# Carpentier-Edwards Physio II Ring Model 5200

## For Single Use Only

## 1.0 Product Description

The Carpentier-Edwards Physio II ring, model 5200, is an annuloplasty ring constructed of cobalt-chromium bands separated by polyester film strips and has a sewing cuff that consists of a layer of silicone rubber covered with a woven polyester cloth.

Transverse colored threads indicate the anterior and posterior commissures and the center of the posterior portion of the ring (Figure 2).

The ring exhibits characteristics of selective flexibility with rigidity in the anterior portion for remodeling and flexibility in the posterior portion for preservation of cardiac motion. The annular plane of the ring is saddle-shaped for apposition to the aortic root.

The design of the ring is intended to provide support after annuloplasty surgery. The ring maintains a fixed maximum annular dimension to prevent excessive distension of the natural valve annulus while adapting to the dynamic motion of the mitral annulus throughout the cardiac cycle.

The ring is provided on a holder to facilitate implantation. The handle, models 1150 and 1151, may be used with the holder to further facilitate implantation. The handles are packaged separately (Figure 3).

## 2.0 Safety in the Magnetic Resonance (MR) Environment


**MR Conditional**

Non-clinical testing has demonstrated that the Carpentier-Edwards Physio II ring, model 5200, is MR conditional. A patient with this ring can be scanned safely, immediately after placement of this implant under the following conditions:

- Static magnetic field of 3 Tesla or less
- Maximum spatial gradient field of 720 gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg for 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 1.8 °C at a maximum whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of MR scanning in a 3 Tesla MR system (Excite, General Electric Healthcare, Software G3.0-052B).

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

## 3.0 Mitral Valve Reconstruction Techniques

The goal of mitral valve reconstruction is to preserve or restore normal leaflet motion, to create a large surface of coaptation, and to stabilize the entire annulus with a remodeling annuloplasty (Ref. 2).

For specific techniques on mitral valve reconstruction, see the clinical literature referenced in this document (Refs. 1-14).

Only surgeons who have received appropriate training in valve repair, should use this device.

Only surgeons who have adequate training to determine whether incompetent heart valves are capable of being repaired, or if replacement is indicated, should use this device.

## 4.0 Indications

The Carpentier-Edwards Physio II ring, model 5200, is intended for the correction of mitral valve insufficiency, or mixed mitral insufficiency and stenosis, where treatment does not necessitate a replacement of the natural mitral valve.

The Carpentier-Edwards Physio II ring is intended to meet the challenges of modern valvuloplasty by maintaining the physiologic annular shape and motion. The annuloplasty ring is designed to follow the functional changes which occur during the cardiac cycle, thereby maintaining coaptation and valve integrity in systole while permitting good hemodynamic in diastole.

The decision to undertake annuloplasty can be made only after visual analysis of the lesion present. The most favorable conditions for annuloplasty using a prosthetic ring are a combination of the distended natural valve ring associated with supple valve cusps and normal chordae tendineae.

The remodeling annuloplasty technique with a Carpentier-Edwards Physio II ring, model 5200, may be used in all acquired or congenital mitral insufficiencies with dilatation and deformation of the fibrous mitral annulus, with the exception of severe congenital malformations (e.g., AV canal or hypoplastic commissures) or severe degenerative valvular diseases where there is considerable excess tissue.

For Type I mitral insufficiencies with no subvalvular lesions and normal valvular movements, this ring technique used alone is sufficient. However, the ring technique must be associated with mitral valvuloplasty repair in Type II insufficiencies with a prolapsed valve due to elongation or rupture of the chordae tendineae or papillary muscle and in Type III insufficiencies with limitation of valvular movements due to fusion of the commissures or chordae, or chordal hypertrophy.

## 5.0 Contraindications

1. Severe organic lesions with retracted chordae.
2. Congenital malformations with lack of valvular tissue.
3. Large valvular calcifications.
4. Evolving bacterial endocarditis.

## 6.0 Warnings

### 6.1 For Single Patient Use Only

This device is designed, intended, and distributed for single use only. Do not reuse this device. There are no data to support the sterility, nonpyrogenicity and functionality of the device after reuse and reprocessing.

The decision to use an annuloplasty ring must ultimately be made by the physician on an individual basis after carefully evaluating the short- and long-term risks and benefits to the patient as compared to alternative methods of treatment.

As with any implanted device, there is potential for an immunological response.

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

Only surgeons who are adequately trained to determine whether a stenotic valve is capable of being repaired via annuloplasty, or if valve replacement is required, should use this device.

Only surgeons who have adequate training to determine whether incompetent heart valves are capable of being repaired, or if replacement is indicated, should use this device.

To avoid the risk of thrombosis or thromboembolism, any loose sutures or threads must be removed.

Surgeons who use annuloplasty rings should be current on all anticoagulation regimes. Bleeding due to anticoagulants is a potential risk.

Hemolysis due to regurgitation is a potential risk. Hemolysis may occur even with mild regurgitation.

Heart block and damage to coronary arteries are potential risks.

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

Do not attempt to deform or otherwise alter the configuration of the ring to conform to a specific annular anatomy, as this could damage the ring. If the ring is not suitably sized for the annulus, a larger or smaller ring should be chosen. Refer to section 10.1 "Measurement and Selection of the Appropriate Ring" for more information.

## 7.0 Precautions

Before clinical application, surgeons should become familiar with the surgical technique and its variations by appropriate training. In addition to the information provided herein, it is important that the references listed be reviewed.

A serial number tag is attached to the ring by a suture. This tag should not be detached from the ring until implant is imminent. Care should be exercised to avoid cutting or tearing of the cloth during removal of the tag.

To avoid damage to the fabric covering the ring, suture needles with cutting edges and metal forceps must not be used during insertion.

To avoid the risk of thrombosis or thromboembolism, any loose sutures or threads must be removed from the ring.

Sutures should be placed through the Carpentier-Edwards Physio II ring as demonstrated in Figure 9. Do not place sutures in the atrial tissue, as impairment of cardiac conduction may occur. Do not place sutures in the circumflex coronary artery or in the right coronary artery. See "Suture Placement" for more information.

To ensure the sterility and integrity of the ring, the ring should be stored in the outer cardboard box until use is imminent. Gentle handling is required for all implantable devices. Inspect the packaging, ensuring that it has not been opened or damaged. Rings that have been removed from the double trays and dropped, soiled, or are suspected of being damaged should not be used.

Sizing the annulus properly is essential. Use only the appropriate sizers, model 1152 or 1252, provided by Edwards Lifesciences to size the annulus. Do not attempt to use the ring holder as a sizer. Refer to section 10.1 "Measurement and Selection of the Appropriate Ring" for more information.

The ring must be removed from the holder prior to implantation. Implantation of the holder 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.

## 8.0 Complications

A full explanation of the benefits and risks must be given to each prospective patient before surgery.

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 device, or to physical or chemical changes in the components, may necessitate reoperation and replacement (sometimes within weeks or months) of the prosthetic device.

Careful and continuous medical follow-up is required so that prosthesis-related complications can be diagnosed and properly managed to minimize danger to the patient.

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

Complications associated with prosthetic ring valvuloplasty compiled from the literature and from reports received through the complaint handling system in accordance with the United States (Federal) regulations establishing Good Manufacturing Practices, 21 CFR section 820.198, include:

Procedural complications: residual or recurrent mitral regurgitation; stenosis; thrombosis; thromboembolism; hemolysis; heart block; low cardiac output, right heart failure; failure or degeneration of the patient's natural valvular apparatus due to progression of the disease, endocarditis, or inadequate/incomplete repair of the valvular and subvalvular structures; suture injury to the coronary arteries; complications related to prolonged bypass, aortic cross clamping and inadequate myocardial protection; tearing of the cloth covering with the use of cutting needles; suture breakage upon incorrect placement of sutures into the ring; bleeding related to the use of anticoagulation therapy; local and/or systemic infection.

Product complications: residual or recurrent mitral regurgitation; stenosis; thrombosis; thromboembolism; hemolysis; 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 leaflet is present; endocarditis.

## 9.0 Postoperative Considerations

To allow for healing and incorporation of the annuloplasty ring by host tissue, regardless of cardiac rhythm, postoperative anticoagulation therapy should be considered following surgery (Ref. 14).

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

## 10.0 Instructions for Use

### 10.1 Measurement and Selection of the Appropriate Ring

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 1152 or 1252 mitral sizers. Figure 4 demonstrates a measurement of the inter-commissural distance of the mitral valve with the sizer. Figure 5 shows a measurement of the anterior leaflet height and surface area after the anterior leaflet has been unfurled (Refs. 8-9).

Various sizers should be tried to select the optimal size of Carpentier-Edwards Physio II ring. The size that corresponds to the intercommissural 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 (Ref. 1).

In patients with functional mitral regurgitation, a downsizing approach may be considered. Recent cardiology guidelines suggest this may offer a benefit to patients with this type of valvular dysfunction (Refs. 10-11). Surgical centers have published results using a downsized remodeling annuloplasty ring in patients with functional mitral regurgitation (Refs. 12-13).

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. In Barlow's disease, the typical size of the ring is between 36 mm and 40 mm. The choice of too small a ring increases the risk of post-repair systolic anterior motion (S.A.M.) (Ref. 2).

### 10.2 Use of Handle and Holder

Insertion of the Carpentier-Edwards Physio II ring may be accomplished using the holder and the optional handle (model 1150 or 1151, which are packaged separately). The holder on the ring is designed with windows which allows visualization of the mitral valve during parachuting. In addition, the holder is angled toward the anterior portion of the ring to further assist with visualization.

Attach the optional handle to the holder in a one-step motion by snapping the handle into the engaging component on the holder. See Figure 6. To bend the handle, grip the ends and gently apply force to bend the stainless steel shaft. Bent angles should be limited to 45° in an up and down direction for a maximum of 30 times for the life of the device. 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 7. Discard the holder. The handle is reusable. For more information refer to section 12.4 "Sterilization Instructions".

Handles should be examined for signs of wear, such as dullness, cracking, or crazing and should be replaced immediately if any deterioration is observed.

Accessories should be replaced on a routine basis. Contact your Edwards Lifesciences sales representative to obtain appropriate replacements.

**The annuloplasty ring must be removed from the holder after the ring is implanted. Implantation of the holder 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.**

### 10.3 Insertion of the Mitral Ring

The annuloplasty is performed by first placing horizontal mattress sutures circumferentially through the annulus 1 to 2 mm outside the junction between the leaflet and the atrium. Suture placement is facilitated by firmly grasping the body of the leaflet tissue with tissue forceps (Refs. 8-9).

### 10.4 Suture Placement on the Ring

The Carpentier-Edwards Physio II ring is designed with a sewing cuff for ease of suture placement. This cuff design is depicted in Figure 9.

In addition, the sewing cuff is delineated by a green circular outflow mark to further assist with suture placement.

Annular sutures are spaced equally in the area between the two commissures and the corresponding segment of

the ring. In the remaining portion of the annulus, the spacing is set to conform the annulus to the shape and size of the ring (Ref. 8). Approximately 12-16 sutures are needed. Refer to Figure 8.

To ensure proper placement of the sutures on the ring and prevent contact with the cobalt-chromium bands of the ring, which may potentially fray the suture material, the following technique is to be used:

| Step | Procedure |
|---|---|
| **1** | The interrupted horizontal sutures should be placed in the Carpentier-Edwards Physio II ring as demonstrated in Figure 9. |
| **2** | If resistance is met 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 9. |

**10.5 Removal of the Ring Holder**

The Carpentier-Edwards Physio II ring is designed with a single-cut holder release. A single suture well is located in the middle of the posterior section of the ring. Caution should be taken not to cut any threads along the anterior portion of the ring. Cutting these threads can create loose threads with the potential for thromboembolism. The raised area is cut with a scalpel (Figure 10). This facilitates rapid removal of the ring from the holder. The retaining suture is permanently connected to the holder and upon withdrawal of the holder, all retaining sutures are removed. After the holder is detached from the ring, the holder is to be discarded.

Figure 11 illustrates the appearance of the properly implanted annuloplasty ring.

**10.6 Evaluating Repair Competency**

The quality of the repair should first be evaluated after tying the sutures to the ring. Saline is injected into the ventricle through the mitral valve to observe the line of coaptation. There should be a symmetrical line that is parallel to the posterior portion of the ring with a ¾ to ¼ ratio of anterior leaflet to posterior leaflet within the orifice. If the line of coaptation is asymmetrical, this suggests a residual leaflet prolapse or restricted leaflet motion; this should be corrected. Also, if the posterior leaflet occupies more than half or more of the ring orifice area, it should be shortened to mitigate the risk of systolic anterior motion (S.A.M.) (Ref. 8).

The quality of the repair is assessed by transesophageal echocardiography (TEE) after completion of cardiopulmonary bypass. This examination should rule out the presence of postvalvuloplasty SAM in patients with excess leaflet tissue (Ref. 2).

If careful application of the ring method of valvuloplasty fails to produce adequate repair of valvular insufficiency as determined by visual inspection or intraoperative testing, the surgeon must be prepared to remove the ring and replace the diseased valve with a prosthetic valve during the same procedure.

## 11.0 Annuloplasty Ring

**11.1 Specifications**

Carpentier-Edwards Physio II Ring Model 5200

Sizes: 24 mm, 26 mm, 28 mm, 30 mm, 32 mm, 34 mm, 36 mm, 38 mm, 40 mm

**11.2 How Supplied**

The Carpentier-Edwards Physio II ring with attached holder is provided sterile and nonpyrogenic in a box containing double plastic trays 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.

**11.3 Storage**

To minimize contamination and to provide maximum protection, the annuloplasty ring (in double trays), the Instructions for Use, and the Implantation Data Card should be stored inside the outer cardboard box in a clean, dry area until needed. The annuloplasty device cannot be used after the expiration date on the label.

## 12.0 Accessories

**12.1 Specifications**

Optional Handles model 1150 and model 1151

**Sizers**

Mitral Sizers model 1152 or 1252

Sizes: 24 - 40

Sizer Handle model 1111, 1117 and 1126 (single use)

Sizer/Handle Tray - Mitral model TRAY1152 or TRAY1252

**12.2 How Supplied**

**The accessories are packaged separately, provided nonsterile and must be cleaned and sterilized before each use. They cannot be sterilized in the original packaging.**

**12.3 Cleaning Instructions**

All sizer, handle, and tray models are supplied nonsterile and must be cleaned and sterilized before using. All handles, sizers, trays, and lids must be cleaned separately and sterilized prior to each use.

Accessories should be replaced on a routine basis. Contact your Edwards Lifesciences sales representative to obtain appropriate replacements.

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

**WARNING: Fragments of the sizers / handles cannot be located by means of an external imaging device.**

For the TRAY1152, clean the tray, mat, and lid separately.

**Instructions for Automated Cleaning:**

**Pre-rinse (as needed):** Klenzyme enzymatic anionic detergent or equivalent.

**Cleaning:** Clean instruments within tray and with lid detached prior to initial use and after each use with a

nonionic detergent cleaning solution (example Instru-Klenz) in a mechanical washer (example STERIS AMSCO Reliance 444), minimum 2 minute wash phase.

**Instructions for Manual Cleaning:**

**Pre-rinse (as needed):** Per hospital procedure.

**Cleaning:** Place the sizer, handle, tray base, tray lid, or tray mat (for TRAY1152 only) instruments in a cleaning solution bath, such as Cidezyme, an enzymatic detergent, for the time and temperature specified by its manufacturer. Ensure that the instruments are covered and do not touch each other. Clean the accessories thoroughly with a soft plastic brush for 5 minutes; remove any superficial impurities with the soft brush. Never use metal brushes or steel wool on the instruments. Always use fresh cleaning solution between cleanings. Afterwards, rinse each accessory thoroughly 5 times for 1 minute with sterile, deionized water.

**Disinfection:** Place the cleaned and inspected instruments in disinfection solution (example Cidex OPA) for the time and temperature specified by the manufacturer. Ensure that the instruments are covered and do not touch each other. Afterwards, rinse each instrument thoroughly 5 times for 1 minute with sterile, deionized water.

Ultrasonic cleaning should not be used for cleaning the 1150 and 1151 handles.

### 12.4 Sterilization Instructions

Sizers and sizer handles (models 1152, 1111, and 1117) must be disassembled before sterilization.

**CAUTION: Do not sterilize any of the accessories in their shipping containers. Sizers and handles must be removed from their plastic pouches prior to sterilization. Each institution should use procedures that include biological indicators to determine the effectiveness of the sterilization procedure.**

**CAUTION: Do not stack trays during sterilization.**

The accessories can be sterilized using the following recommended autoclave sterilization methods:

**Gravity Displacement:**
**Wrapped:**
Temperature: 132 °C - 137 °C (270 °F - 279 °F)
Exposure Time: 10-18 minutes

**Unwrapped ("flash"):**
Temperature: 132 °C - 137 °C (270 °F - 279 °F)
Exposure Time: 5-18 minutes

**Prevacuum:**
**Wrapped:**
Temperature: 132 °C - 137 °C (270 °F - 279 °F)
Exposure Time: 5-18 minutes

**Unwrapped ("flash"):**
Temperature: 132 °C - 137 °C (270 °F - 279 °F)
Exposure Time: 5-18 minutes

For model 1252 accessories, see the Annuloplasty Ring Accessories Care and Sterilization Instructions provided with the 1252 accessories for cleaning and sterilization instructions.

The user is responsible for the qualification of any deviations from the recommended method of cleaning or sterilization.

## 13.0 Case History

### 13.1 Implant Patient Registry

When using an Edwards annuloplasty ring, carefully complete the Implantation Data Card that is packaged with each device. Return the preaddressed portion of the card to our Implant Patient Registry. The remaining portions of the card are provided for hospital and surgeon records. Upon receipt, a wallet-sized identification card will be produced for the patient. This 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 device is replaced, the Implantation Data Card should be used to report this information to our Registry.

### 13.2 Recovered Clinical Implants

Edwards Lifesciences LLC, is extremely interested in obtaining recovered clinical specimens of Carpentier-Edwards Physio II rings for analysis. A written report summarizing our findings will be provided upon completion of our evaluation. Please contact your local company representative for return of recovered rings.

The rings should be placed in a suitable histological fixative such as 10% formalin or 2% glutaraldehyde. Refrigeration is not necessary.

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

Prices and model availability are subject to change without notice.

## 14.0 References


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2. Filsoufi F, Carpentier A. Principles of Reconstructive Surgery in Degenerative Mitral Valve Repair. *Semin Thorac Cardiovasc Surg* 2007;19:103-110.
3. Braunberger E, et al. Very Long-Term Results (More Than 20 Years) of Valve Repair with Carpentier's Techniques in Nonrheumatic Mitral Valve Insufficiency. *Circulation* 2001;104[suppl I]:I-8-I-11.
4. Chauvaud S, et al. Long-Term (29 Years) Results of Reconstructive Surgery in Rheumatic Mitral Valve Insufficiency. *Circulation* 2001;104[suppl I]:I-12-I-15.
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7. Accola KD, et al. Midterm Outcomes Using the Physio Ring in Mitral Valve Reconstruction: Experience in 492 Patients. *Ann Thorac Surg* 2005;79:1276-83.
8. Mitral Valve Repair at the Mount Sinai Hospital, www.mitralvalverepair.org.
9. Carpentier A. Cardiac Valve Surgery: The French Correction. *J Thorac Cardiovasc Surg* 1983;86:323-337.

**10.** Bonow et al. ACC/AHA Guidelines for the Management of Patients with Valvular Heart Disease. *J Am Coll Cardiol* 2006;48(3):63-107.

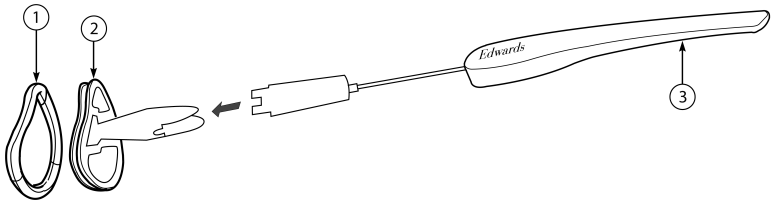
**11.** Vahanian et al. European Society of Cardiology Guidelines on the Management of Valvular Heart Disease. *Eur H Journal* 2007;28:230-268.

**12.** Braun et al. Restrictive Mitral Annuloplasty Cures Ischemic Mitral Regurgitation and Heart Failure. *Ann Thorac Surg* 2008;85:430-7.

**13.** Gazoni LM, et al. A Change in Perspective: Results for Ischemic Mitral Valve Repair Are Similar to Mitral Valve Repair for Degenerative Disease. *Ann Thorac Surg* 2007;84:750-758.

**14.** Meurin P, et al. Thromboembolic Events Early after Mitral Valve Repair. *Int J Cardiol* 2008;126:45-52.

## Figures




1. Ring
2. Holder
3. Handle

**Figure 1**

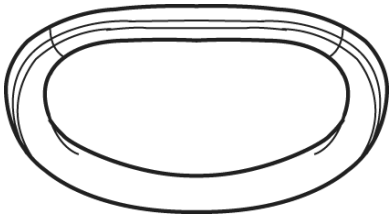


**Figure 2**

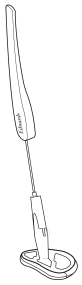


**Figure 3**

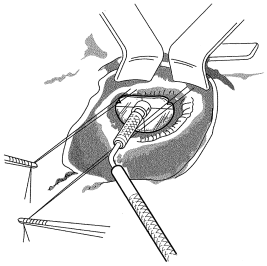


**Figure 4**

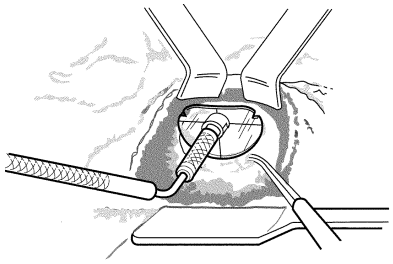


**Figure 5**

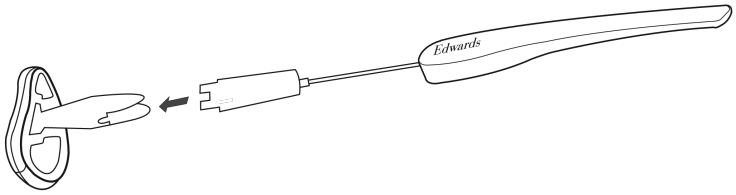



**Figure 6**

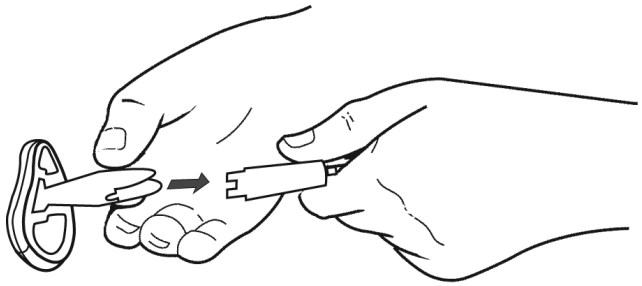


**Figure 7**

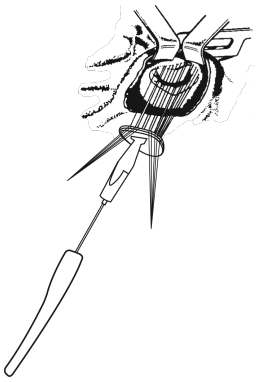
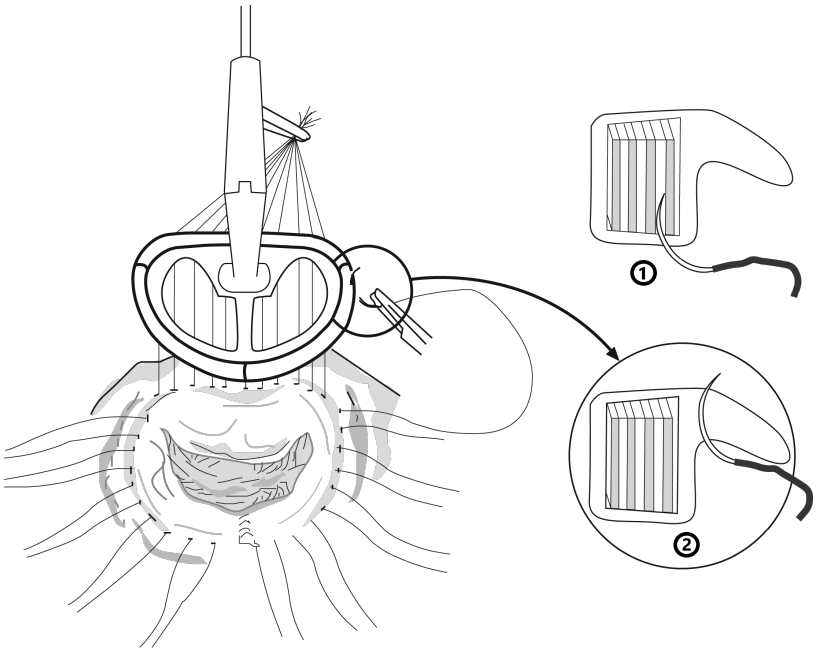


**Figure 8**




1. INCORRECT
2. CORRECT

**Figure 9**

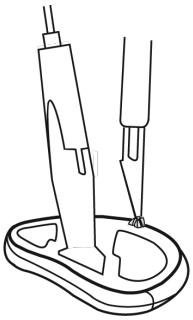


**Figure 10**

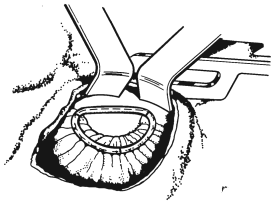


**Figure 11**

## Symbol Legend

| | ISO Reg. No.[1] | English |
|---|---|---|
|  | 2493 | Catalogue Number |
|  | N/A | Caution |
|  | 1641 | Consult instructions for use |
|  | 1641 | Consult instructions for use on the website |
|  | 1051 | Do not re-use |
|  | 2608 | Do not resterilize |
|  | N/A | Quantity |
|  | 2607 | Use-by date |
|  | 2498 | Serial Number |

| | ISO Reg. No.[1] | English |
|---|---|---|
|  | 3082 | Manufacturer |
|  | 2497 | Date of manufacture |
|  | N/A | MR Conditional |
|  | 2724 | Non-pyrogenic |
|  | 2606 | Do not use if package is damaged |
|  | 2503 | Sterilized using steam or dry heat |
|  | N/A | Store in a cool, dry place |
| Rx only | N/A | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. |

**Note:** The labeling of this product may not contain every symbol depicted in the legend.

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