AORTIC AND MITRAL VALVE METERS

Rev. 01 (01/20/2023)

Cód. 610369 D-1

1. Description of the Product

The heart valve meters are made of 304 stainless steel and are intended to assist the surgeon in procedures of heart valve replacement in aortic and mitral positions. They are reusable and its purpose is to assist the surgeon in determining the diameter of the annulus for defining the ideal size of the prosthesis to be implanted.

Accompanying the meter set is the holder cable, also made of 304 stainless steel, used to facilitate positioning of the valve prosthesis and fixation in the ring during implantation.

2. Presentation

Each set is supplied inside stainless steel 304 container and cardboard box containing 06 meters and 01 holder cable (Figure 1), with 03 units for aortic position and 03 units for mitral position with the following sizes:

Aortic: 19, 21, 23, 25, 27 and 29 mm.

Mitral: 25, 27, 29, 31, 33 and 35 mm.

METERS AND HOLDER CABLE ARE NOT PROVIDED STERILE AND MUST BE CLEANED AND STERILIZED BEFORE USE.

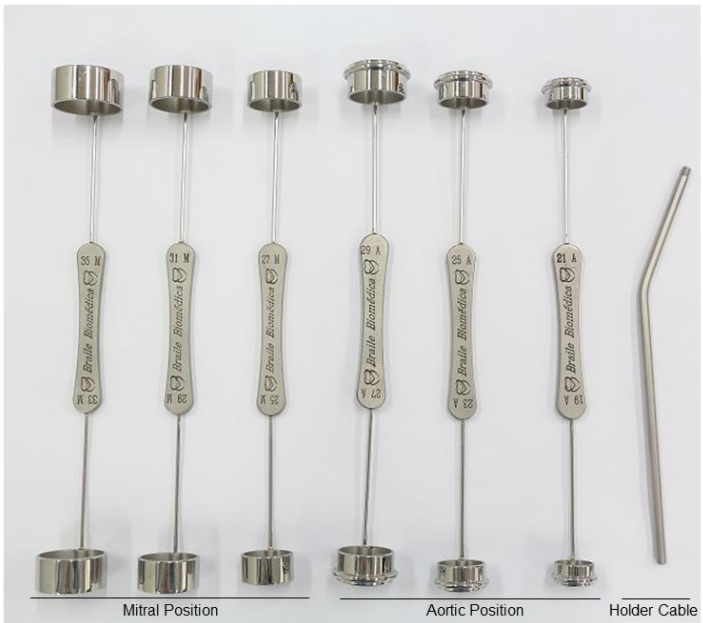

Figure 1. Meters for aortic and mitral positions, and holder cable.

1. Technical Specifications of the Meters

Schematic representation of the meters is shown in Figure 5 and their dimensions described in Table I.

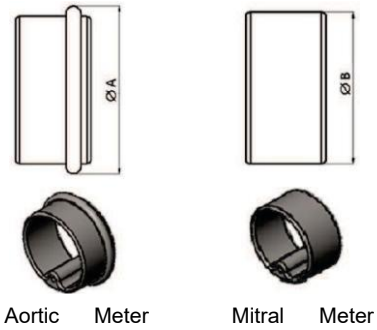

Figure 5. Technical drawing with specifications of aortic and mitral meters diameter.

Table 1. Technical specifications according to external diameter

Size	Aortic (mm)	Mitral (mm)
	ØA	ØB
19	22.0	-
21	24.5	-
23	26.5	-
25	29.0	25.0
27	31.0	27.0
29	33.0	29.0
31	-	31.0
33	-	33.0
35	-	35.0

3. Intended Purpose

The valve meters have the purpose of assisting the surgeon in determining the diameter of the annulus in procedures of heart valve replacement in aortic and mitral positions, defining the ideal size of the prosthesis to be implanted.

The holder cable is intended to facilitate the positioning of the valve prosthesis and fixation in the ring during implantation.

4. Contraindications

Use is contraindicated for the application of implants from other manufacturers or for a purpose other than that for which it was designed.

5. Clinical Benefits

The clinical benefit of Valve Meters is to ensure the implantation of a Braile Bioprosthesis with a diameter compatible with the patient's annulus.

6. Intended Patient Population

The Valve Meters can be use in adult patients, who have a medical indication for replacement of cardiac heart valves.

7. Adverse Events

The use of this medical device may cause: stimulation of localized inflammatory response associated to necrosis, localized toxicity, systemic impairment of metabolic and physiological functions; immune sensitization, hemolysis; thrombosis; thromboembolism, embolization, bacteremia; neurological complications; hemorrhagic or ischemic stroke; symptomatic infectious aneurysms; cerebral abscess; meningitis; toxic encephalopathy; convulsions; rise in the probability of cardiovascular and respiratory system compromise, death.

8. Warnings

- Meters and holder cable should be cleaned and sterilized before each use.
- Do not use the product in case of any evidence of damage, signs of deterioration and possible changes in the shape of its components.
- Although the meters are intended for multiple uses, replace them if surface deterioration occurs.
- Meters are only auxiliary tools to define the ideal diameter of the prosthesis, which is the responsibility of the surgeon.

9. Precautions

- Read the instructions before use.
- Check the integrity of the product before use to ensure its safe use.
- Product intended exclusively for medical use.
- Removing the prosthesis from holder (cutting attachment points) should be done with extreme care for preventing damage to surface of the bioprosthesis leaflets, which may lead to post-implant dysfunction.

- Once attached to holder, in aortic position, the holder cable should not be removed until the prosthesis has been implanted.

10. Instructions for Use

10.1. Cleaning and Sterilizing the Valve Meter Assembly Before Use

The Aortic and Mitral Heart Valve Meters are supplied non-sterile and must be sterilized before each use. Before sterilization, the device must be thoroughly cleaned. The cleaning/disinfection and sterilization procedures described were validated by Braile and proved to be effective. It is the hospital's responsibility to ensure, through process monitoring, that the cleaning and sterilization procedure is carried out, ensuring the effectiveness of the established method. Likewise, any deviation from the following instructions by the hospital must be duly assessed in relation to effectiveness and potential adverse consequences.

Cleaning/Disinfection

- Wash the contaminated device under running water to eliminate residue;
- Immerse the Kit in an enzymatic detergent solution diluted with purified water, according to the manufacturer's recommendations (1:1000), for 5 minutes;
- Remove the device from the enzymatic detergent solution and gently scrub each component with a non-abrasive brush for at least 30 seconds;
- Wash each component with at least 500 ml of purified water until the device is completely clean;
- Immerse the Kit in a neutral detergent solution diluted with purified water at a concentration of 20:1000 for at least 15 minutes;
- Remove the device from the neutral detergent solution and gently scrub each component with a non-abrasive brush for at least 30 seconds;
- Wash each component with at least 500 ml of purified water until the device is completely clean;
- Place the Valve Meters on a clean tray and take them to the drying oven at 100°C for 40 minutes;
- Pack and seal the Kit in surgical paper packaging to be used for sterilization.

Sterilization

Braile recommends that, after the Cleaning/Disinfection stage, the Valve Meters must be subjected to steam sterilization, with the following parameters: temperature of 132°C and exposure time of 10 minutes.

10.2. Use of Meters

To identify the diameter of the prosthesis to be used, the meter is inserted into the valve annulus tightly, but without resistance.

The decision to have an intra-annular or supra-annular implant rest exclusively with the surgeon responsible for the surgery.

Description of intra-annular and supra-annular measurements:

Intra-annular: To implant the aortic valve prosthesis in the intra-annular position, it is necessary to perform the measurement using Braile aortic valve meters. For this type of implant with the patient's aortic valve cusps properly removed along with the calcifications, the meter must fit inside the aortic annulus. When you obtain a meter that fits comfortably in the aortic valve annulus and does not obstruct the coronary ostia, nor in the aortic wall or the sinotubular junction, opt for this size of the aortic valve prosthesis.

Supra annular: To perform this implant, it is necessary to use the Braile aortic valve prosthesis meters. With the patient's aortic valve cusps removed along with the calcifications, position the meter over the aortic annulus, using the cylindrical part of the meter that replicates the valve prosthesis' sealing ring. Therefore, ensure that there is no obstruction of the coronary ostia and observe the relationship between the height of the valve and the wall of the aorta and the sinotubular junction.

10.3. Use of holder cable

Use only the set of meters and holder cable appropriate for the Bovine Pericardium Biological Valvular Prostheses. The use of other prosthesis meters may result in incorrect information to define the prosthesis dimensions.

- The prosthesis must be removed from the container by hand (Figures 2A and 3A)
- Using your hands, unscrew the holder support by turning it counterclockwise (Figures 2B and 3B).
- Fix the cable in the holder by turning it clockwise until the thread is complete (Figures 2C and 3C) to facilitate the positioning of the prosthesis in the implant site.
- Pass the suture threads through the valve prosthesis ring and suture the prosthesis (Figures 2D and 3D).

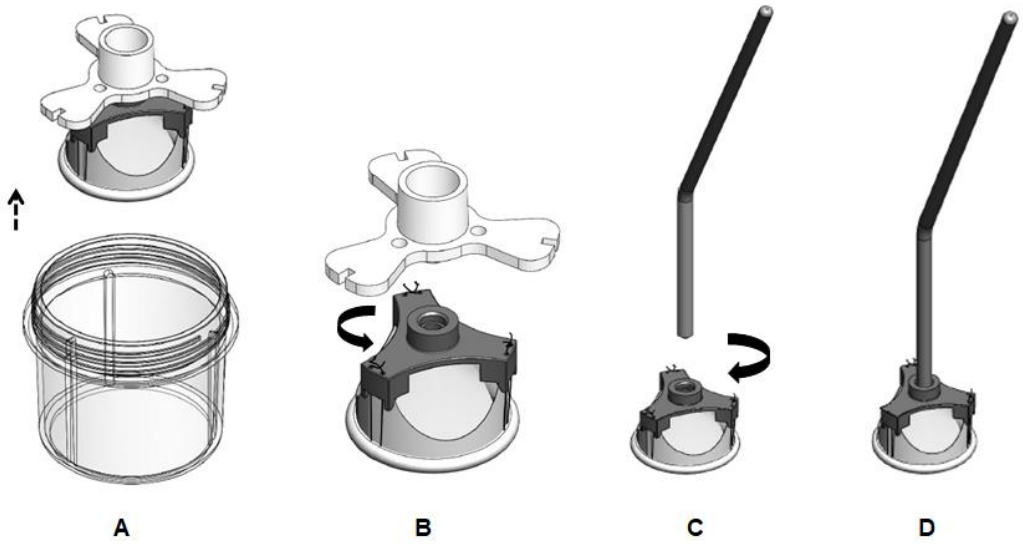

Figure 2. Schematic representation for removing the holder and prosthesis set from the packaging (A and B) and attachment of cable to holder (C and D) in aortic position.

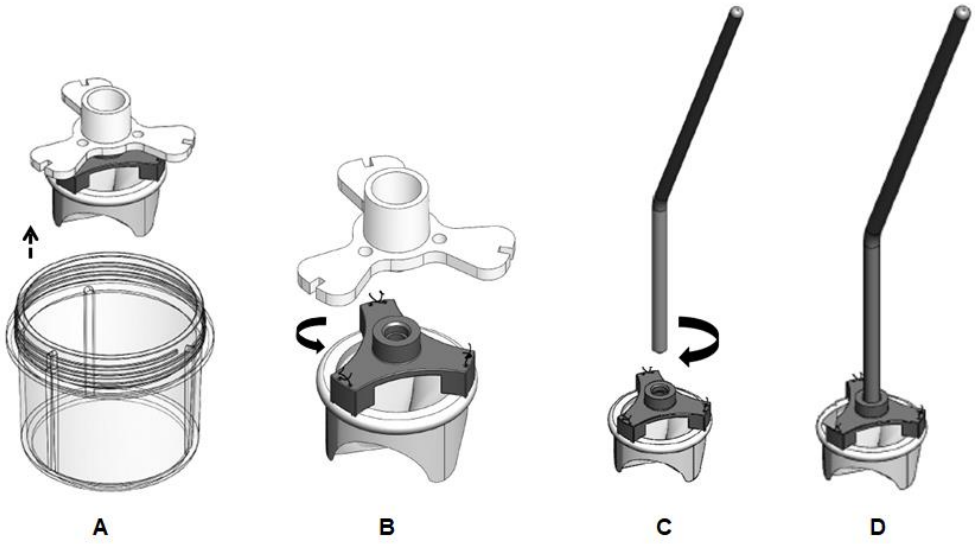

Figure 3. Schematic representation for removing the holder and prosthesis set from the packaging (A and B) and fixation of cable to holder (C and D) in mitral position.

After fixation of the implant in aortic or mitral position, the holder is removed along with the cable, cutting the three visible points that fix the prosthesis to the holder, Figure 4.

Figure 4. Schematic representation of cutting the attachment points of the prosthesis to holder for its removal with the aid of the holder.

Note: It is recommended that the meters and holder cable be cleaned after the end of the surgical procedure, avoiding the hardening of dirt resulting from this procedure. Cleaning must be standardized, avoiding the spread of contamination and damage to the instruments. The entire cleaning process must be carried out with the utmost care, avoiding falls and knocks that could compromise the meters. Any meter that has been dropped or suspected of having been damaged must be separated from the others.

11. Validity

The Heart Valve Meters are valid for ten years after first use, provided they have not been damaged in any way.

12. Packaging

The product is supplied in stainless steel 304 packaging and packed in cardboard box.

13. Storage and Transportation

Storage of the product should be performed in a clean, dry environment and protected from the elements.

The storage and handling conditions of the device must be followed to ensure that the components remain intact for the surgical procedure.

Heart Valve meters must be transported and handled carefully, avoiding knocks or falls, to prevent any damage or change in their characteristics.

14. Description of Symbols

BRAILE
LIFE-SAVING TECHNOLOGIES

	Consult instructions for use
	Non sterile
	Do not use if package is damaged
SN	Serial number
LOT	Batch code
	Date of manufacture
	Manufacturer
	Use by date
REF	Catalogue number
	Keep dry
	Stacking limit by number
	Recyclable
MD	Medical device
UDI	Unique device identifier
EC REP	Authorized representative in the European Community/European Union
CE 2797	Indicates that the product is in compliance with European legislation for medical devices

15. Label Template

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EC REP

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AORTIC AND MITRAL VALVE METERS

Description: XXXXXX

Package Content: 06 meters: 03 aortic, 03 mitral and 01 holder cable / 01 Instruction for Use

ANVISA Registration nº: 10159030105
Technical Name: Heart Valve Meter
Technician in Charge: Vladimir D. A. Ramirez – CRF-SP 09010

Non-sterile product

Sterilize before use

REF XXXXXX SN XXXXXX LOT XXXXXX

BR YYYY/MM/DD

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NON STERILE MD CE 2797

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