



Genesee

BIOMEDICAL, INC.

Design beyond standard.

Instructions for Use

Genesee BioMedical Annuloplasty Accessories

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

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1 Intended Use

The Genesee BioMedical Annuloplasty Accessories are intended to aid the surgeon in the selection of the optimal size of the Genesee BioMedical Annuloplasty Rings or Annuloplasty Bands.

- Sizers are used to select the proper size Genesee BioMedical Annuloplasty Ring or Annuloplasty Band for the patient. The reusable handles are used to manipulate the sizers to determine the correct size of the ring or band.
- Handles are used during implant to facilitate manipulation of ring/band holder. Genesee BioMedical Annuloplasty Rings and Bands are supplied with disposable holders.

All accessories are reusable following proper cleaning and sterilization. *All accessories must be sterilized prior to each use.*

The Genesee BioMedical Annuloplasty Accessories are used with the Genesee BioMedical Annuloplasty Rings and Annuloplasty Bands list in Table 1:

Table 1: Compatible Annuloplasty Rings and Bands

Annuloplasty Ring or Band	Model Number	Description
FlexForm™ Annuloplasty Band with Holder	FBH-##	Flexible annuloplasty band with Holder Sizes: 24,26,28,30,32, 34,36,38,40
FlexForm™ Annuloplasty Ring with Holder	FRH-##	Flexible annuloplasty ring with Holder Sizes: 24,26,28,30,32, 34,36,38,40

Annuloplasty Ring or Band	Model Number	Description
TruForm™ Annuloplasty Ring	TRH-##	Semi-Rigid annuloplasty ring with Holder Sizes: 24,26,28, 30,32,34,36,38,40,42
WellsForm™ Tricuspid Annuloplasty Band	WF-##	Semi-Rigid annuloplasty band with Holder Sizes: 26,28,30,32,34,36
TransForm™ McCarthy Mitral Annuloplasty Ring	TF-##	Semi-Rigid annuloplasty ring with Holder Sizes: 24,26,28, 30,32,34,36,38,40

2 Device Description

The annuloplasty accessories consist of the following reusable sizers and handles (Table 2):

Table 2: Annuloplasty Accessories

Accessory	Model Number	Description
Flexible Silicone Sizers	FRBS	Set of 9 flexible silicone sizers: 24, 26, 28, 30, 32, 34, 36, 38, 40 Mitral/Tricuspid
WellsForm Band Flexible Sizers	WBFS	Set of 6 flexible silicone sizers: 26, 28, 30, 32, 34, 36 Tricuspid
TransForm Silicone Sizers	TFRS	Set of 8 flexible silicone sizers: 26, 28, 30, 32, 34, 36, 38, 40. Mitral
Stainless-Steel Double-Ended Sizer Kit	GSS-4	Set of 4 double-ended sizers: sizes 26/28, 30/32, 34/36, 38/40 Mitral/Tricuspid Includes Sterilization Tray and 2 GRH-U handles
Stainless-Steel Double-Ended Sizer	GSS-XX/XX	Individual Stainless-Steel Double-Ended Sizer-XX/XX Mitral/Tricuspid where XX denotes size.

Accessory	Model Number	Description
		Sizes: 26/28, 30/32, 34/36, 38/40
Tricuspid Stainless-Steel Double-Ended Sizer Kit	GTSS	Set of 3 double-ended Tricuspid sizers: sizes 26/28, 30/32, 34/36 Tricuspid Includes Sterilization Tray and 2 GRH-U handles
Tricuspid Stainless-Steel Double-Ended Sizer	GTSS-XX/XX	Individual Stainless-Steel Double-Ended Tricuspid Sizer-XX/XX Tricuspid where XX denotes size. Sizes: 26/28, 30/32, 34/36
TransForm Stainless-Steel Sizers	TFSS	Set of 4 Stainless-Steel Double-Ended TransForm Sizers: sizes 26/28, 30/32, 34/36, 38/40 Includes Sterilization Tray, 1 GRH handle and 1 GRH-U handle
Annuloplasty Scale	GSC	Annuloplasty Scale with malleable nitinol stem
Annuloplasty Scale Kit	GSC-2	Kit of 2 Annuloplasty Scales, 1 GRH handle, and 1 GRH-U handle within a Sterilization Tray
Handle	GRH	Genesee Reusable Handle with malleable nitinol stem
Handle	GRH-XL	Genesee Reusable Handle with malleable nitinol stem; extra-long handle
Handle	GRH-U	Universal Genesee Reusable Handle with malleable nitinol stem
Handle	GRH-UXL	Universal Genesee Reusable Handle with malleable nitinol stem; extra-long handle
Sterilization Tray	PST-ST5	Sterilization Tray

- *Do not use other manufacturers' handles or sizers from other annuloplasty products.*
- *Do not use other manufacturers' sizers to size the Genesee BioMedical Annuloplasty Rings or Bands.*

- *Use of other manufacturers' sizers may not indicate the appropriate ring or band size.*
- *Tricuspid sizers are only to be used with GBI Annuloplasty Bands for tricuspid repair.*

All accessories must be sterilized prior to each use. All accessories are reusable following proper cleaning and sterilization.

These accessories are intended ONLY for use with Genesee BioMedical Annuloplasty Rings and Annuloplasty Bands. All personnel responsible for handling the reusable accessories should read and understand this information prior to using the instrumentation.

3 Warnings

- Do not force sizers through the annulus as patient injury may occur.
- Do not use sizers provided by another manufacturer. The use of sizers provided by other manufacturers, or the use of the sizing technique employed for another manufacturer's annuloplasty rings, bands, or valves, may result in misleading sizing information for the Genesee BioMedical Annuloplasty Ring or Band.
- The sizers and handles are provided NONSTERILE and must be thoroughly cleaned and sterilized prior to each use.

4 Precautions

- Inspect each device before every use. Carefully inspect each sizer and handle prior to use for flaws or damage that may result from sterilization, handling, or general use. Discard any sizer or handle that shows signs of degradation.

- Do not apply excessive force when engaging the handle to the sizer, as this may damage the sizers.
- Do not use solvent-based cleaners (for example, acetone or toluene) when cleaning the sizers or handles.

5 Directions for Use

Refer to the Genesee BioMedical Annuloplasty Ring or Band Instructions for Use document for information regarding the sizing and implantation of the Genesee BioMedical Annuloplasty Rings and Bands.

6 Use of Handles and Sizers

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

Correct annuloplasty ring and band sizing is an important element of a successful valve repair.

Under-sizing the ring or band can result in:

- valve stenosis
- ring or band dehiscence
- ring or band fracture

Over-sizing the ring or band can result in:

- valve regurgitation
- ring or band fracture

Sizers can be used with the handle for ease of positioning. To attach the handle to the sizer, orient the sizer with the opening in the center of the sizer and insert the handle until it slips into place. See Figure 1.

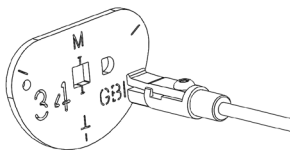


Figure 1: Silicone Sizer FRBS and Handle GRH-U

The flexible 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, in which the sizers 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.

The TransForm silicone sizer's outer edge and parallel slots match the outer and inner profiles of the implanted TransForm Annuloplasty Ring. The radial slots represent the trigone, mid-anterior, and mid-posterior markers. Sizing for commissure-commissure (CC) and anteroposterior (AP) are designated on each sizer. Blue arrows indicate significant features in Figure 2.

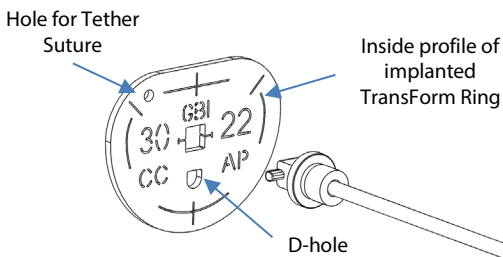


Figure 2: Flexible TFRS Sizer and GRH Handle

The stainless-steel sizer (GSS) is double-sided with sizes marked on each side. The sizer handle sections are malleable and may be adjusted for visualization during use. If the device is indicated for mitral use, the sizer should be oriented with the M in the position of the anterior leaflet. If the device is indicated for tricuspid use, the sizer should be oriented with the T in the position of the septal leaflet. See Figure 3.

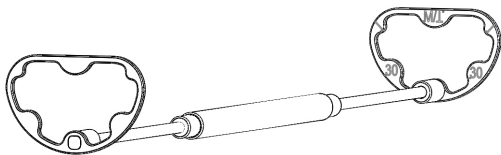


Figure 3: Stainless Steel Double-Ended Sizer GSS-30/32

To determine the proper ring or band size, assess the surface 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.

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 intercommissural distance represents the appropriate 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.

The tricuspid stainless-steel sizers and WellsForm Band flexible sizers are only to be used for tricuspid valve repair. The two markings on each sizer align with the anteroseptal and posteroseptal commissures. The sizer that most closely conforms to the intercommissural distance represents the appropriate Annuloplasty Ring or Band size. The use of a band may be preferred to a ring during tricuspid repair to reduce the risk of damage to the AV node and/or coronary sinus. See Figure 4.

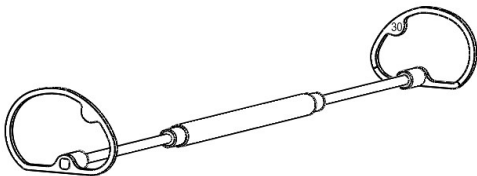


Figure 4: Stainless-Steel Tricuspid Sizer

The TransForm stainless-steel sizers match the complete profile of an implanted TransForm Annuloplasty Ring. The markings represent the trigone and mid-anterior locations. See Figure 5.

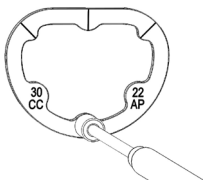


Figure 5: Stainless-Steel TFSS TransForm Sizer

The Annuloplasty Scale (Model GSC) features 1mm tick marks along either side of a straight edge, providing a minimalistic profile to take length measurements during annuloplasty (Figure 6).

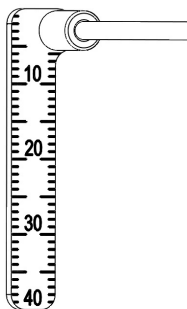


Figure 6: Annuloplasty Scale, GSC

Use the Annuloplasty Scale to measure the mid-anterior leaflet (A2) length and mid-posterior leaflet length, then select the TransForm Ring that will provide a coaptation length to restore valve competence, but not so small that it will cause systolic anterior motion.

Published algorithm¹:

$$\text{Coaptation Length} = \frac{\text{A2} + \text{P2} - \text{Ring AP}}{2}$$

These measurements can be acquired using the scale from the base of the mid-anterior leaflet to the free edge of the leaflet (A2). The posterior leaflet measurement is made after leaflet reconstruction, from the base of the mid-posterior leaflet to the free edge. For posterior leaflet repair techniques involving neochord without resection, use the scale to estimate the

length from the base of the posterior leaflet to the estimated point of coaptation. The A2 length closely approximates the TransForm AP ring diameter to provide a successful repair and leaflet coaptation length.

7 Use of Handle with Ring and Band Holders

The handles are designed to engage and lock in position with all holder-equipped Genesee BioMedical Annuloplasty Rings and Bands. The handles can be used with the holder to position the ring or band for suture placement. To attach the handle to the holder, orient the holder with the socket facing up and slide the handle into place. For GRH handles, line the prongs up with the slots on either side of the holder hub and slide the handle into place. See Figure 7.

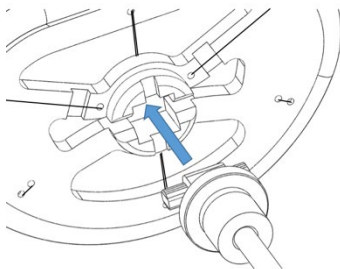


Figure 7: Inserting Handle GRH into FlexForm Holder

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.

8 How Supplied

The Genesee BioMedical Annuloplasty Sizer Set and Accessories are supplied NONSTERILE and must be cleaned and sterilized prior to initial use and before each subsequent use. For reuse, completely detach the sizer from the handle prior to cleaning. The sizers and handle are intended to be stored indefinitely and may be reused with appropriate cleaning and sterilization.

9 Cleaning

Follow standard hospital procedure or protocol as required to thoroughly clean the accessories prior to sterilization. A qualified washer/disinfector may be used for the automated cleaning of GBI Annuloplasty Accessories. Use of a neutral enzymatic detergent is recommended to maintain the longevity of the accessories. The use of some solvent-based cleaners, such as acetone or toluene, may cause early deterioration. The accessories should be examined individually for damage or degradation prior to use. Do not use the accessories if there are signs of damage or deterioration. Table 3 provides instructions for a validated manual cleaning procedure

Table 3: Manual Cleaning Instructions

Step	Process	Minimum Water Quality / Temperature	Cleaning Instructions
1	Rinse	Utility Water 20-35° C	Remove contaminants using running water for 1 min. Use a soft-bristle brush (for example, a nylon toothbrush) to clean the devices thoroughly.
2	Soak	Utility Water 20-55° C	Submerge the devices completely for a minimum of 5 min with enzymatic detergent and water, mixed according to manufacturer's directions. Remove visible contaminants with a soft-bristled brush.
3	Ultrasonic Clean	Utility Water 20-55° C	Submerge the devices completely in an ultrasonic cleaner with enzymatic detergent and water, mixed according to manufacturer's directions. Sonicate for a minimum of 10 min.
4	Rinse	Critical Water 25-50° C	Rinse the devices with running water for 1 min.
5	Dry	N/A	Dry with a clean, lint-free wipe.
6	Inspect	N/A	Visually inspect each device for any remaining contaminants or moisture. If any contaminants remain, repeat the process.

10 Processing and Reprocessing

The Genesee BioMedical Annuloplasty Accessories should be packaged or wrapped for sterilization per standard hospital procedure using Steri-Wrap® cellulose-based wraps or equivalent packaging materials. The accessories should be examined individually for damage or deterioration prior to use. Do not use the accessories if there are signs of damage or deterioration.

11 Sterilization and Re-sterilization

The following steam sterilization cycles have been validated and are recommended to sterilize Genesee BioMedical Annuloplasty Accessories (Table 4).

Table 4: Steam Sterilization Cycle Parameters

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

Note: Proper sterilization of these accessories is the responsibility of the end-user. Hospitals should use a validated method to determine sterilizer effectiveness, such as a biological indicator. Due to variability between sterilization systems, precise sterilization instructions cannot be provided. Contact the hospital sterilizer manufacturer for additional information regarding sterilization procedures.

23. References

1. McCarthy, P. M., Herborn, J., Kruse, J., Liu, M., Andrei, A.-C., & Thomas, J. D. (2022). A multiparameter algorithm to guide repair of degenerative mitral regurgitation. *The Journal of Thoracic and Cardiovascular Surgery*, 164(3):867-876.e5.
<https://doi.org/10.1016/j.jtcvs.2020.09.129>

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