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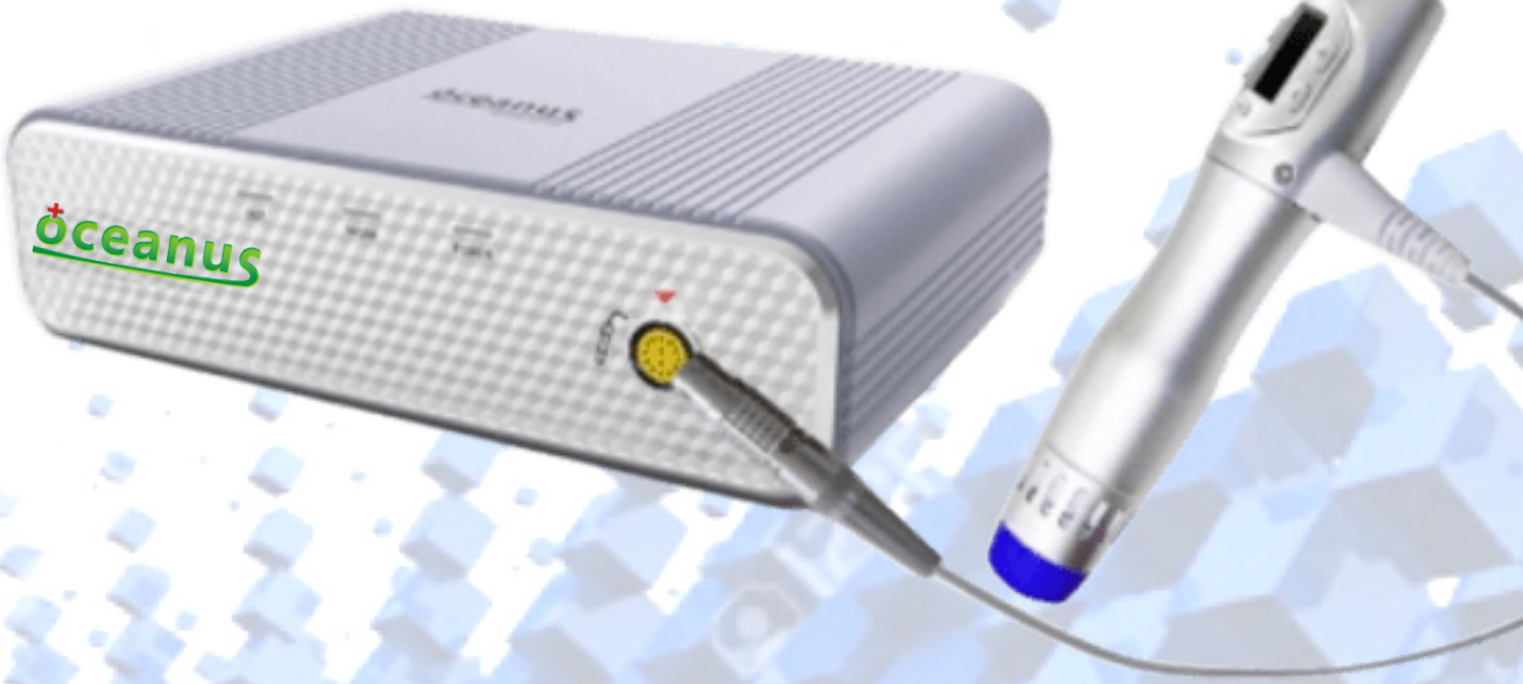
PREPARED BY
SWSNA, LLC

EFFICACY AND SAFETY OF THE OCEANUS PHYSIOPRO II®

SHOCKWAVE THERAPY DEVICE FOR CHRONIC JOINT PAIN

A SYSTEMATIC
POST MARKET MDR REPORT



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OCE-ESWT-003 | WHITEPAPER

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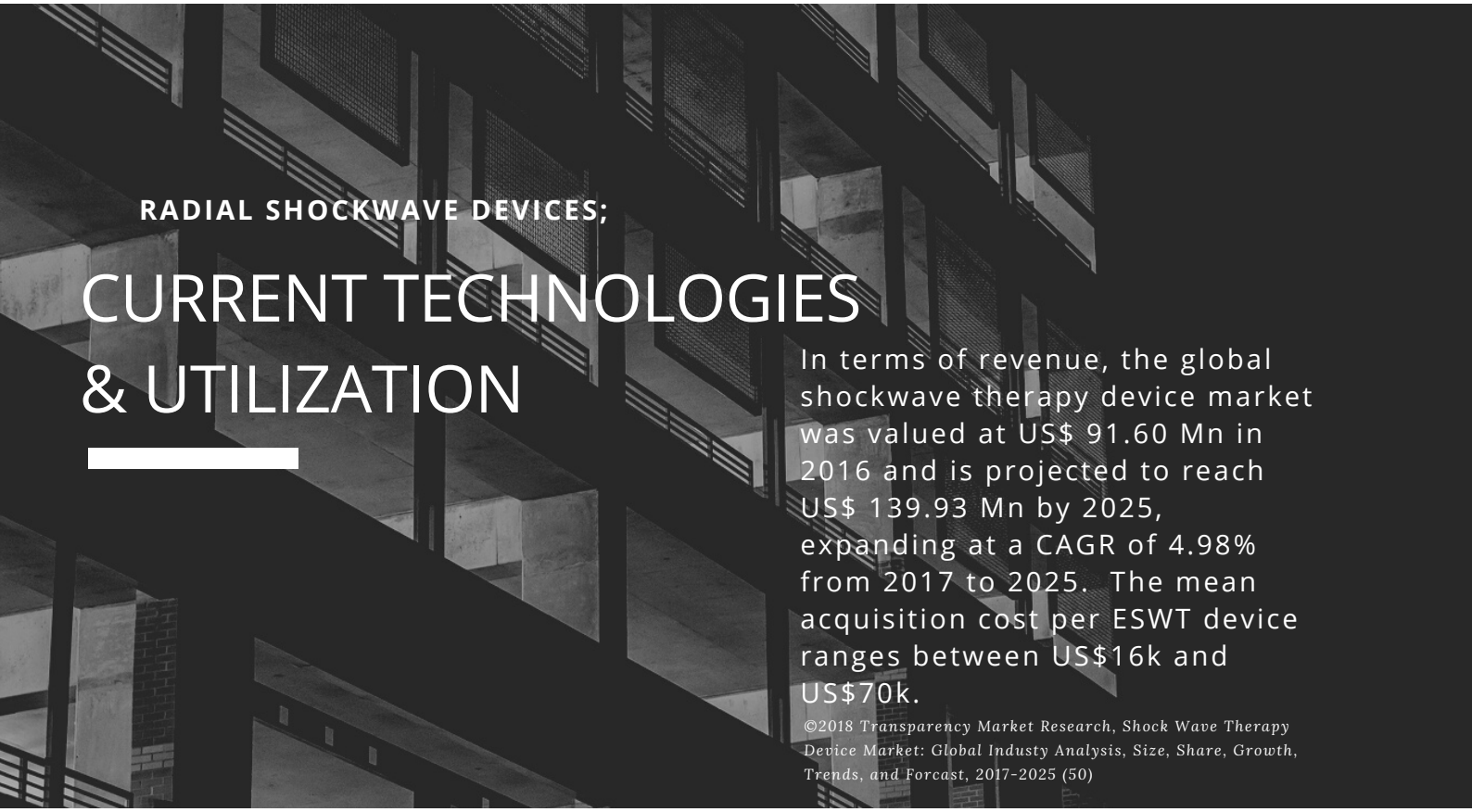


RADIAL SHOCKWAVE DEVICES;

CURRENT TECHNOLOGIES & UTILIZATION

In terms of revenue, the global shockwave therapy device market was valued at US$ 91.60 Mn in 2016 and is projected to reach US$ 139.93 Mn by 2025, expanding at a CAGR of 4.98% from 2017 to 2025. The mean acquisition cost per ESWT device ranges between US$16k and US$70k.

©2018 Transparency Market Research, Shock Wave Therapy Device Market: Global Industry Analysis, Size, Share, Growth, Trends, and Forcast, 2017-2025 (50)

Extracorporeal Shockwave Therapy (ESWT) is a novel, non-invasive solution for soft-tissue and musculoskeletal indications. ESWT is most commonly utilized by physiotherapy, orthopedics, and sports medicine practitioners as a secondary asset used for rapid pain relief and mobility restoration. These are non-surgical therapy devices, which do not require painkillers for treatment. Hence, it makes an ideal therapy to accelerate recovery and efficacious for various acute or chronic indications.

Two types of technical principles are included in ESWT—focused ESWT (F-ESWT) and radial pressure waves (RPW), which are often referred to in the literature as radial shockwaves. These 2 technologies differ in their generation devices, physical characteristics, and mechanism of action, but they share several indications.

Historically global industry leading companies in Extracorporeal shockwave therapy device manufacturing include the following;

- BTL corporate
- Storz Medical AG
- Zimmer Medizin Systeme GmbH
- Dornier MedTech GmbH
- EMS Electro Medical Systems S.A.
- DJO, LLC

Increasing number of orthopedic surgeries and rising incidence of arthritis among the geriatric population is expected to drive focused SWG and radial SWG segments during tTechnological advancements in electromagnetic shock wave therapy devices by reducing the frequency of shock, rise in the number of urological surgeries in GCC, favorable reimbursement scenario, and increase in the number of regulatory approvals for ESWT devices are other factors fueling the global shock wave therapy device market.

EXTRACORPOREAL SHOCKWAVE THERAPY (ESWT)

PHYSICS

Shockwaves are sound waves that have specific physical characteristics, including nonlinearity, high peak pressure followed by low tensile amplitude, short rise time, and short duration (10 ms). They have a single pulse, a wide frequency range (0-20 MHz) and a high pressure amplitude (0-120 MPa).

H. van der Worp, I. van den Akker-Scheek, H. van Schie, J. Zwerver ESWT for tendinopathy: Technology and clinical implications Knee Surg Sports Traumatol Arthrosc, 21 (2013), pp. 1451-1458

ESWT waveform characteristics produce both positive and negative phases of shockwave. The positive phase produces direct mechanical forces, whereas the negative phase generates cavitation and gas bubbles that subsequently implode at high speeds, generating a second wave of shockwaves; referred to as cavitation. Cavitation waveform is a key evidential requirement demonstrated solely by ESWT devices.

In comparison to ultrasound waves, the shockwave peak pressure is approximately 1000 times greater than the peak pressure of an ultrasound wave. Further, ESWT physiological forces are purely concentrated on mechanical energy conversion in terms of force (measured by mJ or Bar) and speed (measured by hertz). The physiological forces in Ultrasonic energy are concerned with thermal properties in contrast.

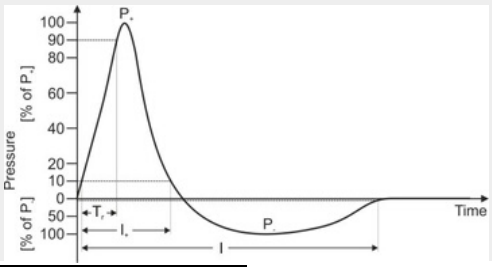
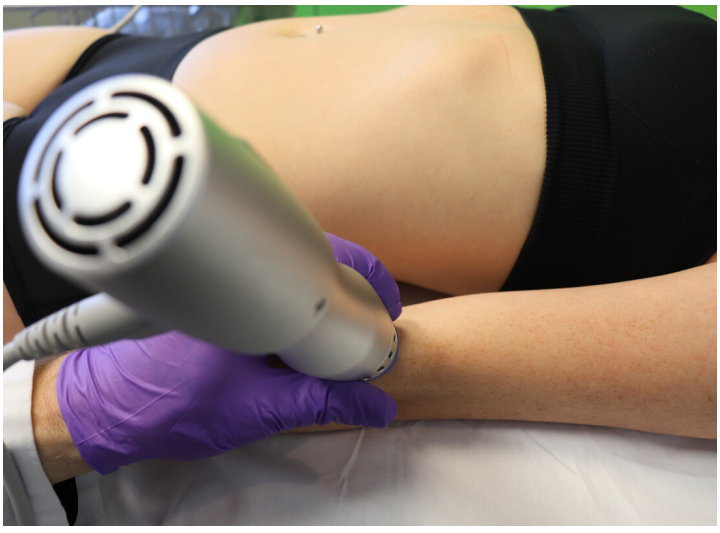


Image Source: Schmitz, Christoph & Csaszar, Nikolaus & Rompe, Jan & Chaves, Humberto & Furia, John. (2013). Treatment of chronic plantar fasciopathy with extracorporeal shock waves. Journal of orthopaedic surgery and research. 8. 31. 10.1186/1749-799X-8-31.

Extracorporeal shockwave therapy is primarily used in the treatment of common musculoskeletal conditions. These include both upper and lower extremity tendinopathies, greater trochanteric pain syndrome, medial tibial stress syndrome, patellar tendinopathy, plantar fasciopathy.

No globally standardized ESWT protocol for the treatment of musculoskeletal conditions have yet been established due to specific differences found between contradicting technologies currently under investigation. Yet the fact remains that ESWT is a clinically significant and valuable medical technology.



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EVIDENCE OF ESWT EFFICACY

*Schmitz C, Császár NB, Milz S, et al. Efficacy and safety of extracorporeal shock wave therapy for orthopedic conditions: a systematic review on studies listed in the PEDro database. Br Med Bull. 2015;116(1):115-138. doi:10.1093/bmb/ldv047

The outcome of keyword searches relating to ESWT on the **PEDro Database*** identified n = 209 records; of which n = 47 were duplicates. All reviews (n = 48) were excluded, as well as records that did not address ESWT (n = 3). Additionally, all ESWT studies on wound healing and chronic decubitus were excluded (n = 5). The remaining records (n = 106) were divided into studies on (a) radial ESWT with positive outcome (i.e. radial ESWT significantly better statistically than either placebo or alternative treatment modalities) (rESWT+; n = 23), (b) radial ESWT with negative outcome (i.e. radial ESWT not significantly better statistically than either placebo or alternative treatment modalities) (rESWT−; n = 3), (c) focused ESWT with positive outcome (fESWT+; n = 66) and (d) focused ESWT with negative outcome (fESWT−; n = 15) (note that one addressed both radial and focused ESWT and, thus, was listed in both groups rESWT+ and fESWT+).

An invaluable resource for scientific, clinical and accredited ESWT data, the International Society of Medical Shock Wave Therapy **(ISMST)** has listed the following as approved standard indications**:

1.1. Chronic Tendinopathies
1.1.1. Calcifying tendinopathy of the shoulder
1.1.2. Lateral epicondylopathy of the elbow (tennis elbow)
1.1.3. Greater trochanter pain syndrome
1.1.4. Patellar tendinopathy1.
1.5. Achilles tendinopathy
1.1.6. Plantar fasciitis, with or without heel spur
1.2. Bone Pathologies
1.2.1. Delayed bone healing
1.2.2. Bone Non-Union (pseudarthroses)
1.2.3. Stress fracture
1.2.4. Avascular bone necrosis without articular derangement
1.2.5. Osteochondritis Dissecans (OCD) without articular derangement
1.3. Skin Pathologies
1.3.1. Delayed or non-healing wounds
1.3.2. Skin ulcers
1.3.3. Non-circumferential burn wounds

**ESWT Indications. (2017, August 08). Retrieved May 1, 2020, from https://www.shockwavetherapy.org/about-eswt/indications/

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ABSTRACT OF OCEANUS PHYSIOPRO II® TECHNOLOGY + SUMMARY OF SAFETY AND EFFECTIVENESS

510k Note: *The FDA incentive to technologically tie when R&D is important and finds that technological tying increases innovation, which is an efficiency not considered in other tying models. Intuitively, technological tying protects the seller from aftermarket entry, ensuring that the seller internalizes the full effect of increased investment in technology on system profits. More importantly, the additional innovation, associated with technological tying, may benefit consumers more than anticompetitive effects hurt them, suggesting that innovation efficiency should be an important consideration in technological tying cases.*

GENERAL INFORMATION

Device Generic Name: Orthopedic Extracorporeal Shock Wave Therapy Device

Device Trade Name: Oceanus SW002 | Oceanus Connect

Applicant Name and Address: Oceanus America | Shenzhen Oceanus Medical Device Co., Ltd, Floor 2, No.16, Lane 2, Yinjin Building, Liuxian 2 Road, Baoan District, Shenzhen,ISO 8905660Date of

Notice of Approval to Applicant: March 2019

Establishment Registration & Device Listing

FDA Home · Medical Devices · Databases

New Search | Back To Search Results

Proprietary Name:	Deep Muscle Stimulator; Radial Pressure Pulse Therapy Device; Ultrasonic Physiotherapy Equipment
Classification Name:	MASSAGER, THERAPEUTIC, ELECTRIC
Product Code:	ISA
Device Class:	1
Regulation Number:	890.5660
Medical Specialty:	Physical Medicine
Registered Establishment Name:	SHENZHEN OCEANUS MEDICAL DEVICE CO., LTD.
Registered Establishment Number:	3013431847
Owner/Operator:	Shenzhen Oceanus Medical Device Co., Ltd.
Owner/Operator Number:	10053056
Establishment Operations:	Foreign Exporter; Specification Developer

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INDICATIONS FOR USE

The Oceanus PhysioPRO II® is a non-surgical alternative for the treatment of chronic joint pain for patients 18 years of age or older with symptoms for 6 months or more and a history of unsuccessful conservative therapy.

CONTRAINDICATIONS

Use of the Oceanus PhysioPRO II® is contraindicated in the following situations:

- Over or near bone growth center until bone growth is complete
- When a malignant disease is known to be present in or near the treatment area
- Infection in the area to be treated
- Over ischemic tissue in individuals with vascular disease
- Patient has a coagulation disorder or if taking anti-coagulant medications
- Patient has a prosthetic device in the area to be treated.

WARNINGS AND PRECAUTIONS

The warnings and precautions for use of the Oceanus PhysioPRO II® for the treatment of chronic proximal plantar fasciitis can be found in the device labeling.

DEVICE DESCRIPTION

The Oceanus PhysioPRO II® shock wave form propagates radially into the tissue from the point of contact. Thus, the device has no "focusing" characteristics, per se, because the maximum energy is directly at the coupling point on the skin surface, targeting the treatment areas of interest that are close to the skin. The maximum possible energy flux density (ED+max) is 0.18 mJ/mm The Oceanus PhysioPRO II® system consists of the following components:

- Control unit (I00- 240 VAC I 50 Hz- 60Hz)
- Handpiece set with a 15 mm applicator
- Coupling gel bottle
- Power supply cord (hospital grade) Compressed air tube
- Component case
- Bluetooth connected mobile application for iOS & Android

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The product mainly consists of a host, therapeutic handle, including an upper and lower case, power supply, main board. Accessories include power line, handle bottom case, keys and aluminium alloy suitcase. Accessories include silicone caps and therapeutic handle/therapeutic handle.

ALTERNATIVE PRACTICES &PROCEDURES

Chronic joint pain is generally treated conservatively with a variety of pharmacological and nonpharmacological therapies. Pharmacological therapies may include OTC or prescription analgesics or non-steroidal anti inflammatory agents (NSAIDs), local anesthetic injections or local corticosteroid injections. Nonpharmacological therapies may include physical therapy such as ice, heat or ultrasound; physiotherapy such as massage and stretching; orthotics, lifestyle modifications, taping, night splints, immobilization, or casting. Current nonconservative treatments for chronic joint pain include shockwave therapy with comparable commercially available shock wave therapy devices or surgery.

ADVERSE EFFECTS OF THE DEVICE ON HEALTH

During the Oceanus PhysioPRO II® voluntary study (2019), a total of 5 non-serious adverse events were reported during the 12 week follow-up period in 5 of the 88 patients (6%) receiving active treatment. Of these reports, 5 adverse events in 5 patients were considered to be not device related.

Potential adverse events that have not been observed in clinical studies of the Oceanus PhysioPRO II® may include:

- Bruising
- Rupture o f the plantar fascia (tissue along the bottom o f the foot)
- Temporary or permanent damage to the blood vessels
- Petechia
- Temporary or permanent nerve damage causing hypesthesia or paresthesia
- Hematoma
- Tendon Rupture

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HANDPIECE LONGEVITY

The longevity of the Oceanus PhysioPRO II® handpiece was validated to have a lifetime in excess of 400,000 impulses (equivalent to about 250 uses). Four handpieces were tested until failure or 1,000,000 impulses, whichever came first. One blocked after 500,000 impulses, another after 800,000 impulses and the remaining two were still functioning at I,000,000 impulses.

ELECTRICAL SAFETY AND ELECTROMAGNETIC INTERFERENCE TESTING

The Oceanus PhysioPRO II® was tested and found to be in conformance with the electrical safety requirements of IEC 60601-1: Medical Electrical Equipment Part 1: General Requirements for Safety, and the electromagnetic compatibility requirements of IEC 60601-1-2: Medical Electrical Equipment- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests.

SOFTWARE VALIDATION

Software verification and validation testing was conducted in accordance with the Oceanus PhysioPRO II® Software Verification and Validation Plan and the device was found to meet all tests requirements, with no known unresolved anomalies remammg.

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BIOCOMPATIBILITY TESTING

Biocompatibility testing was conducted on the applicator, the only physical component of the Oceanus PhysioPRO II® intended to come in contact with the patient. Testing for in vitro cytotoxicity, sensitization, and intracutaneous reactivity was conducted in accordance with the applicable requirements of ISO 0993: Biological evaluation of medical devices - Part 1: Evaluation and Testing, and as specified in FDA's guidance Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices (2019) and in accordance with the principles of Good Laboratory Practice. All test criteria were successfully met.In addition, the manufacturer of the contact gel conducted a human patch test for primary skin irritation and allergic hypersensitivity to the gel. Eighty-eight (88) volunteer subjects with no visible skin diseases and no known allergic hypersensitivities were tested for 24 hours and examined at patch removal and at 48 and 72 hours after removal. There was no evidence of primary irritation or allergic hypersensitivity in any of the subjects.

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SUMMARY OF NON-CLINICAL AND POST-APPROVAL STUDIES INVOLVING THE OCEANUS CONNECT®

U.S. Food and Drug Administration. 2000. 510(K)S For Extracorporeal Shock Wave Lithotripters Guidance. [online] Available at: <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/content-premarket-notifications-510ks-extracorporeal-shock-wave-lithotripters-indicated> [Accessed 18 May 2020].

The Oceanus PhysioPRO II® therapy head with the 15mm diameter radius is designed as a standard lithotripsy therapy head for clinical shock wave applications. The 15mm diameter tip, which produces the shock waves, was previously approved for use in the Zimmer lithotripsy devices, Supplement available prior 510k PMA # P000048. Not technically different to the Oceanus PhysioPRO II®, the Zimmer Lithotripsy device generated sound waves through the mechanical application of electromagnetic energy currents to propel a metallic bullet against the 15mm diameter applicator tip. Shock wave measurements produced by the Oceanus PhysioPRO II® shockwave emitter were characterized and documented in accordance with the parameters defined in the FDA Draft of Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements and lEC 1846. Measurements were recorded using a fiber optic hydrophone.

Measurements of the shock wave field were recorded at the minimal, typical and maximum energy settings as defined in the study protocol. Calculations of focal energy per pulse are based upon equation (4) in section 2.3, Beam Energy, of the draft guidance. The values were calculated including positive and rarefaction portions of the waves.

Completion of calculations determined minimal shock-to-shock variation over the minimum, typical and maximum intensity settings for 5mm, 10mm and 12mm diameters of the pulse frequency ranges, demonstrating the accuracy of the Oceanus PhysioPRO II® pressure pulse generator.The testing also included measurements of pulse intensity integral and effective energy as defined in the guidance. Both parameter values for positive signal and for the complete signal including rarefaction were measured and documented.

EMI I EMC Testing

Testing was conducted on the Oceanus PhysioPRO II® without ultrasound to demonstrate compliance with EN 60601-1-2. This standard regulates the EMIIEMC of medical equipment that includes compliance with EN 55011 for radio frequency emissions. lEC 801-2, IEC 801-3, lEC 801-4, and lEC 801-5 represent immunity to electrostatic discharge (ESD), immunity to radio frequency electromagnetic fields, immunity to fast transients (bursts), and immunity to surges.Testing was conducted on the ultrasound unit used in this study to demonstrate compliance with lEC 60601-1 -2 (for EMC) and lEC 950 (for external TV monitors and other peripherals).P000048 Summary of Safety and Effectiveness Data, 4/2019.

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OTHER TESTING:

Testing was conducted with theOceanus PhysioPRO II® in accordance with 21 CFR 1010, Performance Standards for Electronic Products: General.

Measurements of the shock wave field were recorded at the minimal, typical and maximum energy settings as defined in the study protocol. Calculations of focal energy per pulse are based upon equation (4) in section 2.3, Beam Energy, of the draft guidance. The values were calculated including positive and rarefaction portions of the waves.

In Vitro and Animal Studies

In vitro or animal experiments were not conducted with the Oceanus PhysioPRO II®. Previous studies with similar Oceanus lithotripters were used to support safety of the Oceanus Connect because shock waves are produced similarly.

CONCLUSION:

The preclinical and clinical MDA results presented in this Summary of Safety and Effectiveness provides reasonable assurance that the Oceanus PhysioPRO II® is safe and effective when used in accordance with the device labeling. The results of a multicenter clinical study demonstrate that treatment of chronic tendinopathy with the Oceanus PhysioPRO II® provides relief from chronic joint pain for up to 12 weeks duration in patients who have previously failed mainline conservative treatment.

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FUTURE ADVANCED CLINICIAN ADVANTAGES OF THE OCEANUS CONNECT DEVICE

Herman, A. and Devey, G., 2020. FUTURE TRENDS IN MEDICAL DEVICE TECHNOLOGIES: A Ten-Year Forecast. [online] Fda.gov. Available at: <https://www.fda.gov/files/about%20fda/published/Future-Trends-in-Medical-Device-Technologies--A-Ten-Year-Forecast-%28pdf%29.pdf> [Accessed 18 May 2020].

As demonstrated through the unique balance of functional hardware and dynamic software, the Oceanus PhysioPRO II®is positioned for sustained growth across the entire healthcare and wellness landscape. A decade old forecast by the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) predicted that over the subsequent decade, medical devices would see the most growth in these six disciplines;

- electronics technology;
- detection, diagnosis, and monitoring technologies;
- decentralized care technologies;
- minimally invasive technologies;
- synthetic organs, tissues, and combination device/biological and device/drug technologies;
- demographically oriented technologies.

This premonition is validated by the current capabilities and future advancements anticipated for the Oceanus PhysioPRO II® Radial ESWT device with preliminary advancements being focused strictly on software updates -necessitated by the changing US medical device regulatory requirements- and secondary to new automated reporting capabilities the Oceanus Connect will continue to subscribe specificity and acuity changes to the existing utilization guidelines. Through Bluetooth connective function, the Oceanus Connect may be the only ESWT device currently available to the U.S. market capable of achieving predictive and preventative maintenance notification.

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CITATIONS

H. van der Worp, I. van den Akker-Scheek, H. van Schie, J. Zwerver ESWT for tendinopathy: Technology and clinical implications Knee Surg Sports Traumatol Arthrosc, 21 (2013), pp. 1451-1458

Schmitz C, Császár NB, Milz S, et al. Efficacy and safety of extracorporeal shock wave therapy for orthopedic conditions: a systematic review on studies listed in the PEDro database. Br Med Bull. 2015;116(1):115-138. doi:10.1093/bmb/ldv047

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U.S. Food and Drug Administration. 2000. 510(K)S For Extracorporeal Shock Wave Lithotripters Guidance. [online] Available at: <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/content-premarket-notifications-510ks-extracorporeal-shock-wave-lithotripters-indicated> [Accessed 18 May 2020].

Herman, A. and Devey, G., 2020. FUTURE TRENDS IN MEDICAL DEVICE TECHNOLOGIES: A Ten-Year Forecast. [online] Fda.gov. Available at: <https://www.fda.gov/files/about%20fda/published/Future-Trends-in-Medical-Device-Technologies--A-Ten-Year-Forecast-%28pdf%29.pdf> [Accessed 18 May 2020].

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SHOCK WAVE SOCIETY OF NORTH AMERICA, ST. PAUL, MN
DISCLOSURE OF FINANCIAL VESTMENT AND RESEARCH CONTRIBUTION

FOOTNOTES:
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