MAVERA®
medical devices

REWAY™

Ultrasonic Chronic Total Occlusion System

C R P™

Compression Rarefaction Programmable Technology

MAVERA®
Surgery

“A superior intravascular surgical method going beyond just ‘recanalize ‘the peripheral chronic total occlusions.”

Reway™ Ultrasonic Chronic Total Occlusion System

A Revolutionary Device Offering Better Results

- **Plaque Ablation Selectivity**

Mechanism of Action

Reway™ Ultrasonic Chronic Total Occlusion System is intended to be used in selectively for fragmentation, emulsification, resection, irrigation and/or aspiration of hard tissue (e.g., calcified lesion) in peripheral vasculatures. The CTO crossing mechanism of Reway™ Ultrasonic Chronic Total Occlusion System is a combination of mechanical vibration and cavitation. Mechanical fragmentation is caused by the high-frequency vibration of the Reway™ tip impacting the calcified plaque. The tip of the probe vibrates a distance of approximately 20-50 µm at 20-36,000 cycles per second. This type of low-amplitude and high-frequency mechanical vibration enables the catheter tip to act like a vibrational “jackhammer” and ablate the calcified plaque into particles that are carried away by the bloodstream.

Principle of Operation

System consists of an ultrasound generator, a piezoelectric converter which is used to transform the electricity into ultrasound by piezoelectric ceramic and an element which is used for conducting the ultrasound from the Ultrasonic Piezo Handle to the probe. Generator works with mains electricity (AC current) that produces high-frequency electric current, typically converted into vibration energy within the hand grip. An Ultrasonic Piezo Handle located in a hand grip allows the catheter which is a disposable device to open a channel in the CTO during intravascular surgery by converting the high-frequency current into vibration energy. Typically, it includes a metal wire core (e.g., Stainless Steel) which transfers mechanical energy to the distal end, and a proximal dispensing center with integrated irrigation / suction ports. Also, this device can be operated with a foot switch and may include an integrated suction / aspiration system.

1) Plaque Ablation Selectivity

The most distinctive feature of therapeutic ultrasound-based CTO recanalization is plaque ablation selectivity. Specifically, tissues with high collagen and elastin content are extremely resistant to ultrasonic disruption; however, tissues lacking these components can be very susceptible to disruption. In 1965, Anschuetz and Bernard concluded that normal and atherosclerotic arterial tissue were more resistant to damage than other tissue types. Other early researchers observed that ultrasound destroys atherosclerotic plaque but leaves the adjacent vascular wall relatively unaffected. Ernst investigated this theory further to determine whether high-intensity ultrasound could discriminate between fibrous or calcified plaque and normal arterial wall. The results of the study showed that ultrasonic disruption is inversely related to tissue elasticity—the time to perforate cadaveric arterial wall sites was significantly longer than the fibrous or calcified plaque sites.[1-3]

Indications

Reway™ Ultrasonic Chronic Total Occlusion System is indicated for using selectively for fragmentation, emulsification, resection, irrigation and/or aspiration of hard tissue (e.g., calcified lesion) in peripheral vasculatures. It assists in recanalization of peripheral chronic total occlusions in intravascular surgery by delivering ultrasound energy into totally occluded calcified lesion in the peripheral vasculature. It helps intralumen placement of guidewire through peripheral vasculatures.

PRODUCT LIST
Ultrasonic Generator with Integrated Irrigation Pump (Non-Sterile, Reusable)
Foot Switch (Non-Sterile, Reusable)
Canister Holder Ring (Non-Sterile, Reusable)
Serum Hanger (Non-Sterile, Reusable)
Ultrasonic Piezo Handle (Aluminum) (Non-Sterile, Re-Sterilizable)
Ultrasonic Piezo Handle (Polyamide) (Non-Sterile, Re-Sterilizable)
Probe Torque Tool (Non-Sterile, Re-Sterilizable)
Sterilization Case (Non-Sterile, Re-Sterilizable)
Chronic Total Occlusion Catheter 150cm No Wire, 5Fr (Sterile, Single-Use)
Chronic Total Occlusion Catheter 150cm OTW, 5Fr (Sterile, Single-Use)
Chronic Total Occlusion Catheter 150cm Rx only, 5Fr (Sterile, Single-Use)
Chronic Total Occlusion Catheter 165cm No Wire, 5Fr (Sterile, Single-Use)
Chronic Total Occlusion Catheter 165cm OTW, 5Fr (Sterile, Single-Use)
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Chronic Total Occlusion Catheter 165cm OTW, 6Fr (Sterile, Single-Use)
Chronic Total Occlusion Catheter 165cm Rx only, 6Fr (Sterile, Single-Use)
Irrigation Tubing Set (Sterile, Single-Use)
Aspiration Tubing Set (Sterile, Single-Use)
Canister Set with Tubing (Sterile, Single-Use)

Reway™ Ultrasonic Chronic Total Occlusion System should be used by surgeons or medical staffs who have received the appropriate training.

Reway™ Ultrasonic Chronic Total Occlusion System is indicated for using selectively for fragmentation, emulsification, resection, irrigation and/or aspiration of hard tissue (e.g., calcified lesion) in peripheral vasculatures. Indications, contraindications and instructions for use can be found on the product labeling supplied with each device.

References

[1] *Anschuetz R, Bernard HR. Ultrasonic irradiation and atherosclerosis. Surgery. 1965; 57:549-53.*

[2] *Rosenschein U, Bernstein JJ, Disegni E, et al. Experimental ultrasound angioplasty: Disruption of atherosclerotic plaques and thrombi in vitro and arterial recanalization in vivo. J Am Coll Cardiol. 1990; 15:711-777.*

[3] *Ernst A. In vitro experiments using ultrasound for plaque ablation. In Ultrasound Angioplasty. Pages 93-120, 1996; Boston, Kluwer Academic Publishers.*

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Mavera Medical Devices Inc. guarantees that the products are designed, manufactured and packaged on application of the EN ISO 13485 certified quality management with all possible care, using the most suitable state-of-the-art processes and applying the principle of integrating safety into its design and manufacture. This system is designed to guarantee the safe use of device when it is employed under condition and for the purposes for which it is intended, in accordance with precautions described in the operator's manual and/or instructions for use and to minimize the risks associated with the use of the device as far as possible, although they cannot be totally eliminated. The device must only be used under the responsibility of specialist medical personnel, taking account of the unavoidable risks and the possible side effects and complications of the treatment for which, it is designed, including those referred to in other sections of these instructions for use.

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