



TRICVALVE®

TRANSCATHETER BICAVAL VALVE SYSTEM

INDICATIONS FOR USE

The TricValve® Transcatheter Bicaval Valve System is a set of two self-expanding biological valves for the treatment of patients with hemodynamically relevant tricuspid insufficiency and caval reflux. The bioprosthesis are implanted percutaneously into the inferior and superior vena cava without disturbing the native tricuspid valve. It is especially intended for use in patients at extreme risk or who are inoperable for open surgical therapy.



DESCRIPTION

The TricValve® Transcatheter Bicaval Valve System is made of bovine pericardium leaflets sutured on a nitinol self-expanding stent system. The device is supplied sterile and is non-pyrogenic.

PACKAGING AND STORAGE CONDITION

The TricValve® Transcatheter Bicaval Valve System is packaged in a blister pack which is sealed in a double sealed Tyvek pouch and sterilized with ethylene oxide gas. The valve is pre-loaded inside the delivery system and covered with a protective capsule which is unsheathed for implantation. Store the TricValve® Transcatheter Bicaval Valve System in a dry area at room temperature (8°C to 25°C [46°F to 77°F]). Avoid exposing to extreme temperature fluctuations and direct contact with sunlight. Avoid freezing as it can damage the bioprosthesis.

WARNING: The outer surface of the sealed pouch is not sterile and therefore shall not come into contact with sterile field and instruments.

ORDER NUMBERS

| ORDER NO | PRODUCT NAME |
|--------------|--|
| CE-certified | |
| 1101020025 | TRICVALVE® TRANSCATHETER BICAVAL VALVE WITH DELIVERY SYSTEM FOR SVC 25 |
| 1101020029 | TRICVALVE® TRANSCATHETER BICAVAL VALVE WITH DELIVERY SYSTEM FOR SVC 29 |
| 1101020031 | TRICVALVE® TRANSCATHETER BICAVAL VALVE WITH DELIVERY SYSTEM FOR IVC 31 |
| 1101020035 | TRICVALVE® TRANSCATHETER BICAVAL VALVE WITH DELIVERY SYSTEM FOR IVC 35 |
| Non-CE | for Compassionate Use only |
| 1101020041 | TRICVALVE® TRANSCATHETER BICAVAL VALVE WITH DELIVERY SYSTEM FOR IVC 41 |

SIZES

| TRICVALVE® MODEL | VALVE SIZE | PROXIMAL DIAMETER | DISTAL DIAMETER | MAXIMAL DIAMETER | LENGTH AFTER DEPLOYMENT |
|------------------|----------------------------|-------------------|-----------------|------------------|-------------------------|
| CE-certified | | | | | |
| SVC 25 | 25 | 25 | 20 | 35 | 67 |
| SVC 29 | 29 | 29 | 20 | 40 | 70 |
| IVC 31 | 31 | 34 | 38 | 38 | 66 |
| IVC 35 | 35 | 38 | 47 | 47 | 66 |
| Non-CE | for Compassionate Use only | | | | |
| IVC 41 | 41 | 44 | 55 | 55 | 65 |

**TECHNICAL SPECIFICATIONS**

| MEDICAL DEVICE | TRICVALVE® TRANSCATHETER BICAVAL VALVE SYSTEM | |
|----------------------------|--|--|
| AVAILABLE SIZE | Superior vena cava: SVC 25; SVC 29 Inferior vena cava: IVC 31; IVC 35; IVC 41* | |
| TREATMENT RANGE | Superior Vena Cava SVC 25: 22mm<SVC<31mm SVC 29: 27mm<SVC<34mm | Inferior Vena Cava IVC 31: 24mm<IVC<31mm IVC 35: 28mm<IVC<35mm IVC 41*: 34mm<IVC<41mm |
| ACCESS ROUTE | Transfemoral Vein access to Inferior Vena Cava / Right Atrium | |
| STENT FRAME MATERIAL | Laser cut nitinol wireframe stent | |
| CAVAL VALVE DESIGN | Self-Expanding shape memory alloy valve | |
| FRAME HEIGHT | At relaxed state: SVC 25: 67mm SVC 29: 70mm | At relaxed state: IVC 31: 66mm IVC 35: 66mm IVC 41*: 65mm |
| DELIVERY SYSTEM | Dedicated TricValve® Delivery System | |
| VALVE DELIVERY METHOD | Pre-loaded valve in capsule delivered by unsheathing device | |
| BIOLOGICAL MATERIAL | Cross linked bovine pericardium with P+F proprietary dehydration and anti-calcification treatment. | |
| NUMBER OF LEAFLETS | 3 bovine pericardium leaflets sutured on nitinol frame | |
| DEHYDRATION PROCESS | P+F proprietary process (Chemical dehydration) | |
| ANTI-CALCIFICATION PROCESS | P+F proprietary process (Lipid reduction; oxidative treatment; calcium chelating) | |
| REHYDRATION MEDIUM | Physiological saline solution | |
| PVL PROTECTION | Polyester skirt sewn on nitinol frame | |
| DELIVERY SYSTEM LENGTH | 865±5mm (usable length) | |
| GUIDEWIRE COMPATIBILITY | 0.035in (0.89mm) x 260cm or 300cm Super/Extra Stiff Guidewire | |
| MRI CONDITIONAL | Yes | |
| STERILIZATION | Ethylene oxide sterilization | |
| PACKAGING CONDITION | Blister in double Tyvek pouch and cardboard box | |
| STORAGE CONDITION | Store between 8 to 25°C [46,4 to 77°F]. Do not freeze. | |

* Non-CE Device, Available for Compassionate Use only.

**Legal Manufacturer:**P+F Products + Features GmbH
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Prior to using the devices please consult the instructions for use. Implantation of TricValve® Transcatheter Bicaval Valves should only be performed by physicians who have received or undergone P+F Products + Features GmbH Training on usage of device.