

Advancing Access Management Through Minimizing Complications and Maximizing Hospital Efficiencies



CARDIVA PORTFOLIO OF VASCULAR ACCESS MANAGEMENT PRODUCTS:

- Same platform has been utilized effectively in more than 400,000 procedures
- Facilitates rapid hemostasis
- Has very low complication rates
- Includes vascular closure system and a manual compression assist device
 - VASCADE®, Vascular Closure System
 - Extravascular and bioabsorbable
 - In a randomized, multicenter, prospective trial, the only vascular closure device to demonstrate statistically significant reduction in minor complications as compared to manual compression
 - CATALYST, Manual Compression Assist Device
 - In a randomized, multicenter, prospective trial, platform technology demonstrated statistically significant reduction in Time to Hemostasis (TTH) and Time to Ambulation (TTA) as compared to manual compression

Optimizing Vascular Access Management

ORDERING INFORMATION:

Product	Model Number	Description	Order Quantity
VASCADE 5F VCS	700-500DX-05U	5 French	1 Box (5 Devices/Box)
VASCADE 6/7F VCS	700-580I-05U	6/7 French	1 Box (5 Devices/Box)
CATALYST II	500-580C-10U	5-7 French	1 Box (10 Devices / Box)
CATALYST III	600-580CP-10U	5-7 French	1 Box (10 Devices / Box)

- Minimizing Complications
- Maximizing Hospital Efficiencies
- Improving Patient Care



The VASCADE® Vascular Closure System (VCS) is indicated for femoral arterial access site closure while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures using a 5F, 6F, or 7F procedural sheath.

The VASCADE VCS is also indicated to reduce time to discharge eligibility in patients who have undergone diagnostic endovascular procedures using a 5F, 6F, or 7F procedural sheath.

The Cardiva CATALYST® II System is intended to promote hemostasis at arteriotomy sites as an adjunct to manual compression. The Cardiva CATALYST III System with Protamine Sulfate is intended to promote hemostasis at arteriotomy sites as an adjunct to manual compression in heparinized patients. The Cardiva CATALYST II & III are indicated for use in patients undergoing diagnostic and/or interventional femoral artery catheterization procedures, using 5F, 6F or 7F introducer sheaths.

Before use, physicians should review all risk information, which can be found in the "Instructions for Use."

Founded in July 2002, CARDIVA Medical, Inc. is a privately held medical device company that is focused on developing and commercializing innovative vascular closure technologies designed to help the body heal itself.

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VASCADE®
 Vascular
 Closure System

Cardiva CATALYST®
 Manual Compression
 Assist Device

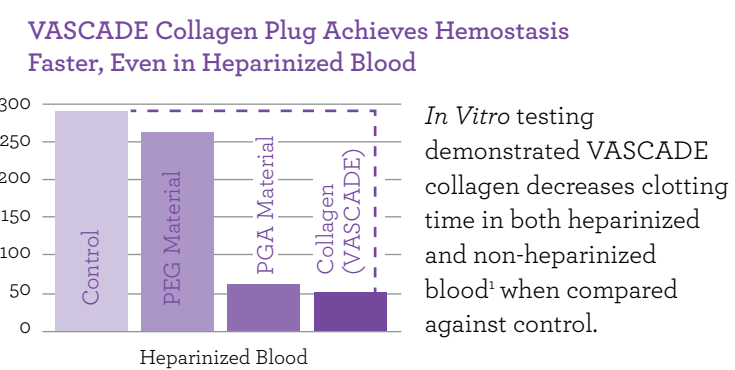


VASCADE® Vascular Closure System

Minimizing Complications, Improving Patient Care, and Maximizing Hospital Efficiency for Vascular Closure

VASCADE is a fully integrated, extravascular, bioabsorbable femoral access closure system that is easy to use, leaves no permanent component behind and has demonstrated safety and efficacy in a wide range of patients.

- EXTRAVASCULAR AND BIOABSORBABLE**
- Enables rapid and secure closure without intravascular anchor
 - Leaves no permanent component behind
 - Collagen plug naturally resorbs over time
 - Allows for future vessel reaccess
 - The only extravascular device to offer collagen and a dual method of action:
 - **Mechanical:** provides tamponade as a result of rapid expansion of implant in presence of fluid
 - **Physiological:** accelerates coagulation by leveraging natural thrombogenic property of collagen to enhance coagulation



¹Porcine blood was heparinized to 0.42 IU of Heparin /1ml of blood. Data on file.

Effective and Rapid Hemostasis for Interventional and Diagnostic Procedures

Safe and Easy to Use

- No need for sheath exchange: deploys through existing procedural sheath
- Provides temporary hemostasis with minimal flow disruption by deploying low profile disc
- Fully-integrated design with unique release mechanism allows for safe and easy collagen exposure
- Exposed collagen rapidly hydrates to provide tamponade
- Disc is collapsed and removed leaving nothing in intravascular space

ZERO major complications

statistically **SIGNIFICANT REDUCTIONS** in minor complications

up to **4x FASTER** to hemostasis

up to **1.5x FASTER** to ambulation

VASCADE – MINIMIZING COMPLICATIONS. RAPID HEMOSTASIS.²

RESPECT Trial

	Diagnostic (N=211)		Interventional (N=209)		Total (N=420)		
	VASCADE	MC	VASCADE	MC	VASCADE	MC	p-value
N	137	74	141	68	278	142	
TTH (mins)	4.0	18.2	5.5	24.9	4.8	21.4	<0.0001
TTA (hrs)	2.6	4.6	5.0	7.2	3.8	5.8	<0.0001
TTDe (hrs)	3.1	5.0	6.6	8.2	4.8	6.5	0.001
Major Complications	0	0	0	0	0	0	1.00
Minor Complications	1%	3%	1%	12%	1%	7%	0.002

Multi-center, prospective, randomized trial of 420 patients across 21 centers (20 in the US and 1 in Australia). Subjects were randomly assigned in a 2:1 ratio VASCADE to MC. 81% of VASCADE cases reported pre-procedure anticoagulant and/or antiplatelet administration (of note **8%** of VASCADE cases had peri-procedure GP IIb/IIIa inhibitors and **77%** of VASCADE cases were administered bivalirudin)

²FDA approval PMA.

Cardiva CATALYST® Manual Compression Assist Device



For Patients Needing Manual Compression, CATALYST is Designed to Improve TTH and TTA.

>50% REDUCTION in mean hold time³

>20% REDUCTION in ambulation time³

CATALYST is designed to provide temporary hemostasis and enhance coagulation within the tissue tract at the puncture site making the experience more efficient for the clinical staff and more comfortable for the patients while preserving the artery and leaving nothing behind in its path.

- Supports the body's natural healing process
 - Enhances tissue apposition, natural elastic recoil and coagulation
 - Helps maintain vessel integrity

BOOM II: Prospective, Investigator-Initiated Trial

	Diagnostic (N=266)		Interventional (N=184)		Total (N=450)		
	Bare CATALYST (N=188)	MC (N=78)	Bare CATALYST (N=139)	MC (N=45)	Bare CATALYST (N=327)	MC (N=123)	p-value
TTH (mins)	11.2	23.2	13.9	38.4	12.3	28.8	<0.0001
TTA (hrs)	3.3	4.5	5.4	6.8	4.15	5.3	0.0002

- Leaves nothing behind allowing for immediate re-access
- Has complication rate similar to Manual Compression
- Available in two versions, CATALYST II & III
 - CATALYST II is coated with Kaolin and Chitosan used to promote coagulation by activating the clotting cascade and causing platelet aggregation
 - CATALYST III is coated with an additional drug, protamine sulfate, acting locally to neutralize heparin and further aid the body's natural healing process

³Data from BOOM II Investigator-Initiated Clinical Study with manuscript submitted for publication. Note: FDA has not yet reviewed reduced TTH or TTA data.