Genesee
BIOMEDICAL, INC.
Design beyond standard.

Instructions for Use

WellsForm™ Tricuspid Annuloplasty Band
Model WF-XX

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

This page is intentionally blank.

1. Device Description

The WellsForm™ Tricuspid Annuloplasty Band has a stiffened portion at the septal and aortic segments. The flexible section runs from the aortic segment, about half of the anterior leaflet, to the posteroseptal commissure to help remodel and stabilize the enlarged portion of the tricuspid annulus found in patients with functional tricuspid regurgitation. The stiffener assembly consists of an MP35N 0.71 mm diameter (polished and formed) alloy. Braided polyester fabric forms the body of the band. The WellsForm Tricuspid Annuloplasty Band has three radial green markers. The first indicates the end of the septal stiffener at the septal/posterior commissure. The second marks the approximate location of the posterior/anterior commissure. The third indicates the end of the stiffener section in the anterior segment of the band. The band conforms to the natural annulus. The size range of the WellsForm Tricuspid Annuloplasty Band is from 26mm to 36mm in 2mm increments. Size refers to the internal diameter of the band. Bands are intended to be implanted in the patient's tricuspid annulus to reduce and stabilize the enlarged portion of the annulus. The internal stiffener, together with the radiopaque "string" in fully flexible section of the band, provides radiographic visualization along the entire circumference of the band. The use of braided

polyester fabric for the body construction provides minimal stretch to maintain annulus stability and minimum needle penetration force for easy implantation. The stiffener ends of the band are designed to conform to the non-planar annulus, thus minimizing band dehiscence.

Size	ID	OD	Gap	Ratio	Septal L mm	Aortic L mm	Total L mm
26	25.9	33.8	8.7	0.34	16.3	20.8	74.3
28	27.8	35.7	9.4	0.34	17.4	22.3	79.1
30	30.0	38.0	10.1	0.34	18.5	23.6	84.6
32	32.0	40.0	10.7	0.33	19.4	25.0	89.5
34	34.0	42.0	11.3	0.33	20.3	26.4	94.5
36	36.0	44.0	11.9	0.33	21.3	27.8	99.5

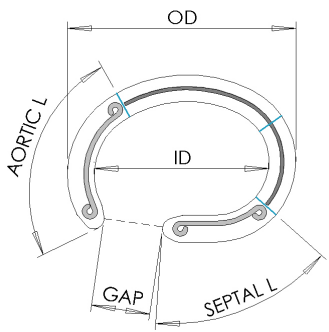

Figure 1 WellsForm Tricuspid Annuloplasty Band Principal Dimensions

2. Indications for Use

WellsForm Tricuspid Annuloplasty Bands are indicated for the surgical reconstruction or remodeling of diseased or damaged tricuspid valves. The band provides support for and restricts expansion of the tricuspid 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.

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

Correct annuloplasty band sizing is an important element of a successful valve repair. Undersizing the band can result in valve stenosis, and/or band dehiscence. Oversizing the band can result in valve regurgitation and/or band 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 band should not be cut, as resultant loose threads can be a source of hemolysis, thrombosis, and/or thromboembolism.

The band 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 bands should be current on all anticoagulation regimens. When postoperative anticoagulant therapy is used, the patient's anticoagulation status should be carefully monitored.

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 band, potentially leading to dehiscence and possible regurgitation.

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

Take care not to damage the annuloplasty band 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 band. These include the following:

- uncorrected or recurrent regurgitation
- systolic anterior motion
- stenosis
- band 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

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 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 bands who undergo dental or other potentially bacteremic procedures must be considered for prophylactic antibiotic therapy.

9. MRI Safety Information, 1.5-Tesla and 3-Tesla

MR Conditional

Non-clinical testing has demonstrated that the WellsForm Tricuspid Annuloplasty Band is MR Conditional.

A patient with the WellsForm Tricuspid Annuloplasty Band can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 5,000-Gauss/cm (50-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 WellsForm Tricuspid Annuloplasty Band 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 WellsForm Tricuspid Annuloplasty Band extends approximately 10-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

10. MRI Safety Information, 7-Tesla

MR Conditional

Non-clinical testing has demonstrated that the WellsForm Tricuspid Annuloplasty Band is MR Conditional.

A patient with the WellsForm Tricuspid Annuloplasty Band can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 7-Tesla, only
- Maximum spatial gradient magnetic field of 6,000-Gauss/cm (60-T/m)

Important Note: The WellsForm Tricuspid Annuloplasty Band must remain outside of all transmit or transmit/receive RF coils during MRI.

11. Packaging

WellsForm Tricuspid Annuloplasty Band is provided sterile for one time use only. The Annuloplasty Bands 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.

12. 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 WellsForm Tricuspid Annuloplasty Band are 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 Annuloplasty Band.

13. Annuloplasty Band Accessories

The accessories consist of sizers and handles. Sizers are used for selecting the correct size band for the individual patient. The handle and stainless-steel sizers have malleable stems. 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)

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 band.

The handle is designed to engage and lock in position with the existing Genesee BioMedical silicone sizers as well as with all Genesee BioMedical Annuloplasty 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 on either side represent the septal commissure locations. See Figure 2, blue arrows indicate slots.

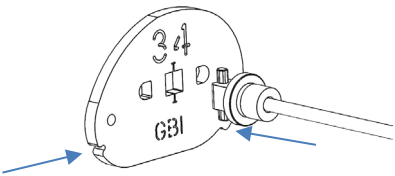

Figure 2: Sizer and Handle

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.

The tricuspid stainless-steel sizers have two markings that align with the septal commissures. The sizer that most closely conforms to the inter-commissural distance represents the appropriate annuloplasty band size. See Figure 3, blue arrows indicate septal commissure markings.

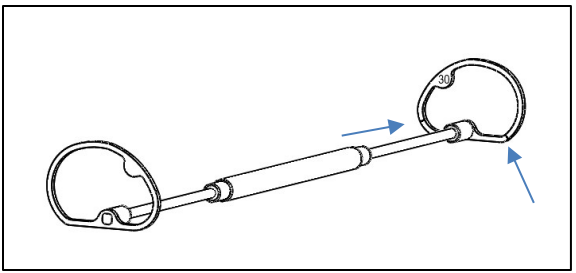

Figure 3 Stainless-Steel Tricuspid Sizer

Precaution: Do not use other manufacturers' annuloplasty sizers, or handles from other annuloplasty products, to size the Annuloplasty Band. Other sizers may not indicate the appropriate band size.

14. 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.

15. Device Preparation

Remove the appropriately sized band from the sterile package using aseptic technique. The Annuloplasty Band 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 band for proper function. Do not cut or tear the band fabric during removal of the serial number identification tag.

16. Tricuspid Band Sizing

Sizers are provided to determine the proper size band. To determine the proper band size, assess the area of leaflets. Assess by measuring the inter-commissural distances of the septal leaflet and the surface of the anterior leaflet. Line the commissures up with the sizer markings to visually assess the size of the remodeled tricuspid annulus, the outside circumference of the sizer roughly corresponds with

the midline of the same-sized WellsForm Band. Do not use annuloplasty sizers from other annuloplasty products or manufacturers to determine the size of the WellsForm Annuloplasty Band.

17. Techniques for Suture Placement and Band Implantation

Implantation can be completed using current and established surgical techniques. One possible method of suturing the band is the following: Place interrupted sutures, approximately 4 mm apart, typically beginning at the anteroseptal commissure and ending near the origin of the coronary sinus. Markers are provided on the sewing cuff to aid in suture placement.

Warning: Do not place sutures in AV node, bundle of His, or other conduction tissue. Note: Pledgets may be used with annular sutures to reduce the possibility of band dehiscence.

18. 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 WellsForm Annuloplasty Band

holder. The handle is used with the holder to position the band 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 4 below).

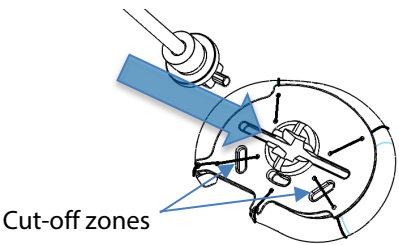

Figure 4: Inserting Handle into Holder

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 WellsForm Annuloplasty Band.

The handle can be used to slide the 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.

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 22 on Re-sterilization).

19. Holder Removal

The holder is removed from the band by cutting two stitches located in the cut-off zones. Locations of the cut-off zones are indicated by arrows (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 band/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 Annuloplasty Band, 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 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. After the holder is detached from the band, discard the holder.

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

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

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

The annuloplasty band should be tested for competence by filling the right ventricle and observing leaflet coaptation.

If the tricuspid valve is regurgitant, note the area of reflux and shorten that area by placing plicating sutures in the band as necessary. Re-pressurize the right ventricle and re-check valve competence. If any reflux remains, place further plicating sutures in the band at appropriate points. Should significant reflux still occur, the surgeon should consider removing the band and replacing the valve. Complete the operation as usual.

20. Use of Anticoagulants

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

21. WellsForm Annuloplasty Band Product Designations

Annuloplasty Bands with Holder:

Model #	Description
WF-26	WellsForm Tricuspid Annuloplasty Band, size 26
WF-28	WellsForm Tricuspid Annuloplasty Band, size 28
WF-30	WellsForm Tricuspid Annuloplasty Band, size 30
WF-32	WellsForm Tricuspid Annuloplasty Band, size 32
WF-34	WellsForm Tricuspid Annuloplasty Band, size 34
WF-36	WellsForm Tricuspid Annuloplasty Band, size 36

22. Cleaning and Sterilization for Accessories

The following accessories are compatible with the WellsForm Annuloplasty Band.

Accessory	Model #	Description
WellsForm Band Flexible Sizers	WBFS	Set of 6 silicone sizers (26, 28, 30, 32, 34, 36)
Tricuspid Stainless-Steel Sizers	GTSS	2 Reusable handles (GRH) and 1 set of 3 double-ended sizers; sizes 26/28, 30/32, 34/36
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.

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

THE FOLLOWING DISCLAIMER OF WARRANTY APPLIES TO UNITED STATES CUSTOMERS ONLY:

ALTHOUGH THE WELLSFORM ANNULOPLASTY BAND AND ACCESSORIES, HEREAFTER REFERRED TO AS "PRODUCT", HAVE BEEN DESIGNED, MANUFACTURED AND TESTED UNDER CAREFULLY CONTROLLED CONDITIONS, DUE TO CONDITIONS AND FACTORS THAT ARE OUTSIDE OF GENESEE BIOMEDICAL'S SUPERVISION AND CONTROL AFTER SALE OF THE PRODUCT, GENESEE BIOMEDICAL HEREBY DISCLAIMS ALL WARRANTIES EXPRESSED OR IMPLIED WITH RESPECT TO THE PRODUCT, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. GENESEE BIOMEDICAL, INC. SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR OTHER TYPE OF DAMAGES INCLUDING, WITHOUT LIMITATION, ANY MEDICAL EXPENSES CAUSED BY OR RELATED TO ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER BASED UPON A WARRANTY, CONTRACT, TORT OR OTHER LEGAL THEORY. GENESEE BIOMEDICAL, INC. NEITHER ASSUMES, NOR AUTHORIZES ANY OTHER PARTY TO ASSUME FOR IT, ANY WARRANTY, REPRESENTATION OR OTHER LIABILITY IN CONNECTION WITH THE PRODUCT OR ITS USE.

THE FOLLOWING DISCLAIMER OF WARRANTY APPLIES TO CUSTOMERS OUTSIDE THE UNITED STATES:

DISCLAIMER OF WARRANTY ALTHOUGH THE ANNULOPLASTY BAND, AND ACCESSORIES, HEREAFTER REFERRED TO AS "PRODUCT" HAVE BEEN CAREFULLY DESIGNED, MANUFACTURED AND TESTED PRIOR TO SALE, THE PRODUCT MAY FAIL TO PERFORM ITS INTENDED FUNCTION SATISFACTORILY FOR A VARIETY OF REASONS. THE WARNINGS CONTAINED IN THE PRODUCT LABELING PROVIDE MORE DETAILED INFORMATION AND ARE CONSIDERED AN INTEGRAL PART OF THIS DISCLAIMER OF WARRANTY. GENESEE BIOMEDICAL, INC., THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT. GENESEE BIOMEDICAL, INC. SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT OR FAILURE OF THE PRODUCT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

If any term or portion of this Disclaimer of Warranty and Liability provision is found to be unenforceable, illegal or contrary to applicable law by a court of competent jurisdiction, the remaining portions of this provision shall not be affected and shall remain valid, and any such unenforceability or illegality in jurisdiction shall not invalidate or render unenforceable this Disclaimer of Warranty and Liability provision any other jurisdiction.

Manufacturer:
Genesee BioMedical, Inc.
700 W Mississippi Ave. Unit D5
Denver, CO 80223-4509, USA
Toll Free: (800) 786-4890
Phone: (303) 777-3000

222039R01