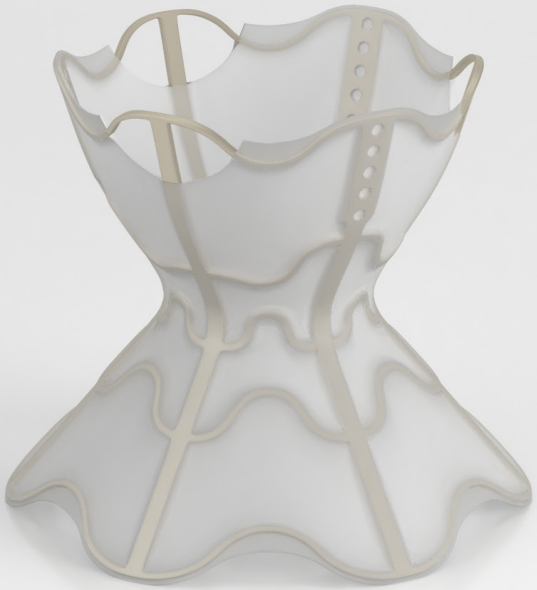
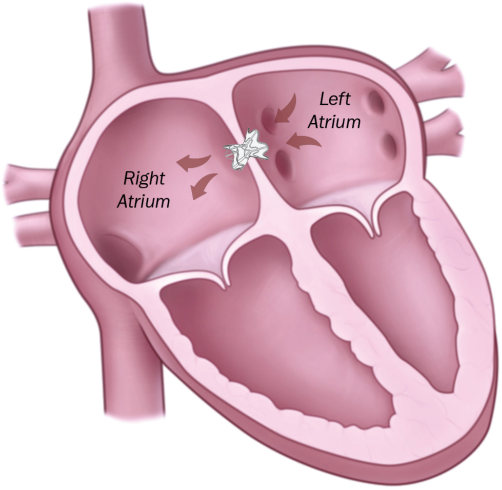
V-WAVE

Ventura®

Interatrial Shunt System





Designed to Reduce Left Atrial Pressure (LAP)

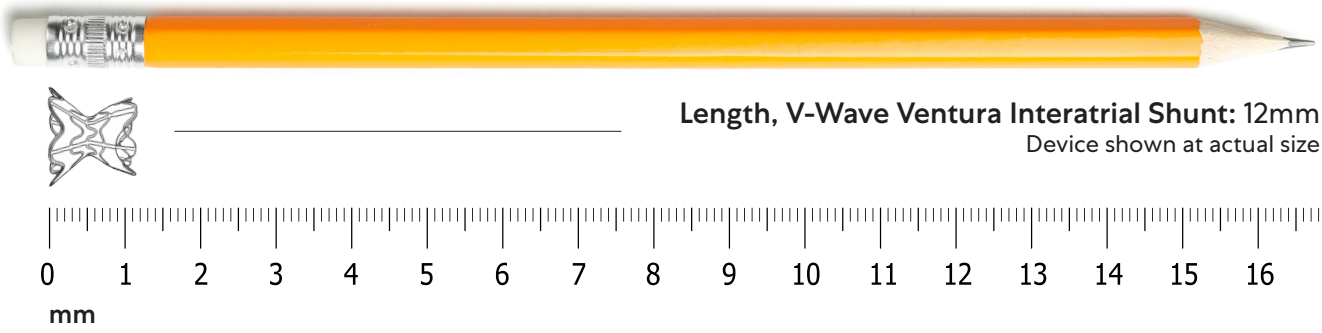
Indicated for Use with adult patients with NYHA Class III and ambulatory Class IV symptoms Heart Failure (HF) with reduced or preserved left ventricular systolic function.

Designed for Venturi Dynamics

- Novel hourglass design for creating *venturi tube* effect from the left atrium to right atrium through a ~5mm neck diameter orifice
- Shunt flows away blood from left side as patient pressures increase

Novel Design Features

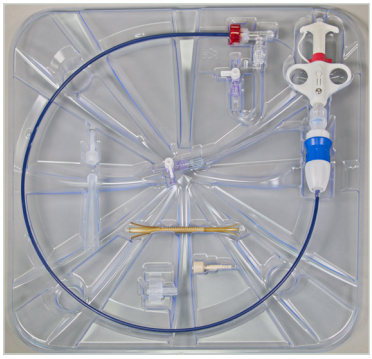
- Hourglass frame designed to securly anchor the shunt to the fossa ovalis, preventing migration or embolization of the shunt
- Biocompatible ePTFE encapsulation designed to limit tissue growth and maintain device patency



Length, V-Wave Ventura Interatrial Shunt: 12mm
Device shown at actual size

V-Wave Ventura Interatrial Shunt System

V-Wave Ventura Interatrial Shunt



V-Wave Ventura Delivery System

Technical Specifications:

Device Composition	• **Nitinol frame** • **ePTFE** (expanded Polytetrafluoroethylene) **encapsulation**
Implant Dimensions	• **Delivery Profile:** minimum 14F • **Device length:** 12mm • **Maximum width:** 14mm (Left Atrium); 11mm (Right Atrium) • **Inner (neck) diameter:** approximately 5mm
Implantation Procedure and Required Equipment	**Transfemoral venous access with transseptal puncture** • **Delivery System:** V-Wave Ventura Delivery System with included Shunt Loading Tools • **Device Introducer:** 14F sheath (provided)

CAUTION: for professional use only. Consult the Instructions for Use for a listing of indications, contraindications, precautions, warnings, and potential adverse events. V-Wave devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Material not intended for distribution in the United States.

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