Shockwave IVL's Pioneering Mechanism of Action: Unique Acoustic Waveform, Consistent Output

A closer look at Shockwave™ IVL's unique acoustic waveform and its circumferential, longitudinal, and pulse-to-pulse consistency.

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Intravascular lithotripsy (IVL) is the energy-based production of ultrasonic acoustic pressure waves for the modification, fracture, and fragmentation of vascular calcification. Since its commercial introduction in 2017, Shockwave IVL (Shockwave Medical, now a part of J&J Med Tech) has become the preferred treatment strategy among physicians treating calcific peripheral artery disease. An underappreciated aspect of Shockwave IVL is its mechanism of action, which consists of a tuned acoustic waveform and a consistent ultrasonic acoustic output that mechanistically explain Shockwave IVL's clinically validated predictable safety and consistent efficacy.[1] This mechanistic foundation is likely to become a critical point of differentiation as new IVL technologies come to market with similar-looking platforms.

SHOCKWAVE'S ACOUSTIC WAVEFORM: TUNED TO PRIORITIZE SAFETY WITHOUT TRADEOFFS FOR EFFICACY

Prior to the commercialization of its first device, Shockwave Medical spent nearly a decade tuning ultrasonic acoustic pressure waves, originally used for kidney stone management, for use in the arterial space. Shockwave IVL modifies calcium through the energy-based production of Shockwaves, which are a specialized form of ultrasonic acoustic pressure waves tuned to prioritize safety without tradeoffs for efficacy. Shockwave's acoustic pressure waveform consists of a very fast transition and high-amplitude positive peak pressure, which is responsible for creating compressive, shear, squeezing, and other forces that modify calcium, followed by a low-amplitude, negative peak pressure that minimizes soft tissue damage from tensile stress (Figure 1).[2] Shockwave IVL's unique and published acoustic waveform is a key component to its robust and growing body of clinical evidence of > 25,000 published patient outcomes across > 600 journals, demonstrating predictable safety and consistent efficacy.[3]

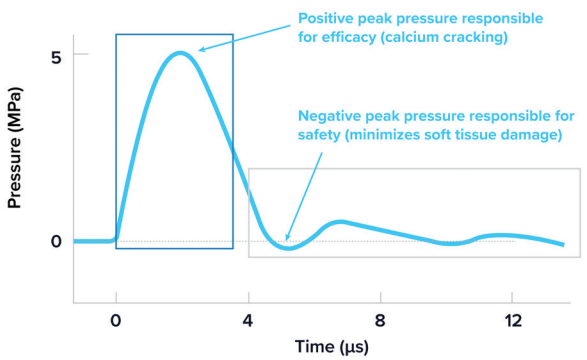

Figure 1. Shockwave IVL's unique acoustic pressure waveform is tuned to prioritize safety without tradeoffs for efficacy across all products.

SHOCKWAVE IVL'S CIRCUMFERENTIAL ENERGY DELIVERY

Shockwave IVL's catheter design consists of a series of emitters with two 180° spaced spark gaps per emitter.

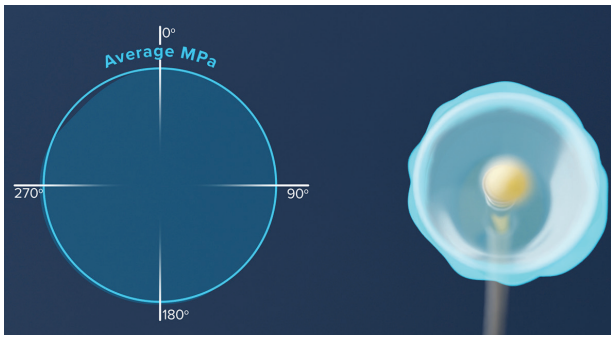

Figure 2. The ultrasonic acoustic output of the spherical Shockwave field is distributed circumferentially around the balloon edge.

Energy travels from the generator and is delivered at the spark gaps, launching two initial Shockwaves (one per spark gap) that merge to create a spherical pressure field around each emitter. The ultrasonic acoustic output of the spherical Shockwave produced is distributed circumferentially around the balloon edge, lacking dead zones or areas with an acoustic output less than the threshold to modify calcium (Figure 2).[4] Shockwave IVL's emitter design prioritizes device delivery and crossing performance while maintaining clinical efficacy across all types of calcium.[5,6]

SHOCKWAVE IVL'S LONGITUDINAL ACOUSTIC OUTPUT AND PULSE-TO-PULSE CONSISTENCY

Shockwave IVL devices consist of strategically placed, tandem-firing emitters that ensure a consistent acoustic output along the length of the device to disrupt calcium regardless of where it is located along the catheter. While the area of highest acoustic output is adjacent to the emitters, the acoustic output of Shockwave E8, Shockwave's 80-mm device for calcific disease above and below the knee, is measured to be therapeutic along the balloon edge and clinically relevant up to 6 mm away from the emitter, allowing for the modification of superficial, deep, and medial calcification (Figure 3).[7]

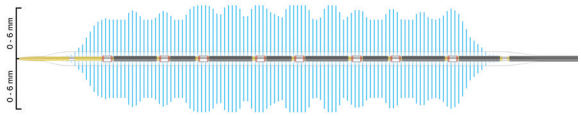

Figure 3. Shockwave E8's acoustic output is therapeutic along the balloon edge and clinically relevant up to 6 mm away from emitters.

One pulse from a Shockwave IVL device activates two emitters in tandem, producing two spherical Shockwaves per pulse. The benefits of Shockwave IVL's tandem-firing emitters are twofold. First, the simultaneously produced Shockwaves intersect between the tandem-firing emitters at the balloon edge, resulting in shock-shock interaction. Shock-shock interaction facilitates a more constant acoustic pressure across the balloon edge as compared to independent-firing emitters.[8] Secondly, tandem-firing emitters maximize treatment capability. Because two Shockwaves are created with each pulse, Shockwave E8's 400 available pulses per catheter provide physicians 800 Shockwaves for modification fracture and fragmentation of calcification. Moreover, these 800 Shockwaves provide a consistent acoustic output from the initial to last Shockwaves available with 98% to 102% WavePower consistency (Figure 4).[9,10]

WHY THIS MATTERS FOR THE FUTURE STATE OF IVL

Shockwave IVL's clinically validated safety and consistent efficacy are rooted in the fundamentals of its mechanism of action: a tuned acoustic waveform designed to modify calcium while protecting soft tissue, circumferential energy delivery without dead zones, longitudinal treatment coverage along the catheter, and pulse-to-pulse consistency

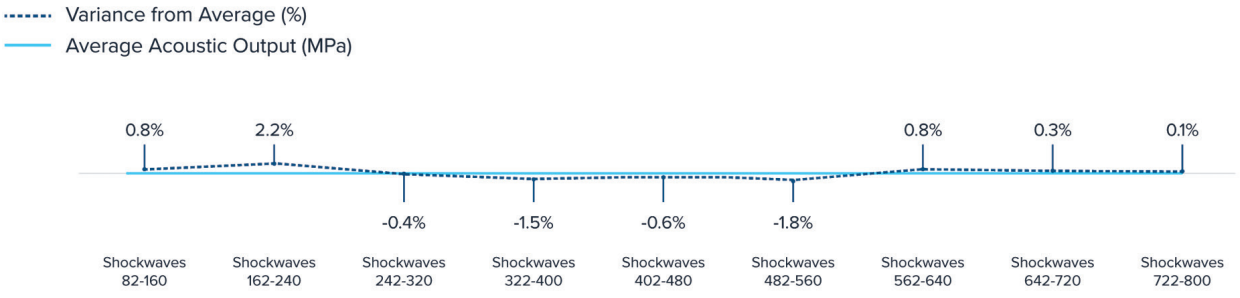

Figure 4. The acoustic output of the 800 available Shockwaves from Shockwave E8 are consistent from the initial to last Shockwaves available.

from the initial to last Shockwaves available per catheter. Together, these features help explain Shockwave IVL's reliable performance and consistent efficacy within real-world patient populations and complex lesion types.[11] Finally, Shockwave IVL is committed to continuing to earn its innovative disruptor reputation by building upon its clinically validated mechanistic foundation and advancing future IVL solutions across new indications and disease states to benefit physicians and, ultimately, the patients they treat. ■

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10. Data on file, Shockwave Medical. Wavepower consistency is a percent of the average acoustic output of Shockwaves per cycle / average acoustic output of total Shockwaves.
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