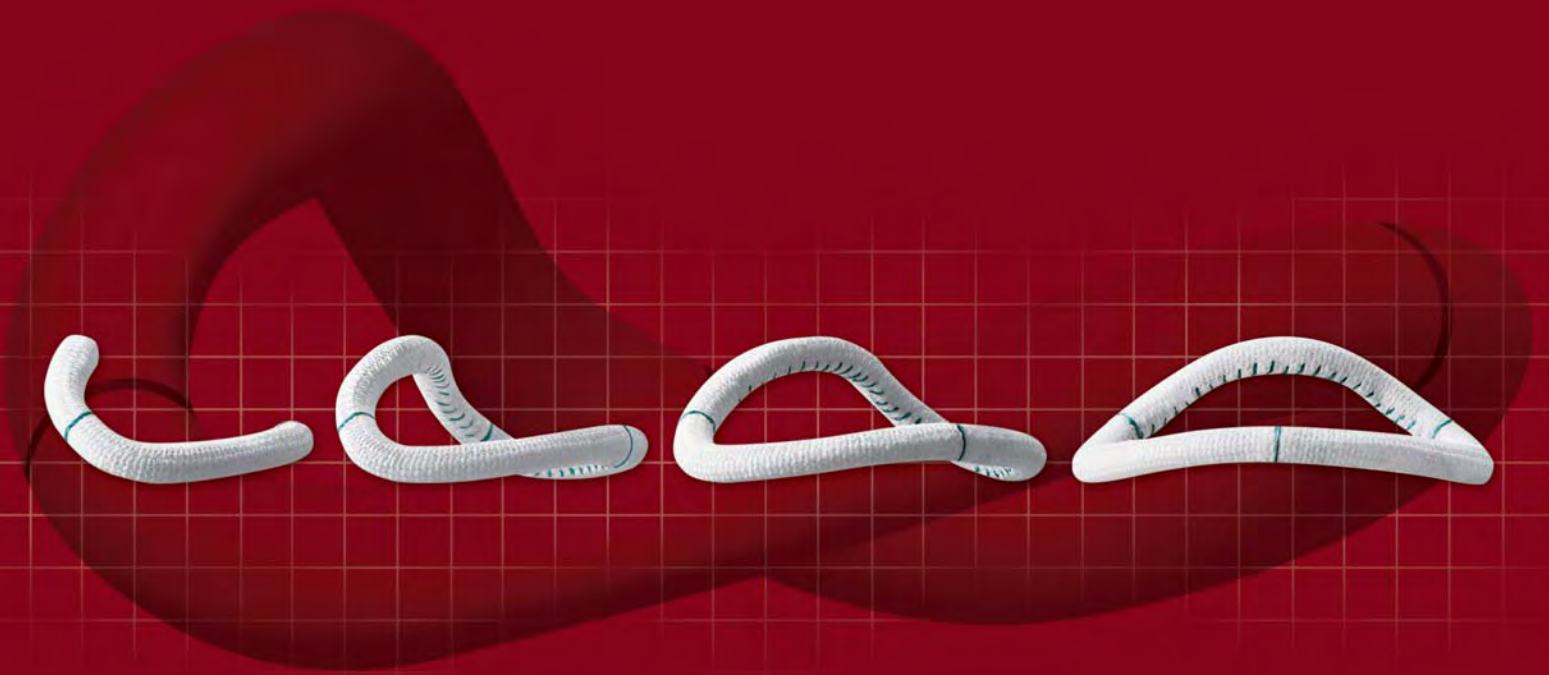


# PROFILE 3D™

Annuloplasty System for Mitral Repair



## PROFILE 3D™ COMPONENTS

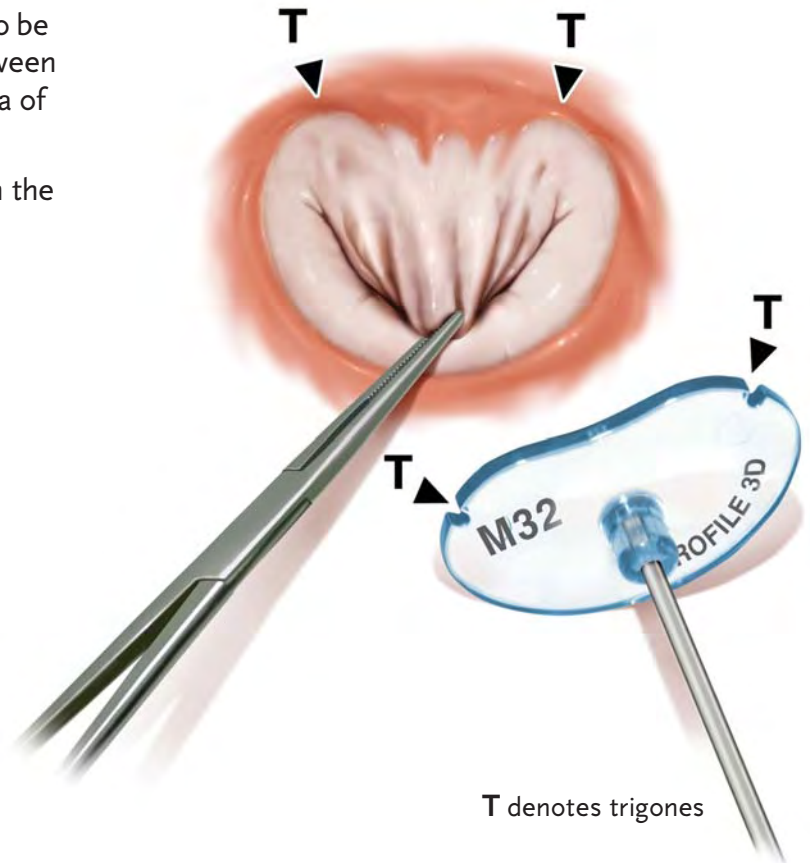
Each Profile 3D™ Ring package contains a single annuloplasty ring assembly consisting of a ring mounted on a holder, packaged in sterile, double-aseptic transfer trays.



## SIZING THE ANNULUS

To determine the proper Profile 3D™ Ring size to be used requires measuring both the distance between the trigones (intertrigonal distance) and the area of the anterior leaflet.

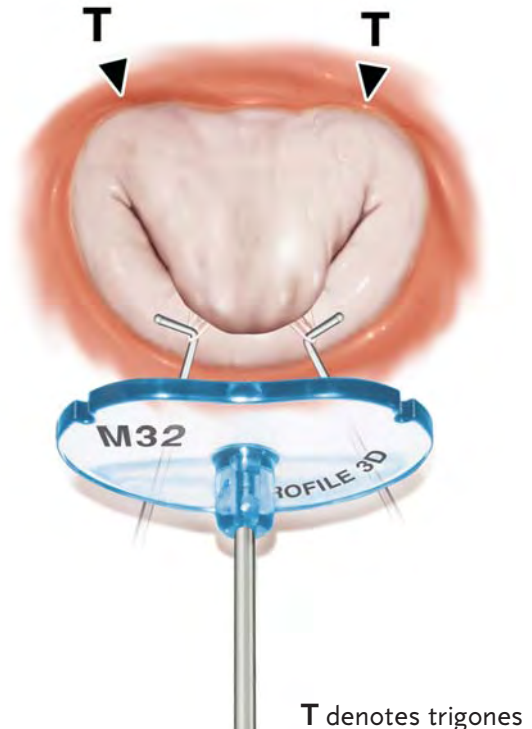
Lower the sizer onto the valve annulus and align the sizer notches with the trigones.



## SIZING THE ANNULUS

Gently extend the anterior leaflet and cover its surface with the selected sizer. The sizer that has a notch spacing most nearly matching the intertrigonal distance and a surface area most nearly matching that of the anterior leaflet corresponds to the size of the ring that should be selected.

Either end of the sizer may be used for sizing.



## PLACING ANNULAR SUTURES

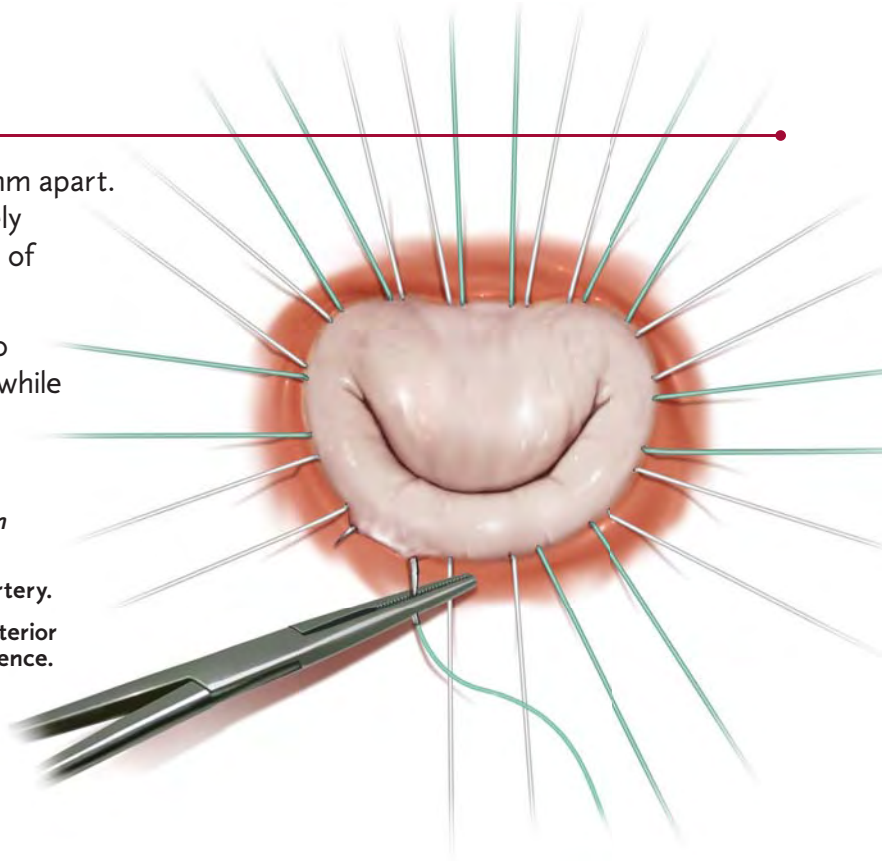
Place sutures in each trigone, approximately 4 mm apart. Place additional interrupted sutures, approximately 4 mm apart, in the anterior and posterior portion of the mitral annulus.

To simplify the maneuver, always use a forceps to hold the free edges of the corresponding leaflet while sutures are passed.

*A total of approximately 10 to 14 sutures should be placed in the annulus.*

**Warning:** Avoid placing sutures in the circumflex coronary artery.

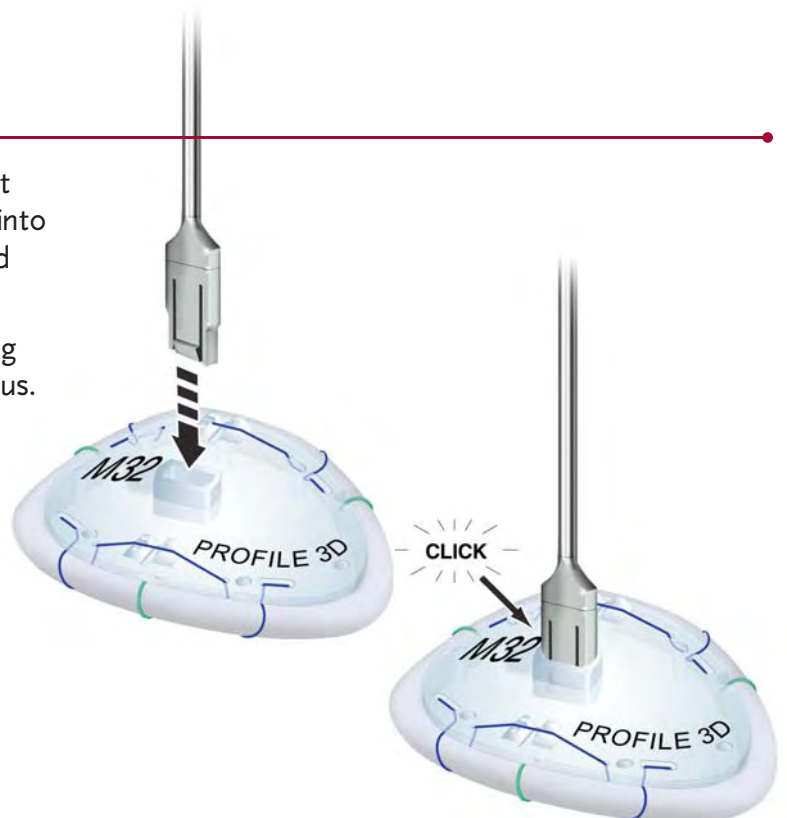
**Note:** Pledgets may be used for trigone sutures and mid-posterior annulus suture to reduce the possibility of ring dehiscence.



## INSERTING THE HANDLE

Align and engage a sterile handle into the snap-fit cavity of the holder. The handle must be inserted into the side of the holder with the snap-fit cavity and printed text.

The thin section of the handle is malleable, allowing the surgeon to align the ring holder with the annulus.

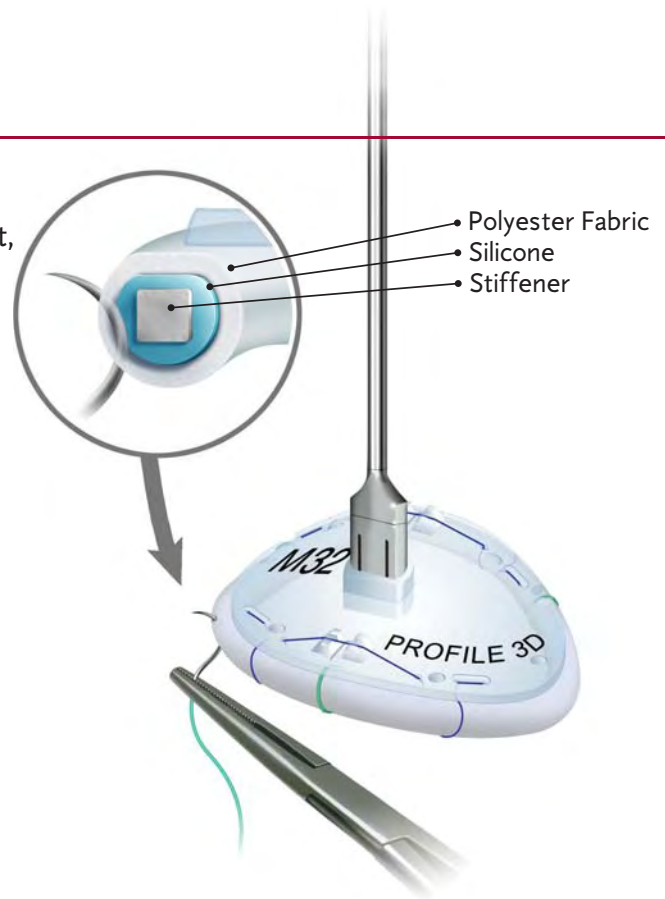


## PLACING PROFILE 3D™ RING SUTURES

Orient the ring assembly to the mitral annulus.

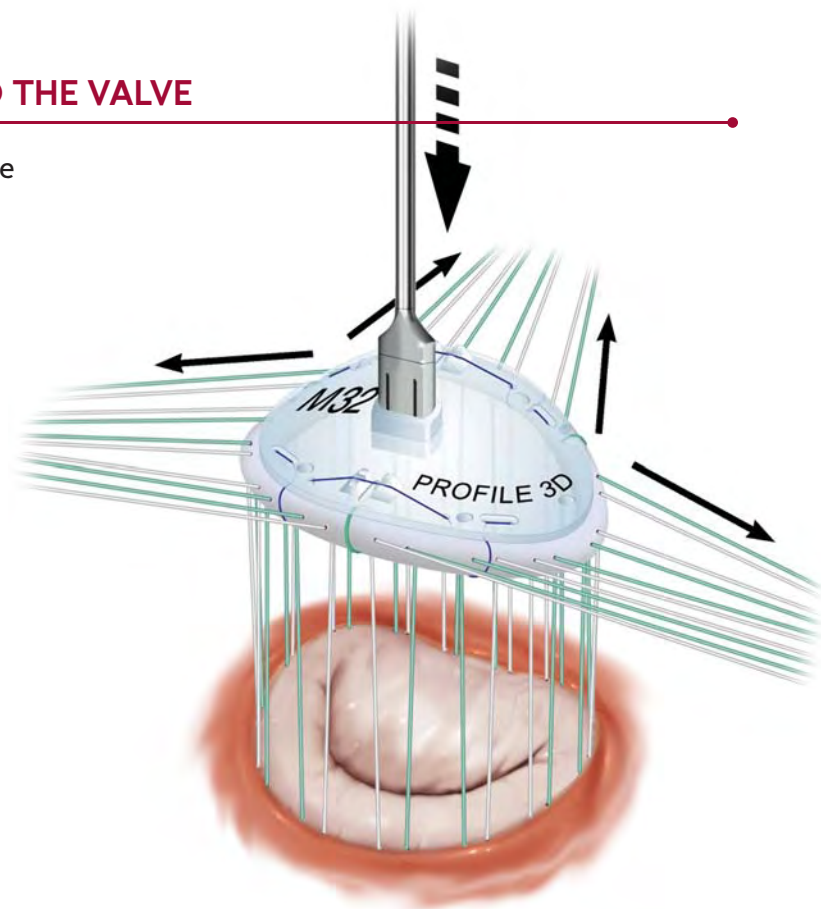
Pass sutures through the ring, approximately 2 mm apart, entering at the bottom of the ring and exiting the periphery of the ring.

Place sutures completely around the ring, including the anterior mitral annulus region.



## LOWERING THE PROFILE 3D™ RING ONTO THE VALVE

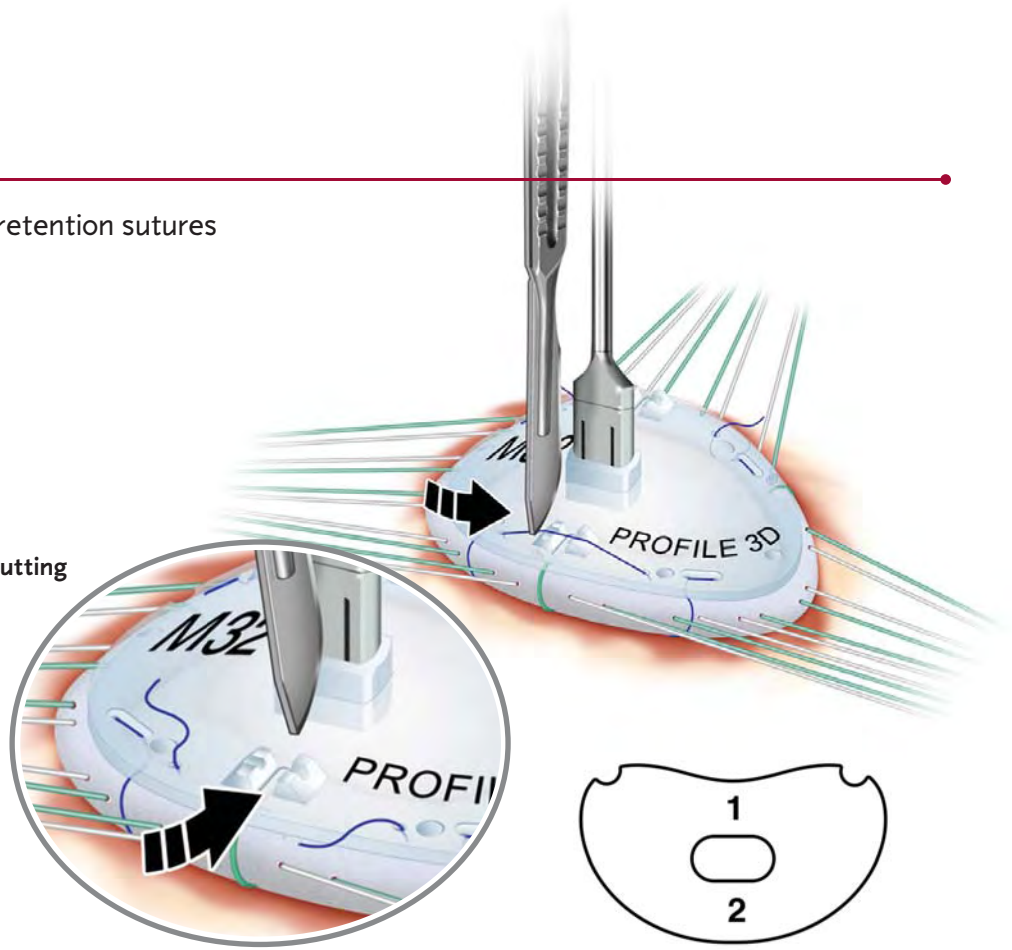
Use the holder/handle to push the ring down onto the valve annulus while pulling back on the sutures.



## REMOVING THE HOLDER

Using a scalpel, cut the two (2) ring retention sutures located on the holder.

**Warning:** Do not cut the ring fabric while cutting the holder retention sutures.

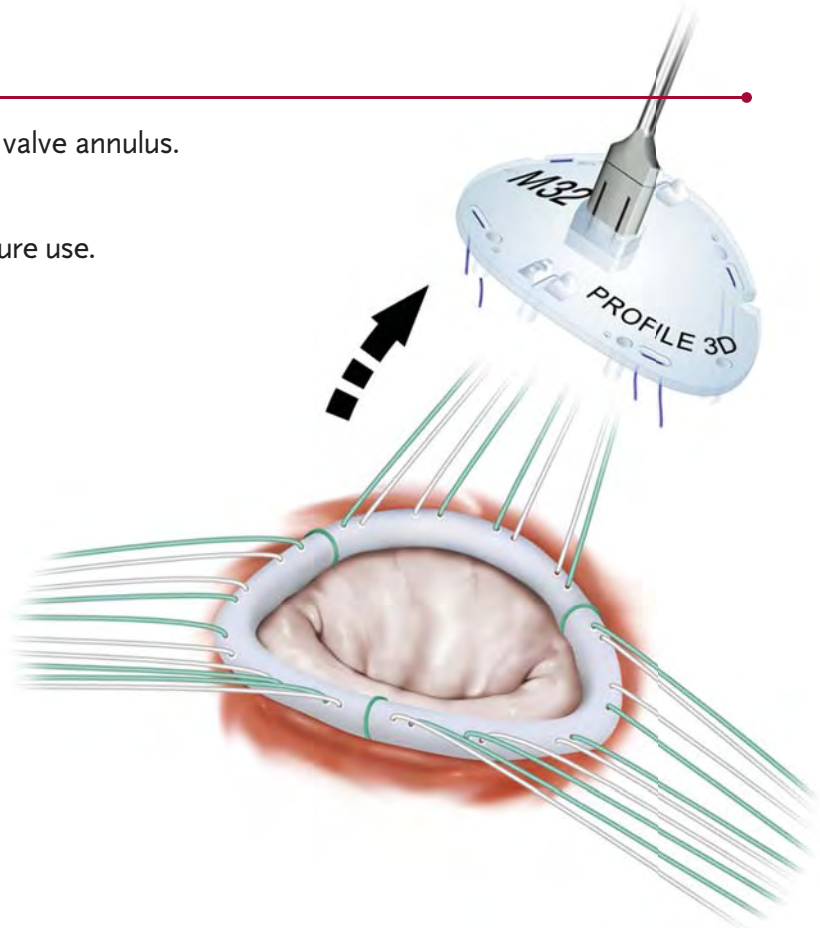


## REMOVING THE HOLDER AND HANDLE

Remove the disposable holder and handle from the valve annulus.

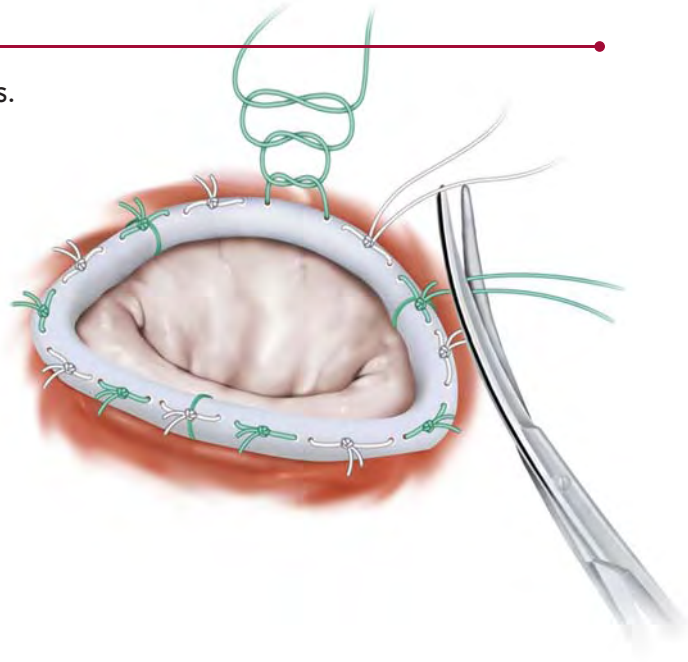
Dispose of the ring holder.

The handle should be cleaned and resterilized for future use.



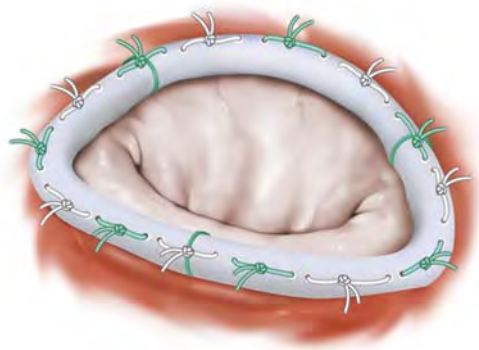
## TYING KNOTS AND TRIMMING SUTURES

Tie all knots around the ring securely and trim all excess sutures.



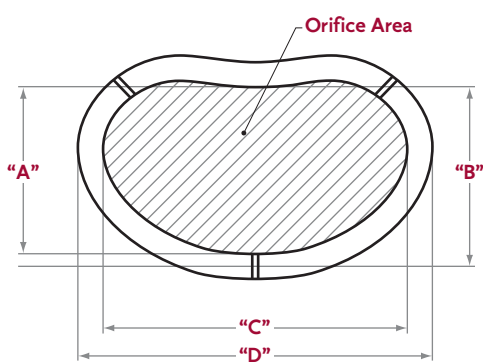
## TESTING FOR VALVE COMPETENCY

Test for valve competency.



# PROFILE 3D™ ANNULOPLASTY RING SPECIFICATIONS AND ORDERING INFORMATION

Order Number	Ring Description	A (mm)	B (mm)	C (mm)	D (mm)	Orifice Area
680R24	Profile 3D™ Annuloplasty Ring, Model 680R, 24 mm	13.4	15.0	24.2	30.5	278 mm <sup>2</sup>
680R26	Profile 3D™ Annuloplasty Ring, Model 680R, 26 mm	14.5	16.1	26.2	32.5	325 mm <sup>2</sup>
680R28	Profile 3D™ Annuloplasty Ring, Model 680R, 28 mm	15.6	17.2	28.2	34.5	376 mm <sup>2</sup>
680R30	Profile 3D™ Annuloplasty Ring, Model 680R, 30 mm	16.7	18.3	30.2	36.5	430 mm <sup>2</sup>
680R32	Profile 3D™ Annuloplasty Ring, Model 680R, 32 mm	17.8	19.4	32.2	38.5	489 mm <sup>2</sup>
680R34	Profile 3D™ Annuloplasty Ring, Model 680R, 34 mm	18.9	20.5	34.2	40.5	550 mm <sup>2</sup>
680R36	Profile 3D™ Annuloplasty Ring, Model 680R, 36 mm	19.8	21.4	36.2	42.5	612 mm <sup>2</sup>
680R38	Profile 3D™ Annuloplasty Ring, Model 680R, 38 mm	20.9	22.5	38.2	44.5	683 mm <sup>2</sup>
680R40	Profile 3D™ Annuloplasty Ring, Model 680R, 40 mm	22.0	23.6	40.2	46.5	756 mm <sup>2</sup>



Order Number	Components and Accessories
7680S	Profile 3D™ Sizer Set (9 Profile 3D™ sizers, 24 - 40 mm)
7686	Annuloplasty Handle (216 mm length)
7686XL	Annuloplasty Handle (373 mm length)
T7680	Profile 3D™ Accessory Tray

## Profile 3D™ Annuloplasty System

**Indications:** This device is indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling. **Contraindications:** Heavily calcified valves, valvular retraction with severely reduced mobility, active bacterial endocarditis. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

For additional information please refer to the Instructions for Use provided with the product or contact your local Medtronic representative.

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

Profile 3D is a trademark of Medtronic, Inc.

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For more information on heart valves visit:  
[www.heartvalves.com](http://www.heartvalves.com)

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