



Medtronic

CG Future[®]

ANNULOPLASTY SYSTEM FOR MITRAL REPAIR

In-Service Guide



Innovating for life.

CG Future® Annuloplasty System RING • In-Service Guide

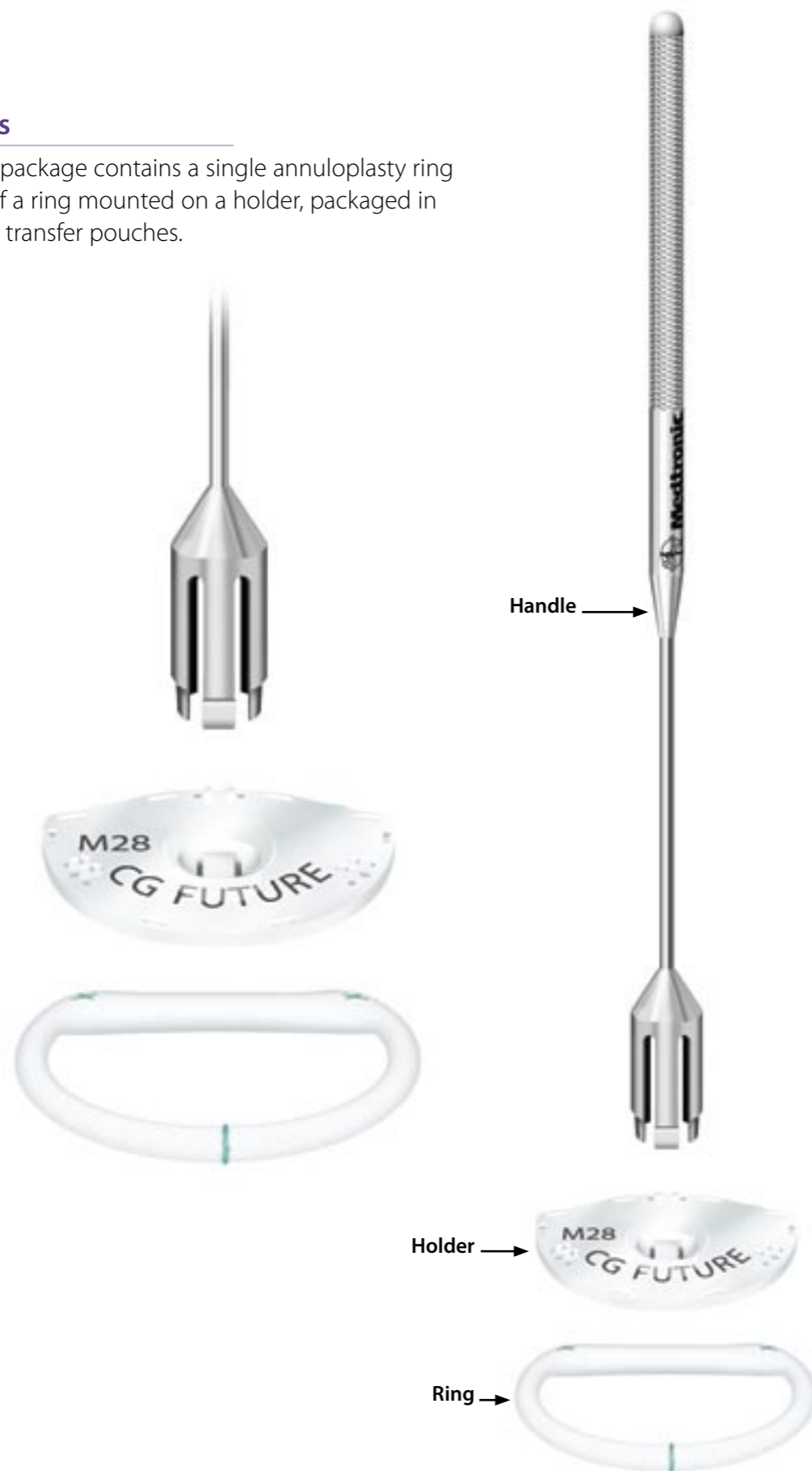
TABLE OF CONTENTS

Ring Components	1
Sizing the Annulus	2
Placing Annular Sutures	3
Inserting the Handle	4
Anchoring the Trigones	4
Placing Ring Sutures	5
Lowering the Ring onto the Valve	5
Removing the Holder	6
Removing the Holder and Handle	6
Tying Knots and Trimming Sutures	7
Testing for Valve Competency	7
Specifications/Ordering Information	18



Ring Components

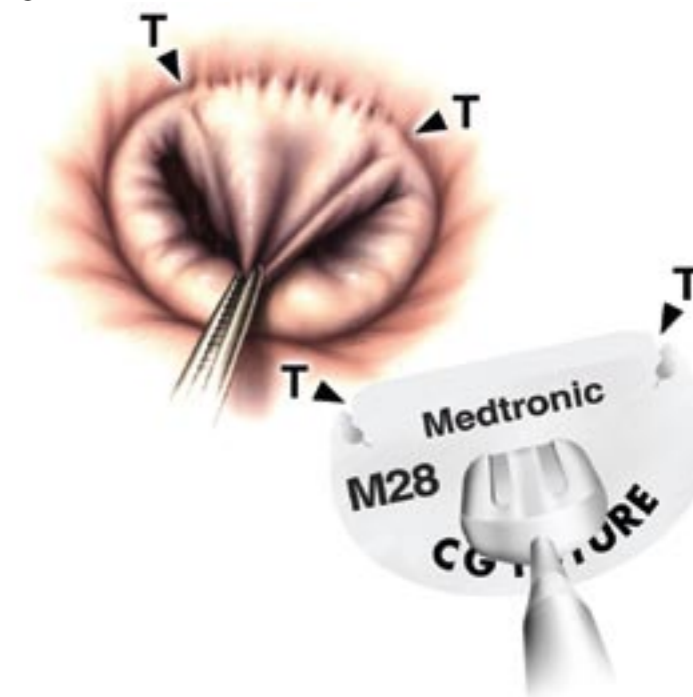
Each CG Future® Ring package contains a single annuloplasty ring assembly consisting of a ring mounted on a holder, packaged in sterile, double-aseptic transfer pouches.



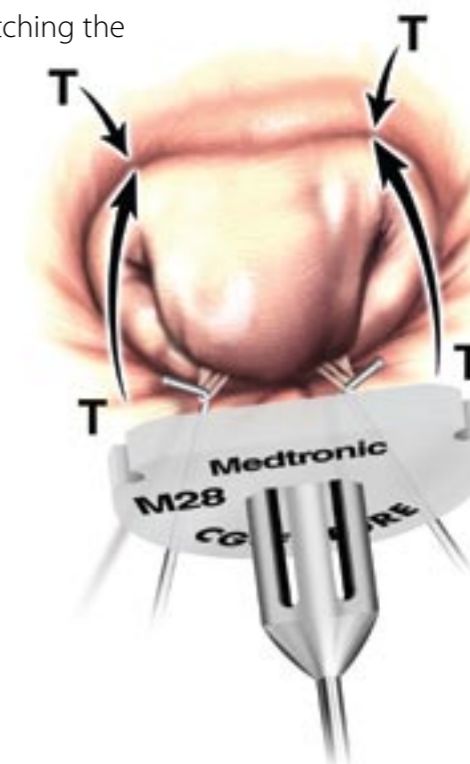
Sizing the Annulus

To determine the proper CG Future® 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.



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.



Placing Annular Sutures

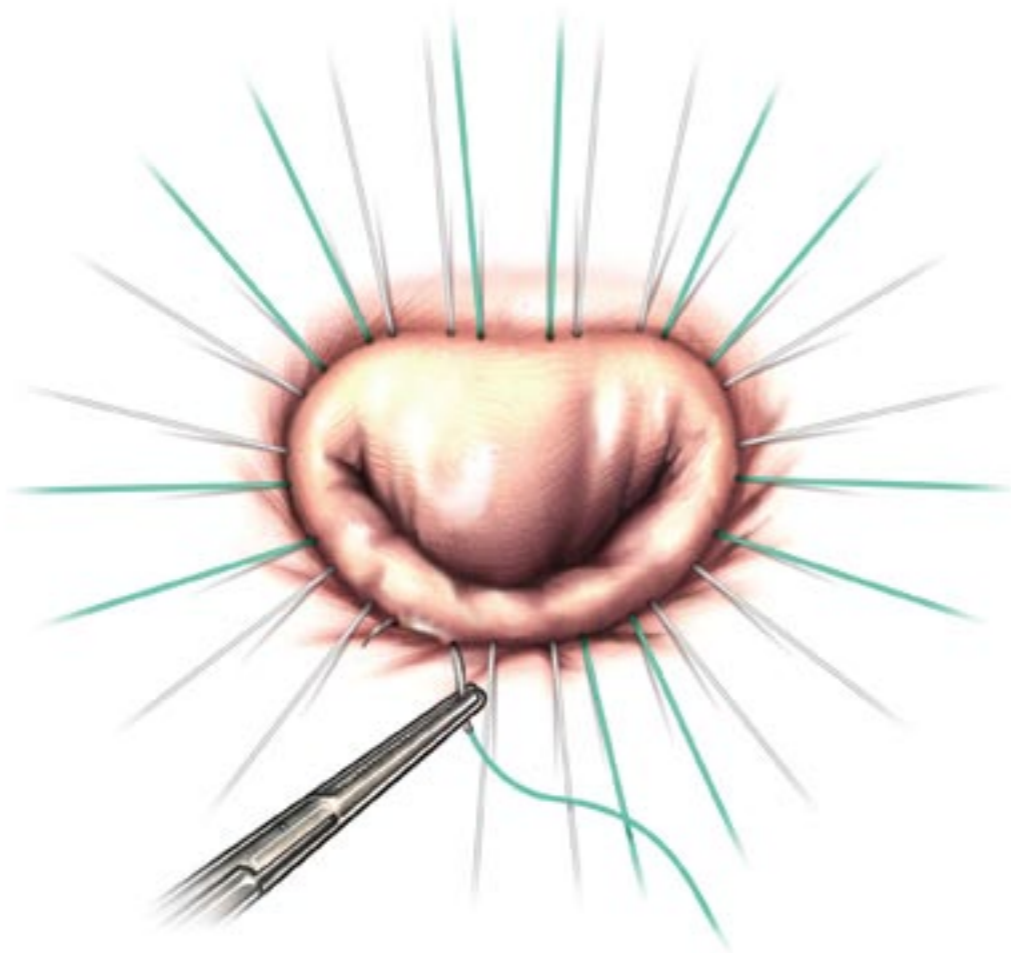
Place sutures in each trigone, approximately 4 mm in width. Place additional interrupted sutures, approximately 4 mm in width, in the anterior and posterior portion of the mitral annulus.

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 for the ring.

Warning: Avoid placing sutures in the circumflex coronary artery.

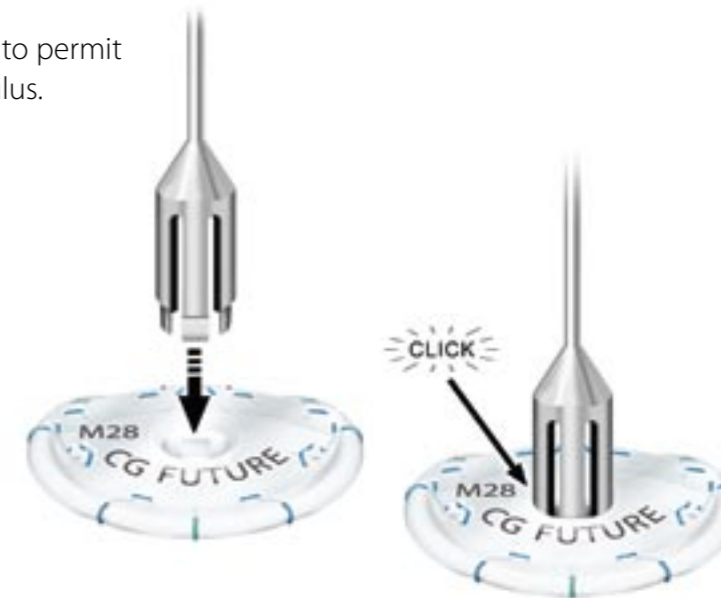
Note: Pledgets may be used for trigone sutures and mid-posterior annulus suture to reduce the possibility of ring dehiscence.



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 to permit alignment of the ring holder with the annulus.



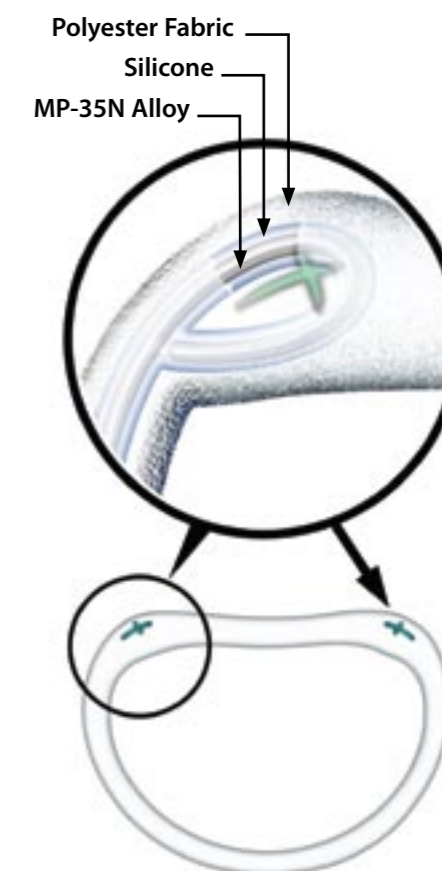
Anchoring the Trigones

Orient the ring assembly on the mitral annulus.

The anchoring sutures placed in the fibrous trigonal tissue should be passed through the eyelets of the ring (both eyelets are indicated by an "t").

Pass only one suture through each of the trigonal markings of the device.

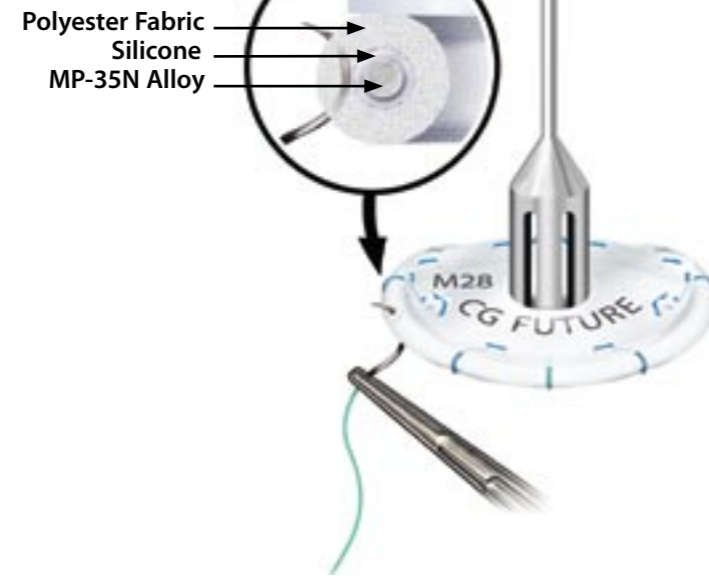
Caution: The ring must be sutured through the eyelets into the trigonal tissue to ensure secure attachment.



Placing Ring Sutures

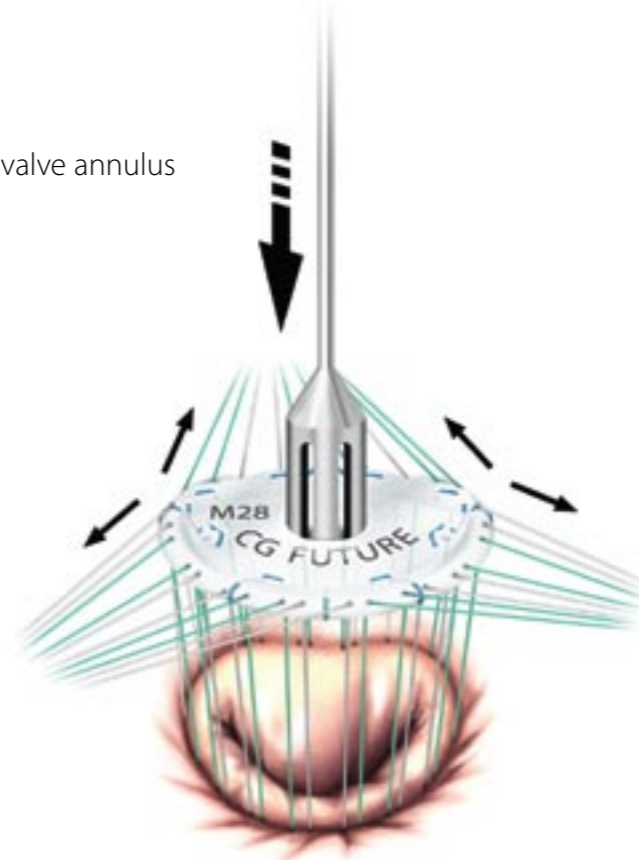
Pass sutures through the ring, approximately 2 mm in width, entering at the bottom of the ring and exiting the periphery of the ring.

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



Lowering the Ring onto the Valve

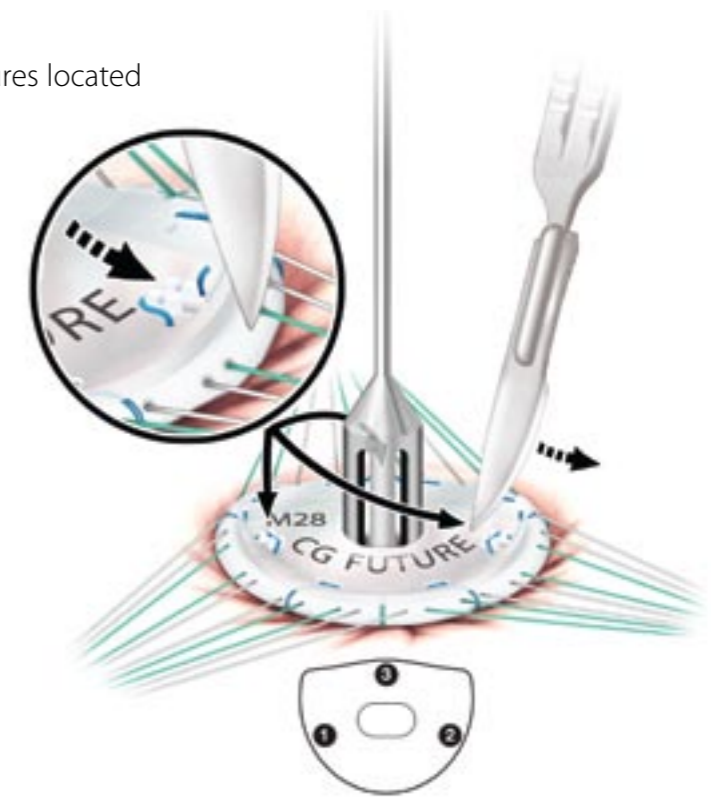
Use the holder/handle to push the ring down onto the valve annulus while pulling back on the sutures.



Removing the Holder

Using a scalpel, cut the three (3) ring retention sutures located on the holder.

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

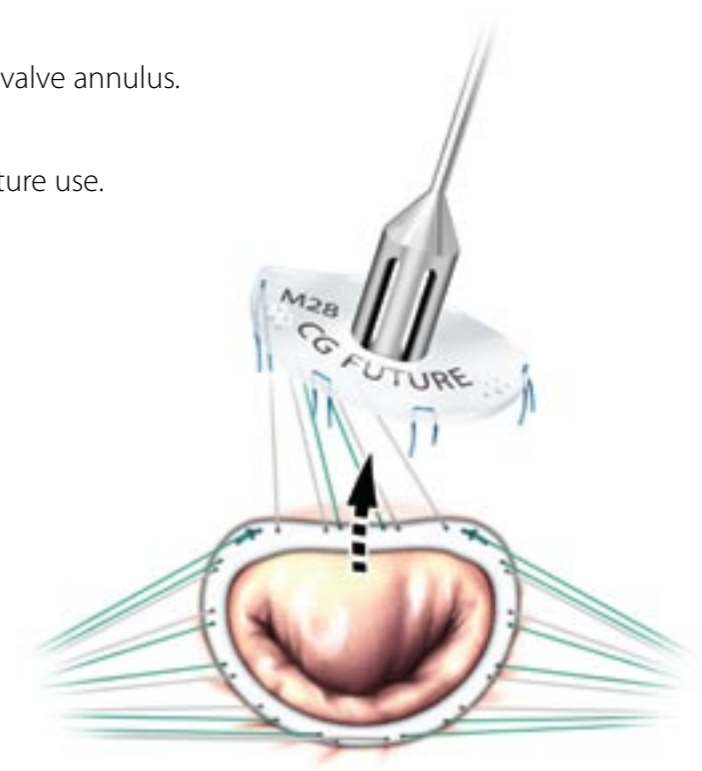


Removing the Holder and Handle

Remove the disposable holder and handle from the valve annulus.

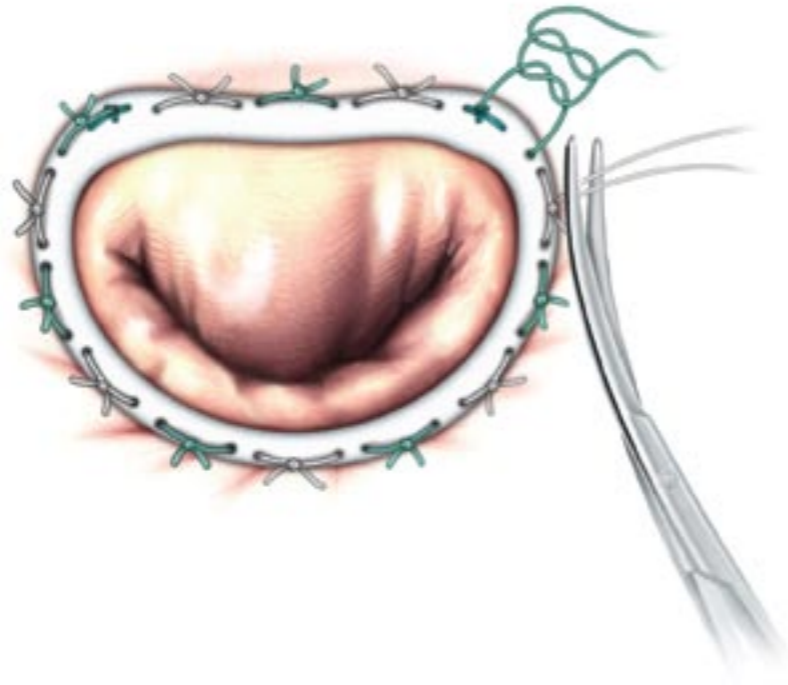
Dispose of the ring holder.

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.



CG Future® Annuloplasty System BAND • In-Service Guide

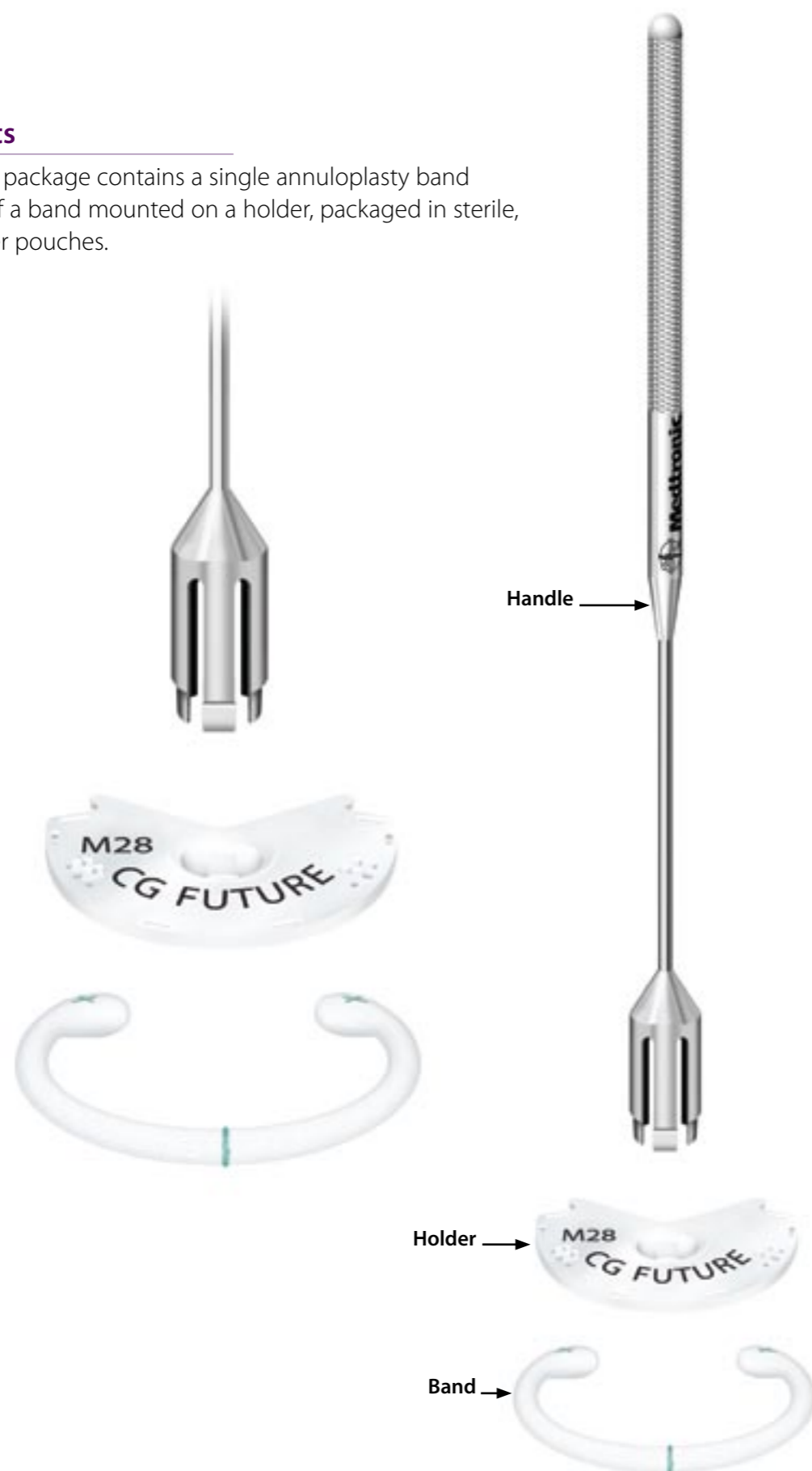
TABLE OF CONTENTS

Band Components	9
Sizing the Annulus	10
Placing Annular Sutures	11
Inserting the Handle	12
Anchoring the Trigones	12
Placing Band Sutures	13
Lowering the Band onto the Valve	13
Removing the Holder	14
Removing the Holder and Handle	14
Tying Knots and Trimming Sutures	15
Testing for Valve Competency	15
Specifications/Ordering Information	18



Band Components

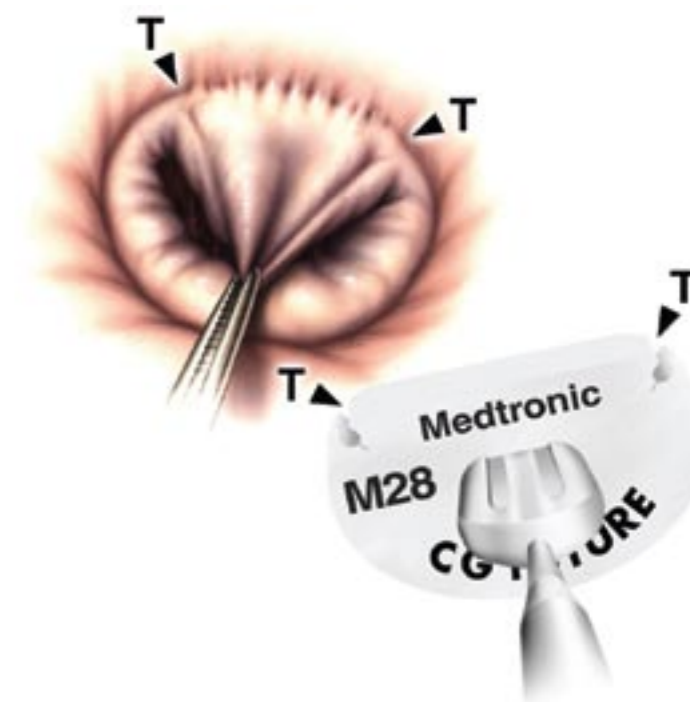
Each CG Future® Band package contains a single annuloplasty band assembly consisting of a band mounted on a holder, packaged in sterile, double-aseptic transfer pouches.



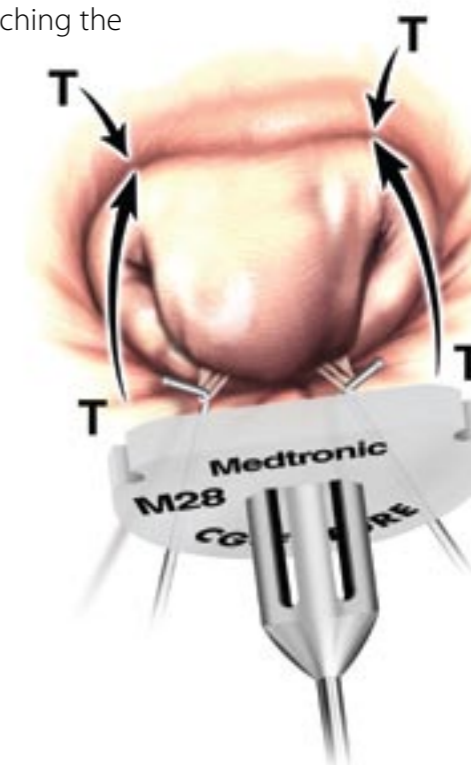
Sizing the Annulus

To determine the proper CG Future® Band 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.



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 band that should be selected.



Placing Annular Sutures

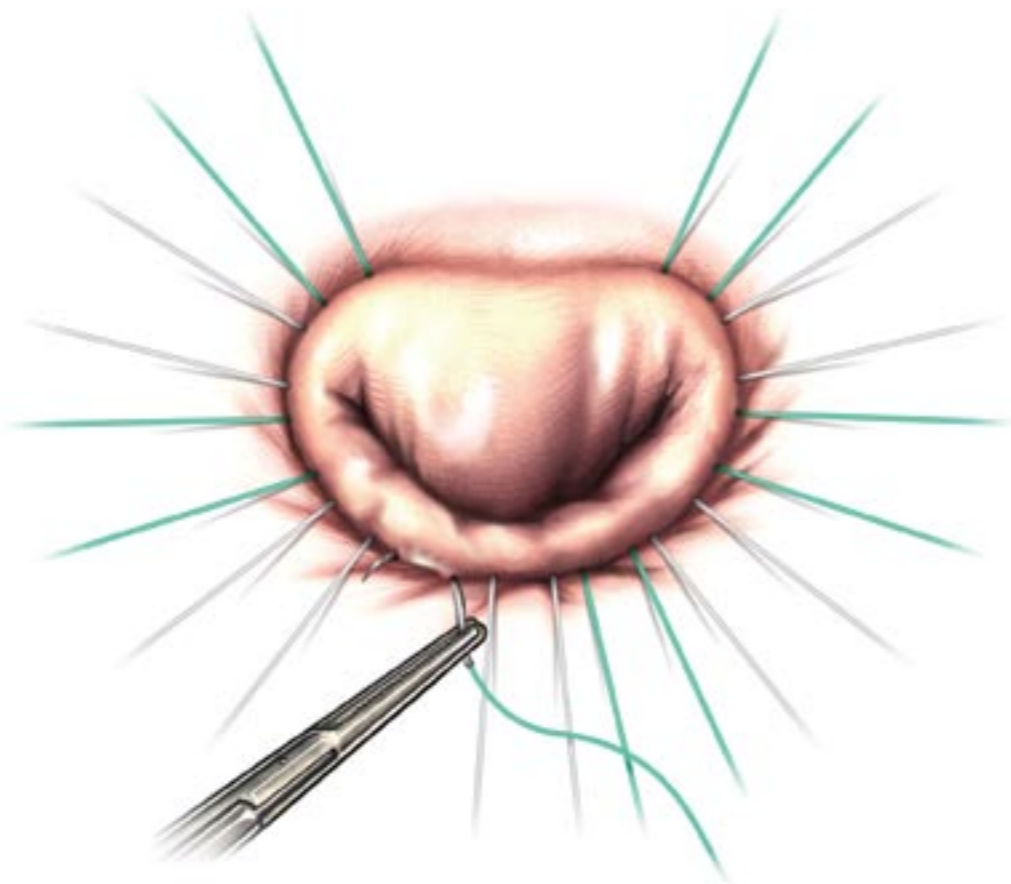
Place sutures in each trigone approximately 4 mm in width. Place additional interrupted sutures, approximately 4 mm in width, in the posterior portion of the mitral annulus.

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 for the band.

Warning: Avoid placing sutures in the circumflex coronary artery.

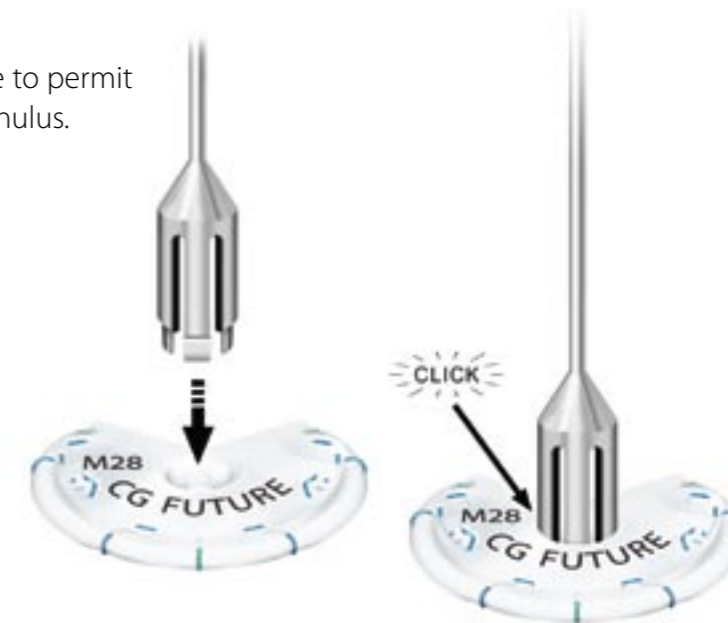
Note: Pledgets may be used for trigone sutures and mid-posterior annulus suture to reduce the possibility of band dehiscence.



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 to permit alignment of the band holder with the annulus.



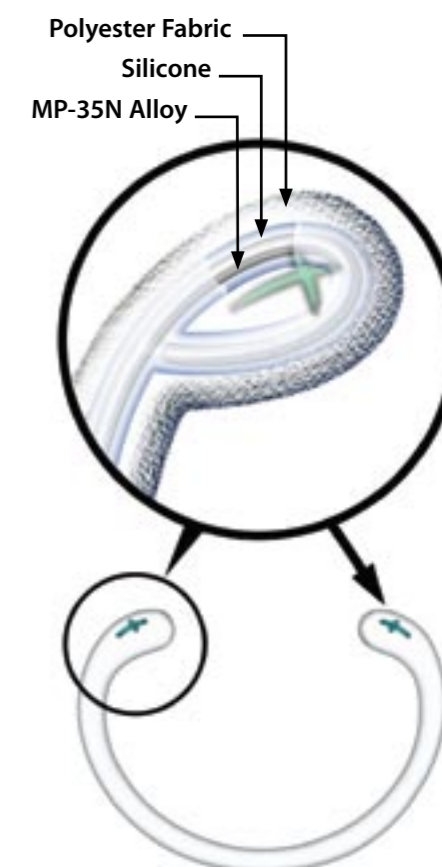
Anchoring the Trigones

Orient the band assembly on the mitral annulus.

The anchoring sutures placed in the fibrous trigonal tissue should be passed through the eyelets of the band (both eyelets are indicated by an "t").

Pass only one suture through each of the trigonal markings of the device.

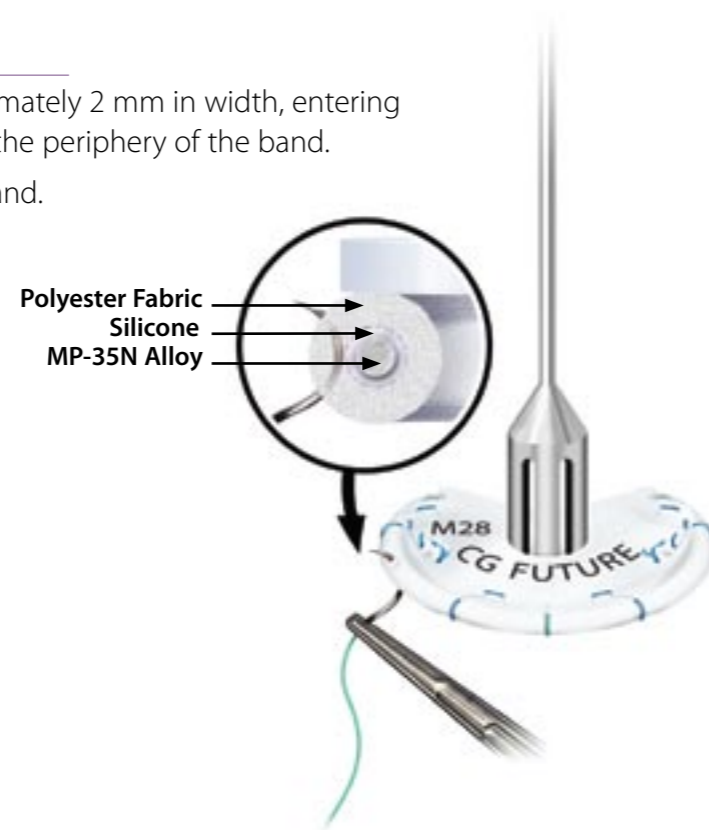
Caution: The band must be sutured through the eyelets into the trigonal tissue to ensure secure attachment.



Placing Band Sutures

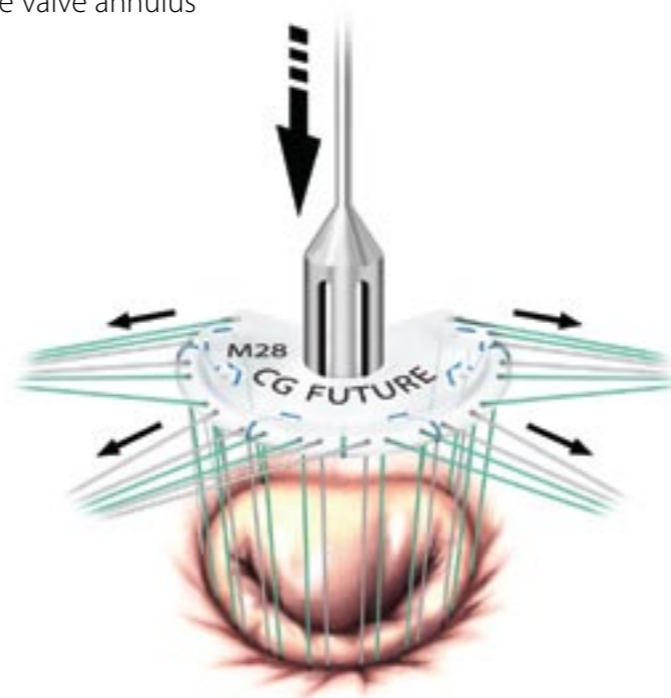
Pass sutures through the band, approximately 2 mm in width, entering at the bottom of the band and exiting the periphery of the band.

Place sutures completely around the band.



Lowering the Band onto the Valve

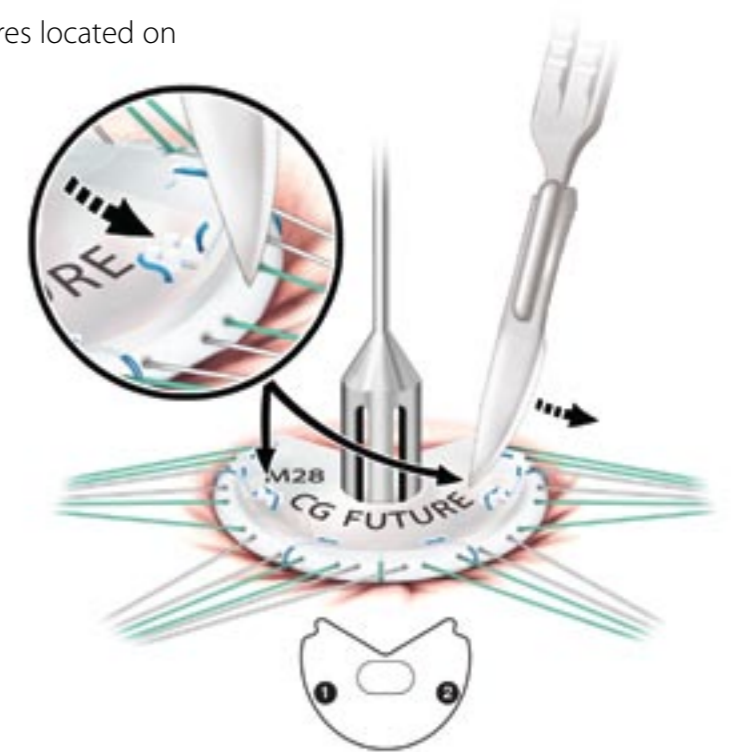
Use the holder/handle to push the band down onto the valve annulus while pulling back on the sutures.



Removing the Holder

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

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

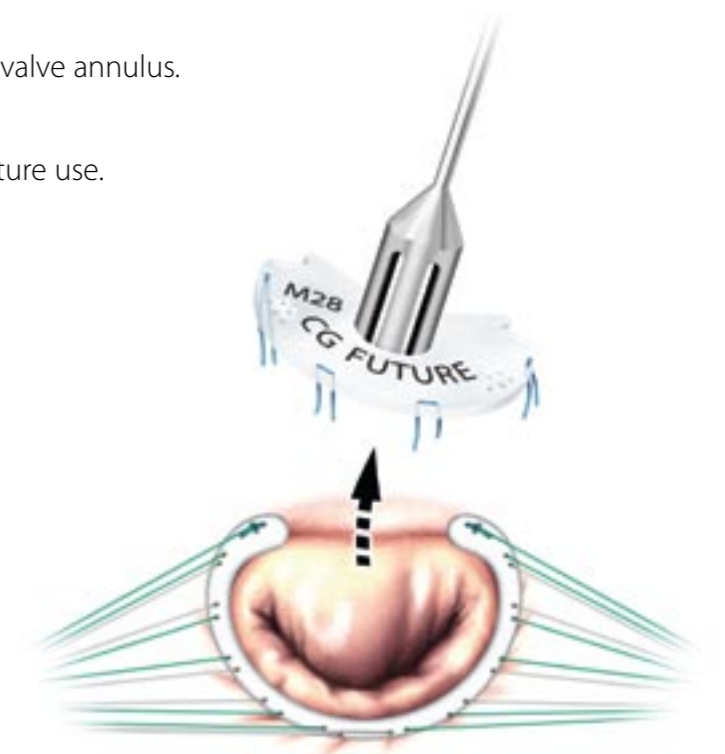


Removing the Holder and Handle

Remove the disposable holder and handle from the valve annulus.

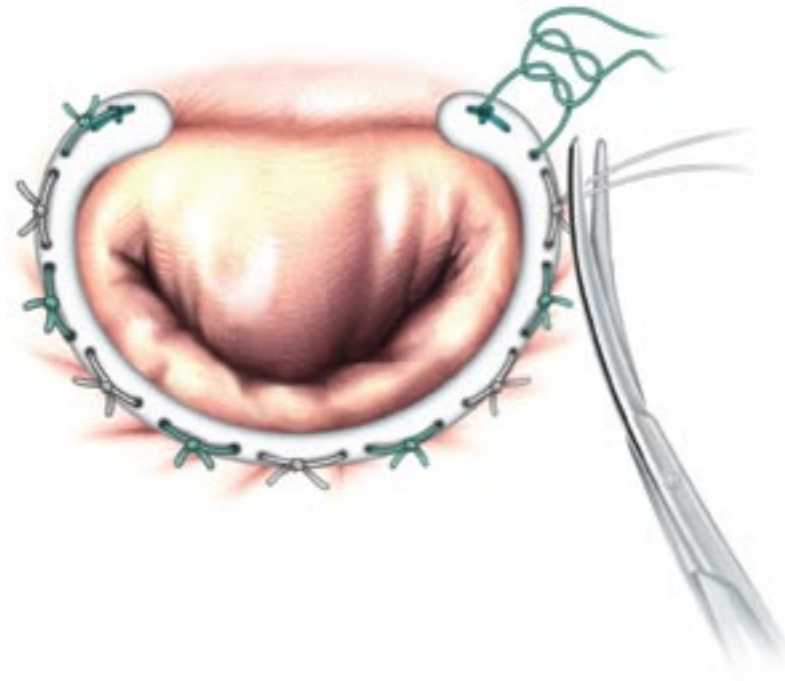
Dispose of the band holder.

The handle should be cleaned and resterilized for future use.



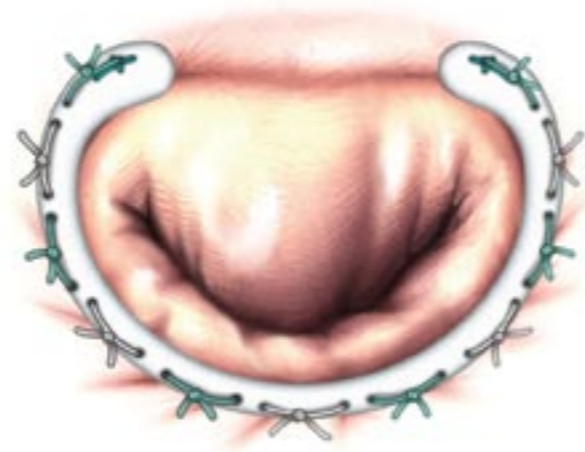
• **Tying Knots and Trimming Sutures**

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



• **Testing for Valve Competency**

Test for valve competency.



Ring Specifications And Ordering Information

	Size	Diameter A	Diameter B	Diameter C	Diameter D	Orifice Area	Order Number
	24 mm	15.27 mm	16.53 mm	24.0 mm	28.9 mm	269.3 mm ²	638RL24
26 mm	16.38 mm	17.64 mm	26.0 mm	30.9 mm	314.9 mm ²	638RL26	
28 mm	17.48 mm	18.73 mm	28.0 mm	32.9 mm	364.3 mm ²	638RL28	
30 mm	18.59 mm	19.85 mm	30.0 mm	34.9 mm	417.3 mm ²	638RL30	
32 mm	19.71 mm	20.97 mm	32.0 mm	36.9 mm	474.7 mm ²	638RL32	
34 mm	20.83 mm	22.09 mm	34.0 mm	38.9 mm	536.0 mm ²	638RL34	
36 mm	21.92 mm	23.18 mm	36.0 mm	40.9 mm	600.9 mm ²	638RL36	
38 mm	23.04 mm	24.29 mm	38.0 mm	42.9 mm	669.4 mm ²	638RL38	

Band Specifications And Ordering Information

	Size	Diameter A	Diameter B	Diameter C	Diameter D	Orifice Area	Order Number
	26 mm	16.38 mm	17.64 mm	26.0 mm	30.9 mm	332.0 mm ²	638BL26
28 mm	17.48 mm	18.73 mm	28.0 mm	32.9 mm	382.8 mm ²	638BL28	
30 mm	18.59 mm	19.85 mm	30.0 mm	34.9 mm	437.4 mm ²	638BL30	
32 mm	19.71 mm	20.97 mm	32.0 mm	36.9 mm	496.3 mm ²	638BL32	
34 mm	20.83 mm	22.09 mm	34.0 mm	38.9 mm	559.2 mm ²	638BL34	
36 mm	21.92 mm	23.18 mm	36.0 mm	40.9 mm	625.1 mm ²	638BL36	
38 mm	23.04 mm	24.29 mm	38.0 mm	42.9 mm	695.7 mm ²	638BL38	

Band/Ring Accessory And Ordering Information

Order Number	Description
7638S	CG Future® Sizer Set (eight sizers)*
7615	Annuloplasty Handle (216 mm length)
7615XL	Annuloplasty Handle (373 mm length)
T7630	CG Future® Accessory Tray

* CG Future COMPOSITE Ring available in size 24 mm.

CG Future® Annuloplasty System See Instructions for Use for a complete list of warnings, precautions, and contraindications.

www.medtronic.com

World Headquarters

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: +1 (763) 514-4000
Fax: +1 (763) 514-4879

Europe

Medtronic International Trading
Sàrl
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
Switzerland
Tel: +(41) 21 802 70 00
Fax: +(41) 21 802 79 00

Canada

Medtronic of Canada Ltd.
6733 Kitimat Road
Mississauga, Ontario L5N 1W3
Canada
Tel: + 1 (905) 826-6020
Fax: + 1 (905) 826-6620
Toll-free: 1 (800) 268-5346

Asia Pacific

Medtronic International, Ltd.
16/F Manulife Plaza
The Lee Gardens, 33 Hysan
Avenue
Causeway Bay
Hong Kong
Tel: +(852) 2891 4456
Fax: +(852) 2891 6830
enquiryap@medtronic.com

Latin America

Medtronic USA, Inc.
Doral Corporate Center II
3750 NW 87th Avenue Suite 700
Miami, FL 33178
USA
Tel: +1 (305) 500-9328
Fax: +1 (786) 709-4244