CARDIVA MEDICAL, INC.

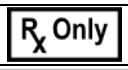
# Cardiva Catalyst™ II

## INSTRUCTIONS FOR USE

**IFU 2218 Rev. T**

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

## GRAPHICAL SYMBOLS ON THE CARDIVA CATALYST™ II PACKAGING

| Symbol | Standard / Regulation* | Standard Reference No. / Symbol Title | Definition |
|---|---|---|---|
|  | ISO 15223-1 | 5.1.1 / Manufacturer | medical device manufacturer |
|  | ISO 15223-1 | 5.1.4 / Use-By Date | date after which the medical device is not to be used. |
|  | ISO 15223-1 | 5.1.5 / Batch Code | manufacturer's batch code so that the batch or lot can be identified. |
|  | ISO 15223-1 | 5.1.6 / Catalogue number | manufacturer's catalogue number so that the medical device can be identified. |
|  | ISO 15223-1 | 5.2.4 / Sterilized using irradiation | medical device that has been sterilized using irradiation. |
|  | ISO 15223-1 | 5.2.6 / Do not resterilize | medical device that is not to be re-sterilized. |
|  | ISO 15223-1 | 5.2.8 / Do not use if package is damaged | medical device that should not be used if the package has been damaged or opened. |
|  | ISO 15223-1 | 5.3.4 / Keep dry | medical device that needs to be protected from moisture. |
|  | ISO 15223-1 | 5.3.7 / Temperature limit | temperature limits to which the medical device can be safely exposed. |
|  | ISO 15223-1 | 5.4.2 / Do not re-use | medical device that is intended for one use, or for use on a single patient during a single procedure. |
|  | ISO 15223-1 | 5.4.4 / Caution | Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |
|  | ISO 15223-1 | 5.4.5 / Contains or presence of natural rubber latex B.2 / Negation Symbol | Indicates that there is no presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device. |
|  | 21 CFR 801.109 | Prescription Device | product is a medical device and Federal Law (USA) restricts this device to sale by or on the order of a physician |
|  | N/A | Package quantity | quantity of systems in package |
|  | ISO 11607-1 | Sterile barrier packaging | Identifies the sterile barrier packaging |

*Standards and Regulations:

**ISO 15223-1:** Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied

**US FDA Title 21 CFR 801.109**: Prescription Devices

**ISO 11607-1:** Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems

## DESCRIPTION

The Cardiva Catalyst™ II consists of a sterile disposable Catalyst II Wire and a sterile disposable Catalyst Clip. The Cardiva Catalyst II promotes hemostasis at a femoral access site after femoral arterial catheterization as an adjunct to manual compression. After completion of catheterization procedure, the Catalyst II Wire is inserted into the artery through the existing introducer sheath. The distal tip of the Catalyst II Wire is deployed, which opens the bi-convex, low profile Catalyst Disc within the lumen of the femoral artery distal to the introducer sheath tip. After removing the introducer sheath over the Catalyst II Wire, gentle upward tension is applied to the Catalyst II Wire to conform the Catalyst Disc to the contours of the vessel securing it against the intima, blocking the arteriotomy. Tension is maintained by applying the Catalyst Clip externally to the Catalyst II Wire at the puncture site. Tension between the Catalyst Disc and the Catalyst Clip creates a site-specific compression of the arteriotomy and establishes temporary hemostasis. During dwell, natural recoil of smooth muscle in the vessel wall occurs at the arteriotomy site. A biocompatible coating on the Catalyst II Wire aides the body's natural hemostatic process and promotes ease of removal. Following appropriate dwell time, the Catalyst Disc is collapsed and the Cardiva Catalyst II is completely removed from the artery. No part of the device is left behind. Final hemostasis of the vessel puncture site occurs with application of manual or mechanical compression after removing the Cardiva Catalyst II.

## INDICATIONS

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

## CONTRAINDICATIONS

The Cardiva Catalyst II is contraindicated for patients with "double wall" arterial punctures.

The Cardiva Catalyst II is contraindicated for patients with allergies to Shellfish.

## Cardiva Catalyst™ II

## WARNING-POTENTIAL ADVERSE EVENTS

Complications may occur and could include the following:

- Arterial thrombus
- Arteriovenous fistula
- Bleeding requiring transfusion
- Bruising
- Hematoma
- Infection requiring extended hospital stay and IV antibiotics
- Pseudoaneurysm
- Embolization
- Vascular repair

**NOTE: The safety and effectiveness of the Cardiva Catalyst II has not been evaluated in the following patients who are/have:**

- Age less than 18
- Pregnant and/or lactating women
- A vascular graft at the target site
- An active bleeding disorder or septicemia at the time of the procedure
- Received a suture based closure device at any time prior to this procedure
- Received an alternate closure device within past 90 days
- Ipsilateral femoral arterial, antegrade and/or venous punctures

## CAUTIONS

- Do not reuse or re-sterilize. The Cardiva Catalyst™ II is intended to be used once only for a single patient. If product is reused or re-sterilized, this may result in infectious or blood borne diseases and/or death.
- Do not use if product is beyond the expiration date.
- Do not use in access sites above the inguinal ligament (supra-inguinal punctures) due to the increased risk of retroperitoneal bleeding
- Do not use in an artery with suspected Intraluminal thrombus, hematoma, pseudo-aneurysm, or A-V fistula
- Do not use if intraprocedural bleeding around sheath is noted as this may indicate back-wall or multiple vessel punctures
- Do not use with introducer sheaths with overall length greater than 25 cm
- Do not use if package is open or damaged, or if the device appears to be damaged or defective

## CLINICAL PROCEDURE

1. Determine if appropriate device is selected, by referring to the table below:

| Device | Sheath Size | Sheath Length | Disc Size |
|---|---|---|---|
| Cardiva Catalyst™ II | 5F, 6F, 7F | up to 25 cm | 6.5 mm |

2. Using standard sterile technique[1], carefully remove the **Catalyst II Wire** and **Clip** from the package. Test device by deploying (holding the **Silver Handle** and pulling back on the **Black Actuator** until it locks in place), visually inspecting (should appear bi-convex, circular and symmetrical with an intact membrane) and retracting (collapse by pressing the actuator forward) the **Catalyst Disc** prior to the procedure **(See Figure 1).**

**NOTE: Prior to Catalyst II Wire insertion, confirm sheath is patent. Angiogram of the groin is recommended.**

3. Gently retract sheath until approximately 10-11cm of sheath remains in the patient **(See Figure 2)**.
   a. In an 11 cm sheath, insert the **Catalyst II Wire** until the **White Gripper** reaches, but does not enter the hub of the sheath.
   b. In a 15 cm sheath, retract the sheath an appropriate distance so approx. 11 cm of sheath remains in the patient. Then insert the **Catalyst II Wire** only until the **White Gripper** just disappears into the hub of the sheath.
   c. In a 25 cm sheath, retract the sheath an appropriate distance so approx. 11 cm of sheath remains in the patient. Then insert the **Catalyst II Wire** to the silver handle.

**CAUTION:** Do not advance **Catalyst II Wire** into the patient if resistance is met due to risk of vascular damage.

4. Gently insert the Catalyst through existing sheath
5. Deploy the **Catalyst Disc** by holding the **silver handle** and pulling the actuator back until it locks in place. Disc is deployed when approximately 7mm of the green mark is visible **(See Figure 3).**

**NOTE:** If the green segment slides back to its original position, handle is not locked and disc is not deployed. Repeat deploying the disc by pulling the black segment more firmly.

**CAUTION**: Do not over deploy the actuator once it is locked in place. This may cause damage to the device.

6. Gently remove sheath without holding the Catalyst. As the sheath slides over the **Catalyst II Wire**, grasp the **White Gripper** when it appears at the distal end of the introducer sheath. Continue sliding the sheath over the **Catalyst II Wire** and discard sheath **(See Figure 4).**

7. Gently lift upward on the **White Gripper** to achieve hemostasis. Continue pulling tension until white coating on wire is visible or maximum travel, indicating maximum allowable tension, is reached and then attach clip to the wire at skin level (wire should be positioned at the back side of the clip **(See figure 5).**

**CAUTION:** Do not attempt to pull past maximum travel. Applying too much tension may cause disc to pull out of vessel. Should this occur, convert to your institution's manual compression.

**NOTE:** Observe puncture site for bleeding and if slow oozing persists for longer than one minute, readjust tension by removing the clip, slightly pulling up on the **White Gripper** until bleeding stops, then reapply the clip at skin level.

**CAUTION:** Tension should be applied using ONLY the **White Gripper**. Do not pull the **Silver Handle** when placing the device against the arteriotomy to avoid excessive tension on the disc and pull through which may cause vascular damage.

**CAUTION:** Make sure the clip is applied at the skin surface without pressing into the skin since this may cause excessive tension on the disc and pull through which may cause vascular damage.

**NOTE:** Slow oozing may occur following clip placement. If slow oozing persists for more than one minute, gently readjust the tension.

8. Position the **silver handle** along the patient's leg, maintaining the angle of access (4X4's may help facilitate). Cover with a sterile towel and secure.

**CAUTION:** If the patient is moved with the device in place, stabilize the leg prior to patient transfer and for the duration of device dwell time to avoid disc pull through.

[1] See Aseptic Presentation Section for additional information.

9. The **Catalyst II System** should dwell for a minimum of 15 minutes for diagnostic cases and a minimum of 120 minutes for interventional cases. During this time the puncture site should be observed periodically to ensure that temporary hemostasis is maintained. Excessive tension applied to the disc by patient coughing, sneezing or other extreme patient movements may cause the disc to pull through the arteriotomy.

**CAUTION**: If the **Catalyst II System** is inadvertently pulled out of patient, convert to manual compression to manage arteriotomy site.

## DEVICE REMOVAL

1. At end of dwell time, apply manual compression to the femoral artery approximately two finger widths proximal to the arteriotomy access site.
2. Maintain proximal manual compression and collapse disc by pressing on the actuator with the index finger. **(See Figure 6)**

**CAUTION:** Prior to the **Catalyst II System** removal, make sure that the disc is completely collapsed to avoid vascular injury.
**NOTE:** The disc is fully collapsed when only ~ 1mm of the green mark is visible.
**NOTE: Care should be taken not to compress directly over the disc during device removal.** If resistance occurs during removal of the wire, reposition compression more proximally or slightly reduce the amount of compression.

3. Remove device. Maintain manual compression until complete hemostasis is achieved.

4. Follow hospital procedure to dress the site after device removal.

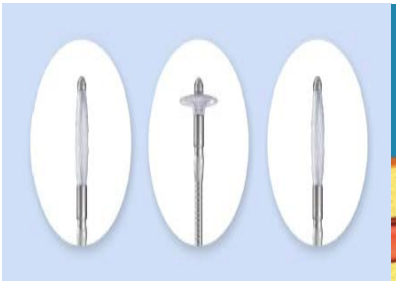


**Figure 1**

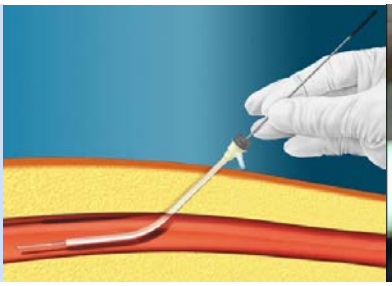


**Figure 2**

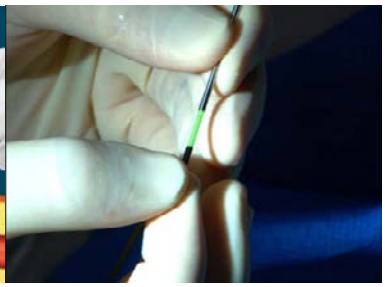


**Figure 3**

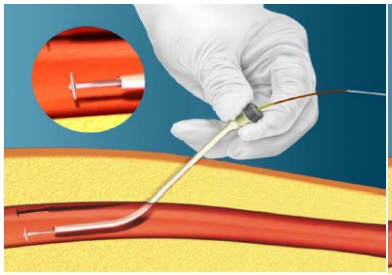


**Figure 4**

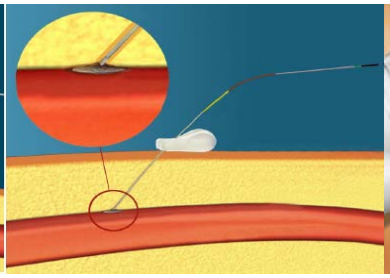


**Figure 5**

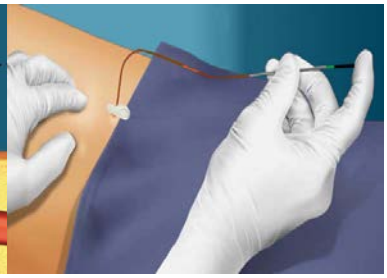


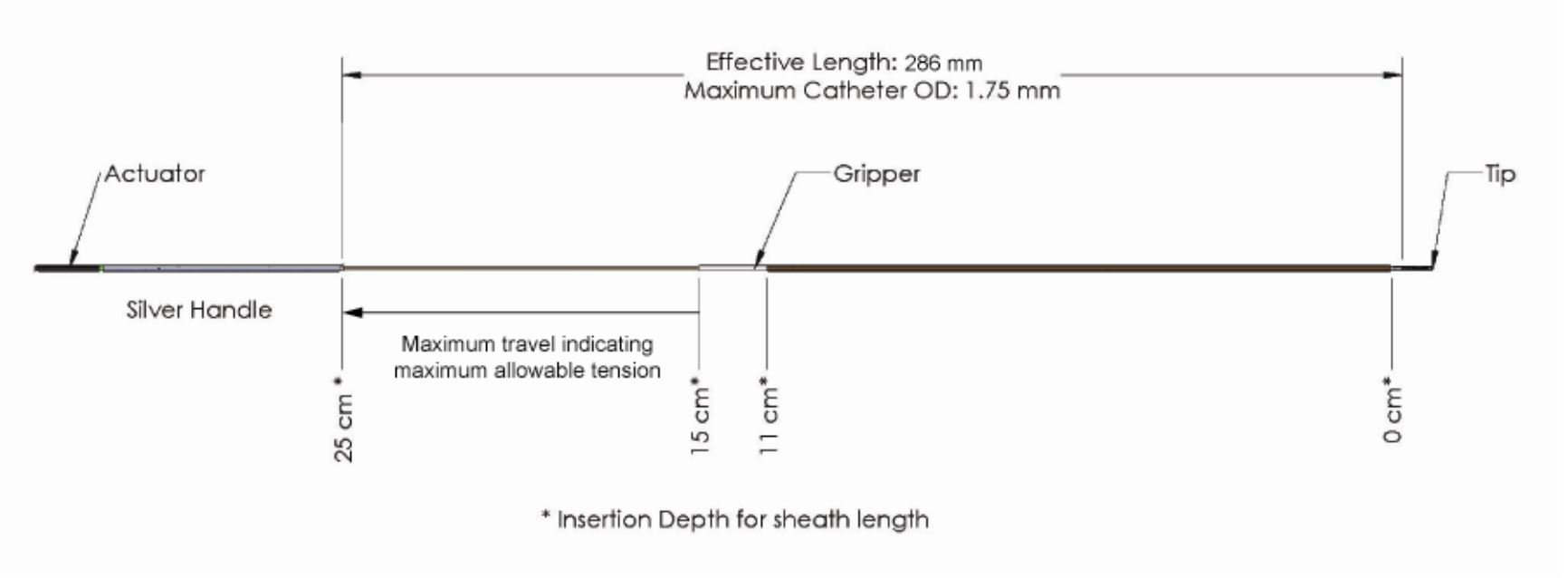
**Figure 6**

**Device Disposal:**
After use, dispose of the contaminated device and/or packaging materials using standard hospital procedures and universally accepted practices for bio-hazardous wastes.

**Additional Information for Step #2 Regarding Aseptic Presentation Steps to Follow:**

- Inspect the product packaging. Observe for any breaks, holes, or openings that would compromise the integrity and sterility of the product.
- Read the label. Check the expiration date and verify correct product/size is used.
- Position near the sterile field. Be sure the scrubbed person receiving the product is prepared and ready to receive it with a clear space in the field.
    - All packaging for sterile products has a designated side to open from. Locate this side and slowly peel the package open.
    - Open the packaging with arms extended to avoid accidental contact with the product or the sterile field. Be sure the product does not come in contact with the edges of the external packaging as they are not considered sterile. Create a large enough opening in the package to remove the product without touching the non-sterile areas.
- Present the product to the scrubbed person.
- Discard packaging following facility protocol.

# CARDIVA CATALYST™ II



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CARDIVA MEDICAL, INC.

# Design *for* what's humanly possible

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**LIMITED WARRANTY**

Cardiva Medical, Inc. warrants that each Cardiva Catalyst™ II System is free from defects in workmanship and material under normal use and service, and provided it is used prior to the stated expiration date. Cardiva Medical, Inc. will not be liable for any incidental, special or consequential loss, damage or expense direct or indirect from the use of its product. Liability under this warranty is limited to refund or replacement of any device that has been found by Cardiva Medical, Inc. to be defective at the time of shipment. Damage to the device through misuse, alteration, improper storage or improper handling shall void this limited warranty. The remedies set forth in this warranty and limitation shall be the exclusive remedy available to any person. No employee, agent or distributor of Cardiva Medical, Inc. has any authority to alter or amend this limited warranty, or assume or bind Cardiva Medical, Inc. to any additional liability or responsibility with respect to this device. There is no express or implied warranty, including any implied warranty of merchantability or fitness for a particular purpose, on the Cardiva Medical, Inc. product(s) described herein.