REVOLUTION™
Peripheral Atherectomy System

Instructions For Use

All instructions should be read before use

DEVICE DESCRIPTION:

The Revolution™ Peripheral Atherectomy System is a minimally invasive catheter-based atherectomy system that utilizes a diamond-coated burr spinning at 140,000 RPM for treatment. The Revolution™ Peripheral Atherectomy System is designed for the ablation and removal of thrombus and atherosclerotic plaque from the peripheral arteries. The device is composed of a disposable hand-held single piece construction drive unit that is attached to a power supply. The drive unit consists of a coaxial sheath and electrically driven drive shaft for spinning the abrasive burr. The drive shaft has a central lumen, compatible with the Revolution™ 0.014" (.36 mm) guidewire. The catheter has 2 side ports for aspiration and infusion connections. The speed switch aids in rapid exchange of the guidewire by providing a slow spinning setting. The wire and abrasive burr are radiopaque for fluoroscopic visualization.

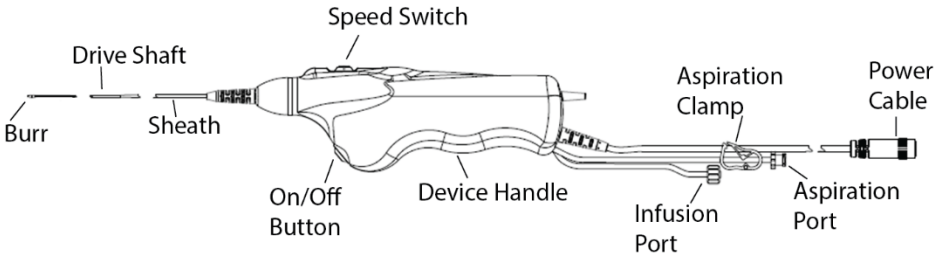

Figure 1: *Revolution™ Peripheral Atherectomy System Diagram*

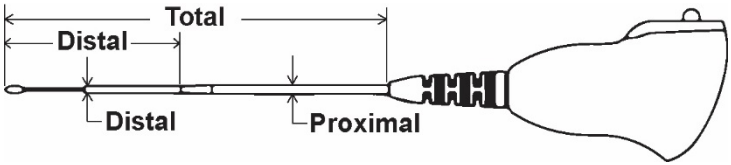

Figure 2: *Device Sizing Diagram*

Table 1: *Revolution™ Peripheral Atherectomy System Specifications*

Reference Number	Burr Diameter	Minimum Introducer Size (Distal/Proximal)[1]	Working Length (Distal/Total)[1]	Maximum Guidewire Diameter[2]	Minimum Vessel Diameter[3]
2006060133	1.33 mm	4F (1.3mm)	60 cm	.014" (.36 mm)	2.0 mm
2006145133		4F (1.3mm) / 6F (2.0mm)	40cm / 145cm		
2006200133		4F (1.3mm) / 6F (2.0mm)	40cm / 200cm		
2006145166LP	1.66 mm	4F (1.3mm) / 6F (2.0mm)	40cm / 145cm	.014" (.36 mm)	2.5 mm
20016145166		5F (1.7mm) / 7F (2.3mm)	40cm / 145cm		
2006200166		4F (1.3mm) / 6F (2.0mm)	40cm / 200cm		
2006145200LP	2.00 mm	4F (1.3mm) / 6F (2.0mm)	40cm / 145cm	.014" (.36 mm)	3.0 mm
2006145200		5F (1.7mm) / 7F (2.3mm)	40cm / 145cm		
2006200200		4F (1.3mm) / 6F (2.0mm)	40cm / 200cm		
2006145233	2.33 mm	5F (1.7mm) / 7F (2.3mm)	40cm / 145cm	.014" (.36 mm)	3.5 mm

[1] *See Figure 2, device sizing diagram for clarification.*
[2] *Recommended Guidewire: Revolution™ Peripheral Atherectomy Guidewire. See Table 2 for length recommendations.*
[3] *Do not use in vessels smaller than the indicated size or harm to the patient may occur.*

Table 2: *Revolution™ Peripheral Atherectomy Guidewire Recommendations*

Reference Number	Guidewire Length	Device Working Length Compatibility
2006GW335	335cm	145cm or 60cm
2006GW445	445cm	200cm

INDICATIONS FOR USE:

Atherectomy of the peripheral vasculature and to break apart and remove thrombus from the peripheral arteries in patients with occlusive atherosclerotic disease.

CONTRAINDICATIONS:

The Revolution™ Peripheral Atherectomy System is contraindicated in the following situations:

- This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise the patient's condition.
- Occlusions through which a guidewire will not pass.
- This system is intended only for infrainguinal peripheral artery disease and is not intended for use in coronary arteries.
- The target lesion is within a bypass graft or stent.
- In patients with angiographic evidence of significant dissection at the treatment site. The patient may be treated conservatively to permit the dissection to heal before treatment.
- This device is contraindicated in patients who cannot receive recommended anti-platelet and/or anticoagulant therapy.

RESTRICTIONS

- Federal law (United States) restricts this device to sale by or on the order of a physician.
- For use only by physicians who are trained on the use of the Revolution™ Peripheral Atherectomy System and peripheral interventional procedures.

WARNINGS:

- Ensure the patient is adequately anticoagulated prior to insertion of the Revolution™ Peripheral Atherectomy System into the patient's vasculature. Maintain adequate systemic anticoagulation until the device has been removed.
- Reference vessel diameter should not exceed a burr/artery ratio of 0.65.
- If mechanical failure of the Revolution™ Peripheral Atherectomy System occurs before or during the atherectomy procedure, discontinue use immediately. Do not attempt to use a damaged device. Use of damaged components may result in system malfunction or patient injury.
- Use only an approved Revolution™ 0.014-inch (.36 mm) guidewire. Ensure to use the correct guidewire length (335cm or 445cm) for device working length.
- Always use fluoroscopy when advancing the guidewire to avoid misplacement, dissection, or perforation. The Revolution™ Peripheral Atherectomy System tracks over the guidewire, so it is imperative that the guidewire be placed through the stenotic lumen.
- Never operate the Revolution™ Peripheral Atherectomy System without saline infusion. Flowing saline is required for cooling and lubricating the Revolution™ Peripheral Atherectomy System during use. Operation without saline infusion may result in permanent damage and possible patient injury.
- Ensure that the torque device is appropriately tightened.
- Prior to operating the device at full speed, the guidewire should be checked to make sure that it is not spinning while the device is activated.
- Monitor flow of ablated material into the aspiration disposal bag during use. If flow of ablated material ceases during the procedure, the device may not be functioning properly. Retract the device and activate to check if aspiration is restored. If no aspiration flow is observed, cease use of the Revolution™ Peripheral Atherectomy System.
- The burr at the distal tip of the Revolution™ Peripheral Atherectomy System rotates at very high speeds. Do not allow body parts or clothing to come into contact with the burr. Physical injury or entanglement may occur.
- Never advance the rotating burr to the point of contact with the guidewire spring tip. Distal detachment and embolization of the tip may result.
- Always keep the burr advancing or retracting while it is at high rotational speeds. Do not allow the burr to remain in one location for more than 2 seconds.

Maintaining the burr in one location while it is rotating at high speeds may lead to arterial injury.

- Never force the burr when rotational or translational resistance occurs; vessel perforation, vessel trauma, or embolism due to burr detachment or wire fracture may occur. If resistance to motion is noted, retract the device and stop treatment immediately. Use fluoroscopy to analyze the situation.
- Do not re-use or re-sterilize device. If the device is re-used, the device may not function as intended and serious infection leading to potential harm and/or death may occur.
- The use of the Revolution™ Peripheral Atherectomy System for in-stent restenosis could lead to damage of stent components and/or the Revolution™ Peripheral Atherectomy System, which may lead to patient injury.

PRECAUTIONS:

- If the Revolution™ Peripheral Atherectomy System's sterile package appears damaged or shelf life has expired, do **not** use the device.
- Follow standard hospital atherectomy policies and procedures, including those related to anticoagulation and vasodilator therapy.
- Because of the torque responsiveness of the Revolution™ guidewire, it is more difficult to handle than other commercially available guidewires used in peripheral angioplasty. Exercise care when using this guidewire. A tight loop, kink, or bend in the guidewire may cause damage and system malfunction during use.
- Hold the proximal end of the guidewire securely when the drive unit is activated using the supplied torque device in the supplied Revolution™ Torque Clip otherwise the guidewire may move or whip resulting in damage or loss of guidewire position.
- Use only normal saline as the infusate. (Drugs such as vasodilators are added to the infusate at the physician's discretion).
- Never inject contrast agent or any other substance that is not approved as part of the Revolution™ Peripheral Atherectomy System into the infusion port as this may cause damage to the Revolution™ Peripheral Atherectomy System.
- When moving the burr back and forth across the lesion, employ a series of intermittent treatment intervals and rest periods.
- **Rest periods are recommended after 30-second treatment intervals, with a maximum total treatment time of 6 minutes**.
- Monitor the saline fluid level during the procedure. Normal saline infusion is critical to Revolution™ Peripheral Atherectomy System performance.
    - Do **not** kink or crush the saline tubing and ensure clamp is open.
    - Check the saline tubing and connections for leaks during the procedure.

- If the Revolution™ Peripheral Atherectomy System stalls and does not restart when re-engaging the ON/OFF button, retract the device and immediately discontinue treatment. Check that the device power cable is connected to the power supply. If the connector is correctly attached to the power supply, use fluoroscopy to analyze the situation. Never force the system when rotational or translation resistance occurs, as vessel perforation, vessel trauma or embolism due to burr detachment or wire fracture may occur and may result in patient injury.
- Ensure that the device tracks smoothly and easily over the guidewire during use. If the drive shaft does not track easily over the guidewire, immediately turn off the system and replace the device.
- Do not activate the Revolution™ Peripheral Atherectomy System while within the introducer sheath or guide catheter.
- Ensure that the Revolution device is within operating temperatures (10-32°C / 50-90°F) and relative humidity (max 65%) prior to the procedure. If the Revolution device is outside of normal operating temperatures, the device may not function normally.

ADVERSE EVENTS

- Practitioners must be aware of potential complications associated with peripheral atherectomy including, but not limited to:

- Additional Intervention
- Allergic reaction
- Amputation
- Death
- Embolism
- Hematoma/Hemorrhage
- Hemodynamic changes
- Hemoglobinuria
- Bleeding complications
- Pain and tenderness
- Access site injury
- Hypotension
- Infection or fever
- Restenosis
- Stroke
- Slow, no flow, abrupt vessel closure
- Surgery including arterial bypass
- Thrombosis and vessel occlusion
- Vessel Trauma (vasospasm, dissection, perforation, pseudoaneurysm, arteriovenous fistula)

There also may be complications associated with distortion, kinks, and fracture of the guidewire and physical deterioration or malfunction of the device, which can lead to patient injury.

HOW SUPPLIED

The following Rex Medical supplied items are required for proper use of the Revolution™ Peripheral Atherectomy System:

1. The Revolution™ Peripheral Atherectomy System Handle
2. The Revolution™ Peripheral Atherectomy System Power Supply, Model: PEAMD72F-14-B2R and Power Cord
3. Disposal bag (500 mL) for material conveyed out of the aspiration port
4. Saline bag spike and infusion tubing
5. Revolution™ Peripheral Atherectomy Guidewire (335cm or 445cm)
6. Revolution™ Torque Device and Clip

In addition to the equipment, the operating room should be equipped as follows:

1. Guide catheter/sheath introducer
2. Standard IV pole
3. IV Pressure Bag
4. Sterile heparinized (10,000 IU/L) 0.9% normal saline
5. Fluoroscopic imaging equipment
6. Standard 110V electrical wall outlet
7. Other equipment as needed for interventional procedures

SUGGESTED PROCEDURE

Revolution™ Peripheral Atherectomy System Test Procedure:

The Revolution™ Peripheral Atherectomy System must be tested prior to inserting the burr into the guide sheath or introducer sheath.

1. **Priming the System:** Remove the Revolution™ Peripheral Atherectomy System from the packaging and inspect for kinks or damage to the catheter. **Warning: Do not use the device if the device or catheter is damaged.** Attach the power cable from the device to the power supply cable, as shown in Figure 3. Using sterile technique, attach the saline bag spike and infusion tubing to a 1,000 mL bag of normal saline and the infusion port of the device, as shown in Figure 4. The saline should be pressurized with an IV pressure bag to ensure steady infusion. The recommended pressure is 20 kPA – 26.7 kPA (150 mmHg – 200 mmHg). Allow the system to flush until saline drips out of the distal tip of the catheter. **Precaution: Always operate the Revolution™ Peripheral Atherectomy System with saline infusion. Flowing saline aids in cooling and lubricating the system. Operation without saline flow may result in permanent damage.**

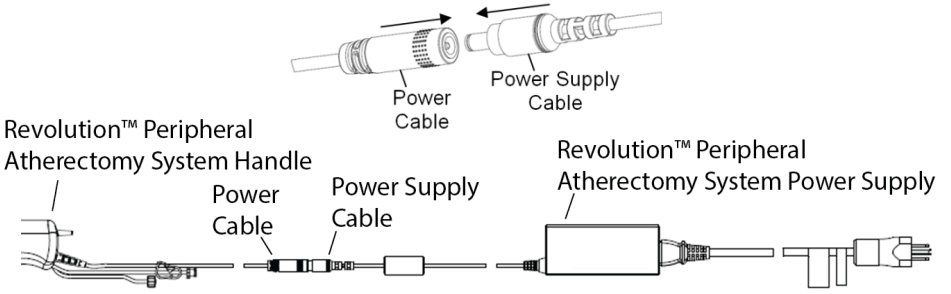

Figure 3: *Connect to power supply*

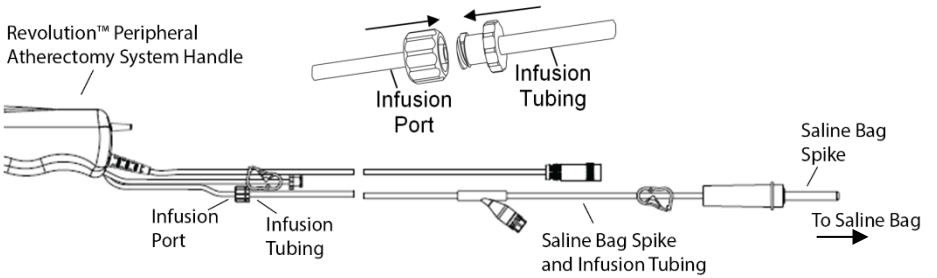

Figure 4: *Connect infusion tubing*

2. **System Test:** Insert the distal tip of the device into a basin filled with normal saline. With the speed switch in the back position (slow speed, Figure 5), depress the ON/OFF button to ensure that the abrasive burr spins freely (refer to Figure 1). Release the button to stop the rotation of the burr, once saline is observed dripping out of the aspiration port. Without removing the distal tip from the basin, push the speed switch to the forward position (fast speed, Figure 5) and depress the ON/OFF button for 5 seconds. Release the button to stop the rotation. **Precaution: Do not use the device if it does not activate immediately when the button is depressed, and deactivate immediately when the button is released in either speed setting.**

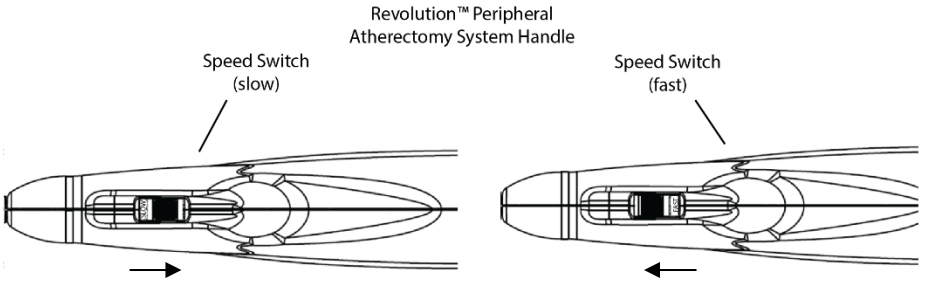

Figure 5: *Test both speed positions*

3. Attach the supplied disposal bag to the aspiration port, as seen in Figure 6. **NOTE: Ensure that the aspiration clamp is opened and the tubing is not damaged. Never activate the device if the aspiration clamp is closed.** The Revolution™ Peripheral Atherectomy System is now ready for use.

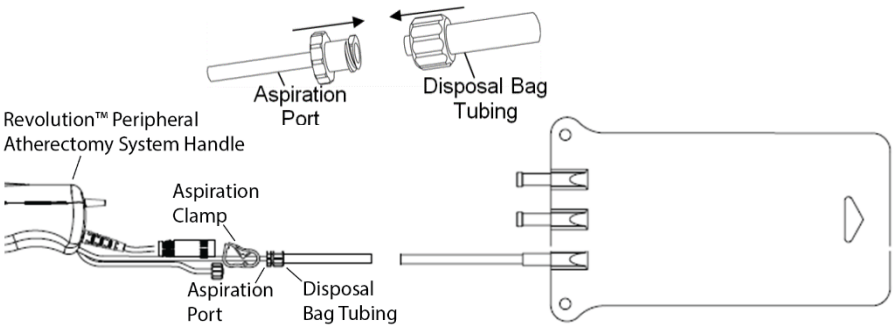

Figure 6: *Connect disposal bag*

Revolution™ Peripheral Atherectomy System Clinical Procedure:

The exact treatment procedure is to be determined by the physician. The following option describes how the procedure may be performed.

1. Complete the Revolution™ Peripheral Atherectomy System atherectomy procedure under continuous fluoroscopy. Do not initiate burr rotation (device activation) unless proper device positioning is confirmed within the lesion.
2. The recommended access sites include femoral, pedal and radial. For radial access a device with a 200cm working length should be used.

   NOTE: This system is intended only for infrainguinal peripheral artery disease and is not intended for use in coronary arteries.
3. Prepare and drape the puncture site as required. Using standard techniques, position an appropriately sized guide sheath or introducer sheath based on burr size in the vessel (refer to Table 1). The burr used to treat the diseased vessel should have a maximum diameter of 65% of reference vessel size.
4. Advance the 0.014" (.36 mm) Revolution™ guidewire through the sheath beyond the lesion to be treated, taking care to remain intraluminal. **NOTE: Ensure to use the correct guidewire length (335cm or 445cm) for device working length.**
5. Insert the proximal end of the Revolution™ guidewire into the distal tip of the device until the guidewire is through the proximal end of the Revolution™ Peripheral Atherectomy System as shown in Figure 7.

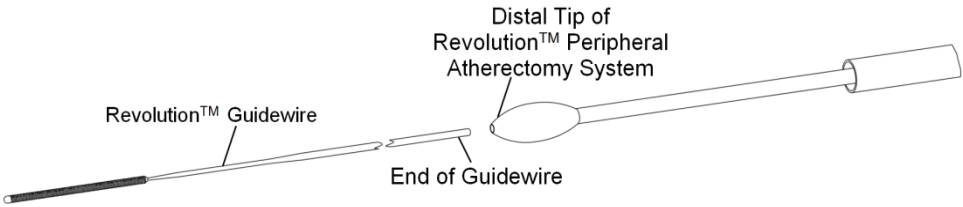

Figure 7: *Load device onto the Revolution™ guidewire*

6. Hold the guidewire stationary and carefully insert the Revolution™ Peripheral Atherectomy System into the guide sheath or introducer sheath. If a hemostasis valve is present, advance the catheter through the hemostasis

valve and gently tighten the valve around the catheter sheath to prevent blood loss. **Precaution: If the hemostasis valve is tightened excessively, it can crush the catheter sheath around the drive shaft and cause permanent damage to the Revolution™ Peripheral Atherectomy System.**

7. Advance the Revolution™ Peripheral Atherectomy System so that the burr is within a few millimeters proximal to the lesion. **Warning: Never activate the burr while within the guide sheath or introducer sheath.** Verify that the guidewire spring tip is positioned a **minimum of 10cm (4in)** distally from the burr.
8. Tighten the torque device tightly to the guidewire behind the guidewire exit as shown in Figure 8. Apply tension to the guidewire by gripping the torque device to provide wire support and allow the drive shaft to track easily over the guidewire.

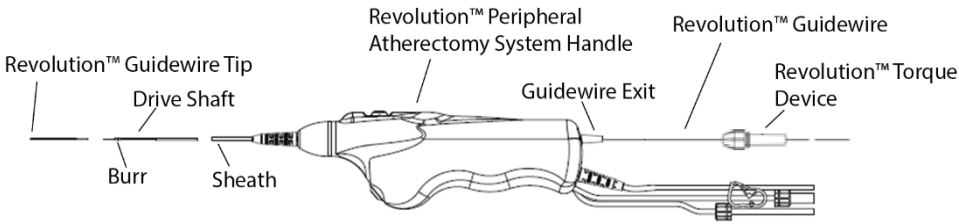

Figure 8: *Tighten torque device to guidewire*

9. Clip the Torque Device Clip to the surgical drape and slide the torque device into the slot on the Torque Device Clip as shown in Figure 9. **WARNING: Ensure that the torque device is appropriately tightened and that it will not spin in the Torque Device Clip.** Replace the torque device if it is not firmly secured in the Torque Device Clip. The torque device should be tightened as close to the handle as possible and is **NOT to exceed 10cm (4in)**. **Precaution: Monitor the smooth tracking of the drive shaft over the guidewire during operation. If resistance is encountered during the procedure, remove the Revolution™ Peripheral Atherectomy System and flush the system.**

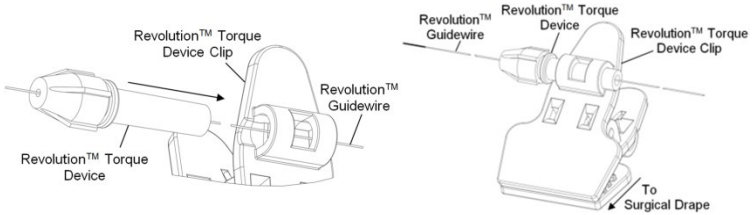

Figure 9: *Tighten torque device to guidewire*

10. Check that the speed switch is in the forward position (fast speed). Under fluoroscopic guidance, press the ON/OFF button to activate rotation of the Revolution™ Peripheral Atherectomy System and allow 1.5 seconds for the device to reach full speed. Advance the catheter at a rate of **1 cm/sec**. In a

tight or total occlusion, periodically pause and withdraw the burr slightly in a smooth pecking motion to allow for improved blood flow. Continue advancing until the burr has crossed the lesion. **Warning: If the Revolution™ Peripheral Atherectomy System stalls and does not restart, retract the device and immediately discontinue treatment. Check that the device power cable is connected to the power supply. If the connector is correctly attached to the power supply, use fluoroscopy to analyze the situation. Never force the system when rotational or translation resistance occurs, as vessel perforation, vessel trauma or embolism due to burr detachment or fractured wire may occur and may result in patient injury.**

11. With the ON/OFF button continually depressed so that the device is still rotating, withdraw the abrasive burr to the proximal side of the lesion. As desired, continue ablating the lesion by moving the abrasive burr back and forth through the lesion in the method described above. **Warning: Always keep the burr advancing or retracting while activated. Maintaining the burr in one location while it is rotating may lead to arterial injury and/or entrapment of the Revolution™ Peripheral Atherectomy System. Do NOT allow the burr to remain in one location for more than 2 seconds.**
12. Release the ON/OFF button so that the Revolution™ Peripheral Atherectomy System is no longer rotating and image the vessel. **Warning: When the Revolution™ Peripheral Atherectomy System is not activated, arterial pressure may force excess blood into the disposal bag. Always shut the aspiration clamp, as seen in Figure 6, when the device is not in use. Before subsequent use, ensure that the clamp is opened and tubing is not damaged. Never activate the device with the aspiration clamp shut.** If continued treatment is required, push the speed switch to the back position (slow speed) and depress the ON/OFF button to fully remove particulate from within the system. Ensure the system is flushed with heparinized saline and push the speed switch back to the forward position (fast speed) before activating the Revolution™ Peripheral Atherectomy System again.
13. To remove the Revolution™ Peripheral Atherectomy System from the body, hold the torque device on the proximal end of the guidewire and use standard over-the-wire guidewire management technique. Push the speed switch to the back position (slow speed) and depress the ON/OFF button to assist in rapid exchange.
14. Perform a post-atherectomy angiogram.
15. Treat with any adjunctive angioplasty or stenting deemed necessary by the physician per standard hospital protocol.
16. Perform the final angiogram.
17. Remove the sheaths and achieve hemostasis at the puncture site per hospital protocol.

TRANSPORT:

Transport conditions not to exceed 60°C (140°F) and -29°C (-20°F).

STORAGE:

Storage temperature to be within 50 - 104°F (10 - 40°C). Do not expose to organic solvents, ionizing radiation, ultraviolet light magnets, and sources of electromagnetic interference (EMI). Relative humidity to be between 30% - 60%.

DISPOSAL:

Dispose of the handheld unit in accordance with the Waste Electrical and Electronic Equipment Directive (WEEED) and according to the standard institutional procedures for medical waste including single-use, blood contacting devices.

WATER INGRESS PROTECTION:

IPX2: Protection against water ingress

ELECTROMAGNETIC COMPLIANCE:

The Revolution Peripheral Atherectomy System has been tested and is compliant with the EMC limits for IEC 60601-1-2:2014 including immunity and emission levels for a professional healthcare facility environment CISPR11 Group 1 Class A.

The manufacturer defines essential performance as the system starting, running, stopping at the operator's discretion.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Parameter	Value
Electrical cable length: Electrical outlet to power supply	4.6m (15.0 ft.)
Electrical cable length: Power supply to device handle	4.8m (15.7 ft.)

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Revolution Peripheral Atherectomy System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 3: *Test specifications for enclosure port immunity to RF wireless communications equipment (IEC 60601-1-2:2014, Table 9)*

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900 DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50% duty cycle square wave signal.
[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 4: *Revolution device compliance for each emissions and immunity standard*

Test	Standard	Requirement			Result
Radiated Emissions	CISPR 11	30 MHz – 1 GHz Group 1 Class A			**PASS**
Conducted Emissions	CISPR 11	Freq(MHz)	QP(dB)	AVG(dB)	**PASS**
		.15-.5	66→56	56→46	
		.5-5	56	46	
		5-30	60	50	
Harmonic Current Emissions	IEC 61000-3-2	Class A			**PASS**
Voltage Fluctuations and Flicker	IEC 61000-3-3	Class A			**PASS**
Electrostatic Discharge	IEC 61000-4-2	± 8 kV Contact ± 2, 4, 8 and 15 kV Air			**PASS**
Radiated RF Immunity	IEC 61000-4-3	3 V/m 80 MHz - 2.5 GHz			**PASS**
Radiated RF Immunity	IEC 61000-4-3 IEC 60601-1-2: 2014 Table 9	Mobile Device Frequencies with Specific Levels			**PASS**
Electrical Fast Transients/Bursts	IEC 61000-4-4	± 2 kV power supply lines With 100 kHz Rep Frequency			**PASS**
Surge Immunity	IEC 61000-4-5	± 1kV Line to Line ± 2kV Line to Earth			**PASS**
Conducted Immunity	IEC 61000-4-6	3Vrms 150 kHz – 80 MHz and 6 Vrms ISM Frequencies			**PASS**
Power Frequency Magnetic Field Immunity	IEC 61000-4-8	30 A/m 50 Hz/60 Hz			**PASS**
Voltage Dips, Short Interruptions and Voltage Variations	IEC 61000-4-11	Voltage (%U_T) Level		Duration (Cycles)	**PASS**
		Dip 100%		0.5	
		Dip 100%		1	
		Dip 30%		30	
		Interruption 100%		300	

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY:

There is no express or implied warranty, including without limitation and implied warranty of merchantability or fitness for a particular purpose, on the Rex Medical product(s) described in this publication. Under no circumstances shall Rex Medical be liable for any direct, incidental or consequential damages other than as expressly provided by specific law. No person has the authority to bind Rex Medical to any representation or warranty except as specifically set forth herein.

Descriptions or specifications in Rex Medical printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties. Rex Medical will not be responsible for any direct, incidental or consequential damages from reuse of the product.

CLINICAL DATA:

The REVEAL clinical study was a prospective, multicenter, non-randomized, single arm, US IDE study to evaluate the safety and effectiveness of the Revolution™ Peripheral Atherectomy System when used in patients with symptomatic infrainguinal lower extremity arterial occlusive disease. The 121 subjects (with 146 treated lesions) were enrolled in accordance with the vessel sizing and anatomical requirements corresponding to each Revolution™ device size. The primary safety endpoint was evaluated in the Intention to Treat (ITT) population with freedom from 30-day Major Adverse Events (MAE), defined as the composite of all-cause mortality, clinically driven TLR, perforation of the target vessel, clinically significant distal embolization or major target limb amputation; as adjudicated by an independent clinical events committee. The primary effectiveness endpoint was assessed on a per lesion basis in the Per Protocol population with technical success, defined by ≤50% diameter stenosis after atherectomy with the Revolution™ Peripheral Atherectomy System and prior to adjunctive therapy, as measured by an independent core laboratory on the post-atherectomy contrast angiogram. Patients were monitored for 6 months following baseline atherectomy treatment.

The 30-day freedom from MAE rate was 97.3% (110/113) and technical success was achieved in 90.2% (111/123) of the lesions treated in the per protocol group. Both primary endpoints met the predefined IDE study success criteria. Table 5 summarizes the safety and effectiveness data results from the REVEAL study.

Table 5: *Summary of Safety and Effectiveness in the REVEAL clinical study*

Parameter	Results (n=121 patients, 146 lesions, *unless otherwise noted*)
Demographics:	
% Male	58.7% (71/121)
Age (yr.)	72 ± 9.4
Diabetes	60.3% (73/121)
Target Lesion Locations & Diameters	
SFA	20.7% (30)
Popliteal	16.6% (24)
BTK	65.5% (95)
RVD (n=141)	3.1 ± 0.9 mm
Target Lesion Length (n=131)	26.8 ± 26.8 mm
Pre-Revolution % Diameter Stenosis (n=132)	73.2% ± 19.2%
Post-Revolution % Diameter Stenosis (n=123)	42.1% ± 13.7%
Final Post Procedure % Diameter Stenosis (n=127)	20.1% ± 8.1%
Technical Success (lesions)[1]	90.2% (111/123)
Procedural Success (lesions)[2]	93.7% (119/127)
Clinical Results	
ABI (Per Protocol population)	
Baseline	0.75 ± 0.26
30 days	0.95 ± 0.29
6 months	0.92 ± 0.29
Rutherford Score (Per Protocol population)	
Baseline	3.6 ± 1.0
30 days	1.8 ± 1.8
6 months	1.6 ± 1.7
MAE through 30 days (ITT population)	
Freedom from All-cause Mortality	100% (121/121)
Freedom from Clinically Driven TLR	100% (121/121)
Freedom from Major Limb Amputation	100% (121/121)
Freedom from Target Vessel Perforation[3]	99.2% (120/121)
Freedom from Distal Embolism[3]	98.3% (119/121)
MAE through 6 months (ITT population)	
Freedom from All-cause Mortality	97.5% (118/121)
Freedom from Clinically Driven TLR	86.8% (105/121)
Freedom from Major Limb Amputation	96.7% (117/121)
Freedom from Target Vessel Perforation[3]	99.2% (120/121)
Freedom from Distal Embolism[3]	98.3% (119/121)

[1]Stenosis ≤ 50% post-Revolution
[2]Stenosis ≤ 30% final
[3]There were 2 site-reported distal embolization's during the index procedure, neither of which was observed on the core laboratory-reviewed procedural angiograms. There was one target vessel perforation reported by the site, also not observed by the core laboratory. These 3 events were CEC-adjudicated as unrelated to the device and account for the MAEs within 30 days, despite absence of the complication on the angiograms reviewed by the core laboratory.

Refer to the appropriate packaging for symbols that apply:

LOT	Lot Number
REF	Model Number
	Use-by date
40 °C max. 10 °C min.	Storage Temperature limitation 50 - 104°F (10 - 40°C)
	Keep dry
	Keep away from sunlight
STERILE EO	Sterilized using Ethylene Oxide gas
2 STERILIZE	Do not Re-Sterilize
2	Single use only
	Refer to Instruction Manual/Booklet
	Inspect package for damage
	Biological hazard
	Manufacturer
RxOnly	Federal (USA) law restricts this device to sale by, or on the order of, a physician
	Defibrillation-Proof Type BF Applied Part
UL CERTIFIED E490043	General Medical Electrical Equipment
IPX2	Degree of protection provided by enclosures (IP Code)

Manufactured by:

Rex Medical, L.P.
Conshohocken, PA 19428
Tel (610) 940-0665
Fax (610) 940-1590
www.rexmedical.com