CARDIAMED

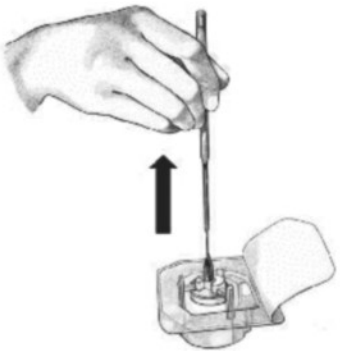
Instructions for use

PROSTHETIC HEART VALVE

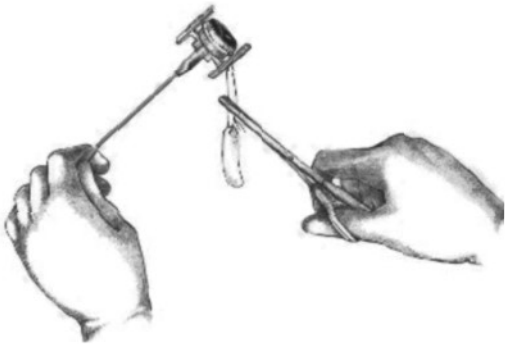
1

2

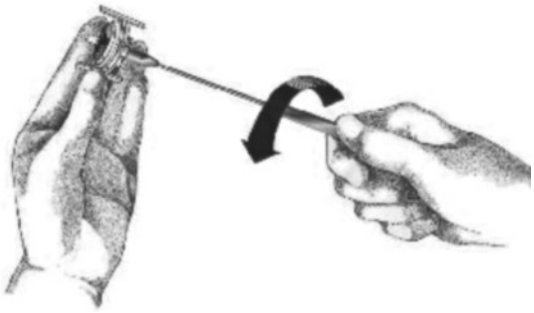
3



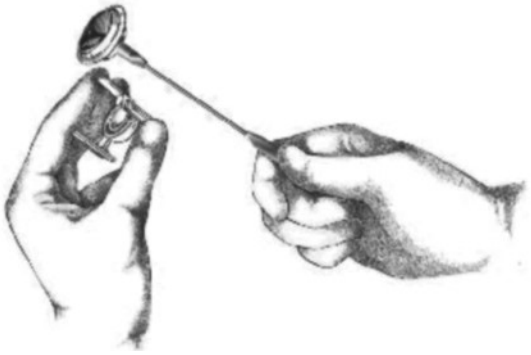
4



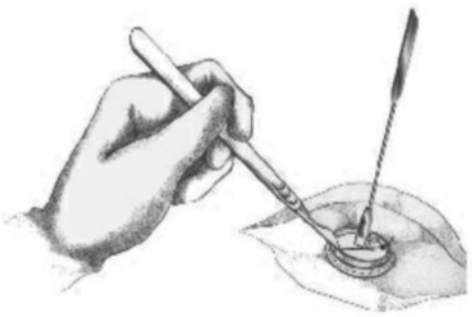
5



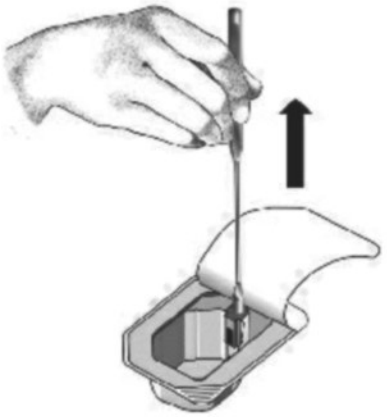
6



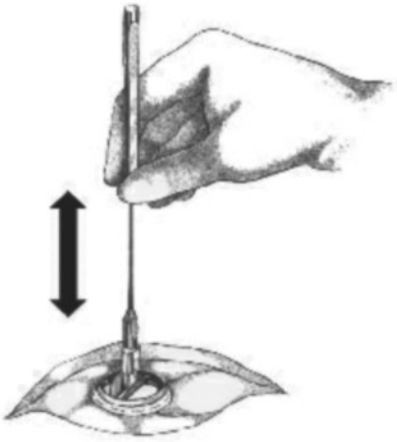
7



8

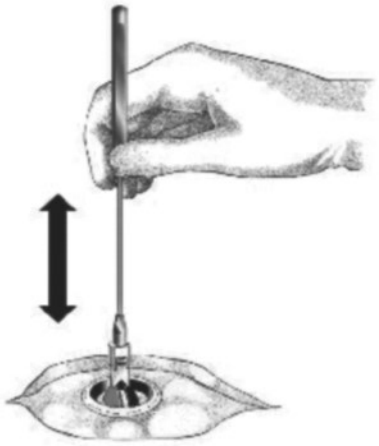


9



10

11



12

DO NOT REUSE

CAUTION

TEMPERATURE LIMITATION

USE BY

STERILIZED USING ETHYLENE OXIDE

SERIAL NUMBER

MANUFACTURER'S BATCH CODE

MANUFACTURER'S CATALOG NUMBER

DO NOT USE IF PACKAGE IS DAMAGED

KEEP DRY

KEEP AWAY FROM SUNLIGHT

CARDIAMED

Instructions for use

PROSTHETIC HEART VALVE

TABLE OF CONTENTS

1 DESCRIPTION OF THE PROSTHETIC HEART VALVE AND ITS ACCESSORIES

1.1 The valve consists of the following components:

- housing with stiffening titanium-alloy ring;
- sewing cuff of various forms to ensure the best anatomical fit of the valve;
- two semi-disk shaped leaflets pivoting between open and closing positions.

Design of the hinge mechanism and leaflet geometry provide the leaflets rotating around the central axis of the valve thus practically eliminating stagnation zones behind the valve.

Optimal hydrodynamic profile of the leaflets ensures minimal drag for the blood flow. High reliability of the valve is achieved the composition of the housing and leaflets out of solid pyrolytic carbon which has unique biocompatibility and excellent wear resistance.

The enhanced thromboresistance of the valve is achieved by means of special design clearances which generate swirling streams of regurgitant blood flow that wash the valve and surrounding heart structures.

1.2 Different modifications of the CARDIAMED valve are available for the surgeon to ease the selection of the valve for implantation.

1.3 Each valve is provided on a holder, and supplied with a test probe, two disposable sterile handles and two disposable sterile sizers, which correspond to the tissue annulus diameter of the valve.

1.4 All valve accessory parts are made of medical purpose plastics. They are sterile and intended for single use purpose only.

ATTENTION: RESTERILIZATION OF THE VALVE ACCESSORY PARTS IS PROHIBITED!

1.5 The valve holder consists of a guard protecting the valve from mechanical impacts during shipment and handling and a support to which the valve is attached by sutures.

1.6 The test probe is used for verifying the function of the leaflets.
The test probe with V-shape tip marked as “A1” should be used to verify the function of aortic valves ADM.17 – ADM.23, while test probe with V-shape tip marked as “A2” should be used to verify the function of aortic valves ADM.25 - ADM.29.
The test probe with M-shape tip marked as “M” should be used for checking the function of mitral valves MDM.

1.7 The digits marked on the surface of the sizer indicate the tissue annulus diameter of the corresponding valve.

1.8 The handle (**fig.1**) has a bendable element made of ductile metal. The handle is intended to be attached to the valve holder, the test probes and sizers.

1.9 A tag with the following data is attached to the sewing cuff of the valve:

- logo of the manufacturer of the valve;
- valve designation;
- serial number according to manufacturer's numbering system;
- year of manufacture.

Valve designation includes:

- ADM for aortic valve or MDM for mitral valve;
- tissue annulus diameter;
- alphanumeric code for valve modification. The first digit of the code designates a thread the sewing cuff is made of, where:

1 - sewing cuff made of polyester thread;
R – Reduced sewing cuff.

- The digit is followed by the designation of the sewing cuff, where:
  In - intrasupra-annular;
  Su - supra-annular.

2 INDICATIONS FOR USE

The Prosthetic heart valves CARDIAMED ADM and MDM are intended for replacement of diseased aortic and mitral native human heart valves respectively.

3 CONTRAINDICATIONS

Implantation of the prosthetic heart valve into patients with detected intolerance to anticoagulant medications is prohibited.

4 ADVERSE EVENTS

Potential prosthetic valve-related adverse events are as follows: cardiac arrhythmias, endocarditis, hemolysis, thromboembolism, anticoagulant-related hemorrhage, leaflet entrapment by tissue ingrowth, leaflet escape or leaflet fracture, leakage (transvalvular or perivalvular), inappropriate sizing, housing fracture, prosthetic valve thrombosis, sewing cuff separation from the valve housing; valvular insufficiency; stenosis, thromboembolism.

5 PREPARATION FOR IMPLANTATION

5.1 The CARDIAMED valve is supplied in a sterile package, sterilized with ethylene oxide. It does not require any additional hygienic procedures if shipment conditions have been fulfilled and sterility expiration date indicated on the label of the secondary container has not expired. The labels of the containers serve as antibacterial filters.

ATTENTION! THE USE OF THE VALVE IS PROHIBITED IF THE LABEL OF THE PRIMARY CONTAINER IS DAMAGED OR IF "USE BY" DATE EXPIRED.

ATTENTION! THE VALVE PACKAGE SHOULD BE OPENED DIRECTLY BEFORE SURGICAL PROCEDURES. DO NOT TOUCH THE VALVE WITH FINGERS!

5.2 Keep a stock of aortic and mitral valves of all sizes in operating room in order to have them readily available for proper valve sizing.

5.3 In order to select the right valve size for implantation you should use the original sizers supplied with the valve.

ATTENTION:
DO NOT USE SIZERS FROM OTHER VALVE MANUFACTURERS!

5.4 Open the carton box with a valve size visually corresponding to tissue annulus diameter of the diseased native valve.

ATTENTION! WHEN THE CARTON BOX IS OPENED, VERIFY THAT ALL CARTON AND CONTAINER LABELS MATCH WITH RESPECT TO VALVE MODIFICATION, TISSUE ANNULUS DIAMETER AND SERIAL NUMBER. IN THE EVENT OF ANY NON-MATCHING INFORMATION, DO NOT USE THE VALVE.

5.5 Upon surgeon's request:

a. a person with non-sterile hands takes the package containing one handle out of the carton box and opens it approximately to the middle by peeling it apart without touching the handle;

b. a person with sterile hands takes out the handle from its package without touching the handle package;
c. a person with non-sterile hands takes the blister containing one sizer out of the carton box with one hand and opens it with the other hand by peeling off the label;
d. a person with sterile hands attaches the sizer to the handle by inserting the collet clamp of the handle into the opening of the sizer until it stops (**fig.2**). The handle with sizer attached is handed over to the surgeon.

5.6 To determine appropriate valve size the surgeon inserts the sizer into fibrous ring (tissue annulus). If the sizer fits inside without stretching the annulus too hard, the surgeon should use the valve size indicated on that sizer. When the diameter of the sizer does not correspond to the fibrous ring diameter, please remove the previous sizer from the handle and dispose the sizer, then repeat steps (5.4,) 5.5 c and 5.5 d using another sizer (smaller or bigger) and repeat the sizing procedure again.

5.7 After selecting the appropriate valve size and modification, store the second sterile sizer and second sterile handle available in the carton box, for future use.

5.8 Upon surgeon's request:
a. Remove the outer container with the valve from the carton box with one hand and open it by peeling off the label with the other hand. A person with sterile hands takes the inner container out of the outer container with forceps without touching the non-sterile surfaces of the outer container and then opens the primary container similarly;
b. Insert the collet clamp of the handle into the opening of the valve holder until it stops and then take the valve holder with the valve out of the container, do not yet dispose the container (**fig. 3**);
c. after verifying that data on the valve tag and data on the container label match, cut the tag suture above the knot and remove the suture together with the valve tag (**fig. 4**);
d. while holding the legs of the valve guard by the left hand, turn the handle counter-clockwise at 90° with the right hand (**fig.5**);
e. remove the handle with the attached valve sutured to the holder through the guard slot (**fig.6**) and handover to the surgeon.

5.9 Precautions during valve handling:
- avoid any contact of the valve with the substances which can cause postoperative thromboembolism or negative reactions in human organism;
- avoid any contact of the valve with mechanical and abrasive materials which can damage polished surfaces of the valve;
- do not apply any force to the valve that could break or deform it;
- the use of a valve that accidentally has been dropped on the table or on the floor is prohibited.

6 RECOMMENDATIONS FOR IMPLANTATION

6.1 Because of the diversity and complexity of each case, the used surgical techniques and valve suturing method, as well as pre- and postoperative therapy, are up to the surgeon.
However, the directions below, which take into account the specifics of the valve design and clinical experience, support the surgeon to avoid possible complications caused by inappropriate valve handling.

6.2 During valve handling hold the valve only by the special valve holder and the handle. The flexible part of the handle may be bent considering the anatomical peculiarities.

ATTENTION! IT IS NOT ALLOWED TO BEND THE HANDLE WHILE SEIZING THE PROSTHESIS, THE HOLDER OR THE ACCESSORY!

6.3 The compulsory rotation of the leaflets around the longitudinal valve axis requires that special care must be taken to ensure free movement of leaflets in any position. The surgeon must assure that the valve leaflets are free from contact with surrounding structures. Therefore:

- carefully prepare area where the valve will be positioned;
- carefully check the inner chambers of the heart for remaining abnormal pathology;
- determine accurately tissue annulus size using the valve sizers.

Due to high hemodynamic efficiency of the valve there is no need to use a valve with bigger tissue annulus diameter.

ATTENTION! WHEN IN DOUBT, USE A VALVE WITH SMALLER TISSUE ANNULUS DIAMETER!

ATTENTION! PRIOR TO VALVE SUTURING YOU SHOULD CHECK THAT THE VALVE IS SUTURED TO THE HOLDER CORRECTLY.
AORTIC PROSTHETIC VALVE (ADM) SHOULD ENTER THE TISSUE ANNULUS WITH THE VISIBLE CONCAVE SURFACES AND CONTACT PLANE OF THE LEAFLETS
MITRAL PROSTHETIC VALVE (MDM) SHOULD ENTER THE TISSUE ANNULUS WITH CONVEX SEMI-CIRCULAR SURFACES OF THE LEAFLETS

6.4 You can use continuous or interrupted suturing technique for suturing the valve into tissue annulus. The suture stitches should be placed on the flat annular part of the sewing cuff. In order to prevent any damage of the sewing cuff sutures attaching the cuff to valve housing, do not pass the needle close to the valve housing.

6.5 After positioning and suturing the valve into tissue annulus, but prior to tightening of the knots, the valve should be detached from the holder by cutting the suture located on the top surface of the holder support. Once the suture is cut, remove the holder with the handle from the valve (**fig.7**).

ATTENTION! MAKE SURE THAT SUTURE ENDS LEFT AFTER KNOT TIGHTENING ARE OF MINIMAL LENGTH SO THAT THEY CANNOT GET INTO THE VALVE ORIFICE!

ATTENTION! DURING AORTIC VALVE REPLACEMENTS MAKE SURE THAT THE VALVE HOUSING DOES NOT BLOCK THE CORONARY OSTIA.
ATTENTION! MOBILITY OF THE LEAFLETS SHOULD BE VERIFIED AFTER IMPLANTATION!

6.6 To verify leaflets mobility of the aortic valve take the handle previously used for valve holder and attach it to the test probe supplied inside the valve inner container by inserting the collet clamp of the handle into the opening of the test probe until it stops. Take out the test probe (**fig.8**). (Test probe marked as “A1” or “A2” depending on the valve size).

- align the plane of the test probe with the contact plane of the leaflets;
- place the test probe between the leaflets. The leaflets should come apart and open the valve;
- lift the test probe up. The leaflets should close the valve (**fig. 9**);
- align the plane of the test probe normal to the contact plane of the leaflets and shift the probe close to the orifice surface of the housing so that the surfaces forming V-protrusion contact the flat outflow surfaces of the leaflets;
- by applying little force move the test probe with the leaflets for some angle around the central axis of the valve;
- verify again that the leaflets open and close freely;
- by repeating the rotation of the leaflets around the central axis of the valve and verifying their free opening and closing make sure that there are no obstacles for leaflets mobility along the whole perimeter of the valve housing (**fig. 10**).

To verify leaflets mobility of the mitral valve take the handle previously used for valve holder and attach it to the test probe supplied inside the valve inner container by inserting the collet clamp of the handle into the opening of the test probe until it stops. Take out the test probe (**fig.8**). (Test probe marked as M).

- position the plane of the test probe normal to the contact plane of the leaflets;
- lower the test probe on the leaflets. The leaflets should pivot and close the valve;
- turn the handle with the leaflets for some angle around the central axis of the valve;
- lift the test probe up. The leaflets should pivot and open the valve (**fig.11**);
- repeat the rotation of the leaflets around the central axis of the valve and verify their free opening and closing to make sure that there are no obstacles for leaflet mobility along the whole perimeter of the valve housing (**fig.12**). After tightening of the knots at the sewing cuff verify visually that there are no sutures in the ori- fice area of the valve.

ATTENTION! IF ANATOMICAL PECULIARITIES OF THE CARDIAL CAVITY OR PATHOLOGICAL ANOMALIES DO NOT ENSURE FREE MOTION OF THE LEAFLET IN ANY POSITION THE VALVE SHOULD NOT BE APPLIED.

ATTENTION! DURING IMPLANTATION ANY CONTACT BETWEEN THE PROSTHETIC VALVE AND METAL OR HARD PLASTIC DRAINING CATHETER OR OTHER INSTRUMENTS MUST BE AVOIDED AT ALL TIME. DO NOT PASS DIAGNOSTIC CATHETERS THROUGH THE PROSTHESIS. THIS ACTION MAY CAUSE VALVE DAMAGE AND MAY LEAD TO LEAFLET ESCAPE. ANY ACTIONS DIRECTED TO THE VALVE MUST BE REASONABLE.

6.7 Anticoagulant therapy is recommended for all patients with the implanted prosthetic heart valves when they have no contraindications to this therapy.

6.8 The necessary information for the patient concerning, in particular, patient's pre- and postoperative behaviour should be given to the patient by the physician. This information is also given in patient's manual supplied by the manufacturer as an option.

6.9 Patient identification card on the self-addressed post card should be completed directly after the implantation and forwarded to your distributor. Patient identification card should be attached to the medical patient's history.

6.10 In case the sealed secondary and primary containers had been opened, but for some reason the valve was not implanted, the use of the valve is prohibited, please contact your local distributor.

ATTENTION! RESTERILIZATION OF THE VALVE AND ITS ACCESSORIES IS PROHIBITED!

ATTENTION! IF THE VALVE HAS BEEN IN CONTACT WITH BLOOD THE REUSE OF THE VALVE IS PROHIBITED!

Presterilization cleaning and sterilization of the valve within the medical facilities Is prohibited and will damage and contaminate the valve surfaces. The consequences of the prosthetic valve reuse may be: infection, immune reaction of rejection, thromboembolism and/or valve thrombosis.

7 MAGNETIC RESONANCE IMAGING (MRI) CONDUCTING

MRI with capacity 1,5 T conducted for patients with implanted prosthetic valves did not show negative effects. No valve influence on the surrounding structures and their images was found. Neither changes nor disorders in valve functioning were found.

8 CONDITIONS OF SUPPLY

The valve sutured to the holder is supplied in individual sterile inner blister container together with test probe. The inner blister container is placed in the outer blister container. The outer blister container is placed in a carton box together with instruction for use, post card for patient identification, four patient identification forms, two handles and two sizers which correspond to the tissue annulus diameter of the valve.

9 TRANSPORTATION AND STORAGE

9.1 The valve packaged in its original shipping package can be transported by all means of transport (at ambient temperature from –50°C to +50°C).

9.2 The valve should be stored in its original shipping package. The storage conditions should be clean, cool an dry, at
ambient temperature from +5°C to +40°C and relative humidity 80%.

10 STERILITY GUARANTEE

Sterility expiration date of the valve is shown on the valve label.

11 LIABILITY

CardiaMed B.V. cannot give implicit or explicit warranty on the quality of the results of implantation or on their effectiveness in the treatment of the disease due to many factors which are beyond its control such as the surgical implantation technique, the condition of the individual patient, the preoperative prosthetic valve handling, etc.
Therefore CardiaMed B.V. declines any liability for the consequences arising from the use of the prosthesis. Under no circumstances will CardiaMed B.V. be liable for any material or moral damage following the use of its products.
CardiaMed B.V. makes no warranty express or implied other than the warranty that the CardiaMed prosthetic heart valve conforms to CardiaMed prosthesis standard and international recommendations in this field and has been manufactured and packaged with proper care and with techniques that are regarded as best suitable given the present state of technology.

CardiaMed B.V.
Mandenmakerstraat 15B
5405 BJ Uden
The Netherlands

T +31 (0)413 37 85 54
E info@cardiamed.com
I www.cardiamed.com