



TRICVALVE®

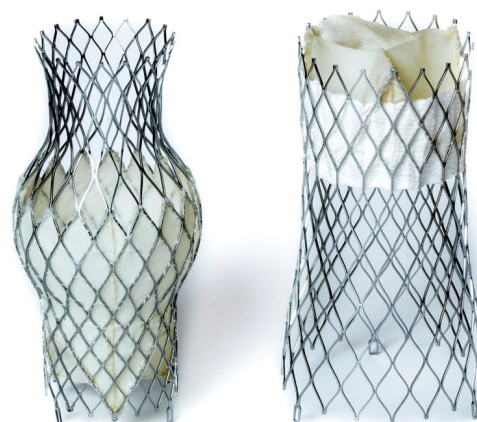
TRANSCATHETER BICAVAL VALVES SYSTEM

INDICATIONS FOR USE

TricValve® Transcatheter Bicaval Valves is a system 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 Valves 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 Valves 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 Valves 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.

RE-ORDERING NUMBERS

RE-ORDER NO	IDENTIFY
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 certified	
1101020033	TRICVALVE® TRANSCATHETER BICAVAL VALVE WITH DELIVERY SYSTEM FOR SVC 33
1101020041	TRICVALVE® TRANSCATHETER BICAVAL VALVE WITH DELIVERY SYSTEM FOR IVC 41
1101020045	TRICVALVE® TRANSCATHETER BICAVAL VALVE WITH DELIVERY SYSTEM FOR IVC 45

SIZES

TRICVALVE® MODEL	VALVE SIZE	PROXIMAL DIAMETER	DISTAL DIAMETER	MAXIMAL DIAMETER	LENGTH AFTER DEPLOYMENT
CE certified					
SVC 25	25	25	20	35	66
SVC 29	29	29	20	40	69
IVC 31	31	34	38	38	65
IVC 35	35	38	47	47	65
NON CE certified					
SVC 33	33	33	20	45	72
IVC 41	41	44	55	55	65
IVC 45	45	49	60	60	70

**TECHNICAL SPECIFICATIONS**

MEDICAL DEVICE	TRICVALVE® TRANSCATHETER BICAVAL VALVES SYSTEM	
AVAILABLE SIZE	Superior vena cava: SVC 25mm; SVC 29mm; SVC 33mm Inferior vena cava: IVC 31mm; IVC 35mm; IVC 41mm; IVC 45mm	
TREATMENT RANGE	Superior Vena Cava SVC 25: 22<SVC<31 SVC 29: 27<SVC<34 SVC 33: 33<SVC<39	Inferior Vena Cava IVC 31: 24<IVC<31 IVC 35: 28<IVC<35 IVC 41: 34<IVC<41 IVC 45: 38<IVC<45
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: 69mm SVC 33: 72mm	At relaxed state: IVC 31: 65mm IVC 35: 65mm IVC 41: 65mm IVC 45: 70mm
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	Normal saline	
PVL PROTECTION	PTFE skirt sewn on nitinol frame	
DELIVERY SYSTEM LENGTH	870 mm ± 10 mm	
GUIDEWIRE COMPATIBILITY	0.035in (0.89mm) x 260 or 300cm Super/Extra Stiff Guidewire	
MRI CONDITIONAL	Clinical testing shows bicaval valve is MRI conditional.	
STERILIZATION	Ethylene oxide sterilization	
PACKAGING CONDITION	Blister pack in a Tyvek pouch	
STORAGE CONDITION	Store between 8 to 25°C [46,4°F to 77°F]. Do not freeze.	

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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.