UNIRING®, Universal Annuloplasty System
Overview and Surgical Guidelines
UNIRING®, Universal Annuloplasty System

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Product description

1. Ring

The Northrup Universal Annuloplasty System UNIRING® is a unique ring of only one size, combining segmental rigidity with overall flexibility. It is made with 15 implantable rigid oval suture-platforms (5.5 mm length x 3.0 mm width x 1.2 mm thickness) in sequence, each with 2 suture-holes 3.0 mm apart in sequence (Figure 1), plus 2 suture-platforms for fixation on the holder. The suture-platforms are injection-molded from polyester including 20 % of barium sulfate for radio-opacity. Polyester thread is braided over the platforms leaving 2.0 mm flexible joints between platforms. The polyester joints are heat-sealed to prevent fraying of the polyester thread when unused suture-platforms are cut away.

Because the rigidity of UNIRING® is segmental and not continuous, with intervening segmental flexibility at the joints, the annulus is able to maintain its normal three-dimensional shape. The rigidity of the suture-platform also guarantees either a measured plication (Figure 2) or stabilization (Figure 3) of annular tissue beneath the suture-platform with a mattress suture.

Moreover, each suture-platform performs a buttress function as a rigid pledget, guaranteeing knot security of each individual mattress suture, because the knot can always be tied tightly and predictably without slippage due to crimping of the ring.

The rigid suture-platforms categorically prevent any crimping or foreshortening of the longitudinal dimension of the ring, since each suture incorporates a single separate non-deformable rigid element, guaranteeing precision of the final implant dimension (Figures 4, 5). Since the polyester braiding has almost no elasticity, UNIRING® also guarantees a fixed maximum circumference, preventing late annular dilatation in whatever portion of the annulus the ring is attached.
The overall 7.5 mm. interval spacing of the suture-platforms guarantees secure apposition of the ring to the tissue annulus, since nearly 75% of the circumferential length of the annuloplasty ring consists of the sum total of all the suture-platforms, each of which engages the tissue annulus by an individual mattress suture. The implantable length is 112.5 mm, long enough to accommodate valves of any size, even if complete circumferential coverage of the annulus is required.

The heat-sealed joints create overall flexibility and allow the ring to be customized to any size to cover any percentage circumference of the mitral or tricuspid annulus, by simply cutting away the unwanted suture-platforms.

Flexible joints should also reduce overall tension on each of the individual sutures by reducing any shared tension from other sutures, which would be the case with any rigid ring possessing continuous rigidity and forcing the annulus into a prescribed shape.
2. Holder

The holder is manufactured from polycarbonate (USP class VI) and is designed to facilitate ring implantation and customization. The ring is mounted on the holder and held in place with two sutures. Suture-guides indicate where the two needles of a horizontal mattress suture in the tissue annulus engage each suture-platform. Cutting guides straddle the middle of the joints between the suture-platforms to facilitate cutting with a surgical blade. Numbers on the holder opposite the joints indicate which joints should be cut based on the ring size. The numbers indicate the number of suture-platforms required for a given ring size.

Figure 8

After all the annular mattress sutures have been placed through the suture-platforms, one-to-one, the unneeded suture-platforms are simply separated at the appropriate heat-sealed joints with a surgical blade. The residual suture-platforms not being used will remain with the holder. In the case of endoscopic delivery of UNIRING®, the ring can be detached from the holder after sizing and cutting away the unwanted suture-platforms.

Figure 9

3. Handle

The handle is manufactured from polycarbonate (USP class VI) and stainless steel overmoulded. The steel section in the handle allows for presentation of the holder and sizers in the plane of the valvular orifice.
4. Sizers

The nine sizers (sizes 24 mm to 40 mm) are manufactured from polycarbonate (USP class VI). On one side they allow to size the mitral valve, on the other side, the tricuspid valve.

5. Packaging

The outer box package contains a double plastic tray with inside the ring UNIRING® on the holder, nine sizers and two handles, the Instructions For Use, and the implant data card.

Ring Annuloplasty Techniques and Evolving Designs

Modern ring annuloplasty techniques originate from Carpentier’s original concept of “valvular remodeling on a frame” published in French in 1969 and in English in 1971. His idea was to permanently correct the valvular insufficiency by resizing and reshaping the dilated annulus with a preformed rigid (“non-deformable”) ring affixed to the annulus with numerous interrupted horizontal mattress sutures.

In the interest of preserving the flexibility of the mitral annulus, Duran and Ubago introduced a completely circumferential flexible ring in 1976. In 1995, Cosgrove et al introduced a partially circumferential flexible band attached only to the posterior mitral annulus. In the same year, Carpentier et al introduced the “Physio-Ring,” a complete ring with a combination of selective rigidity at the anterior section and selective flexibility at the posterior section.

The short- and long-term results of mitral repair are impressive. It appears to be the only heart valve operation which has the potential to return patients to expected survival at least for 10 years, and possibly longer, if performed before significant left ventricular dysfunction and symptoms. It has a lower operative mortality rate and better long-term survival than replacement and has long-term re-operation rates comparable to those of mechanical valve replacement, and much better than tissue valve replacement. The durability of repair is impressive as evidenced by the very low long-term re-operation rates in Carpentier’s original series.

It is quite possible that an annuloplasty ring with overall flexibility and segmental rigidity, which preserves the normal three-dimensional shape of the annulus, prevents crimping upon implantation, maximizes apposition of the ring to the tissue annulus with each individual suture, minimizes shared tensions between individual
sutures and (in the case of the mitral annulus) fully engages the intertrigonal fibrous skeleton, will qualify as a “next generation” ring.

In 1998, Northrup, et al.\textsuperscript{10} introduced the concept of a \textit{suture-platform}, which forms the basis of the Northrup Universal Annuloplasty System. When the suture-platforms were placed in series and covered with a flexible material, a unique annuloplasty concept with \textit{segmental rigidity} and \textit{overall flexibility} was achieved.

In the case of the suture-platform, foreshortening or crimping of the overlying flexible ring material is impossible because each mattress suture engages an individual rigid suture-platform \textit{within} the mattress suture loop.

The current iteration of this annuloplasty ring employs polyester as the flexible ring material, as described above under Product Description. Preservation of the saddle shape of the mitral annulus has been documented with this ring during a series of clinical implants.\textsuperscript{11}

\section*{Indications}

\textit{UNIRING}\textsuperscript{\textregistered} is indicated as reinforcement for repair of the human cardiac mitral and tricuspid valves damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring. The annuloplasty ring should be used only in cases where visual inspection confirms that the valve is repairable and does not require replacement.

\textit{UNIRING}\textsuperscript{\textregistered}, because of its overall flexibility, is designed to maintain the normal physiologic annular motion and shape. It is considered to be \textit{universal} because it can be used when either \textit{complete} or \textit{partial} coverage of the annulus is desired.

The decision to perform an annuloplasty requires direct visual inspection of the valve by the surgeon. It requires a dilated and flexible annulus (free of calcium) and flexible valve leaflets in sufficient amount to close the mitral orifice. The closure plane of the leaflets must remain consistently below the plane of the orifice during the cardiac cycle with at least 5 mm. of an overlapping surface of coaptation of the leaflets.

In cases with Carpentier Type I (normal) leaflet motion,\textsuperscript{12} \textit{UNIRING}\textsuperscript{\textregistered} may be used alone. For Type II (excessive) leaflet motion (prolapse),\textsuperscript{12} annuloplasty must be combined with additional procedures aimed at restoring normal leaflet coaptation below the plane of the valve orifice. For Type IIIa leaflet motion (diastolic restriction),\textsuperscript{5} annuloplasty must also be combined with additional procedures aimed at increasing the flexibility of the leaflets. For Type IIIb leaflet motion (systolic restriction),\textsuperscript{5} an undersized annuloplasty (by at least 2 sizes) may be used alone, or in combination with specific subvalvular procedures aimed at reverse remodeling of the ventricle. If specific ventricular procedures are used to facilitate reverse remodeling, undersizing of the annuloplasty ring may not be necessary.

Except in patients with ischemic or cardiomyopathic mitral regurgitation, the ring size must relate to the surface area of the anterior mitral leaflet (see \textit{Sizing} in \textit{Instructions for Use}). If it is undersized and/or if the
residual height of the posterior leaflet exceeds 15 mm, systolic anterior motion (SAM) and left ventricular outflow tract obstruction is a risk in patients with degenerative valve disease.

For tricuspid annuloplasty, the ring size must also relate to the surface area of the anterior tricuspid leaflet (see Sizing in Instructions for Use). UNIRING® could also be used to plicate or stabilize an aortic annulus with a valve-sparing procedure, as has been reported with another commercially available flexible annuloplasty device originally intended for mitral annuloplasty. Because of its very low profile, it could be placed inside the aorta just below the plane of the annulus at the nadir of the sinuses or on the outside of the aorta.

Contraindications

1. Severe organic lesions with retracted chordae.
2. Congenital malformations with lack of leaflet tissue.
3. Large leaflet calcifications.
4. Residual annular calcifications rending the annulus inflexible.
5. Active endocarditis.

Warnings

For single patient use only. Do not reuse.

The decision to recommend an annuloplasty ring to a patient, resides with the operating surgeon, based primarily on echocardiographic evidence of valve-repairability and his experience with valve repair. Risks and benefits of valve repair vs. replacement must be carefully explained to the patient in order to ensure proper informed consent. The surgeon must be facile with valve repair techniques, including ring annuloplasty.

Unless contraindicated, low-intensity anticoagulation is recommended for the first 2 months after ring implantation to minimize the risk of thrombo-embolism as the exposed cloth and sutures are incorporated into the tissue annulus.

Prophylactic antibiotics, according to usual guidelines, should be given to patients with implanted annuloplasty rings when undergoing various dental and surgical procedures.

Sizing should be done carefully and precisely. Oversizing could result in inadequate coaptation of the valve leaflets, leading to residual mitral regurgitation. Undersizing, could result in systolic anterior motion (SAM), left ventricular outflow tract obstruction or mitral stenosis.

Removal of unwanted suture-platforms must be done with a surgical blade and must take place in the middle of the heat-sealed joints to avoid exposing the suture-platform. The holder, with the cutting guides, is designed to facilitate this procedure.

Removal of the ring from the holder by cutting the two sutures at the top of the holder must not take place. For endoscopic introduction of UNIRING® ring, it is recommended that sizing and cutting of the ring take place before it is introduced into the endoscope, not after. The holder is designed to retain the unwanted, detached suture-platforms as a unit, in order to avoid loose ring remnants entering the surgical field.
Precautions

Surgeons should not attempt an annuloplasty without appropriate familiarity, training and experience with annuloplasty techniques. It is also important that all the information included herein be carefully reviewed.

A serial number tag is attached to each ring with a fine suture. The tag must be removed prior to implantation but not before implantation is imminent. Care must be taken not to cut the polyester covering of the ring.

**Cutting needles and sharp forceps must not be used during ring implantation, in order to prevent damage to the polyester covering of the ring.**

Annular mattress sutures must not overlap, in order to prevent buckling of UNIRING. (See Suture Placement in the Tissue Annulus in Instructions for Use.)

To ensure the sterility and integrity of UNIRING®, it should be stored in the outer cardboard box until ring implantation is imminent. UNIRING® must be handled with care. It should not be used if it is dropped, soiled or suspected of being damaged after it has been removed from the double trays.

Proper sizing is critical and must be done only with UNIRING® sizers provided. The holder should not be used as a sizer and should not come in contact with the valve.

Except when delivered through an endoscope, sutures should be placed in the ring before separation of the unwanted suture-platforms and before separation of the ring from the holder.

**The holder must not make contact with the valve,** or else the valve could be damaged. The unwanted suture-platforms must be cut away and the annuloplasty ring must be removed from the holder before implantation. The UNIRING® holder is not analogous to the templates of some other commercially available flexible rings and bands, which must remain attached to the ring until after the sutures are tied. These templates of other products must remain attached to their respective flexible rings and bands until after the sutures are tied in order to prevent crimping of the ring. In contrast, UNIRING® cannot crimp or foreshorten because each individual mattress suture engages an individual rigid, non-deformable suture-platform (Figures 1, 4 and 5).

**The sutures securing UNIRING® ring to UNIRING® holder must never be cut.** Otherwise the unwanted ring remnants could escape as loose bodies into the surgical field.

Annuloplasties should not be attempted without the availability and expertise of intraoperative transesophageal echocardiography.

During treatment for certain Type 1 mitral valve defects, especially in the treatment of dilated cardiomyopathy or deformation of the annulus as a result of posterior-inferior or infero-lateral infarcts, the result of the annuloplasty must be verified by checking that the leaflets are in perfect apposition.
Complications

Informed consent requires an in-depth discussion of potential complications with the patient before surgery.

Although rare, serious complications sometimes leading to the death of the patient have occurred with annuloplasty rings. In addition, complications related to unique patient reactions to an implanted device or to physical or chemical changes in the components of the implanted ring and sutures (polyester or barium sulfate) may require reoperation and explantation of the device.

Long-term follow up with serial transthoracic echocardiography and other modalities is essential to detect and appropriately manage any complications resulting from an annuloplasty ring.

Specific complications historically associated with annuloplasty ring implantation have been reported in peer-reviewed literature and through a system of handling complaints in accordance with the United States regulations establishing Good Manufacturing Practices 21 CFR Part 820 Section 198 or any relevant materiovigilance regulations. Specific complications include, or could include: residual mitral or tricuspid regurgitation; recurrent mitral or tricuspid regurgitation; mitral or tricuspid stenosis; A-V block; low cardiac output; right heart failure; failure or degeneration of the patient's valve apparatus due to disease progression, endocarditis; incomplete/inadequate repair of the various components of the valve; suture injury to the circumflex coronary artery; suture injury to the non-coronary cusp of the aortic valve; leaflet perforation or immobilization from incorrect suture placement; complications related to prolonged cardiopulmonary bypass, aortic cross-clamping or inadequate myocardial protection; ring dehiscence (partial detachment of the ring from tissue annulus); ring malfunction due to distortion at implantation or physical or chemical deterioration of the ring components; fracture of the ring components; tearing of the polyester covering with cutting needles or sharp forceps; exposure of the suture-platform due to cutting at the heat-sealed joint too close to the suture-platform or damage from forceps or needles; suture-breakage due to incorrect suture placement into the ring; hemorrhage from anticoagulant therapy; hemolysis resulting from ring dehiscence; systolic anterior motion (SAM) and left ventricular outflow obstruction due to excess leaflet tissue in relation to the final orifice dimensions; thromboembolism.

Instructions for Use

1. Sizing

In order to achieve a valve orifice with a normal three-dimensional shape and size, and a normal relationship of valve tissue to final annulus dimensions, correct sizing is important. For mitral and tricuspid annuloplasty in degenerative and rheumatic cases, the surface area of the anterior leaflet is assumed to represent the correct dimension of the normal valve orifice during systole. Accordingly, the anterior leaflet is unfurled and the transparent sizer is applied to the leaflet (Figure 16). The same technique is used for the tricuspid valve (Figure 17). The sizer which best approximates the surface area of the leaflet is then chosen. Undersizing is appropriate in cardiomyopathic and ischemic cases unless a subvalvular or ventricular procedure is also performed.

Figure 16

![Figure 16](image1)

Figure 17

![Figure 17](image2)
Nine sizers and two handles are provided with each UNIRING® ring and holder. The sizes include: 24, 26, 28, 30, 32, 34, 36, 38, 40.

Each sizer has 2 sides, one with the letter “M” for the mitral (Figure 11) and one with the letter “T” for the tricuspid (Figure 12). On each side of the sizer, the letter “M” or “T” is on the left.

The numbers on the left, in association with the letters, are typical sizes with which surgeons are usually familiar. They refer to the intercommissural distance in millimeters at either extremity of the anterior mitral leaflet or septal tricuspid leaflet and assume a normal relationship between the intercommissural distance and the circumference of the valve orifice. The numbers on the right indicate the number of suture-platforms (and, therefore, the number of individual mattress sutures) corresponding to the given ring size.

The hole in the middle of the sizer engages the handle from either side. Notches are present at the end of the straight side of the sizer to indicate the position of the two commissures (anterior and posterior) straddling the anterior leaflet on the mitral (“M”) side and the position of the two commissures bounding the septal leaflet (anteroseptal and posteroseptal) on the tricuspid (“T”) side. The surface area of each sizer, therefore, correlates closely in most cases to the distance between the notches. Accordingly, sizing of the intercommissural distance is an alternative method to determine the correct size of the annuloplasty ring for either the mitral or the tricuspid valve in most cases, unless the anterior leaflet is excessively high.

Additional half-oval markings are present along the perimeter of the sizers to represent the position and number of suture-platforms on the final dimension of the tissue annulus required for a given size. The total number of suture-platforms required to fashion a completely circumferential ring around a mitral annulus and a nearly completely circumferential ring around the tricuspid annulus is indicated on the sizer. A space without a suture-platform marking is present along the perimeter of the left-hand portion of the straight side of the tricuspid sizers. This represents the area of the conduction system, where suturing is avoided. The surgeon could add an extra suture-platform along the septal annulus if there weren’t concerns about interfering with the conduction system with the additional mattress suture.

A final “middle” mark is present in the middle of the curved portion of the sizer to indicate where the “middle” suture is placed. On the mitral (“M”) side of the sizer, the middle mark is at bottom, corresponding to the middle of the middle scallop (P-2) of the posterior leaflet. On the tricuspid (“T”) side of the sizer, the middle mark is on the right, close to the one o’clock position, corresponding roughly to the anteroposterior commissure of the tricuspid valve.

2. Suture Placement in the Tissue Annulus

It is recommended that sizing be done first, in order to determine the correct number of sutures required (See Sizing in Instructions for Use). The number of sutures depends on the size of the ring required, with larger rings requiring more sutures. For complete mitral rings, a total of 9-15 sutures are required. For tricuspid rings, a total of 7-12 sutures are required.

Individual braided polyester horizontal mattress sutures, 2-0 for mitral (CARDIOFLON® or CARDIOXYL®) and either 2-0 or 3-0 for tricuspid (CARDIOFLON® or CARDIOXYL®) are placed in the tissue annulus to correspond one-to-one to the required number of suture-platforms of a given ring size. It is essential that the needle is introduced 1-2 mm. behind the annulus with the needle always aimed toward the ventricle at a 10° angle, coming back out after traversing the annulus 1-2 mm behind the annulus. Always aiming the needle toward the ventricle will eliminate the risk of injuring the aortic valve, the circumflex coronary artery and the A-V node. Keeping the angle of approach at only 10° will eliminate the risk of engaging leaflet tissue or chordae in the suture. For plicating sutures (Figure 2), a 3/8-curve needle is easier to manipulate without the need to bend the wrist as much as with a 1/2-curve needle.

It is suggested that the valve be sized first in order to know how many sutures will be required. Some surgeons prefer placing annular sutures early, in order to aid in exposure. If the valve is sized first, the surgeon will then know exactly how many sutures to place.

For the mitral valve, the “middle” horizontal mattress suture should be placed first in sequence in the middle of the posterior annulus. The sizer can then applied to the tissue annulus to indicate the exact position of the “first” and “last” horizontal mattress suture, corresponding to the position of the ends of the annuloplasty ring.
If a partial ring is desired, sutures in the intertrigonal portion of the anterior annulus can simply be eliminated. After the “middle” suture and the “first” and “last” sutures are placed, the remaining required horizontal mattress sutures are spaced according to the amount of tissue engaged with each suture in the intervening annulus.

Figure 16

For stabilization of the annulus (Figure 3), the suture loop of the individual horizontal mattress suture should incorporate only 3 mm. of tissue, the same distance between the two holes in each suture-platform.

Figure 3

This is the usual strategy along the anterior annulus. For plication of the annulus (Figure 2), larger amounts of annular tissue are incorporated within each horizontal mattress suture loop where there is a greater degree of annular dilatation. This is the usual strategy along the posterior annulus, with dilatation generally greater more posteriorly.

Figure 2
Sutures should not be placed immediately next to each other. There must be a 3 mm. space of tissue between individual mattress sutures, regardless of how much annular tissue is incorporated with each suture loop. These small spaces are necessary to accommodate the flexible joints of UNIRING® ring and to prevent overlapping and buckling of the suture-platforms.

For the tricuspid valve, the “first” suture (a plicating suture) should always be placed just above the anteroseptal commissure in the vertical part of the anterior annulus.

![Figure 17](image)

The sizer can then be applied to the tissue annulus to indicate the exact position of the “last” suture (a stabilizing suture), at the precise location along the right-hand portion of the septal annulus. The position of the “middle” suture (a plicating suture) is indicated on the sizer and is in the region of the anteroposterior commissure at approximately the one o’clock position. The remaining required sutures are spaced according to the amount of tissue engaged with each suture in the intervening annulus. The anteroposterior and posteroseptal commissures represent the area of greatest dilatation, followed by the base of the anterior and posterior leaflets (Figure 18).

![Figure 18](image)

### 3. Suture Placement in the Ring

The number of sutures in the tissue annulus must match the number of suture-platforms exactly, one-to-one.

UNIRING® holder is designed to facilitate suture placement. Suture guides indicate where the two needles of each mattress suture penetrate the ring at either end of each suture-platform. If one chooses not to keep the holder attached to the ring during suture placement, the holes can be easily found even though there are no external markings on the ring. The holes are just inside the edge of each end of the oval suture-platform and just next to the joint between suture-platforms. The holes can be visualized if the ring is held up to the light. It is important to avoid using sharp forceps on the ring if this method of suture placement is employed, in order to avoid damage to the overlying polyester braid.
4. Customization of the Ring

UNIRING® ring comes in only one size, precisely so the surgeon can customize the ring based on the specific annuloplasty requirements of the individual patient. The ring was manufactured with enough suture-platforms to accommodate a valve annulus of any size. Accordingly, it was anticipated that one or more suture-platforms would not be needed in most cases. The technique for eliminating the unwanted suture-platforms is described below in Eliminating Unwanted Suture-Platforms in the Instructions for Use.

The sizers indicate the final position of the suture-platforms on the mitral and tricuspid annulus (Figures 11, 12). If less complete (partial) annular coverage is desired, alternative “first” and “last” sutures can be determined from the position of the suture-platforms on the sizer. In most cases, a partial ring would result in only one or two fewer sutures. However, it is important to know exactly where to place the “first” and “last” suture in the tissue annulus from the sizer applied directly to the tissue annulus, because the holder doesn’t provide accurate imagery to the surgeon of the final appearance of the ring on the annulus.

5. Eliminating Unwanted Suture-Platforms

Once the annular sutures have been placed in UNIRING® ring, the unwanted suture-platforms are eliminated by simply cutting the joints with a surgical blade in the cutting guide on the outside edge of the “first” and “last” suture platforms. With the sutures in place, it is obvious which joints to cut. There are also numbers on the holder to indicate where to cut based on the number of suture-platforms used. The cutting guides on the holder facilitate a clean separation in the middle of the heat-sealed joints.

6. Separation of the Ring from the Holder

Once the unwanted suture-platforms have been cut away, UNIRING® ring will easily pull away from the holder, leaving the unwanted suture-platforms attached to the holder by the two sutures at the top of the holder. It is important not to cut the sutures at the top of the holder, in order to avoid loose pieces of the ring escaping into the surgical field.

7. Valve Competency Testing

Saline injection into the ventricle through the mitral and tricuspid orifice is helpful to determine valve competency after annuloplasty. The line of closure of the anterior mitral leaflet should be parallel to the posterior annulus with between 1/3 and 1/4 of the anteroposterior diameter occupied by the posterior leaflet. If the posterior leaflet occupies more than this amount, it may be too high, risking systolic anterior motion (SAM) and left ventricular outflow tract obstruction. The line of closure of the anterior tricuspid leaflet should follow the same pattern with the septal leaflet. The amount of overlapping surface of coaptation of the opposing leaflets should be noted, and should be at least 5 mm (preferably 6-8 mm). If this measurement is not clear, a sterile marking pen or methylene blue can be used to indicate the upper contact point of each leaflet when the ventricle is full of saline. After the saline is evacuated from the ventricle, the distance from the contact point to the free margin can then be measured.
It should be noted that saline testing doesn’t always produce a water-tight closure even if a perfect repair has been accomplished. The profile and position of the leaflets and the amount of coapting surface are the important data to document with the saline test and are the important predictors of a good long-lasting result.

If it becomes obvious that a satisfactory result has not been achieved with the saline test or is evident at the end of the operation when the valve is interrogated with transesophageal echocardiography, the surgeon must be prepared to go back and either re-repair or replace the valve. Except in very rare circumstances, any more than 1+ residual mitral regurgitation is unacceptable.

The completed mitral and tricuspid annuloplasties are illustrated in Figures 19, 20.

**Figure 19**

**Figure 20**

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**Annuloplasty Ring**

1. **Specifications**

UNIRING®: Ring, Holder, Sizers and Handles.
Sizes: 24 mm, 26 mm, 28 mm, 30 mm, 32 mm, 34 mm, 36 mm, 38 mm, 40 mm.

2. **How supplied**

UNIRING® ring with attached holder, 9 sizers and 2 handles, is sterile and non-pyrogenic in a box containing double plastic trays to facilitate handling and transfer to the sterile field in the operating room. The outer tray is opened first and the inner tray is delivered to the sterile field.

Storage

Storage issues are minimized with a UNIRING® of only one size. There is no need for large inventories, which will minimize front-end costs and any risk of product date expirations.

The outer cardboard package should remain unopened until needed at the time of surgery. This will minimize contamination of and provide maximum protection for its contents: the UNIRING® ring and holder, the handles, the sizers, the Instructions for Use and the Implant Data Card. Stock rotation will probably not be necessary due to the fact that UNIRING® comes in only one size. The older dated boxes should be used first. UNIRING® cannot be used after the dated stamped on the label.

UNIRING® shouldn’t be resterilized.

3. **Accessories**

The accessories, which include the handles and the sizers available in each UNIRING®, are initially sterile in the double trays. As they are disposable, it is not needed to clean and resterilize them.
Patient Implant Registry

An **Implantation Data Card** is packaged with each UNIRING®. Pé ters Surgical requests that each Data Card be carefully completed and in the preaddressed envelop mailed to our Patient Implant Registry. The remaining portions of the card are provided to the hospital and surgeon records. Upon receipt by our Registry, a wallet-sized identification card will be produced for the patient. This card allows the patient to inform health-care providers the type of implant they have when seeking care. Whenever a UNIRING® ring is discarded or replaced, the Implantation Data Card should be used to report this information to the Pé ters Surgical Patient Implant Registry. It is important to note that prosthetic annuloplasty rings are trackable devices pursuant to the Medical Device Tracking regulation and their usage must be reported to the manufacturer.

Recovered Clinical Implants

Peters Surgical is very interested in recovering any explanted UNIRING® rings for analysis. A written report summarizing our findings will be provided after our evaluation is completed. The local company representative can be contacted to facilitate the return of any recovered rings. The explanted rings can be placed in 10% formaldehyde.

Patents

UNIRING® is manufactured and sold under the following United States patents:

- No. 5,593,424. Northrup III. Apparatus and method for reducing and stabilizing the circumference of a vascular structure.
- No. 5,709,695. Northrup III. Apparatus for reducing the circumference of a vascular structure.
- No. 5,961,539. Northrup III, et al. Method and apparatus for sizing, stabilizing and/or reducing the circumference of an anatomical structure.