Genesee
BIOMEDICAL, INC.

Instructions for Use

FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band

FlexForm™ Annuloplasty Ring with Holder Model FRH
FlexForm™ Annuloplasty Band with Holder Model FBH
FlexForm™ Annuloplasty Ring without Holder Model FRN
FlexForm™ Annuloplasty Band without Holder Model FBN

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

1. Device Description

FlexForm™ Annuloplasty Rings and Annuloplasty Bands are fully flexible annular rings and bands designed to reduce and stabilize the valve annulus in patients undergoing mitral or tricuspid repair.

The rings and bands are made of braided polyester fabric and contain a circumferential flexible radiopaque marker. This internal radiopaque marker provides radiographic visualization along the entire circumference if required.

The rings and bands are available in nine sizes: 24, 26, 28, 30, 32, 34, 36, 38 and 40.

The differences between the rings and bands are as follows: The FlexForm™ Annuloplasty Ring is a complete annular ring. Five markers are provided on the ring; two markers indicate the approximate location of the trigones; three additional markers are provided as aids for suture placement in the posterior section. The FlexForm™ Annuloplasty Band is a partial ring, without an anterior segment. The key dimensions are the same as the FlexForm Annuloplasty Ring, except for the absence of the anterior segment. Five markers are provided on the band; two markers indicate the approximate location of the trigones; three markers are provided as aids for suture placement in the posterior section. The choice of ring or band is based on surgeon preference.

2. Indications for Use

The FlexForm™ Annuloplasty Rings and FlexForm™ Annuloplasty Bands are indicated for use in patients undergoing surgery of diseased or damaged mitral or tricuspid valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty rings and bands provide support for the mitral or tricuspid annulus and restrict expansion of the annulus.

3. Contraindications

- Severe, generalized or localized bacterial endocarditis
- Heavily calcified valves
- Greatly dilated annulus (not reducible by standard techniques)
- Severe valvular dysfunction (not correctable by standard techniques)
- Valvular retraction with severely reduced mobility
- Congenital malformations with lack of valvular tissue

4. Warnings

Only surgeons who have received adequate training to determine whether incompetent, stenotic, or diseased heart valves are capable of being repaired or replaced should use this device.

Correct annuloplasty ring and band sizing is an important element of a successful valve repair. Undersizing the ring or band can result in valve stenosis, and/or ring dehiscence. Oversizing the ring or band can result in valve regurgitation and/or ring dehiscence.

Do not place sutures in the coronary sinus, right coronary artery, AV node or other conduction tissue, as this may result in impairment of the cardiac conduction system.

Suture knots must be securely tied. Loose knots and long suture tails may be a source for hemolysis, thrombosis, or thromboembolism.

Do not cut the ring or band, as resultant loose threads can be a source of hemolysis, thrombosis, and/or thromboembolism.

Do not alter or deform the ring or band to conform to annular anatomy as this could lead to possible valve regurgitation and stenosis.

Intraoperative and/or postoperative echocardiography should be used to evaluate the effectiveness of the valve repair. Minimizing regurgitation is an important element of an effective repair.

Surgeons who use annuloplasty rings or bands should be current on all anticoagulation regimens.

When postoperative anticoagulant therapy is used, the patient's anticoagulation status should be carefully monitored.

Patients with intra-atrial thrombi or a giant left atrium may benefit from long-term anticoagulation therapy.

The surgeon may determine that patients in atrial fibrillation remain on anticoagulation therapy until sinus rhythm is established.

5. Precautions

Do not use cutting edge needles, as they may damage the annuloplasty ring or band, potentially leading to dehiscence and possible regurgitation.

Take care not to damage the annuloplasty ring or band during handling.

This device is for single patient use only.

Do not reuse, reprocess, or re-sterilize this product. Reuse, reprocessing, or re-sterilization 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.

6. Potential Adverse Events

While infrequent, certain complications have been reported when using an annuloplasty ring or band. These include the following:

- uncorrected or recurrent regurgitation
- stenosis
- dehiscence
- hemolysis (even with mild regurgitation)
- low cardiac output/systolic anterior motion
- heart block
- damage to coronary arteries
- endocarditis
- thrombosis
- thromboembolism
- anticoagulant-related hemorrhage
- leaflet perforation
- outflow tract obstruction

The potential for these complications should be considered when selecting the most beneficial surgical procedure for each patient. To avoid or minimize occurrence of these adverse events, the annuloplasty repair, including sizing and implantation, should be conducted in accordance with the methods described in these Instructions for Use by surgeons with appropriate training and experience in valve repair.

7. Individualization of Treatment

To allow for healing and incorporation of the annuloplasty ring or band by host tissue, regardless of cardiac rhythm, postoperative anticoagulation therapy should be considered for at least six weeks following surgery.

8. Patient Counseling Information

Patient Dental Care: Patients with annuloplasty rings or bands who undergo dental or other potentially bacteremic procedures must be considered for prophylactic antibiotic therapy.

9. MR Safety Information

Non-clinical testing has demonstrated that the FlexForm™ Annuloplasty Ring and Band are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

Static magnetic field of 3.0 Tesla or less Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m) or less Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Mode)

Under the scan conditions defined above, the FlexForm™ Annuloplasty Ring and Band are expected to produce a maximum temperature rise of 2.7°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 2 mm from the FlexForm™ Annuloplasty Ring and Band when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

10. Packaging

The FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band are available in the following sizes: 24, 26, 28, 30, 32, 34, 36, 38 and 40.

The rings and bands are provided sterile for one time use only. They are sterilized using irradiation, and supplied in double-aseptic transfer pouches contained in an

outer carton. The packaging system is designed to ease placement of the device into the sterile field. The ring or band assembly is sterile if the pouches are undamaged and unopened. The outer surfaces of the outer pouch are NONSTERILE and must not be placed in the sterile field.

11. Storage

Store the product in the original packaging, including the outer shelf carton, in a clean, cool, and dry area to protect the product and minimize the potential for contamination.

The sterility and non-pyrogenicity of the FlexForm™ Annuloplasty Rings and Bands are validated to remain unaffected until the Use-By date identified on the shelf carton, provided the pouches are not opened or damaged.

12. Annuloplasty Sizers

FlexForm™ Sizers, Model FRBS, are used to determine the correct size of the ring or band.

Sizers are provided NONSTERILE; they must be cleaned and sterilized prior to each use. The sizers are reusable; however, they must be cleaned and sterilized by autoclave (steam) sterilization prior to each use.

Proper size selection is an important part of valvular annuloplasty to help restore proper function. Use a FlexForm™ Annuloplasty Sizer Set (Catalog Number FRBS) and FlexForm Annuloplasty Handle (Model GRH or Model GRH-XL) for size selection.

13. Use of Handles and Sizers

Handles and sizers are provided NONSTERILE; they must be cleaned and sterilized prior to each use.

The handle is designed to engage and lock in position with the silicone sizers as well as with all holder-equipped FlexForm™ Annuloplasty Rings and Bands.

To attach the handle to the sizer, locate and orient the square recess in the sizer. Gently insert the handle head into the square recess in the sizer until the protrusions on both sides of the handle head are fully inserted through the T-slots on both sides of the square recess. The slots represent the spacing of the intercommissural distance. (Blue arrows indicate slots.) (See Figure 1 below.)

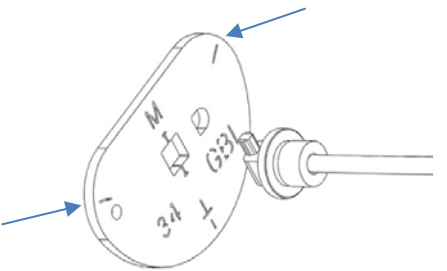

Figure 1 Sizer and Handle

The silicone sizers have a small hole that may be used for placement of a tether suture on the sizer. Use of a tether suture is recommended as this may aid sizer removal when sizing is completed.

The flexible silicone rubber sizers are designed to be adaptable for port-access and minimally invasive approaches, and can be folded for easier placement. The flexible sizers can be held and manipulated by surgical instruments using the center square hole and the offset D-hole in the sizer.
Precaution: Do not use other manufacturers' annuloplasty sizers, or handles from other annuloplasty products, to size the FlexForm™ ring and band. Other ring and band sizers may not indicate the appropriate ring and band size.

13. Handling Instructions

Inspect the pouches containing the device, ensure they have not been opened or damaged. The device is sterile as long as the inner pouch has not been compromised. If the inner pouch is damaged, do not implant the device. If the outer pouch is damaged, the exterior surface of the inner pouch may not be sterile.

Open the outer transfer pouch and, while still holding the bottom of the outer pouch, pass the inner pouch into the sterile field. The inner pouch should be opened only in the sterile field.

14. Device Preparation

The FlexForm™ Annuloplasty Ring and Annuloplasty Band may be used with or without the handle (Model GRH or GRH-XL). Remove the appropriately sized ring or band from the sterile package using aseptic technique.

For the annuloplasty ring, remove the serial number identification tag by cutting the retaining suture. Dispose of the retaining suture.

For the annuloplasty band, remove the serial number identification tag by cutting the retaining suture that connects the band ends. Be certain that the retaining suture is completely removed from the band. Dispose of the retaining suture.

Record the serial number printed on the identification tag in the patient's record. Verify that the serial number matches the serial number on the package.
Warning: The serial number identification tag must be removed from the ring and band for proper function. Do not cut or tear the ring and band fabric during removal of the serial number identification tag.

15. Use of Handle with Holders

Handles and sizers are provided NONSTERILE; they must be cleaned and sterilized prior to use.

The handle can be used with the optional holder (Models FRH and FBH) to position the ring or band for suture placement. To attach the handle to the holder, orient the holder with the turret facing up and slide the handle in place. See Figure 2.

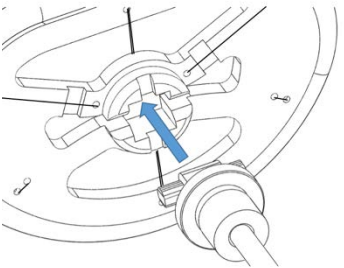

Figure 2 Handle and Holder

Take care to place the handle on the front side of the holder with the holder facing up. The handle will not fit into the backside of the holder. To remove the handle, gently pull the handle while the holder is secured.

The metal shaft of the handle is made of malleable nitinol that will straighten during the recommended steam sterilization cycle.
Do not use other manufacturers' annuloplasty sizers or handles from other annuloplasty products

16. Mitral Annulus Sizing

To determine the proper ring or band size, assess the area of both the anterior and posterior leaflets. For mitral valve

procedures, orient the sizer with the "M" facing upright. Gently extend the posterior and anterior leaflets and cover the surface with the sizer. The sizer with a surface area that most closely matches the surface area of the anterior and posterior leaflets, corresponds to the size of the ring or band that should be selected. The slots represent the spacing of the intercommissural distance.

17. Annulus Suture Placement

Implantation can be completed using current and established surgical techniques. One possible method of suturing the ring and band is the following: Place interrupted sutures, approximately 4 mm apart, continuing along the annulus and ending at the midpoint of the anterior leaflet. Approximately 8 to 10 sutures should be placed in the valve annulus. Markers are provided on the posterior section of the ring and band to aid in suture placement.

Warning: Do not place sutures in the coronary sinus, right coronary artery, AV node, bundle of His, or other conduction tissue.

Note: Pledgets may be used with annular sutures to reduce the possibility of ring/band dehiscence.

18. Ring or Band Suture Placement

Orient the ring or band assembly on the annulus. Pass the sutures through the ring or band, approximately 2 to 4 mm apart, entering at the bottom of the ring and exiting on the top of the ring. When passing the sutures through the FlexForm Ring or Band, pass the two limbs of each mattress suture through the FlexForm Ring or Band so that they are 2 to 4 mm apart. This will reduce the risk of bunching when tying the sutures.

Use the handle to slide the ring or band down onto the valve annulus while gently placing tension on the sutures. If required, bend the handle stem by grasping the handle with one hand and applying pressure to the handle stem between the thumb and forefinger of the other hand. Do not grasp the annuloplasty holder when bending the handle stem.

19. Holder Removal (Model FRH and Model FBH)

Remove the ring or band from the disposable holder (Model FRH and Model FBH) by cutting the two black retention sutures on the holder. The location of the suture cut-off zones is identified by two black markers: ⧗

(See Figure 3) Location of cut-off zones is indicated by blue arrows. Use of a No.11 scalpel blade is recommended. Place the blade under the suture and cut in an upward motion away from the holder. Cutting the suture in both cut-off zones is required. **Do not cut any other black sutures.** Do not cut the ring/band fabric while cutting the holder retention sutures.

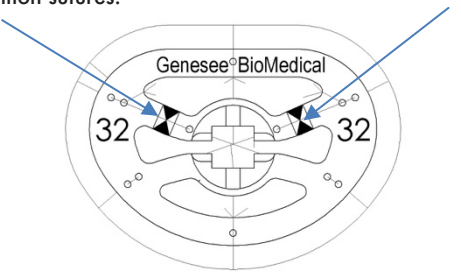

Figure 3 Holder Cut-Off Zones

Remove the holder from the ring/band using atraumatic forceps if necessary. If required, disengage the handle from the holder by gently pressing against the surface of

the holder when pulling the handle away from the holder. Dispose of the holder.

Warning: The holder must be removed from the ring/band at the end of the procedure for proper function. Under no circumstances is the holder to be left attached to the annuloplasty ring or band.

Tie the sutures around the ring or band securely and trim all excess sutures.

Test valvular competence: The annuloplasty ring or band should be tested for competence by filling the left ventricle and observing leaflet coaptation. Assess mitral valve competence by any suitable means (e.g. by injecting saline solution through the valve with a large syringe, or via a left ventricular drain, if present, or by removing the aortic cross clamp and temporarily rendering the aortic valve incompetent). If the mitral valve is regurgitant, note the area of reflux. If, for example, leakage occurs near the left commissural cusp, shorten that area of the ring or band by placing plicating sutures in the ring or band as necessary. Re-pressurize the left ventricle and re-check mitral valve competence. If any reflux remains, place further plicating sutures in the ring or band at appropriate points. Should significant reflux still occur, the surgeon should consider removing the ring or band, and replacing the valve. Complete the operation as usual.

20. Tricuspid Annulus Sizing

The appropriate size of the ring or band required for tricuspid repair can be based upon the circumferential distance between the anteroseptal and posteroseptal commissures. With the sizer oriented so the letter "T" is upright, ring or band size can be determined by matching the slots on the sizer with the inter-commissural distance along the base of the septal leaflet. The sizer that most closely conforms to the inter-commissural distance

represents the appropriate FlexForm Annuloplasty Ring or Band size. The use of a band may be preferred to a ring in the tricuspid position to reduce the risk of damage to the AV node and/or coronary sinus.

21. Tricuspid Implantation

The band or ring should be positioned with the mid-marker positioned at the commissure between the posterior and anterior leaflets. Implantation can be done using current implantation technique.

One possible method of suturing the ring is the following: Place evenly spaced interrupted horizontal mattress sutures through the annulus around the full circumference of the valve in the case of the ring. Place these sutures approximately 2 mm to the atrial side of the leaflet hinge.

Warning: Avoid damage to the AV conduction system and coronary sinus when implanting the tricuspid ring.

Pass the sutures through the FlexForm Ring or Band. Pass the two limbs of each mattress suture through the ring so that they are 2 to 4 mm apart. This will reduce risk of bunching of the ring or band when tying the sutures. To prevent annular shortening, pass the two limbs of the sutures in the septal segment of the ring or band with the same spacing as in the adjacent annulus. After implantation, tie and cut the implanting suture tails close to the knots. Refer to **Section 19** for holder removal (Model FRH and Model FBH).

After suturing the ring or band into place, test the valve for competence by filling the right ventricle with saline and observing leaflet coaptation. If the tricuspid valve is regurgitant, note the area of reflux and shorten that area of the band or ring by placing plication sutures as necessary. Repressurize the right ventricle and re-check tricuspid valve competence. If any reflux remains, place

further plicating sutures in the band or ring at appropriate points. Should significant reflux still occur, consider removing the band or ring and replacing the valve.

22. Use of Anticoagulants

Anticoagulation therapy should be considered post-implantation and for those patients with atrial fibrillation.

23. FlexForm™ Annuloplasty Accessories

The accessories consist of nine sizers and a handle. Sizers are used for selecting the correct size of ring or band. The FlexForm™ Sizers are made of flexible silicone. The detachable sizer handle has a malleable stem. The sizers and handles are supplied nonsterile and must be cleaned and steam sterilized before the first use and all subsequent uses. More information may be found in the FlexForm™ Accessories Instructions for Use.

24. Product Designations

FlexForm™ Annuloplasty Rings with Holder:
Model FRH-24; FRH-26; FRH-28; FRH-30; FRH-32; FRH-34; FRH-36; FRH-38; FRH-40

FlexForm™ Annuloplasty Bands with Holder:
Model FBH-24; FBH-26; FBH-28; FBH-30; FBH-32; FBH-34; FBH-36; FBH-38; FBH-40

FlexForm™ Annuloplasty Rings without Holder:
Model FRN-24; FRN-26; FRN-28; FRN-30; FRN-32; FRN-34; FRN-36; FRN-38; FRN-40

FlexForm™ Annuloplasty Bands without Holder:
Model FBN-24; FBN-26; FBN-28; FBN-30; FBN-32; FBN-34; FBN-36; FBN-38; FBN-40

FlexForm™ Annuloplasty Ring & Band Sizer Accessories:
Model FRBS: includes 9 sizers (one sizer for each ring or band size)

FlexForm™ Annuloplasty Handles:
Model GRH: Reusable Handle
Model GRH-XL: Reusable Handle, Extra long

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