

The QuickClose

Vascular Closure Device (VCD)
by CardioDex

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ICI meeting 2009
Innovations in Cardiovascular Interventions



Disclosures

I have the following financial relationships to disclose:

Medical Advisor of CardioDex

*Level of remuneration: moderate**

**Level of remuneration: high (over \$50,000 yearly), moderate (10-50,000), modest (under 10,000)*

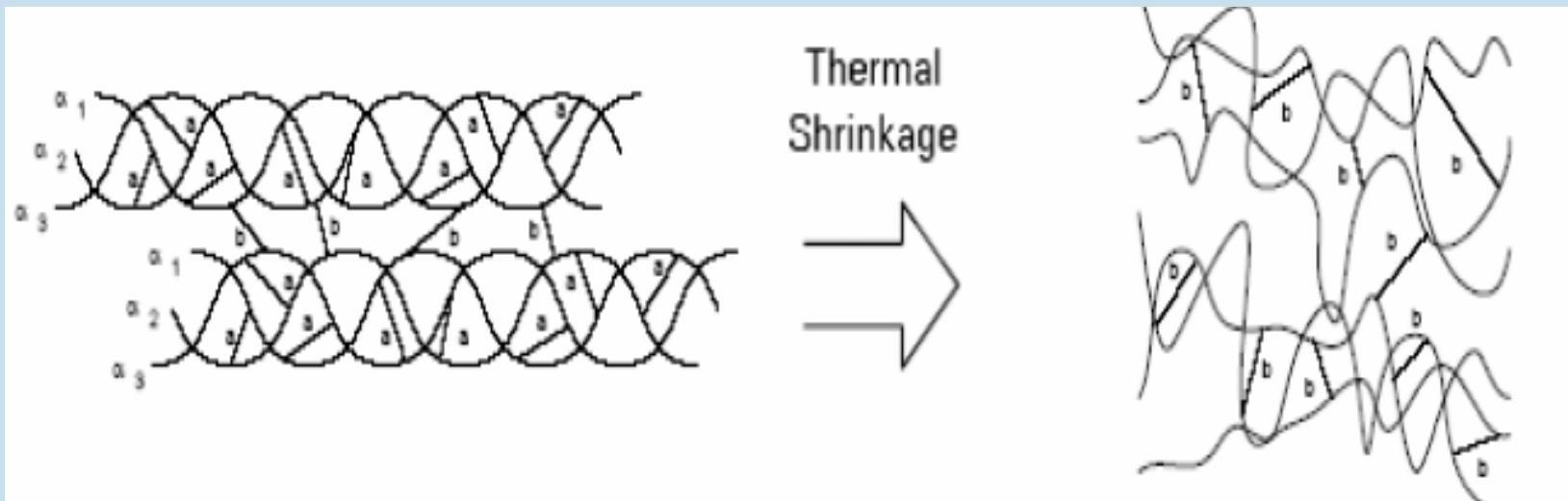
The QuickClose

- Active VCD
- Following diagnostic and interventional percutaneous catheterization procedures
- 5-6Fr introducer sheath size

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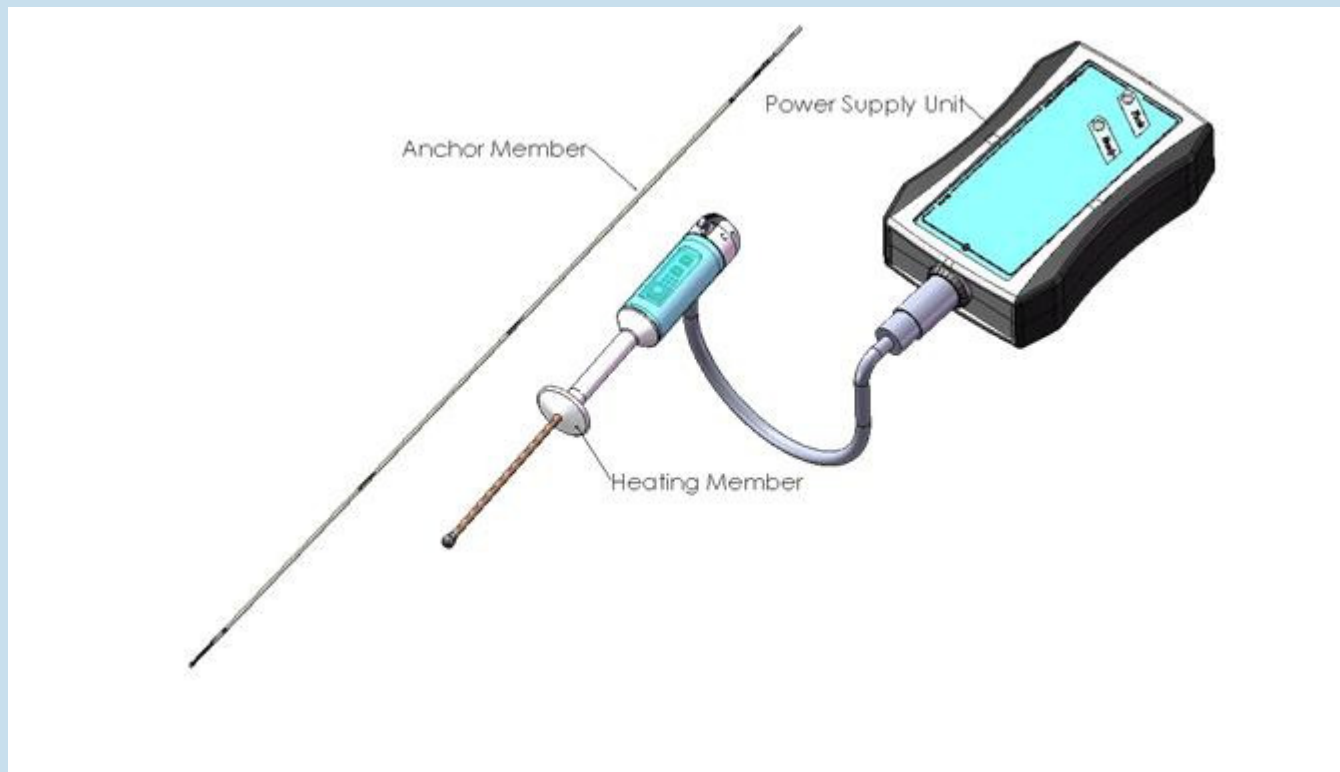
- Deliver precise energy to the puncture site
- Thermal induced closure mechanism
 - ◇ Shrinkage of Collagen and Elastin
 - ◇ Fusion of loose periadvential tissue
 - ◇ Clot formation

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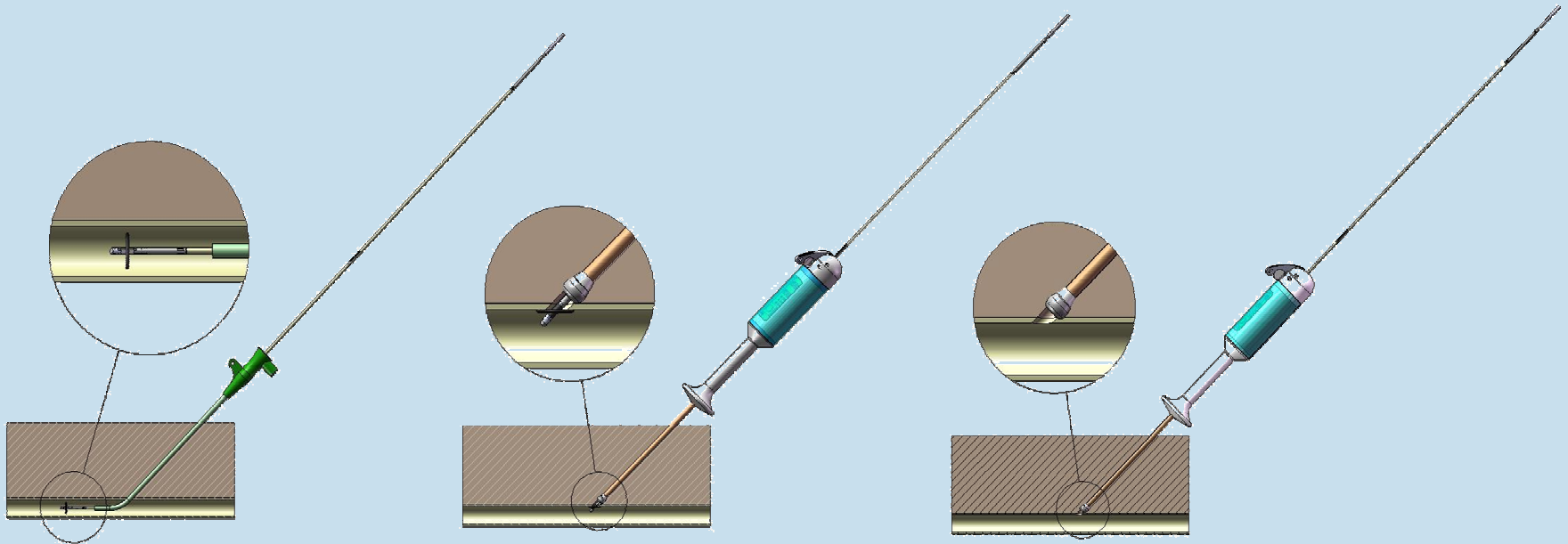


Heat-driven denaturation and shrinkage is an **irreversible** process.

Description



Procedural Description



Advantages

- Reduce time to Hemostasis (TTH)
- Eliminate the need to use compression devices thus relieving the patient from un necessary pain and discomfort
- Reduce time to Ambulation (TTA) and time of bed restriction
- Low complication rate since nothing is “left behind” with easy extraction and manual compression fall back at any procedural step
- Location proximity repetitive usage availability since “nothing is left behind”
- Easy, quick, clear and intuitive use
- Short learning curve

First human use

- Two clinical studies (Mexico, Germany)
- Timeline: February-September, 2009
- Evaluate the safety and efficacy of femoral artery closure

Objectives

Safety Objectives –

Establish a rate of complications:

- Vascular repair requiring surgery or Ultrasound guided treatment
- Bleeding related to the access site requiring a blood transfusion
- Femoral artery total occlusion/ nerve injury
- Infection requiring IV antibiotics and extending hospital stay
- Hematoma ≥ 6 cm
- AV fistula
- Pseudoaneurysm
- Pedal pulse diminished by ≥ 2 grades

Objectives

Primary Efficacy Objectives -

- Time to Hemostasis (TTH)

Determined by measuring the time in minutes from the time the anchor and heating member are fully retracted out of the body to when hemostasis has been obtained

- Time to Ambulation (TTA)

Determined by measuring the time in hours from the time the anchor and heating member are fully retracted out of the body until the patient is able ambulate 35 meters

Objectives

Secondary Efficacy Objectives -

- Device success

Determined by successful preparation and delivery of energy to the access site using the QuickClose system

- Procedural success

Determined by achieving hemostasis at the access site and freedom from any major complication using the QuickClose system

Key Inclusion Criteria

- Age ≥ 18 years
- Without child bearing potential
- Placement of a 5-6F arterial sheath in the Common femoral Artery (CFA)

Key Exclusion Criteria

- Prior manual compression within the previous 6 weeks
- Prior closure system within the previous 25 weeks
- Prior surgical repair of blood vessels
- Significant bleeding diathesis or platelet dysfunction
- Life expectancy of less than 1 year due to terminal illness
- Currently being treated for an infection
- Receiving GP 2b/3a inhibitors or required warfarin therapy within 2 weeks

Key Exclusion Criteria

- INR results >1.2 on day of procedure
- Myocardial Infraction within the previous 72 hours
- Received thrombolytic within previous 72 hours
- Currently enrolled in an investigational system or drug study
- Absent of pedal pulse
- Autoimmune disease
- BMI $\geq 40\text{kg/m}^2$

Baseline Demographics

# of patients- Total (N)	69
Mean age (years)	63.3 ± 9.5
Gender (%)	Female 56 Male 44
Diabetes malitus %	38
BMI (kg/m ²)	29.3 ± 4.5

Procedural Characteristics

	Diagnostic N(%)	Interventional N(%)
Type of procedure	43(62%)	26(38%)
ACT level (sec) prior to sheath removal	162 ± 14	225 ± 35

Results

Safety Endpoints

Complication	Cases(%)
Vascular repair requiring surgery	0(0)
Bleeding related to the access site requiring a blood transfusion	0(0)
Femoral artery total occlusion	0(0)
Infection requiring IV antibiotics and extending hospital stay	0(0)

Results

Safety Endpoints

Complication	Cases(%)
Hematoma ≥ 6 cm	1 (2%)
AV fistula	0
Pseudoaneurysm	0
Pedal pulse diminished by ≥ 2 grades	0
Femoral nerve injury	0

Results

Primary Effectiveness Endpoints

	Diagnostic	Interventional
TTH (min) Average	4.1 ± 1.71	5.3 ± 3.0
Median	3.59	4
TTA (hours) Average	3.2 ± 3.3	3.6 ± 1.6
Median	2.1	3.5

Results

Secondary Effectiveness Endpoints

	Mexico N(%)	Germany N(%)
Device success	52(94)	17(94)
Procedural success	52(83)	17(94)

Conclusion

- ✓ The QuickClose system demonstrated Proof of concept
- ✓ Achieving successful safety and efficacy end points
- ✓ CardioDex is in the process of initiating a third study with Sheba Medical Center

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Thank You