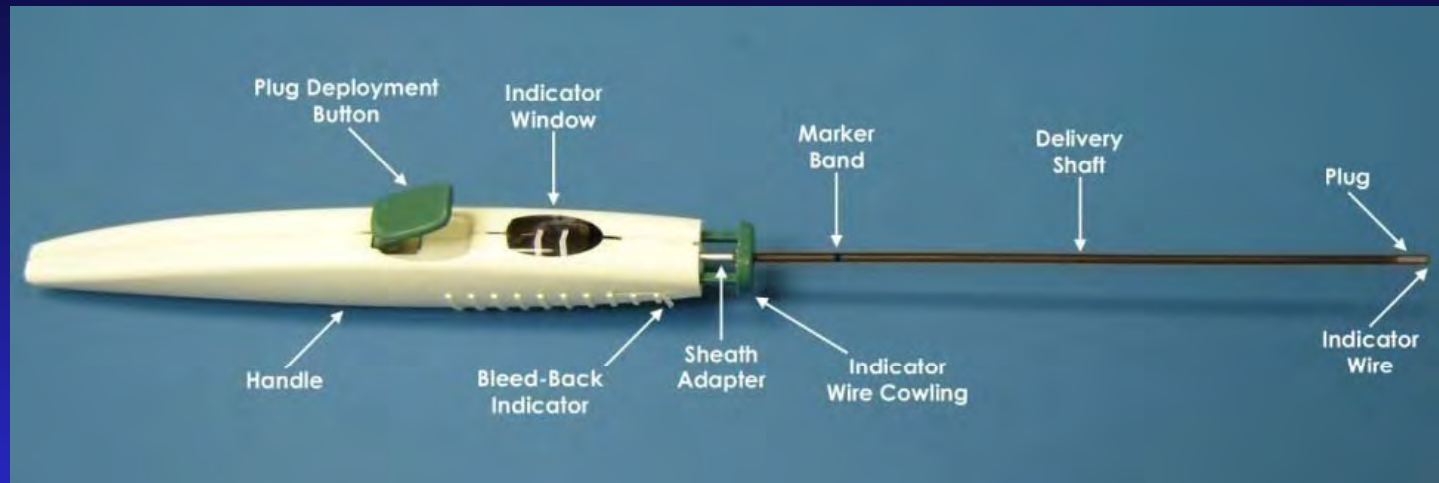
"This acquisition is an excellent fit with our strategy to build a comprehensive portfolio of vessel closure devices that meets the varied needs of clinicians," said Robert B. Hance, president, Abbott Vascular Devices, Abbott Laboratories. "IVS' technology is intended to offer clinicians an easy-to-use closure option -- without sacrificing confidence in the close -- and will be a natural complement to Abbott Vascular Devices' currently marketed closure technologies."

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# Competitive Systems

## Cordis ExoSeal



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## Cordis Corporation Acquires Ensure Medical, Inc.

Miami Lakes, FL, and Warren, NJ (July 13, 2006) – Cordis Corporation, a Johnson & Johnson company, the worldwide leader in cardiac and vascular technologies, today announced that it has acquired Ensure Medical, Inc., a privately held company in Sunnyvale, CA, that develops devices for post-catheterization closure of the femoral artery.

The lead investigational technology from Ensure Medical, Inc., is a femoral artery closure device (ACD), which uses a synthetic bioabsorbable polymer to stop bleeding and close the site of the arterial puncture. ACDs are designed to enable expedited closure time and reduce bed-stay when compared to conventional manual compression methods for wound access site closure. Nearly eight million patients undergo cardiac catheterization procedures annually.

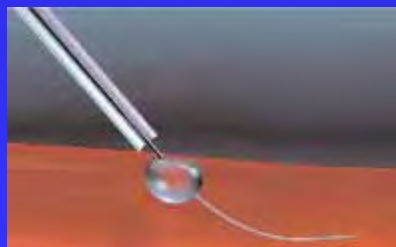
As a result of the acquisition, Johnson & Johnson expects to incur an estimated onetime after-tax charge of approximately **\$52 million**, or \$.02 per share, related to the expensing of in-process research and development. Other terms of the transaction were not disclosed.

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# Past and Current Published Valuation of AccessClosure, Inc.

<u>Round</u>	<u>Date</u>	<u>Amount Raised (MM)</u>	<u>Post Money Valuation (MM)</u>	<u>Company Stage</u>
1	Feb 02	3.5	9.0	Product Development
2	Aug 03	10.00	25.00	Product Development
3	Nov 04	7.8	41.00	Clinical Trials
4	March 06	30.00	103.00	Clinical Trials
5	Dec 07	35.0	Unknown	Regulatory Approval



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# Potential Funding / Exit Options

- Acquisition
  - Current Target Price: TBD + Milestone Payments
- Sub-license Technology
  - For technology included in our IP and not currently being developed;
  - For other than our primary fields of use;
  - Company may also consider a limited time option to license certain technologies covered by the Company's IP.
- Joint Venture with an Existing Company
  - Potential, limited distribution rights.
- Follow Up Financing
  - Corporate / Other Sources



# Benefits of Acquiring VCS, Inc.

## ■ Intellectual Property

- ◆ Strong, early (pre 2001), broad, enabling and extensive portfolio - more than 16 issued and pending patents;
- ◆ Use as priority document(s) for CIP cases;
- ◆ Ability to use the IP for any current or future patent litigation.

## ■ Technology

- ◆ Safe and effective - Simple to learn, Simple to use,;
- ◆ Significantly less expensive than competitors' systems, while still realizing typical medical device margins of 70% to 80%;
- ◆ Considerable sales potential;
- ◆ Multiple access closure technology options – All can be designed as extravascular solutions
  - ◆ Mechanical (Removable and Permanent) – removable version is 510(k)able;
  - ◆ Swellable, Bioabsorbable Tubular Plug and Bioabsorbable Plug,
  - ◆ Thermal.

## ■ Current Acquisition Price

- ◆ Acquisition would include multiple technology systems, not just one as was the case with the other vascular access closure company acquisitions.

## ■ Group

- ◆ Access to a small, skilled, focused, efficient, and highly motivated group, including world class interventional cardiologists.

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[www.vclosure.com](http://www.vclosure.com)

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