

Instruction for Use of Mechanical Heart Valve Accessories Kit

1. Product name

General name: Mechanical Heart Valve Accessories Kit

Trade name: Triton™

2. Introduction

The Triton™ Mechanical Heart Valve Accessories Kit is used in conjunction with Comed B.V.'s Triton™ Prosthetic Heart Valve for the replacement of malfunctioning native or prosthetic aortic and/or mitral heart valves.

The Triton™ Mechanical Heart Valve Accessories Kit package includes the following items:

- 9 standard valve sizers, 7 Advanced Performance (AP) valve sizers
- 7 aortic end rotators, 7 mitral end rotators
- 1 handle
- 1 actuator
- 1 tray
- Instruction for Use

3. Indications for Use

3.1 Standard Valve Sizers (Fig.1)

The white handle Standard Valve Sizers are intended to aid the surgeon in the selection of the optimal size of Triton™ Standard Heart valves (aortic valve and mitral valve).

Using the cylindrical valve sizer which should pass through the annulus without resistance to determine appropriate valve sizing, and the corresponding valve size is indicated on the handle nearest the sizer head:

The metal rod between the sizer head and the handle is flexible, enabling easier positioning of the sizer head into the heart valve tissue.

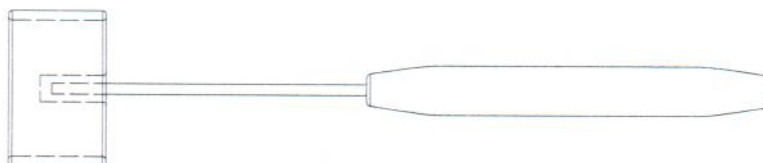


Fig.1 Standard valve sizer

3.2 AP Valve Sizers (Fig.2)

The blue handle AP Valve Sizers are intended to aid the surgeon in the selection of the optimal size of Triton™ AP Heart valves (aortic valve).

Using the cylindrical valve sizer which should pass through the annulus without resistance to determine appropriate valve sizing, and the corresponding valve size is indicated on the handle nearest the sizer head. Once the annular size has been determined, the flanged end of the sizer is used to mimic the placement of the sewing cuff. The flanged end of the sizer should not pass through the annulus.

The metal rod between the sizer head and the handle is flexible, enabling easier positioning of the sizer head into the heart valve tissue.

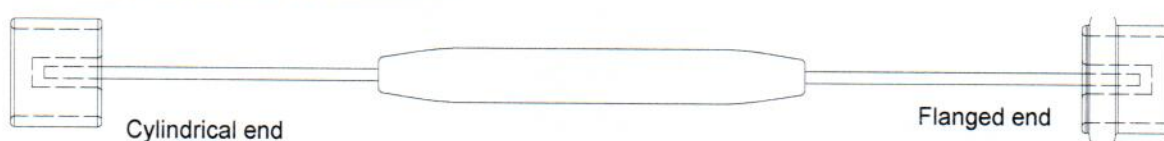


Fig.2 AP valve sizer

3.3 Rotators (Fig.3 and Fig.4)

Rotators are used to adjust the mechanical valve opening thus to optimize the direction of blood flow. Select the rotator with the same specification size as the valve. Screw the rotator on to the handle to connect securely. Insert the rotator into the mechanical valve already sutured in place. Now the opening position of the valve can be adjusted. Do not force the rotator as this may damage the heart valve tissue.

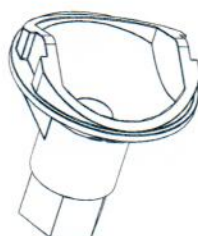


Fig.3 Aortic end rotator



Fig.4 Mitral end rotator

3.4 Actuator (Fig.5)

The free movement of the valve leaflet in mechanical valve can be tested by using the non-invasive, non-metallic actuator provided in the mechanical heart valve accessories kit. If the valve leaflet does not move freely due to tissue interference or suture impact, the valve should be rotated to a new position. Alternatively the obstruction should be removed to avoid the dysfunction.



Fig.5 Actuator

3.5 Handle (Fig.6)

The Handle is used to provide extra length and positioning options for the placement of heart valve. The metal shaft of the handle is flexible



Fig.6 Handle

The table below indicates the specifications for the sizer, rotator and mechanical heart valve.

Standard sizer		AP sizer		Aortic end rotator		Mitral end rotator	
Sizer	Valve	Sizer	Valve	Rotator	Valve	Rotator	Valve
19	19A/19M	16	16AP	19A	19A/16AP/16AF	19M	19M/16MP/16MF
21	21A/21M	18	18AP	21A	21A/18AP/18AF	21M	21M/18MP/18MF
23	23A/23M	20	20AP	23A	23A/20AP/20AF	23M	23M/20MP/20MF
25	25A/25M	22	22AP	25A	25A/22AP/22AF	25M	25M/22MP/22MF
27	27A/27M	24	24AP	27A	27A/24AP/24AF	27M	27M/24MP/24MF
29	29A/29M	26	26AP	29A	29A/26AP/26AF	29M	29M/26MP/26MF
31	31A/31M	28	28AP	31A	31A/28AP/18AF	31M	31M/28MP/28MF
33	33M	/	/	/	/	/	/
35	35M	/	/	/	/	/	/

Notice:

It is important that the native heart valve corresponds closely in size to the valve sizer head. The implantation of an incorrect mechanical valve size would result in complications and possible valve dysfunction.

Several factors could affect the selection of a mitral valve. The ratio* between the prosthetic valve and the heart chamber should be taken into account to avoid complications following the prosthetic valve implantation.

* The ratio is the amount of space of the prosthetic valve would occupy in the heart chamber after the implantation

4. Cleaning and Sterilization

Warning

The Triton™ Mechanical Heart valve Accessories Kit provided is NON-STERILE; it must be cleaned and sterilized prior to initial use and each reuse.

Notice:

When cleaning, avoid the use of solvent-based detergents such as disinfectors. A disinfectant solution may damage the components of Triton™ Mechanical Heart Valve Accessories Kit. Only surfactant cleaning agent and decontaminant are recommended.

4.1 Cleaning

The following manual cleaning and disinfection method is recommended.

- a) Rinse device with warm tap water and a hospital approved surfactant for a minimum of two (2) minutes.
- b) Scrub the device with a soft-bristled cleaning brush to remove all visible debris.
- c) Place the device in an ultrasonic bath containing enzymatic detergent prepared according to manufacturer's directions of the ultrasonic bath = for a minimum of five (5) minutes.
- d) After sonication, scrub the accessories using a cleaning brush to remove any remaining visible debris.
- e) Rinse device with warm tap water for a minimum of fifteen (15) minutes to remove detergent.
- f) Dry (according to Hospital standard) and package device to the tray for sterilization.

Misuse of these devices or improper techniques may result in damage. Inspect each device before use. The Triton™ Mechanical Heart Valve Accessories Kit should not be used if there are visible signs of cracking, deformation or other evidence of aging that may affect function. This is to the judgement of the user.

4.2 Sterilization

The sterilization of Triton™ Mechanical Heart Valve Accessories Kit should be performed according to the following recommended steam sterilization method:

Method	Minimum Temperature	Maximum Temperature	Minimum Time
Steam	250° F (121° C)	254° F (123° C)	15 minutes









5. Storage

After packaging, the product should be stored in a clean environment with a relative humidity of less than 80%, free of corrosive gas, and with a temperature between 5°C ~40°C.

6. Removal and disposal of the product

The removal and disposal of the product should only be performed by physicians who have received adequate training, conforming to ISO 12891-1 and local laws and regulations.

7. Explanation of symbols

Symbol	Description
	CATALOGUE NUMBER
	NON-STERILE
	DATE OF MANUFACTURE
	CAUTION
	KEEP AWAY FROM SUNLIGHT
	KEEP DRY
	CONSULT INSTRUCTION FOR USE
	MANUFACTURER

8. Manufacturer

 **COMED B.V.**

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9. DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

The product quality has been strictly inspected. Comed B.V. does not guarantee the success operation and undesirable consequences. Comed B.V. has no liability for any other expenses

or consequential losses incurred by using the products. The company disclaims any warranty, including any expressed or implied warranty, commercial warranty, and warranty for particular purpose.

Suggestion: Comed B.V. recommends adopting high pressure steam to sterilize but the number of steam cleans should not exceed one hundred (100) cleaning sessions.