TTK CHITRA HEART VALVE

Rigid Tilting Disc Heart Valve Substitute

Model TC1

Rigid Tilting Disc

Heart Valve Substitute

INSTRUCTION MANUAL

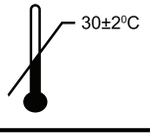
A TTK Product

Instructions for Use

Rigid Tilting Disc
TTK Chitra Heart Valve
Substitute

Explanation of Symbols

SN	Serial Number
REF	Catalogue Number
LOT	Batch Number
	Date of Manufacture
	Use By Date
	Do not Resterilize
	Single Use
STERILE EO	Sterilized using Ethylene Oxide
	Caution
	Consult Instructions for Use

	Keep Away from Sunlight
	Keep Dry
	Do Not Use if Package is Damaged
	Protect from heat and radioactive sources
	Fragile, Handle with care
	MR Conditional
	Manufacturer
	Upper Temperature Limit
EC REP	Authorized Representative in European Community
	Non-sterile*

* For accessories

Contents

1 Indication

The Rigid Tilting Disc TTK Chitra Heart Valve Substitute, falls within the general category of Mechanical Heart valve prosthesis. It is intended for use as a replacement valve in patients with a diseased, damaged or malfunctioning aortic or mitral heart valve. This device may also be used to replace a previously implanted prosthetic heart valve.

2 Description

The Rigid Tilting Disc TTK Chitra Heart Valve substitute, hereinafter referred to as TTK Chitra Heart Valve has three components namely frame, disc and sewing ring. The frame is integrally machined from Cobalt Chromium alloy (Haynes 25) and the disc from Ultra High Molecular Weight Poly Ethylene (UHMWPE). The sewing ring of Poly Ethylene Terephthalate (PET) is fixed around the frame.

During its functioning, the disc of the valve opens towards its intended (outflow) side and closes in the opposite direction (Refer figure 1). Opening and closing rates, as well as duration are determined by myocardial contractility and the resulting pressure variations in the cardiovascular system. The valve is designed to produce low resistance in the open position and minimal regurgitation on closure.

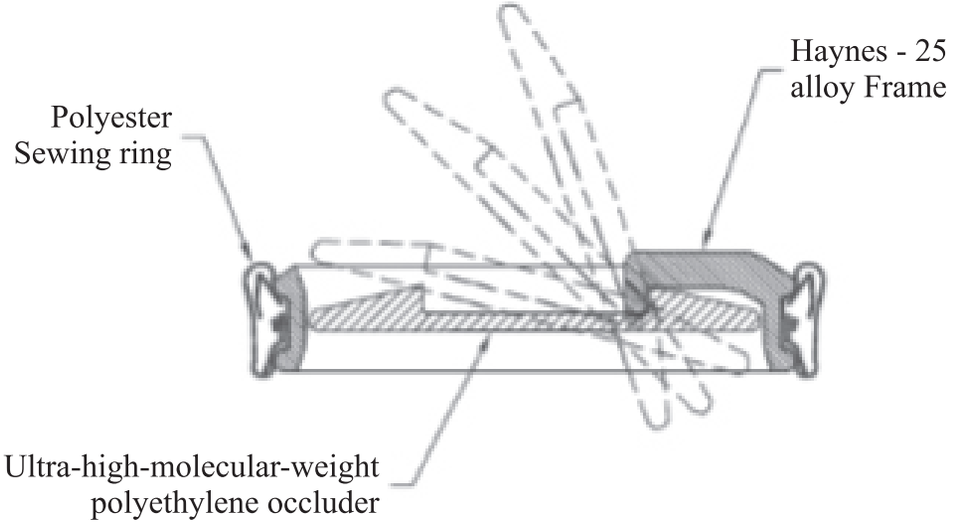


Figure 1
Cross section of
TTK Chitra Heart Valve (Aortic)

3 Available Models

The TTK Chitra Heart Valve is available both in aortic and mitral model in 9 sizes. An ID number tag is attached to each sewing ring which uniquely identifies the valve. The first character of the ID number indicates the year of manufacture and the second character indicates the valve size. The last six digits is the unique serial number.

A typical example is as follows:

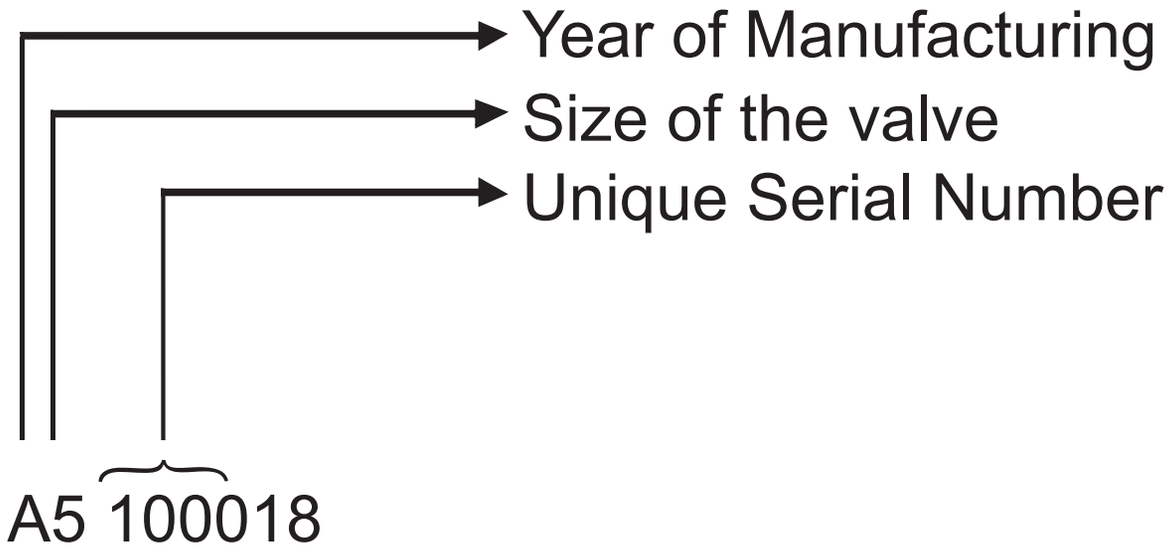
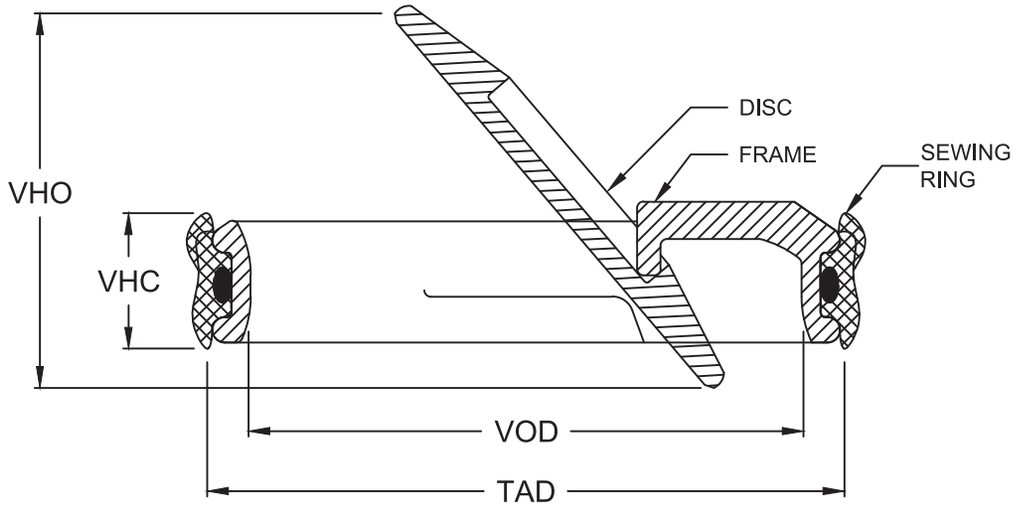


Figure 2 : Cross Section of TTK Chitra Aortic and Mitral Heart Valve

Aortic



Mitral

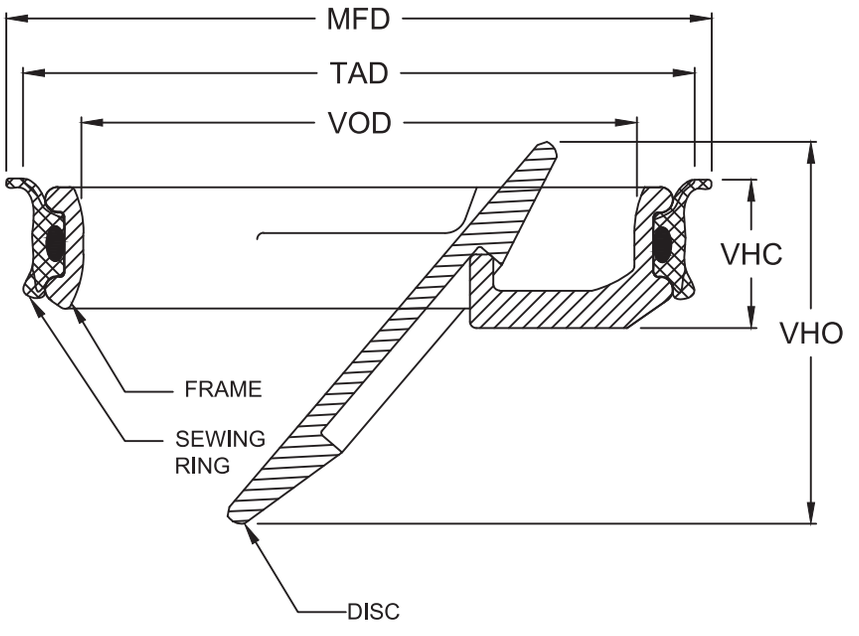


Table 1: Valve Specification

Model	Valve Size	Valve Type	Sewing Ring Configuration	TAD	VOD	VHC	VHO	MFD
TC 1	17	Aortic	17 mm	17.0	12.8	5.0	12.0	-
	19	Aortic	19 mm	19.0	14.4	5.0	13.5	-
	21	Aortic	21 mm	21.0	16.0	6.0	15.0	-
	23	Aortic	23 mm	23.0	18.0	6.0	16.9	-
		Mitral		23.0	18.0	6.0	16.9	29.0
	25	Aortic	25 mm	25.0	20.0	6.0	18.7	-
		Mitral		25.0	20.0	6.0	18.7	31.0
	27	Aortic	27 mm	27.0	22.0	6.0	20.5	-
		Mitral		27.0	22.0	6.0	20.5	33.0
	29	Aortic	29 mm	29.0	24.0	6.0	22.5	-
		Mitral		29.0	24.0	6.0	22.5	35.0
	31	Mitral	31 mm	31.0	26.0	6.0	24.4	37.0
	33	Mitral	33 mm	33.0	26.0	6.0	24.4	39.0

Legend : **TAD :** Tissue Annulus Diameter **VOD :** Valve Orifice Diameter
MFD : Mitral Flange Diameter **VHC :** Valve Height Closed
VHO : Valve Height Open

4 Packaging

Each TTK Chitra Heart Valve is double packed and supplied sterile.

The primary packaging consists of an inner and outer container made of transparent polycarbonate with silicone rubber inserts. The outside of the inner polycarbonate container is also sterile, provided the outer polycarbonate container is neither opened nor damaged. The outer polycarbonate container is only internally sterile. ⚠ **THE OUTER POLYCARBONATE CONTAINER MUST NOT BE BROUGHT IN TO A STERILE ENVIRONMENT**.

The secondary packaging is made of laminated paper carton. A colour scheme of red is used for aortic valve packing and blue for mitral valve packing.

A label bearing the type, model and serial number of the particular valve is affixed on the outer polycarbonate container and carton. In addition a

label bearing serial number and batch number of the valve is affixed on the top of the outer polycarbonate container.

5 Accessories

The TTK Chitra Heart Valve Accessory Set, which is reusable, consists of :

Double Headed Malleable Sizer
Holder Head
Holder Handle
Test Probe with Single Headed Malleable Sizer

Every Accessory Set is identified by a unique identification number which is engraved on each component in the Set.

CAUTION : Accessories are supplied **Non Sterile** and must be sterilized each time before use.

Double Headed Malleable Sizer

Malleable Sizer set is available as an aid in measuring the tissue annulus diameter. The Sizer set is made of polyacetal and stainless steel. The size of each Sizer is engraved on its side.

Holder Head

The Holder Head is used to handle the TTK Chitra Heart Valve during implantation. It also allows the valve to be rotated inside the sewing ring to orient the valve as required.

The size of the valve is marked on the side of the Holder Head.

Holder Handle

The Holder Handle is attached to the Holder Head and is interchangeable with any Holder Head within the Set.

Test Probe with Single Headed Malleable Sizer

The Probe is used for testing the free movement of the disc after implantation.Test probe has a single -headed malleable sizer for size 17 at its distal end.

Sterilization of Accessories

⚠ Accessories are supplied **Non Sterile** and must be cleaned and sterilized before use. Accessory Set can be sterilized using any standard Ethylene Oxide sterilization cycle. It can also be autoclaved using any standard autoclave cycle with **a maximum cycle temperature of 121^{0}C.**

WARNING : **Repeated sterilization may damage the accessories. Inspect them carefully before and after sterilization and replace them if there are any signs of wear.**

Refer instruction for use of TTK Chitra Heart Valve Accessory set for further information on accessories.

6 Sterility and Resterilization

The TTK Chitra Heart Valve is supplied sterile. The valves are sterilized by the manufacturer using Ethylene Oxide. Sterility is guaranteed up to the expiry date printed on the packaging provided the packaging is neither opened nor damaged.

WARNING : The TTK Chitra Heart Valve should not be resterilised by the user. Such resterilization by any method without proper preparation and mounting in the valve container may cause distortion or deterioration of the components of the valve.

In case if the valve becomes unsterile during handling or otherwise, the valve must be returned to the manufacturer in the original packing.

7 Disposal

All component materials and packaging materials are environmentally safe and hence can be safely incinerated. Biologically contaminated components should be decontaminated at the site of contamination prior to incineration. Metal frame may remain after incineration.

8 Contraindication

⚠ TTK Chitra Heart Valve is contraindicated for patients unable to tolerate long term anticoagulation therapy

.

9 Complication

The complications associated with TTK Chitra Heart Valve implantation include, but are not

limited to, stenosis, regurgitation, haemolysis, infections, thrombus, or thromboembolism, valve dehiscence, unacceptable haemodynamic performance, hemorrhagic complications secondary to anticoagulation therapy, prosthetic failure, heart failure or death. Any one of these complications may require re operation or removal of the device.

10 Instruction for Use

10.1 Valve Sizing

TTK Chitra Heart Valve Accessory Set including the Sizers, Holder heads, Holder Handle and Test Probe must be cleaned and sterilized prior to surgery and made available in the operating room.

Use only TTK Chitra Heart Valve Sizers to measure the patient's tissue annulus diameter. Valve size is determined by passing the sizer through the tissue annulus of the patient. The

sizer should pass easily through the annulus with minimal resistance. Do not force the sizer through the tissue annulus. Valve over sizing or under sizing should be avoided.

Note :

1. **Mitral valve size selection should not be based exclusively on annulus size. Consideration should be given to the proportion of the prosthetic valve to the ventricular cavity and the potential for complications that could occur because of post operative compensation and reduction in heart size.**
2. **Cardioplegia, for myocardial preservation, may cause the mitral annulus to measure larger than normal. It is advised that the surgeon consider selecting a prosthetic valve which is smaller than indicated by the sizer which would be appropriate to the proportions anticipated when the heart is no longer flaccid.**

3. **In the case of aortic valves the size of the prosthesis must be chosen taking the location of coronary ostia and whether the aortic root is particularly rigid or fragile. The supra annular position may cause interference with coronary ostia.**

10.2 Preparing the valve

1. Check the valve secondary package for sticker. If the sticker is missing, please send back the valve to the manufacturer.

2. Inspect the valve package for any damage. If damaged, DO NOT use the valve.
3. Ensure that the shelf life of the device has not expired. If it has, the sterility of the valve is not guaranteed.
4. Check all the information on the label.
5. Remove the primary polycarbonate container from the secondary unit carton.

6. Inspect the primary polycarbonate container for any damage. Check whether the hologram and bacteria filter are intact. The sterility of the TTK Chitra Heart Valve is guaranteed only if the packaging is perfectly intact.
7. Hold the primary polycarbonate container in the upright position (as indicated by the direction of arrows). Cut and remove the hologram.
8. Remove the outer polycarbonate container top by rotating in the anticlockwise direction (Refer figure 3). Present the inner polycarbonate container to the sterile operating person. Note that the inside of the outer polycarbonate container will be sterile if the container is not damaged. Hence the inner polycarbonate container should be handled in a sterile environment.

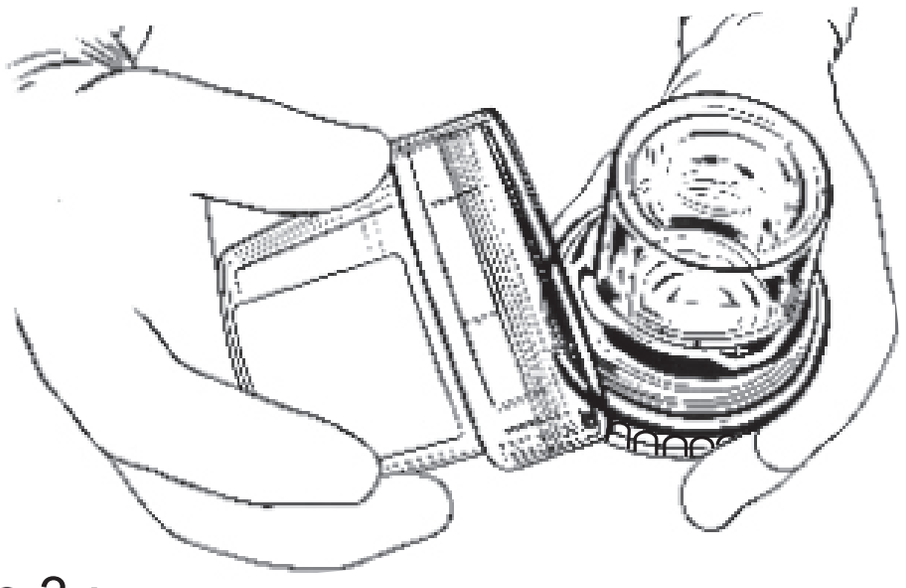


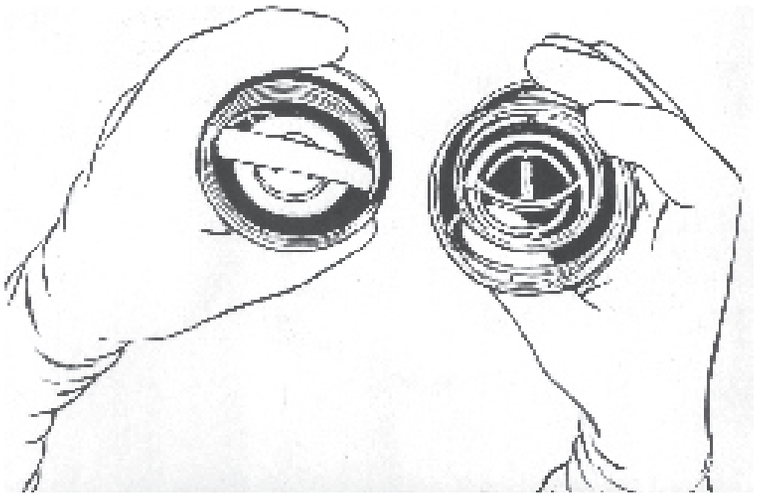
Figure 3 :

Remove the outer polycarbonate container top

WARNING: Do not bring the outer polycarbonate container into the sterile environment.

9. Hold the inner polycarbonate container in the upright position (as indicated by the direction of arrows) and remove the inner polycarbonate container top by rotating in the anti clockwise direction (Refer figure 4).

Figure 4 :



Remove the inner polycarbonate container top

10. Verify the ID No. tag on the valve with that printed on the label and implantation data card.

10.3 Removing the Valve from the container

The valve box is designed to allow the valve to be placed directly on the holder without touching the valve itself. The valve is prepositioned in the correct orientation for either aortic valve or mitral valve implantation.

Note : ⚠ The valve is packed in such a way that the disc opens upwards in the case of aortic valves and it opens downwards in the case of mitral valve.

1. Select the appropriate size Holder Head and insert the Holder Handle into the Holder Head (Refer figure 5).

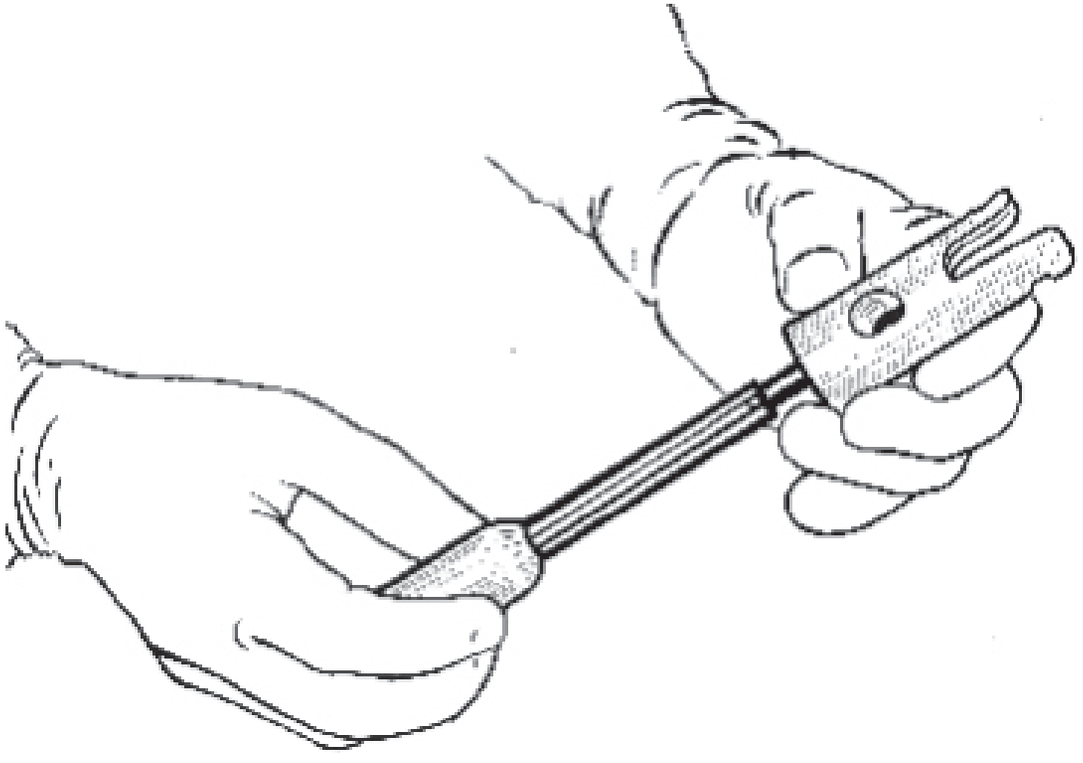


Figure 5 : Insert the Holder Handle into the Holder Head

2. Insert the Holder into the orifice of the valve by positioning the larger finger of the Holder into the major orifice and then rocking the small fingers into position over the minor strut.

3. Rotate the Holder Handle clockwise into the Holder Head until the valve is just secured. Do not over tighten. The ID number tag must be removed from the sewing ring now.
4. Remove the valve with the Holder from the inner polycarbonate container (Refer figure 6).

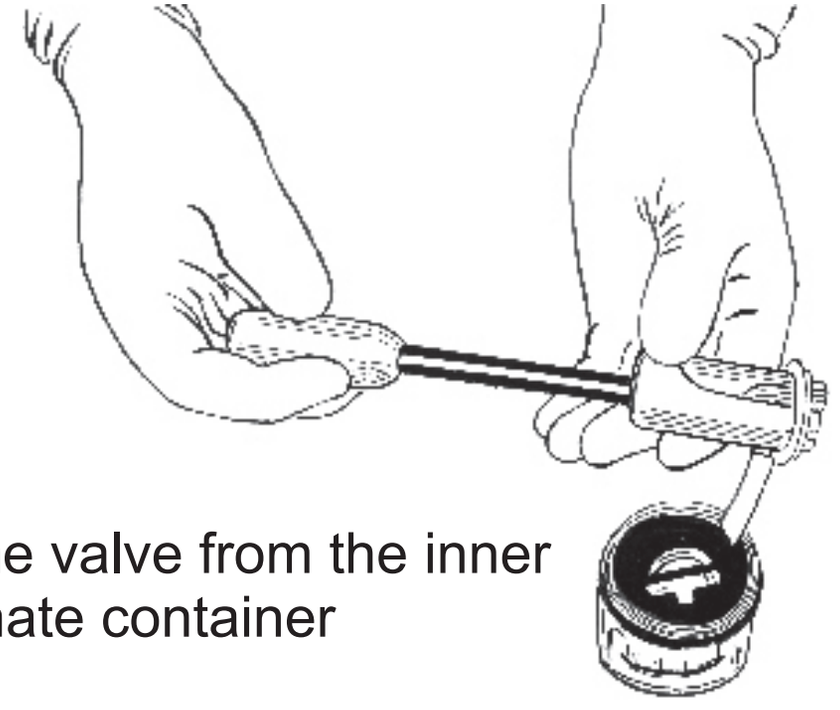


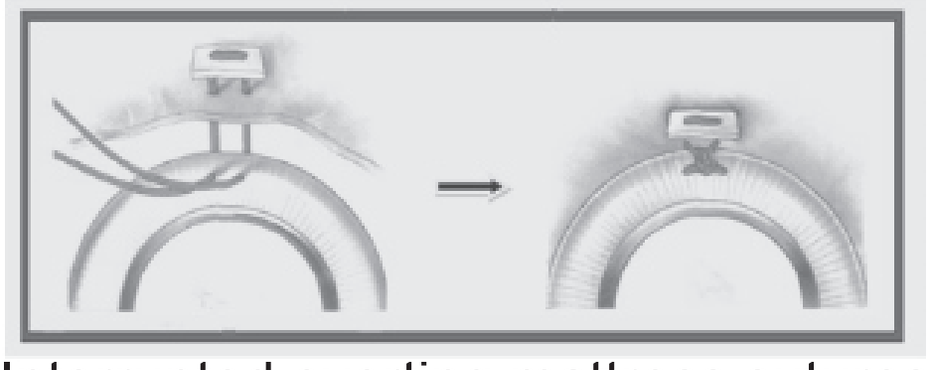
Figure 6 :
Remove the valve from the inner polycarbonate container

5. Hold sewing ring with one hand and rotate the valve in clockwise direction within the sewing ring to assure its freedom to rotate in the event that in situ repositioning is required.

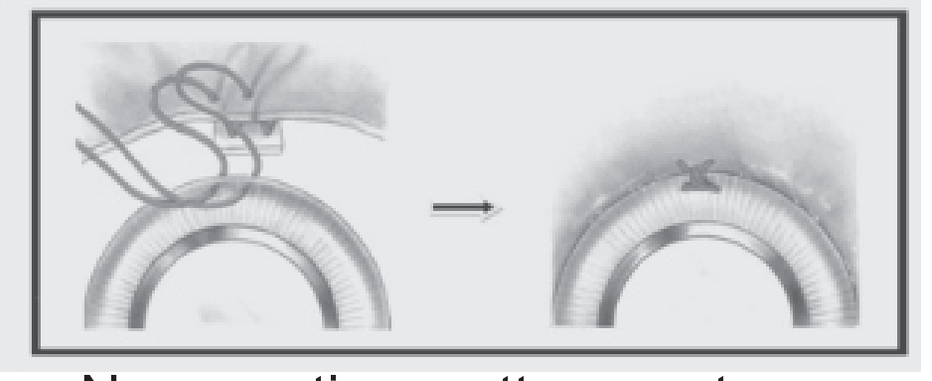
10.4 Suturing Techniques

⚠WARNING: Before suturing check the orientation of the valve to ensure the blood flow is always directed towards the inflow side of the valve. (Refer figure 1)

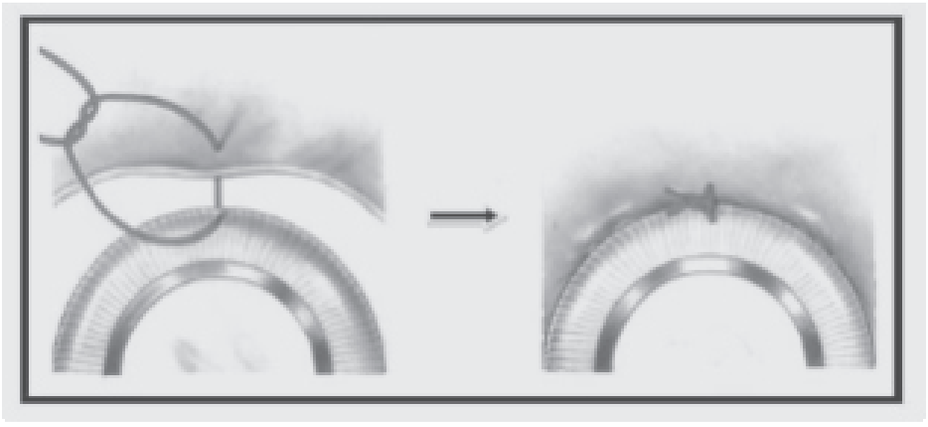
The mitral sewing ring is designed for Supra annular placement only. The recommended suturing techniques are illustrated below:



Interrupted everting mattress sutures

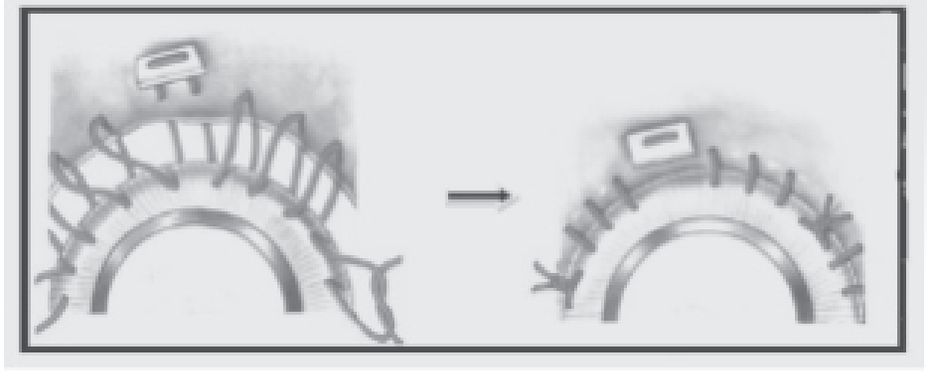


Non everting mattress sutures



Simple interrupted sutures

Figure of eight sutures



Continuous running sutures
(interrupted in quadrants, thirds or halves)

Due to the complex nature of the surgical procedures in which the valve is used, choice of the non **degradable** suture material and method of suturing the prosthesis in place are left to the discretion of the Surgeon.

However the key element in safe and secure fixation is not the use of a particular suture material or technique, but the correct placement of sutures and suture tails. The suture marker present on the sewing ring of TTK Chitra Heart Valve aid in the placement and alignment of sutures.

1. After placing the sutures in the valve sewing ring, position the valve in the tissue annulus.
2. Release the valve from the holder by rotating the holder head in anticlockwise direction.
3. Free movement of the disc has to be tested using the test probe.If the disc does not move freely due to tissue interference or suture impingement, the valve should be reoriented properly by using the valve holder.

4. Once the valve is properly seated and the disc free movement is assessed, the sutures may be tied and knotted.
5. After suturing check for disc free movement using the test probe.

10.5 Rotation of the valve

If the valve needs to be rotated after implantation, re-insert the Holder into the valve and hold the sewing ring stationary with a clamp to prevent the sutures from tearing out during rotation. Rotate the valve in clockwise direction to the desired orientation.

WARNING : Using other instruments or systems to rotate the valve may seriously damage the valve.

10.6 Post operation management

Drug therapy prescribed during and after surgery is left to the discretion of Surgeon.

10.7 MRI Imaging of Valve

MR Conditional

The Rigid Tilting disc Aortic/Mitral TTK Chitra Heart Valve Substitute Model TC1 was determined to be MR-conditional.

Non-clinical testing demonstrated that the “Rigid Tilting disc Aortic/Mitral TTK Chitra Heart Valve Substitute Model TC1” is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions of Static Magnetic Field:

- Static magnetic field of 3-Tesla or less.
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the Rigid Tilting disc Aortic/Mitral TTK Chitra Heart Valve Substitute Model TC1produced the following temperature rise during MRI performed for 15 min of scanning (i.e., per pulse sequence) in the 3-Tesla (3 Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.7^{O}C

Therefore, the MRI-related heating experiments for the Rigid Tilting disc Aortic/Mitral TTK Chitra Heart Valve Substitute Model TC1 at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9-W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occured in association with these specific conditions was equal to or less than +1.7^{O}C.

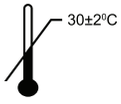
Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Rigid Tilting disc Aortic/Mitral TTK Chitra Heart Valve Substitute Model TC1. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 20-mm relative to size and shape of the Rigid Tilting disc Aortic/Mitral TTK Chitra Heart Valve Substitute Model TC1.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	2,608-mm^2	890-mm^2	4,058-mm^2	4,981-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

11 Storage

 The TTK Chitra Heart Valve must be stored in a clean, cool and dry place.



The valve should not be refrigerated.

The shelf life of TTK Chitra Heart Valve is recorded on the secondary package label and storage temperature as 30±2^{0}C

12 Precautions and Warning

- TTK Chitra Heart Valve is indicated for Single use only. Reuse of the valve will result in biological cross contamination.
- TTK Chitra Heart Valve should be implanted by a qualified and trained cardiac surgeon.
- The valve must be handled in a manner which avoids contact with particulate matter that could cause unfavorable blood reactions or embolism. Sterile procedures must be followed while handling the valve.

- Contact with or handling by metal or other sharp instruments should be avoided as they may scratch the highly polished valve surface and deform the components which may lead to valve damage.
- Implantation of a TTK Chitra Heart Valve without the TTK Chitra Accessory Set or use of other Accessory Sets may result in structural damage to the valve.
- The ID number tag attached to the TTK Chitra Heart Valve sewing ring shall not be removed until the surgeon has decided on a particular valve size and secured the valve on the holder for suturing.
- Avoid using cutting edge surgical needles for suturing the valve as this may damage the sewing ring.
- Long suture ends and un-excised and loose tissue pieces may interfere with the proper functioning of the device.

- 

Do not attempt to resterilize TTK Chitra Heart valve.
-  Do not use a TTK Chitra Heart Valve if its container or seal is opened or damaged or its shelf life period has expired.
- If there is any doubt as to the cleanliness or structural integrity of the TTK Chitra Heart Valve after it has been handled, it should then be returned to the manufacturer for inspection. The valve being returned must be packed carefully in its original container to prevent damage during transportation.
- Post operative catheterization which involves passing a catheter through a TTK Chitra Heart Valve will cause valvular insufficiency and can result in disc dislodgement or damage. Hence dynamic assessment by Doppler Echo Cardiography is preferable and recommended.
-  The TTK Chitra Heart Valve should not be gamma irradiated as this may result in the deterioration of the sewing ring.

- Implanting TTK Chitra Heart Valve in patients with endocarditis may result in the contamination of the valve.

13 Implantation Data Card

The TTK Chitra heart valve implantation data card forms the basis of recording vital valve implant data. Immediately after the valve has been implanted, fill up the implantation data card and mail the same to the following address.

TTK Healthcare Limited
Heart Valve Division
Plot A -28, KINFRA Apparel Park
St. Xavier's College P.O.Thumba,
Trivandrum, Kerala, India - 695 586
Phone : +91 471 2707002 / 2707004
E-mail : heartvalve@ttkhealthcare.com

14 Disclaimers of Warranties

WARNING

Implanted cardiac prosthetic valves are continuously exposed to the extremely hostile environment within the human body. Valves may fail to function for a variety of causes including, but not limited to medical complications. Despite the expertise of all due care in design, component selection, manufacture, and testing prior to sale, valves may easily be damaged before, during or after insertion by improper handling or other intervening acts. Consequently, no warranty can be made to ensure that; failure or cessation of function of valves will not occur, that the body will not react adversely to the implantation of valves, or that medical complications will not follow the implantation of valves.

VALVES ARE SOLD IN AN “AS IS” CONDITION. THE ENTIRE RISK AS TO THE QUALITY AND PERFORMANCE OF VALVES IS WITH BUYER, TTK HEALTHCARE LTD., DISCLAIMS ALL WARRANTIES, EXPRESSED OR IMPLIED, WITH RESPECT TO VALVES, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.TTK HEALTHCARE LTD SHALL NOT BE LIABLE TO ANY PERSON FOR ANY MEDICAL EXPENSES OR ANY DIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM FAILURE, REMOVAL OR REPLACEMENT OF ANY VALVE, OR CAUSED BY ANY DEFECT, FAILURE OR MALFUNCTION OF ANY VALVE, WHETHER A CLAIM FOR SUCH DAMAGE IS BASED UPON WARRANTY, CONTRACT, TORT, OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND TTK HEALTHCARE LTD. TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO VALVES.

Manufactured and Marketed by :

TTK Healthcare Limited
Heart Valve Division
Plot A -28, KINFRA Apparel Park
St. Xavier's College P.O.Thumba,
Trivandrum, Kerala, India - 695 586
Phone : +91 471 2707002 / 2707004
E-mail : heartvalve@ttkhealthcare.com

Issue No.: 4.5
W.E.F.: 10-08-2022