Edwards

Physio Flex Annuloplasty Ring, Model 5300

Instructions for Use

Rx Only

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

1.0 Product Description

The Physio Flex annuloplasty ring is a semi-rigid, open, mitral annuloplasty ring with an asymmetrical open anterior segment (see **Figures 1 and 2**).

The ring (**Figure 3**) has an asymmetrical open anterior segment corresponding to the mitral annulus below the aorto-mitral curtain (**segment 1**). The complete portion (**segment 2**) of the ring begins at the anterolateral commissure and extends beyond the posteromedial commissure and the posteromedial trigone into the anterior annulus (**segment 3**).

The ring design has a rectangular Nitinol core which enables different flexibilities in-plane (1) and out-of-plane (2) (**Figure 4**).

The ring flexibility progressively increases in-plane from size 24 mm to 30 mm. It remains relatively constant from size 30 mm to 40 mm. For each ring size, the out-of-plane flexibility is greater than the in-plane flexibility (see **Table 1**).

Table 1

Size	In-Plane Flexibility (A)	Out-of-Plane Flexibility (B)
24 mm – 30 mm	Progressively increases	Greater than in-plane
30 mm – 40 mm	Remains constant	

The ring also has a progressive saddle height with a complete posterior saddle and an open anterior saddle. The ratio of the saddle height to the A-P (antero-lateral to postero-medial) dimension progressively increases from size 24 mm to size 36 mm. It remains constant from size 36 mm to 40 mm (**Figure 5**).

The Nitinol core is covered with a silicone sleeve and an external, knitted, polyester cloth. The sewing cuff is designed for ease of needle penetration and suture placement. A green circumferential suture line placed between the outer perimeter of the ring and the outer perimeter of the Nitinol core identifies the suture placement area (see **Figure 2**).

The ring has two commissure markers and a mid-posterior marker to facilitate orientation during implantation (see **Figure 6**).

The ring incorporates a holder with a proximal arm (**Figure 7**) for connection to handle models 1150 and 1151 (**Figure 8**). The holder arm is designed with a section made of stainless steel that can be bent to facilitate access and positioning of the ring on the valve annulus.

The Physio Flex annuloplasty ring is available in sizes 24, 26, 28, 30, 32, 34, 36, 38 and 40 mm.

The Physio Flex annuloplasty ring is designed to be used with sizer model 1252.

2.0 How Supplied

The Physio Flex annuloplasty ring comes pre-attached to a holder and is provided sterile and nonpyrogenic. Packaging consists of a box containing a dual sterile barrier package, two trays sealed with lids, one inside the other to facilitate handling and transfer to the sterile field at the time of surgery. After opening the outer tray, the inner tray may be placed directly into the sterile field.

3.0 Intended Use and Indications for Use

The Physio Flex annuloplasty ring, model 5300, is intended to repair a malfunctioning mitral heart valve.

The Physio Flex annuloplasty ring, model 5300, is indicated for patients who require the correction of mitral valve insufficiency, or mixed mitral valve disease, where treatment does not necessitate replacement of the natural mitral valve.

4.0 Contraindications

Use of the Physio Flex annuloplasty ring is contraindicated in patients with the following conditions:

1. Congenital malformation with lack of valvular tissue. (e.g., AV canal or hypoplastic commissures)
2. Severe mitral annular calcification involving the leaflets.

5.0 Warnings

FOR SINGLE USE ONLY. This device is designed, intended, and distributed for SINGLE USE ONLY. DO NOT RE-STERILIZE OR REUSE THIS DEVICE. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Such action could lead to illness or an adverse event, as the device may not function as originally intended.

This device predominantly contains Nitinol, an alloy of Nickel and Titanium. The device also contains cobalt, iron, carbon, niobium, copper, and chromium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials. Safety of the Physio Flex annuloplasty ring has not been tested in patients with Nickel allergy.

This device was manufactured without latex, but may have been produced in a latex-containing environment.

Patients who are considered to have a high risk for intracardiac infection must be considered for prophylactic antibiotic therapy.

If used with evolving bacterial endocarditis, endocarditis may reoccur after implant.

Heart block, damage to circumflex arteries and coronary sinus are potential risks.

The choice of too small a ring increases the risk of post-repair systolic anterior motion (S.A.M.).

Non-metal fragments of holders, handles, and sizers are not radiopaque and cannot be detected by means of an external imaging device.

Do not attempt to deform or alter the ring to conform to a specific annular anatomy, as it could damage the ring. If the ring is not suitably sized for the annulus, select a larger or smaller ring.

Do not cut any threads on the ring. Cutting these threads can create loose threads with the potential for thromboembolism or hemolysis.

Remove the holder from the ring after the ring is implanted. Implantation of the holder with the ring can cause patient injury or death. In the event that a holder needs to be located within the surgical site, a radiopaque pin within the holder can be detected under x-ray.

6.0 Precautions

Do not use the ring after the expiration date on the label.

Inspect the packaging, ensuring that it has not been opened or damaged. Do not use rings that have been removed from the double trays and dropped, soiled, or possibly damaged.

Gentle handling is required for all implantable rings. To ensure the sterility and integrity of the ring, the ring should be stored in the product box until implantation is imminent.

Examine sizers and handles for signs of wear, such as dullness, cracking or crazing. If you observe any deterioration, replace the sizers and/or handles immediately.

Sizing the annulus properly is essential. Use only the appropriate sizers, model 1252, provided by Edwards Lifesciences to size the ring and the annulus. Do not use the ring holder as a sizer.

A serial number tag is attached to the ring by a suture. Do not detach this tag until implant is certain and sizing is completed. During removal of the tag, avoid cutting or tearing the cloth.

Suture needles with sharp cutting edges or forceps with teeth must not be used during insertion to avoid damage to the fabric covering the ring.

Sutures should be placed through the ring as demonstrated in **Figure 9**. Do not place sutures in the atrial tissue, as impairment of cardiac conduction may occur. Avoid suture placement that may injure or compromise the circumflex arteries.

7.0 Complications

Serious complications, sometimes leading to death, have been associated with the use of prosthetic rings. In addition, complications due to individual patient reaction to an implanted ring or to physical or chemical changes in the components may necessitate reoperation and replacement of the prosthetic ring, sometimes within weeks or months.

Careful and continuous medical follow-up (per the surgeon's standard of care routine) is required so that prosthesis-related complications can be diagnosed and properly managed to minimize risk to the patient.

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

Following is a list of complications associated with mitral valve repair and prosthetic ring annuloplasty compiled from literature and from reports received through the Edwards complaint handling system.

Procedural and Product Complications:

- residual or recurrent mitral regurgitation;
- stenosis;
- thrombosis;
- thromboembolism;
- hemolysis;
- heart block;
- low cardiac output, right heart failure;
- recurrence of mitral regurgitation due to progression of natural degenerative disease, endocarditis, or inadequate/incomplete repair of the valvular and subvalvular structures;
- injury to coronary sinus;
- suture injury to the circumflex artery;
- complications related to prolonged bypass, aortic cross clamping and inadequate myocardial protection;
- tearing of the cloth covering with the use of cutting needles;
- bleeding related to the use of anticoagulation therapy;
- local and/or systemic infection;
- partial dislodgement of the ring from its site of attachment (ring dehiscence);
- malfunction of the ring due to distortion at implant or physical or chemical deterioration of ring components;
- fracture of the ring components;
- fraying of the suture material;
- systolic anterior motion (S.A.M.) and left ventricular outflow tract obstruction (L.V.O.T.O.) whenever a large posterior or anterior leaflet is present;
- endocarditis;
- left atrial ventricular disruption or rupture;
- metal allergic reactions;
- fibrous tissue overgrowth or pannus.

For a patient/user/third party in the European Economic Area; if, during the using of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and your national competent authority, which can be found at https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

8.0 Storage

To minimize contamination and to provide maximum protection, store the annuloplasty ring (in dual sterile barrier package) and Implantation Data Card contained inside the outer cardboard box in a clean, dry area until needed.

9.0 Accessories

Sizers: Mitral Sizer model 1252,
Sizes: 24 – 40 mm

Tray: Mitral model TRAY1252

Holder Handles: Model 1150 (2 inches) and Model 1151 (4 inches)

9.1 How Supplied

Accessories are packaged separately, provided non-sterile and must be cleaned and sterilized before each use. Do not sterilize accessories in their original packaging.

Replace accessories on a routine basis. Contact your Edwards Lifesciences sales representative to obtain appropriate replacements.

9.2 Warnings

Non-metal fragments of the sizers and handles cannot be located by means of an external imaging device.

9.3 Precautions

Examine sizers and handles for signs of wear, such as dullness, cracking or crazing. Replace sizer / handle if any deterioration is observed.

Do not use other manufacturers' ring sizers, or sizers other than Edwards Lifesciences Physio II mitral sizer model 1252, to size the Physio Flex annuloplasty ring, model 5300. Inaccurate sizing may cause damage to the annuloplasty ring or leaflet tissue, injure the heart, or result in mitral regurgitation, or patient mismatch.

9.4 Accessories Cleaning and Sterilization Instructions

For model 1252 accessories, see the annuloplasty Ring Care and Sterilization Instructions provided with the 1252 accessories.

10.0 Physician Training

The techniques for implanting this ring are similar to those used for the placement of any annuloplasty ring. No special training is required to implant the Physio Flex annuloplasty ring, model 5300. It is the surgeon's decision when and if to repair a mitral valve in the presence of degenerative or functional mitral regurgitation.

11.0 Measurement and Selection of the Appropriate Ring

Step	Procedure
1	Use model 1252 sizers to measure the mitral valve for annuloplasty ring size. Ring selection is based on measurements of the inter-commissural distance and the height and/or surface area of the anterior leaflet using the Edwards model 1252 sizers. **Figure 10** shows a measurement of the anterior leaflet height and surface area after the anterior leaflet has been unfurled. The size that corresponds to the inter-commissural distance (between the two notches on the sizer) and the height of the anterior leaflet is the one that should be selected. The free edge of the anterior leaflet must not extend more than 1 mm beyond the inferior edge of the sizer. In patients with functional mitral regurgitation, a downsizing approach may be considered. If the surgeon is deciding between two sizes in patients with degenerative valve disease, the selection of the greater size is recommended in most instances.
2	Remove the serial number tag once the ring has been selected.

12.0 Use of Handle and Holder

The holder comes pre-attached to the ring. The Physio Flex annuloplasty ring is inserted using the holder attached to the handle (model 1150 or 1151, which is packaged separately).

Step	Procedure
1	Attach the handle to the holder in a one-step motion by snapping the handle into the engaging component on the holder (**Figure 11**).
2	To bend the handle, grip the ends and gently apply force to bend the stainless steel shaft (**Figure 12**).
3	Bend holder wire, if necessary to facilitate access, without holding the ring. See **Figure 13**.

13.0 Ring Implantation

Step	Procedure
1	Place each suture through the annulus 1 to 2 mm outside the junction between the leaflet and the atrium (**Figure 14**). At least one suture is required above the posterior commissure (as shown by the dashed circle). This additional suture corresponds to the segment of the ring past the posterior commissure marker.
2	Pass the sutures through the green marks on the outflow side of the sewing cuff (**Figure 15**) of the selected ring. If resistance is felt when the suture needle is passed through the ring, pull the suture needle out of the ring and begin again by placing the suture through the sewing cuff as demonstrated in **Figure 15**.
3	Use the bendable holder to parachute and position the ring onto the annulus.

14.0 Removal of the Ring Holder

The Physio Flex annuloplasty ring is attached to a single-cut release holder.

Step	Procedure
1	A single suture well (**Figure 16**) is located on the posterior section of the holder. Cut the retaining suture thread in the raised area with a scalpel (**Figure 16**). This enables removal of the holder from the ring.
2	Gently detach the holder from the ring using the holder handle. The retaining suture is permanently connected to the holder and upon withdrawal of the holder, the retaining suture will be removed. Do not leave the holder attached to the ring after the ring is implanted.
3	After the holder is removed from the ring, the handle can be removed from the holder by gripping the holder at the connection point and pulling the handle off. See **Figure 17.** After the holder is detached from the ring, the holder is to be discarded. **Note: The holder is for single-use only.** The handle is reusable. For more information, refer to Sterilization Instructions provided with the 1252 accessories.
4	Tie the suture knots to secure the ring onto the annulus and cut the sutures.
5	**Figure 18** illustrates a properly implanted Physio Flex annuloplasty ring.

15.0 MRI Safety Information

MR Conditional

Non-clinical testing demonstrated that the Physio Flex annuloplasty ring, model 5300, is MR conditional. A patient with this ring can be safely scanned immediately after placement of this implant, under the following conditions:

- Static magnetic field of 3.0 tesla or less
- Maximum spatial gradient field of 3000 gauss/cm
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg per 15 minutes of scanning (i.e. per pulse sequence)

In non-clinical testing, the ring produced a temperature rise of less than or equal to 2 °C at a maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR scanning in 1.5 and 3.0 tesla MR systems.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the ring. Optimization of MR imaging parameters is recommended.

16.0 Case History

16.1 Implant Patient Registry

When using an Edwards annuloplasty ring, carefully complete the Implantation Data Card that is packaged with each ring. Return the pre-addressed portion of the card to the Implant Patient Registry, and keep the remaining portions for hospital and surgeon records. Upon receipt of the Implantation Data Card, the Implant Patient Registry will produce a wallet-sized identification card for the patient. The card allows patients to inform healthcare providers what type of implant they have when they seek care. When a ring is discarded or a previous Edwards ring is replaced, use the Implantation Data Card to report this information to Edwards Registry.

A Patient Identification Card is provided to each patient implanted with the Physio Flex annuloplasty ring.

16.2 Recovered Clinical Implants and Device Disposal

Edwards Lifesciences is interested in obtaining recovered clinical specimens of the Physio Flex annuloplasty ring, model 5300, for analysis. Contact the local representative for return of recovered rings.

- If the unopened package with sterile barrier is intact i.e. the inner Tyvek tray has not been opened, return the ring in its original packaging
- If the inner Tyvek tray is opened but ring is not implanted: Contact the local representative for return of recovered ring
- Place explanted rings in a suitable histological fixative such as 10% formalin or 2% glutaraldehyde. Refrigeration is not necessary
- Explanted ring: Contact the local representative for return of recovered ring

Used devices may be handled and disposed of in the same manner as hospital waste and bio-hazardous materials in accordance with local regulations, as there are no special risks related to the disposal of these devices.

Figures

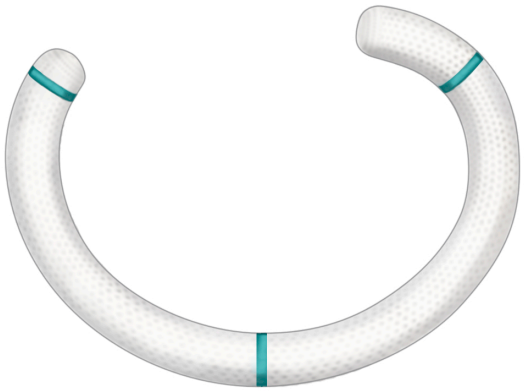


Figure 1: Atrial view

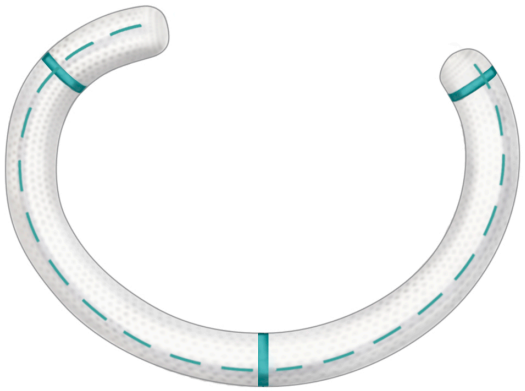


Figure 2: Annular view

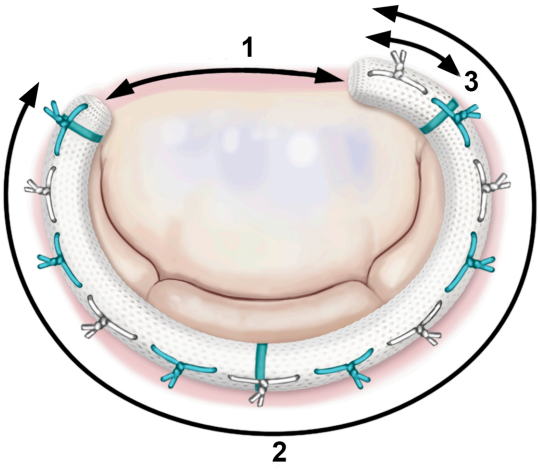


Figure 3

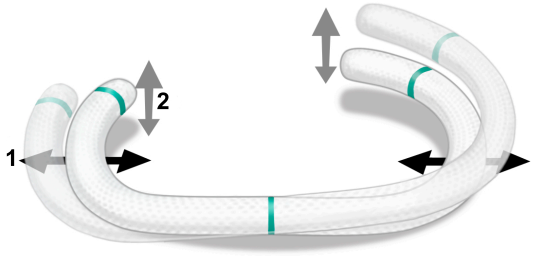
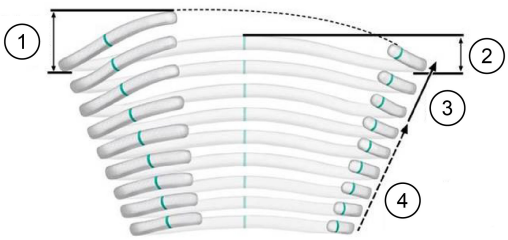
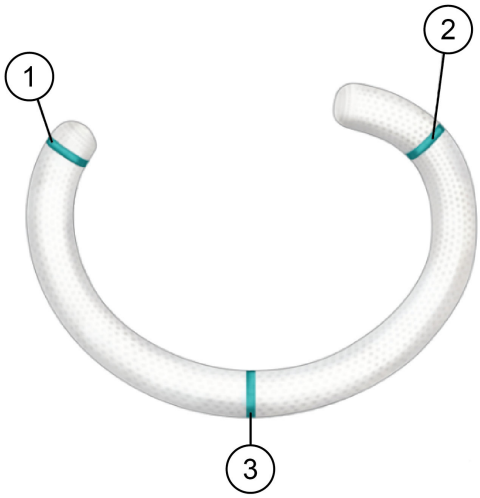


Figure 4



1. Anterior saddle height
2. Posterior saddle height
3. Constant saddle Size 36 mm-40 mm
4. Progressive saddle increase Size 24 mm-36 mm

Figure 5



1. Anterolateral commissure marker
2. Posteromedial commissure marker
3. Mid-posterior marker

Figure 6: Commissure Placement

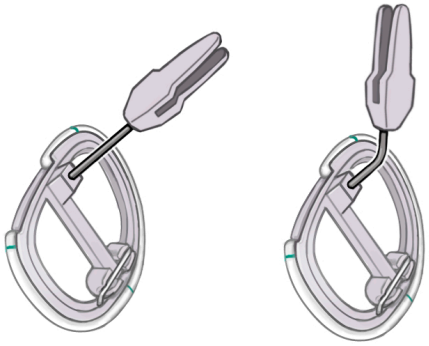
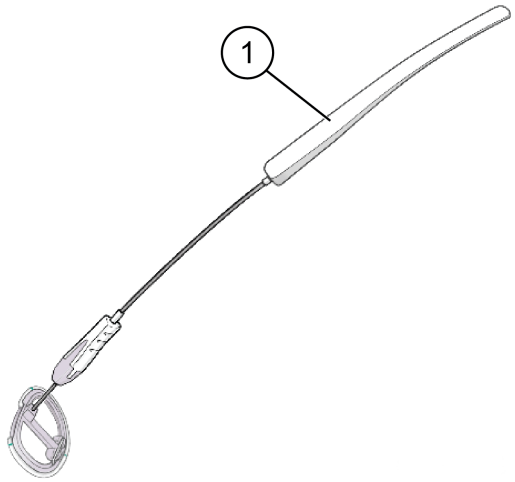
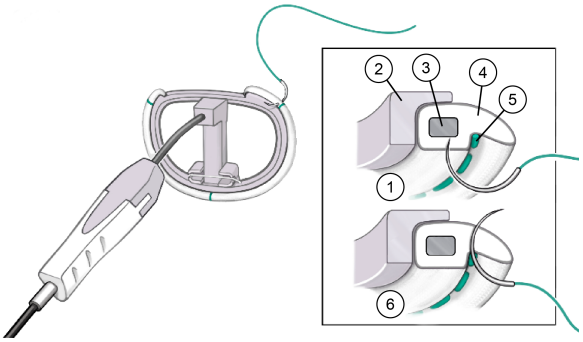


Figure 7



1. Handle Model 1150 or 1151

Figure 8



1. Incorrect
2. Holder
3. Core
4. Sewing cuff
5. Circumferential suture
6. Correct

Figure 9

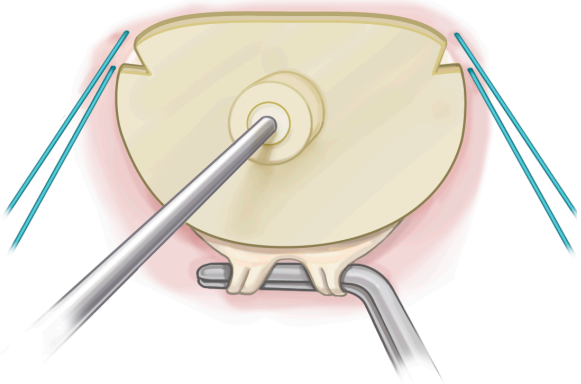


Figure 10

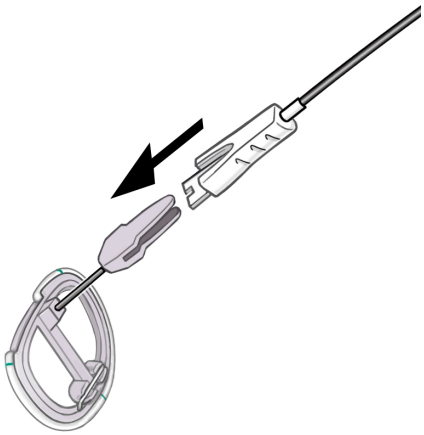


Figure 11

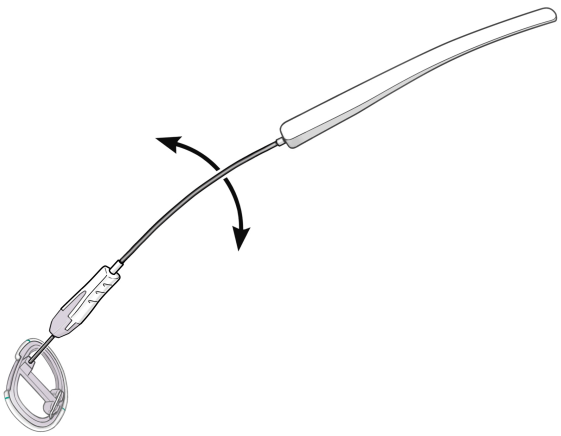


Figure 12

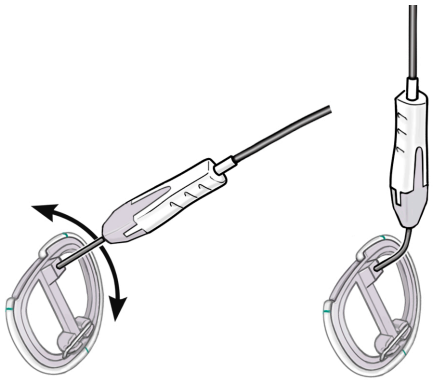


Figure 13

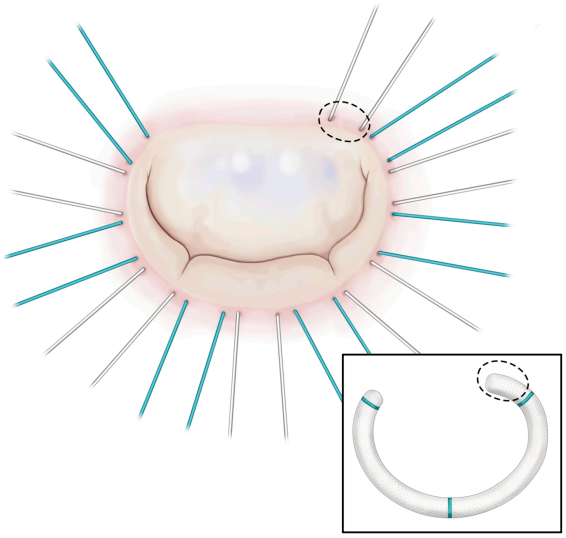
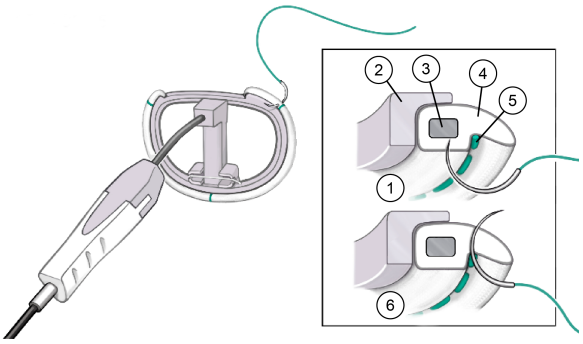


Figure 14



1. Incorrect
2. Holder
3. Core
4. Sewing cuff
5. Circumferential suture
6. Correct

Figure 15

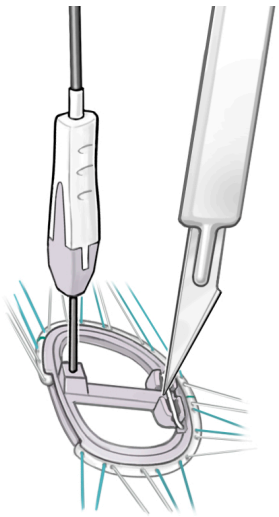


Figure 16

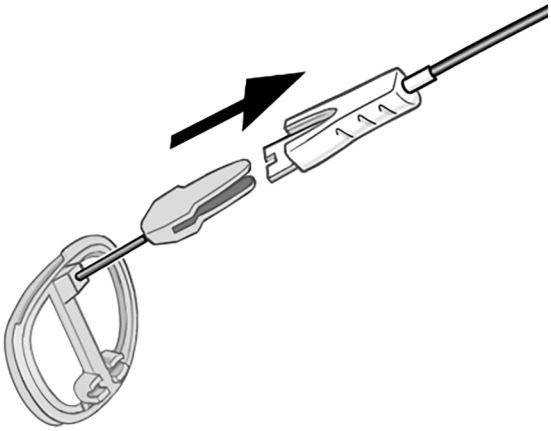


Figure 17

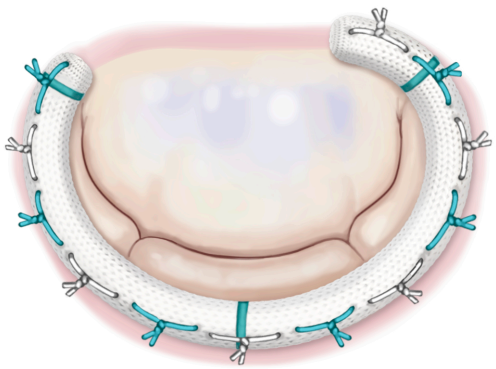
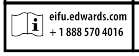


Figure 18

Symbol Legend

	ISO Reg. No.[1]	English
	3082	Manufacturer
	N/A	Authorized representative in the European Community
	2497	Date of manufacture
	2607	Use-by date
	2493	Catalogue Number
	2498	Serial Number
	2608	Do not resterilize
	2503	Sterilized using steam or dry heat
	2606	Do not use if package is damaged
	1641	Consult instructions for use on the website

	ISO Reg. No.[1]	English
	N/A	Store in a cool, dry place
	0434A	Caution
	1051	Do not re-use
	2724	Non-pyrogenic
	N/A	MR Conditional
Rx only	N/A	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
CE	N/A	Conformité Européenne (CE Mark)
#	N/A	Quantity
SZ	N/A	Size

[1] ISO 7000 *Graphical symbols for use on medical equipment - Registered symbols*

EC REP

Edwards Lifesciences Services GmbH
Edisonstrasse 6
85716 Unterschleissheim
Germany

CE 0123

04/21
10046877001 A / DOC-0173848 A

Manufacturer
Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA
Made in USA

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU