Genesee
BIOMEDICAL, INC.
Design beyond standard.

Instructions for Use

TruForm™ Sievers Annuloplasty Ring
Model TRH

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

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1. Device Description

The TruForm™ Sievers Annuloplasty Ring, Model TRH, is an implantable 3D anatomically shaped annuloplasty ring for mitral valve repair. The TruForm Sievers Annuloplasty Ring is a single-use device intended to stabilize the mitral annulus in patients undergoing a remodeling or reconstructive surgery of diseased or damaged mitral valves. The device is provided sterile for one-time use only. The TruForm Sievers Annuloplasty Ring is constructed with a titanium alloy stiffener with a silicone band spacer. The ring is covered by a polyester cloth sewing cuff. Markers are provided on the ring as a guide for suturing. The marker placement is shown in blue in the diagram below. The TruForm Sievers Annuloplasty Ring is available in the following sizes: 24, 26, 28, 30, 32, 34, 36, 38, 40 and 42. (See Figure 1)

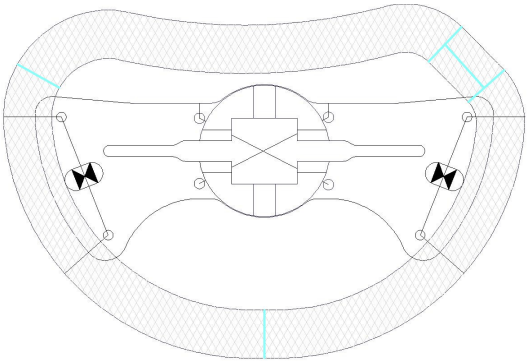

Figure 1 TruForm Sievers Annuloplasty Ring on Holder

2. Indications for Use

The TruForm Sievers Annuloplasty Ring is indicated for the correction of mitral valvular insufficiency where the lesions are not so severe as to require total valve replacement.

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.

Only surgeons that have received appropriate training in valve repair, including ring implant and sizing techniques, should use this device.

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

Sutures should not be placed in the coronary sinus, right coronary artery, AV node, bundle of His 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.

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

The ring should not be altered or deformed to conform to annular anatomy as this could lead to possible regurgitation and stenosis.

Intraoperative and/or postoperative echocardiography assessment 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 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, potentially leading to dehiscence and possible regurgitation.

Do not alter or deform the ring to conform to the anatomy.

Take care not to damage the annuloplasty ring during handling.

This device is for single patient use only.

Do not re-use, reprocess, or re-sterilize this product.

Re-use, 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. These include the following:

- uncorrected or recurrent regurgitation
- left ventricular outflow tract obstruction
- systolic anterior motion
- stenosis
- ring fracture
- 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 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 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 TruForm Sievers Annuloplasty Ring is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the TruForm Sievers Annuloplasty Ring is expected to produce a

maximum temperature rise of 2°C after 15-minutes of continuous scanning (i.e., per pulse sequence). In non-clinical testing, the image artifact caused by the TruForm Sievers Annuloplasty Ring extends approximately 5-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

10. Packaging

The TruForm Sievers Annuloplasty Ring is provided sterile for one time use only. The TruForm Sievers Annuloplasty Rings are sterilized using gamma radiation, and are 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 device 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 TruForm Sievers Annuloplasty Ring is validated to remain unaffected until the Use-By date identified on the shelf carton, provided the pouches are not opened or damaged.

Caution: Do not re-sterilize the TruForm Sievers Annuloplasty Ring.

12. TruForm Sievers Annuloplasty Ring Accessories

The accessories consist of sizers and handles. Sizers are used for selecting the correct size ring for the individual patient. The detachable handle has a malleable stem. The sizers and handles are supplied non-sterile and must be cleaned and steam sterilized before the first use and all subsequent uses.

Information regarding the accessories may be found in the Genesee BioMedical Annuloplasty Accessories Instructions for Use. (Provided with accessories)

13. Annuloplasty Sizers

Use Genesee BioMedical Annuloplasty Sizers to determine the correct size of the ring. Proper size selection is an important part of valvular annuloplasty to help restore proper function.

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.

14. Annuloplasty Handles

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

Do not use other manufacturers' annuloplasty sizers or handles from other annuloplasty products. Do not oversize the ring.

The handle is designed to engage and lock in position with the silicone sizers as well as with all Genesee BioMedical Annuloplasty Rings and Bands with holders.

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 intertrigonal markers. (See Figure 2 below, blue arrows indicate slots.)

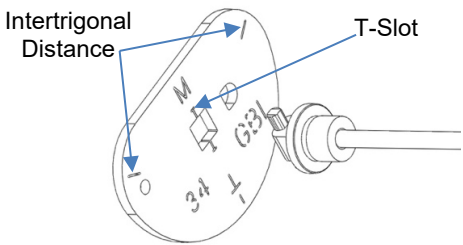

Figure 2: Sizer and Handle.

The silicone sizers have a small hole that may be used for placement of a tether suture. 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 insertion

and 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 TruForm Sievers Annuloplasty Ring. Other sizers may not indicate the appropriate ring size.

15. Device Handling

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.

16. Device Preparation

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

Remove the serial number identification tag by cutting the retaining suture. 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 for proper function. Do not cut or tear the ring fabric during removal of the serial number identification tag.

17. Mitral Annulus Sizing

Sizers are provided to determine the proper size ring. To determine the proper ring size, assess the area of both the anterior and posterior leaflets. 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 that should be selected. If the surface area of anterior and posterior leaflet is smaller than the 26mm sizer or bigger than the 40mm sizer, the annuloplasty ring size 24mm or 42mm should be selected. Do not use annuloplasty sizers from other annuloplasty products or manufacturers to determine the size of the TruForm Sievers Annuloplasty Ring.

18. Techniques for Suture Placement and Ring Implantation

Implantation can be completed using current and established surgical techniques. One possible method of suturing the ring is the following: Place interrupted sutures, approximately 4 mm apart, continuing along the annulus and ending at the midpoint of the anterior leaflet. Approximately 12 to 14 sutures should be placed in the valve annulus. Markers are provided on the sewing cuff 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 dehiscence.

19. Use of Accessories, Handles and Holder

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 TruForm Sievers Annuloplasty Ring holder. The handle is used with the holder to position the ring for suture placement.

To attach the handle to the holder, locate and orient the square recess in the holder. Gently insert the handle head into the square recess in the holder until the protrusions on both sides of the handle head are fully inserted through the slots on both sides of the square recess. (See Figure 3 below.)

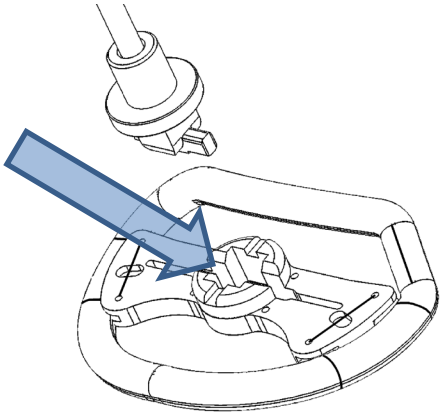

Figure 3

The metal shaft of the handle is made of malleable nitinol that will straighten during the recommended steam sterilization cycle.

Take care to place the handle on the front side of the holder with the holder facing up. To remove the handle, gently pull off the handle while the holder is secured.

Precaution: Do not use annuloplasty accessories from other annuloplasty products or manufacturers to implant the TruForm Sievers Annuloplasty Ring.

The handle can be used to slide the ring 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. (Figure 4)

The handle is attached to the holder by pressing the handle into the turret on the holder.

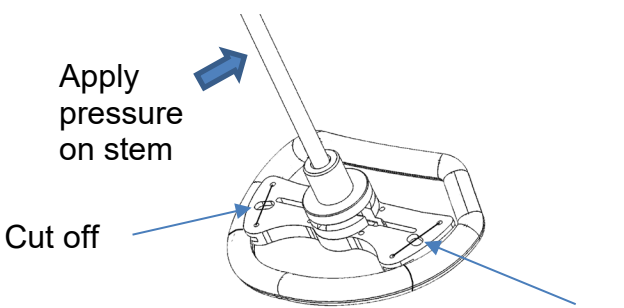

Figure 4

The handle is removed from holder by gripping the holder at the connection point while pulling the handle off. The handle is reusable (see section on Resterilization).

20. Holder Removal

The holder is removed from the ring by cutting two stitches located in the cut-off zones. Location of the cut-off zones (Figure 3 & 4) is indicated by arrows. (Shown in Figure 4.) Use of a No.11 or 15 scalpel blade is recommended for cutting the stay-suture. 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.

It is recommended that the holder and handle be removed during the implantation procedure just prior to tying the sutures. After the holder is detached from the TruForm Sievers Annuloplasty Ring, the handle is disconnected from the holder by gripping the holder at the connection point while pulling the handle off.

The handle is reusable. (See Instructions for Use of Genesee BioMedical Annuloplasty Accessories). Remove the holder from the ring 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. After the holder is detached from the ring, discard the holder.

Warning: Under no circumstances is the holder to remain attached to the annuloplasty ring after implantation.

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

Uncorrected or recurrent regurgitation is a potential complication associated with annuloplasty rings.

The annuloplasty ring 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 by placing plicating sutures in the ring as necessary. Re-pressurize the left ventricle and re-check mitral valve competence. If any reflux remains, place further plicating sutures in the ring at appropriate points. Should significant reflux still occur, the surgeon should consider removing the ring and replacing the valve. Complete the operation as usual.

21. Use of Anticoagulants

Thrombosis and thromboembolism are potential complications associated with annuloplasty rings. There is a possible need for postoperative anticoagulant therapy, surgeons should consider anticoagulation regimens for patients with annuloplasty rings. Anticoagulation therapy should be considered post-implantation and for those patients with atrial fibrillation.

22. TruForm Sievers Annuloplasty Ring Product Designations

Annuloplasty Rings with Holder:

Model Number	Description
TRH-24	TruForm Sievers Annuloplasty Ring size 24
TRH-26	TruForm Sievers Annuloplasty Ring size 26
TRH-28	TruForm Sievers Annuloplasty Ring size 28
TRH -30	TruForm Sievers Annuloplasty Ring size 30
TRH -32	TruForm Sievers Annuloplasty Ring size 32
TRH-34	TruForm Sievers Annuloplasty Ring size 34
TRH-36	TruForm Sievers Annuloplasty Ring size 36
TRH-38	TruForm Sievers Annuloplasty Ring size 38
TRH-40	TruForm Sievers Annuloplasty Ring size 40
TRH-42	TruForm Sievers Annuloplasty Ring size 42

23. Cleaning and Sterilization for Accessories

The following accessories are compatible with the TruForm Sievers Annuloplasty Ring.

Accessory	Model #	Description
Flexible Silicone Sizers	FRBS	Set of 9 silicone sizers (24, 26, 28, 30, 32, 34, 36, 38, 40)
Stainless Steel Sizers	GSS-4	2 Reusable handles (GRH) and 1 set of 4 double-ended sizers; sizes 26/28, 30/32, 34/36, 38/40
Handle	GRH	Reusable malleable handle
Handle XL	GRH-XL	Reusable malleable handle, extra long

Procedure for cleaning and sterilization of the accessories is provided below.

Manual Cleaning Procedure

#	Process	Temp	Cleaning Instructions
1	Rinsing	Room Temperature	Remove contaminants using running water for 1 min. Use a soft-bristle brush (for example, a nylon toothbrush) to clean the device thoroughly.
2	Soaking	Room Temperature	Submerge the device completely for a minimum of 5 min with enzymatic detergent and water, mixed using manufacturer's directions. Remove visible contaminants with a soft-bristled brush.
3	Ultrasonic Clean	Room Temperature	Submerge the device completely in an ultrasonic cleaner with enzymatic detergent and water, mixed using manufacturer's directions. Sonicate for 10 min.
4	Rinsing	Warm	Rinse the device with running water for 1 min.
5	Dry	N/A	Dry with a clean, lint-free wipe.
6	Inspection	N/A	Visually inspect each device for any remaining contaminants or moisture. If any contaminants remain, repeat the process.

Steam Sterilization Procedure

Cycle Type	Pre-Vacuum	Pre-Vacuum
Temperature	132°C (270°F)	135°C (275°F)
Exposure	4 minutes	3 minutes
Drying Time	20 minutes	16 minutes

Cycle Type	Pre-Vacuum for CJD
Temperature	134°C (273°F)
Exposure	18 minutes
Drying Time	30 minutes

For more information regarding accessories refer to the Genesee BioMedical Annuloplasty Accessories Instructions for Use.

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