Reducer System

A Percutaneous Treatment Option for Patients with Refractory Angina

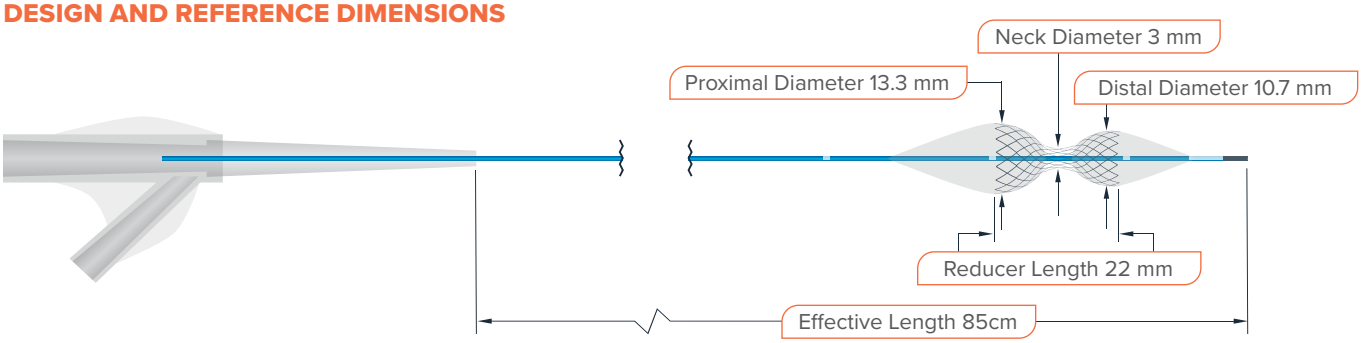
SHOCKWAVE REDUCER

Shockwave Reducer Device is designed to create a permanent, controlled narrowing of the coronary sinus to treat symptoms of refractory angina. Reducer is a seamless tubular mesh design, made of surgical grade stainless steel.

The single model conforms to the range of anatomical configurations and sizes characteristic of most patients.
Reducer is pre-mounted on a semi-compliant Balloon Catheter and the final Reducer implant profile is dependent on the inflation pressure of the delivery balloon.

Reducer Balloon Catheter is an over-the-wire design with a unique hour glass shape deployment balloon. The proximal and distal portions of the balloon have differing diameters to conform to the tapered typical anatomy of the coronary sinus (CS).

DESIGN AND REFERENCE DIMENSIONS



Average diameters at 4 atm

REDUCER ORDERING INFORMATION

Product Name	Catalogue #	Reducer Length (mm)	Outer Diameter (pre-mounted Reducer OD mm)
Reducer System	R1385CEV	22.0 mm	2.45mm

REDUCER SYSTEM KIT COMPONENTS

Quantity	Content
1	Reducer Pre-mounted on a Reducer Balloon Catheter (Model # RED-001)
1	9F Straight Guiding Catheter (Cordis Vista Brite Tip 55cm Ref# 598-943p)
1	9F Rotating Hemostasis Valve (Y-connector) (Merit AccessPLUS, K12-10979)

GENERAL PRODUCT SPECIFICATIONS

Reducer	Surgical grade, 316L stainless steel
Balloon material	Pebax 7233 SA01 MED
Balloon rated burst pressure	6 atm
Balloon marker bands	Platinum-Iridium (90%/10%)
Catheter material	Pebax 7233 SA01 MED
Hemostatic valve material	Polycarbonate
Guiding catheter compatibility	9F Cordis Vista Brite Tip or 9F Boston Acuity Pro

Guide wire compatibility	0.035” Standard J-Tip
Method of sterilization	Ethylene oxide gas
Shelf life	24 months
Single product use	Do not reuse or resterilize

INDICATIONS/INTENDED USE The Reducer System is intended for patients suffering from refractory angina pectoris despite guideline directed medical therapy, who are unsuitable for revascularization by coronary artery bypass grafting (CABG) or by percutaneous coronary intervention (PCI).

CONTRAINDICATIONS The Reducer is contraindicated for use in patients with recent (within 3 months) acute coronary syndrome, recent (within 6 months) PCI revascularization by stent or CABG, recent (within 30 days) unsuccessful PCI, unstable angina (recent onset angina, crescendo angina, or rest angina with ECG changes) during the last 30 days, decompensated congestive heart failure (CHF) or hospitalization due to CHF during the last 3 months, left ventricular ejection fraction of less than 30%. For a full list, refer to the product Instructions for Use (IFU) at https://ifu.neovasc.com.

WARNINGS AND PRECAUTIONS FOR SINGLE USE ONLY. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, and/or resterilization creates a risk of contamination of the device and/or failure which could cause patient injury, illness or death. Note product “Use By” date. Sterilized with ethylene oxide gas.

Placement of the Reducer should only be attempted at a location in the proximal segment of the CS, 2-4cm distal to the ostium, where the CS diameter is measured to be between 13mm and 9.5mm. Failure to comply may lead to CS dissection and/or perforation or Reducer migration and may result in patient death.

CAUTION In the United States, Shockwave Reducer is an investigational device, limited by United States law to investigational use.

The Reducer is subject of Investigational testing and is being studied in the COSIRA-II trial in Canada. The Reducer is commercially available in certain countries outside the U.S. and Canada.

Please contact your local representative for specific country availability.

Prior to use please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events: ifu.neovasc.com.

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