SHOCKWAVE C2 AERO

SHOCKWAVE C2 AERO DELIVERS

Shockwave C2 Aero Offers Improved Deliverability and Crossability[1]

Designed to be More Deliverable[1]

A redesigned shaft and more flexible marker bands enable improved delivery

Created to Cross[2]

Shorter, more tapered tip and new 25cm hydrophilic coating on the distal shaft allow for better crossability

Remodeled for Repositioning[3]

More flexible balloon material designed for more compact rewrap

1. Compared to Shockwave C2+ in simulated use bench testing. Based on feedback from physicians who participated in the Limited Market Release Survey
2. Designed with more tapered tip and new hydrophilic coating compared to Shockwave C2+
3. Designed with more flexible material compared to Shockwave C2+

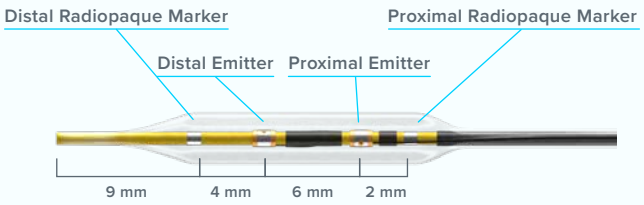
Johnson&Johnson MedTech

SHOCKWAVE MEDICAL

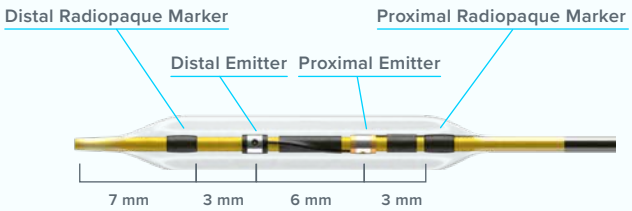
EQUIDISTANT EMITTER PLACEMENT

Similar Size and Dimensions as Shockwave C2+

SHOCKWAVE C2+



SHOCKWAVE C2 AERO

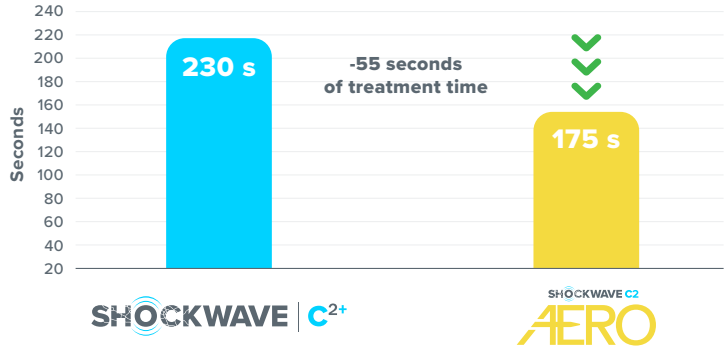


The distal and proximal emitters were shifted 1 mm forward for equal distance between emitters and marker bands

The distal emitter is also 3 mm closer to the tip on Shockwave C2 Aero as compared to Shockwave C2+

THE WAIT IS OVER

More Efficient Pause Time[1]



WHAT THIS MEANS FOR YOU

SHOCKWAVE C2 AERO **has a five second pause time,**

compared to ten second pause time of SHOCKWAVE C2+

Overall Treatment Time Cut by 24%[1]

1. Assuming one catheter is used in the procedure. Follow IFU.

NEW CATALOG NUMBERS FOR SHOCKWAVE C2 AERO

Catalog Number	Diameter (mm)	Length (mm)	Pulses (Max)	Guidewire Compatibility (in)	Guide Catheter Compatibility	Working Length (cm)	Tip Profile (in)	Max Crossing Profile (in)
C2AIVL2512	2.5	12	120	0.014	6F	138	.022	0.044”
C2AIVL3012	3.0	12	120	0.014	6F	138	.022	0.045”
C2AIVL3512	3.5	12	120	0.014	6F	138	.022	0.045”
C2AIVL4012	4.0	12	120	0.014	6F	138	.022	0.047”

Coronary IVL Safety Information

In the United States: Rx only. Indications for Use— The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C2+ and Shockwave C2 Aero Catheter is indicated for lithotripsy- enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting. **Contraindications—** The Shockwave C2+ and Shockwave C2 Aero System is contraindicated for the following: This device is not intended for stent delivery. This device is not intended for use in carotid or cerebrovascular arteries. **Warnings—** Use the IVL Generator in accordance with recommended settings as stated in the Operator’s Manual. The risk of a dissection or perforation is increased in severely calcified lesions undergoing percutaneous treatment, including IVL. Appropriate provisional interventions should be readily available. Balloon loss of pressure was associated with a numerical increase in dissection which was not statistically significant and was not associated with MACE. Analysis indicates calcium length is a predictor of dissection and balloon loss of pressure. IVL generates mechanical pulses which may cause atrial or ventricular capture in bradycardic patients. In patients with implantable pacemakers and defibrillators, the asynchronous capture may interact with the sensing capabilities. Monitoring of the electrocardiographic rhythm and continuous arterial pressure during IVL treatment is required. In the event of clinically significant hemodynamic effects, temporarily cease delivery of IVL therapy. **Precautions—** Only to be used by physicians trained in angiography and intravascular coronary procedures. Use only the recommended balloon inflation medium. Hydrophilic coating to be wet only with normal saline or water and care must be taken with sharp objects to avoid damage to the hydrophilic coating. Appropriate anticoagulant therapy should be administered by the physician. Precaution should be taken when treating patients with previous stenting within 5mm of target lesion IVL pulses may potentially interfere with certain implanted electrical devices (e.g., ventricular support systems). **Cautions–** C2 and C2+ should not be re-inserted once they are pulled out of the patient’s body. C2 Aero may be re-inserted up to 3 times in the same patient when used in accordance with the IFU. **Potential adverse effects consistent with standard based cardiac interventions include–** Abrupt vessel closure - Allergic reaction to contrast medium, anticoagulant and/or antithrombotic therapy- Aneurysm-Arrhythmia-Arteriovenous fistula-Bleeding complications-Cardiac tamponade or pericardial effusion- Cardiopulmonary arrest-Cerebrovascular accident (CVA)- Coronary artery/vessel occlusion, perforation, rupture or dissection-Coronary artery spasm-Death-Emboli (air, tissue, thrombus or atherosclerotic emboli)-Emergency or non- emergency coronary artery bypass surgery-Emergency or non- emergency percutaneous coronary intervention-Entry site complications-Fracture of the guide wire or failure/malfunction of any component of the device that may or may not lead to device embolism, dissection, serious injury or surgical intervention- Hematoma at the vascular access site(s)-Hemorrhage- Peripheral Ischemia-Pseudoaneurysm-Renal failure/insufficiency-Restenosis of the treated coronary artery leading to revascularization-Shock/pulmonary edema-Slow flow, no reflow, or abrupt closure of coronary artery-Stroke-Thrombus- Vessel closure, abrupt-Vessel injury requiring surgical repair- Vessel dissection, perforation, rupture, or spasm. **Risks identified as related to the device(s) and its use:** Allergic/immunologic reaction to the catheter material(s) or coating-Device malfunction, failure, or balloon loss of pressure leading to device embolism, dissection, serious injury or surgical intervention-Atrial or ventricular extrasystole-Atrial or ventricular capture. **Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events.** www.shockwavemedical.com/IFU. Please contact your local Shockwave representative for specific country availability and refer to the Shockwave C2 Aero instructions for use containing important safety information.