

# COLLAR® Papillary Muscle Exposure Device

**THE COLLAR DEVICE IS A FLEXIBLE SURGICAL RETRACTOR DESIGNED TO RETRACT VALVE LEAFLET TISSUE WHEN INSERTED WITHIN THE VALVE ANNULUS.**

The device consists of a main body component (Figure 1A) which extends laterally to become the retraction wings. The distal tips of the retraction wings (Figure 1B) are bifurcated for additional tissue traction. The posterior aspect of the device has circumferential traction raisings, a stiffening rib (Figure 1C) along the superior border and a stabilization flange (Figure 1D) along the inferior border.

The Collar device is available in 2 sizes (small and large) which are packaged together in a disposable set.

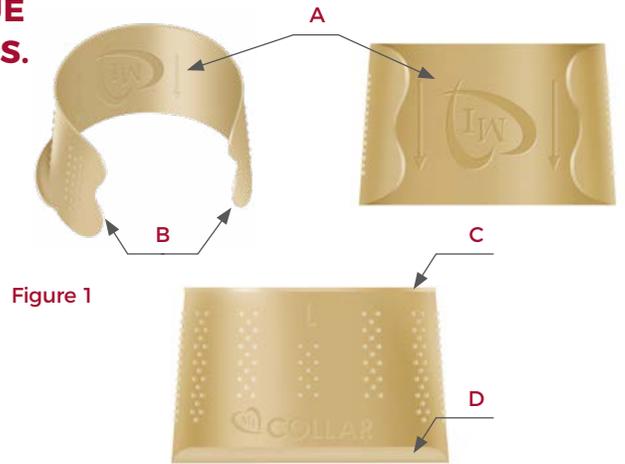


Figure 1

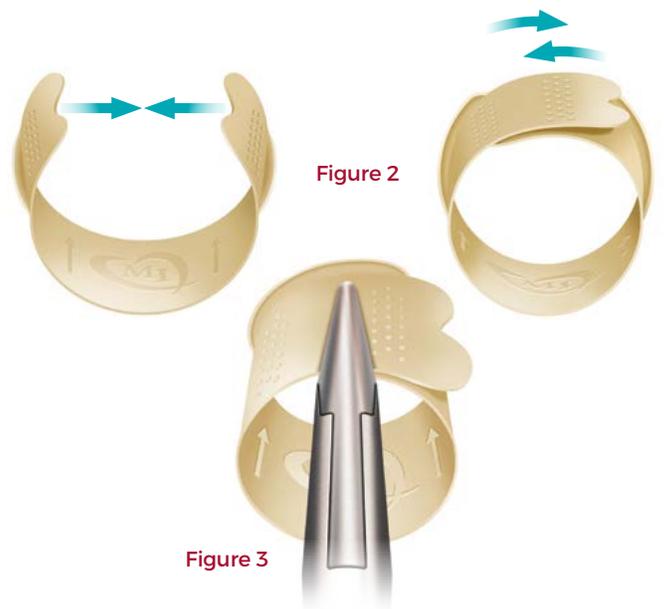


Figure 2

Figure 3

## PREPARATION FOR INSERTION

Roll the lateral wings of the appropriately sized Collar device inwards in compliance with the pre-formed curvature (Figure 2).

Grasp the overlapping wings with an insertion clamp so that the device may be inserted into the annulus in compliance with the marking arrows for insertion direction (Figure 3).

## INSERTION AND DEPLOYMENT

Insert the rolled device within the valve leaflets (Figure 4).



Figure 4

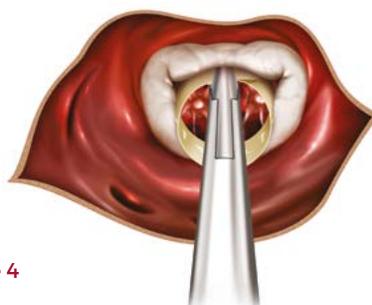


Figure 5

Release the device from the insertion clamp and allow the lateral wings to unfurl within the annulus to provide leaflet retraction (Figure 5).

## REPOSITIONING

To reposition the device for optimal retraction orientation, grasp the distal wing tips and pull them toward one another until they overlap. Rotate the Collar device to the desired position within the annulus (**Figure 6**).

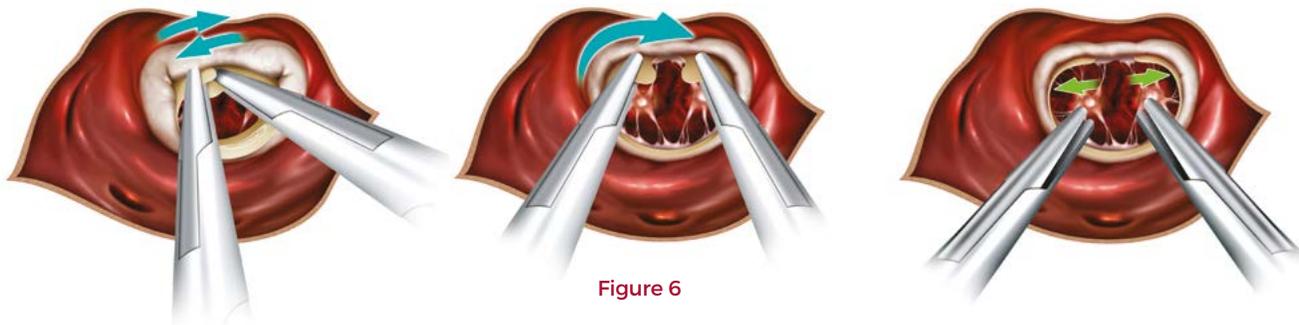


Figure 6

## REMOVAL

To remove the Collar device, grasp the distal end of one of the wing tips and pull the tip through the center towards the opposing side in an overlapping manner (**Figure 7A**). Remove the Collar device from within the annulus by pulling the entire device outward (**Figure 7B**).

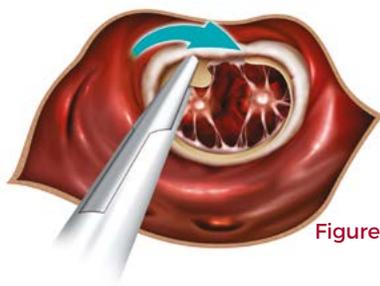


Figure 7A



Figure 7B

## ORDERING INFORMATION

ORDER #	DESCRIPTION
MI-COTIE-001	Box of 6 sterile pouches 2 Sizes COLLAR PAPILLARY MUSCLE EXPOSURE DEVICE per sterile pouch

## DEVICE SPECIFICATIONS

DESCRIPTION	A (CM)	B (CM)
COLLAR PAPILLARY MUSCLE EXPOSURE DEVICE (Small)	2.3	9
COLLAR PAPILLARY MUSCLE EXPOSURE DEVICE (Large)	3	11



**INDICATIONS:** The COLLAR device is intended for use to retract valve leaflet tissue during specific cardiac surgical procedures.

**CONTRAINDICATIONS:** None known.

**WARNINGS AND PRECAUTIONS:** This device is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not use if package or product is damaged. It is the responsibility of the user to dispose of the device in accordance with local regulations and hospital procedures.

For additional information please refer to the Instructions for Use provided with the product.

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