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Swiss LithoClast® Trilogy Lithotripter

Product Review for the Purchasing Committee

Contents

Product Overview

Swiss LithoClast Trilogy Lithotripter

Physicians use the Swiss LithoClast Trilogy Lithotripter, a proprietary dual-energy, single-probe lithotripsy and stone removal system, to fragment and remove stones in the kidney, ureter and bladder. The Trilogy system consists of capital, reusable, single-use and accessory equipment. The capital equipment consists of a console with an LCD touch-screen interface for adjusting settings and a foot switch for activating energy and suction. The reusable handpiece transduces electrical energy into ultrasound and ballistic energy delivered through a single-use probe.

Images are for reference only.

Regulatory Information

Regulatory summary

Regulation Medical Specialty	Gastroenterology/Urology
Regulation Description	Electrohydraulic Lithotripter
Device Classification Name	Lithotripter, Ultrasonic. Device class II
Trade/Device Name	The Swiss LithoClast® Trilogy Lithotripter
Intended Use	The Swiss LithoClast Trilogy is indicated for fragmentation and removal of urinary tract calculi in the kidney, ureter and bladder.
510(k) Number	K173234 , K181997, K181364 and K182490
Regulation Number	21 CFR 876.4480
FDA Classification	The Swiss LithoClast Trilogy will be marketed in the US in accordance with the U.S. 21 code of Federal Regulations as an intracorporal lithotripter. Intracorporal lithotripters are Class II devices and are subject to the premarket notifications (510(k)) process.
Clearance Date	The Swiss LithoClast Trilogy Lithotripter was originally cleared by the FDA on January 10, 2018.

FDA 510(K) Clearance Letter

January 10, 2018

E.M.S. Electro Medical Systems SA
% Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, MA 01002

Re: K173234
Trade/Device Name: Swiss LithoClast Trilogy
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic Lithotripter
Regulatory Class: II
Product Code: FEO, FFK
Dated: October 4, 2017
Received: October 5, 2017

Dear Sheila Hemeon-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

FDA 510(K) Clearance Letter

TFA-1027 Rev A
Exp. N/A
Country: USA

August 30, 2018

EMS Electro Medical Systems SA
% Sheila Hemeon-Heyer, JD, RAC
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, MA 01002

Re: K181997
Trade/Device Name: Swiss LithoClast Trilogy
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic Lithotripter
Regulatory Class: II
Product Code: FEO, FFK
Dated: July 30, 2018
Received: August 1, 2018

Dear Sheila Hemeon-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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Sincerely,

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

FDA 510(K) Clearance Letter

June 20, 2018

EMS Electro Medical Systems SA
% Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, MA 01002

Re: K181364
Trade/Device Name: Swiss LithoClast Trilogy
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic Lithotripter
Regulatory Class: II
Product Code: FEO, FFK
Dated: May 22, 2018
Received: May 23, 2018

Dear Sheila Hemeon-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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Sincerely,

Timothy Martin -S
2018.06.20 19:26:41 -04'00'

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

FDA 510(K) Clearance Letter

October 9, 2018

EMS Electro Medical Systems SA
% Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, MA 01002

Re: K182490
Trade/Device Name: Swiss LithoClast® Trilogy
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic Lithotriptor
Regulatory Class: II
Product Code: FEO, FFK
Dated: September 13, 2018
Received: September 14, 2018

Dear Sheila Hemeon-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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Sincerely,

Glenn B. Bell -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Cleaning, Disinfecting and Sterilizing

Steps A through G must be followed for reprocessing of all multi-use components. Under Step C, either C1 (manual) or C2 (automated) processing may be used. Thorough cleaning and sterilization are required. Disinfection following the cleaning step is only necessary if required by national law.

⚠ Do not exceed the recommended maximum number of reprocessing cycles, please refer to the Technical data section of the corresponding instruction manual.

☞ For cleaning and disinfecting agent, please refer to the instruction for use provided by the manufacturer.

Step A: Preparation at the point of use

⚠ For the handpiece, place the protective cap onto the handpiece connector before cleaning.

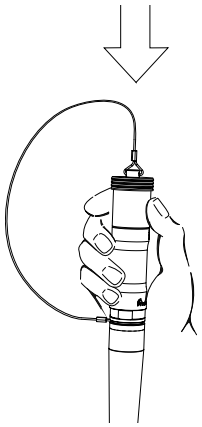

Figure 58

⚠ Do not remove the protective cap until reprocessing is completed.

Start reprocessing procedure immediately after use

1. Remove gross soiling by wiping the instrument;
2. Brush all accessible surfaces with a soft Bristol nylon brush until all visible residues are removed;
3. Rinse the product under running tap water for 20 seconds minimum.

Step B: Pre-cleaning

4. Rinse the product under running tap water for 20 seconds;
5. Immerge the product in 0.5% neutral enzymatic cleaning solution (Cidezyme, ASP or equivalent) for 5 minutes. Ensure that all lumina are completely filled with the cleaning solution. For this, rinse the lumina with a 20ml syringe (disposable) filled with cleaning solution at least three times in the normal direction of flow;
6. Rinse the product under running tap water for 30 seconds.

Step C: Cleaning, disinfection and drying process

BSC recommends performing C2 Automated cleaning, disinfecting and drying.

Step C1. Manual cleaning, disinfection and drying process

Cleaning

We recommend using Neodisher® Mediclean or equivalent as the cleaning agent as it has been used for the validation study.

- Wipe the product with a damp cloth;
- Rinse the product under running tap water for 20 seconds;
- Immerge the product in 0.5% Neodisher® Mediclean or equivalent cleaning solution for 10 minutes at 30°C. Make sure that all surfaces are moistened. For all lumina, make sure that they are completely filled with the cleaning solution. For this, use a 20ml syringe filled with the cleaning solution and inject the solution at least three times in the normal direction of flow;
- Rinse the product with deionized water. All lumina are rinsed with a water jet gun in pulsed mode (water pressure <2 bar) in the normal direction of flow for 20 seconds or until no soil is emerging.

Disinfection (if required by national laws)

The following test devices, materials & machines have been used for the validation study:

- Disinfection agent: Cidex® OPA.
- Immerse the product in a disinfectant solution Cidex® OPA (or equivalent) for 5 minutes. Ensure that all surfaces are moistened. For all lumina, make sure that they are completely filled with the disinfecting solution. For this, use a 20ml syringe filled with the disinfecting solution and inject the solution at least three times in the normal direction of flow;
- Rinse the product with deionized water for 60 seconds, while paying special attention to each gap, slit or hidden surface. All lumina have to be thoroughly rinsed with deionized water for 3 minutes with a 20ml syringe.

⚠ Disinfection must be performed no later than 1 hour after the cleaning phase.

⚠ Sterilization must be performed after disinfection.

⚠ In rare instances, Cidex OPA solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies.

Drying

Dry the outside of the instrument with a lint-free towel. Dry the lumen of the products with filtered compressed air (max. pressure 3 bar).

The instrument must never be heated >138°C.

Step C2. Automated cleaning, disinfection and drying process

Automated cleaning, disinfection and drying validation has been performed using a Miele G7836 CD washing machine, and the cleaning agent Neodisher® Mediclean or equivalent. BSC recommends using Neodisher® Mediclean for their products.

For this step, a washer/disinfector machine must have suitable baskets to hold small, fragile products and rinsing connections for the attachment to product lumina.

The program of the washer/disinfector machine shall be able to perform the following steps.

Place the instrument in a suitable rack and start the program. The following program has been shown to be effective:

- 2 min pre-washing with cold water (<40°C). Drain;
- 5 min washing with 0.5% detergent (Mediclean or equivalent) at 55°C. Drain;
- 3 min rinsing with cold deionized water (20°C). Drain;
- 2 min rinsing with cold deionized water (20°C). Drain.

Special instructions of the manufacturer for the washer/disinfector must be followed.

Disinfection (if required by national laws)

Automated thermal disinfection in a washer/disinfector taking into consideration national requirements in regards to A0-Value (see EN 15883) e.g. 93°C for 3 minutes.

A machine cleaning and disinfection method should always be used for cleaning/disinfection because of the increased effectiveness of this method.

Sterilization must be performed after disinfection.

Drying

Drying of outside of instrument through drying cycle of the washer/disinfector (e.g. 20 min at 100°C).

If product is not completely dry, perform additional manual drying using filtered compressed air (max. pressure 3 bar). Ensure all lumina are dried.

The instrument must never be heated >138°C.

Step D: Functional Testing, Maintenance

If stains are still visible on the product after cleaning/disinfection, the entire cleaning/disinfection procedure must be repeated. Products with visible damage, chips/flakes, corrosion or bent out of shape must be disposed of (no further use is permissible).

Step E: Packaging for sterilization

For prevacuum steam sterilization:

Prior to sterilization, the products must be placed in a suitable sterilization container or sterilization packaging: Compliant with EN ISO 11607 or EN 868.

For STERRAD sterilization (handpiece only):

Double wrap the handpiece in Tyvek® sterilizer pouches for STERRAD systems before placing in the sterilizer.

For AMSCO V-PRO sterilization (handpiece only):

Double wrap the handpiece in Vis-U-All Low Temperature Sterilization Self-seal pouch before placing in the sterilizer.

Step F: Sterilization

All multiuse components should follow step F1, except the handpiece which should follow step F2.

Step F1. Prevacuum sterilization - for all multiuse components except handpiece.

Sterilization of instruments by applying a fractionated prevacuum process (according to ISO 13060 and ISO 17665) taking into consideration the respective country requirements.

Parameters for the prevacuum cycle:

- Three prevacuum phases
- Minimum sterilization temperature of 132°C for 3 minutes
- Drying time: minimum 20 min

Step F2. H_2O_2 gas sterilization - for handpiece only.

The multiuse components other than handpiece have been validated only with prevacuum steam sterilization.

The Trilogy handpiece can only be sterilized using one of the following H_2O_2 gas sterilizer:

- STANDARD Cycle of the STERRAD NX and 100NX,
- SHORT Cycle of the STERRAD 100S,
- LUMEN Cycle of the AMSCO V-PRO-1, VPRO-60 and VPRO maX.

Do not use any other H_2O_2 gas sterilizer or sterilization cycle.

Step G: Storage

Storage of sterilized instruments in a dry, clean and dust-free environment at modest temperatures of 5°C to 40°C.

Clinical/Scientific Data

PRESENTED AT

WORLD CONGRESS OF ENDOUROLOGY

■ ANNUAL CONGRESS ■

September 12–16, 2017 ▪ Vancouver, Canada

Presentation Title: IN VITRO COMPARISON OF A NOVEL SINGLE-PROBE DUAL-ENERGY LITHOTRIPTER TO CURRENT GENERATION DEVICES

Author Block: D Wollin, B Winship, W Tom, D Radvak, R Jiang, C Scales, M Ferrandino, W Simmons, GM Preminger, M Lipkin

– Duke University Medical Center, United States

Introduction

Current lithotripters for percutaneous renal surgery include the ShockPulse (Olympus) and LithoClast™ Select (ElectroMedical Systems/Boston Scientific). These dual-energy lithotripters use a combination of ultrasonic fragmentation with impactor function to clear stones more efficiently. The LithoClast Trilogy (ElectroMedical Systems/Boston Scientific) is a novel single-probe, dual-energy lithotripter that utilizes ultrasonic vibration with suction capability along with an electromagnetically generated impact.

Objective

The objective of this study was to compare the stone clearance efficiency of these three devices in an *in vitro* setting.

Materials and Methods

1 cm^3 cube-shaped BegoStone phantoms were created to a hardness that mimics calcium oxalate monohydrate stones (BegoStone-to-water ratio 5:1). A single stone was placed in a hemispherical silicone support in a water bath. Each lithotripter (ShockPulse, LithoClast Select - with or without pneumatic function - and LithoClast Trilogy) was utilized under direct vision to fragment and suction the phantom utilizing a 300cc/min constant suction rate and comparable fragmentation settings. The time to stone clearance for each trial was recorded; 10 trials were performed per device. Statistical analysis was performed with ANOVA.

Results

The LithoClast Select with pneumatic function had the longest clearance time of 138 seconds. The minimum clearance was 18 seconds with the LithoClast Trilogy. When comparing the four treatment methods, there was a difference between groups by one-way ANOVA ($F[3,36] = 53.00$, $p=2.75xl0^{-13}$). Post hoc tests showed that LithoClast Select with pneumatic was significantly slower than all other devices and LithoClast Trilogy was significantly faster than all other devices (all $p<0.01$). LithoClast Select without pneumatic was similar in clearance time to the ShockPulse. (Figure 1).

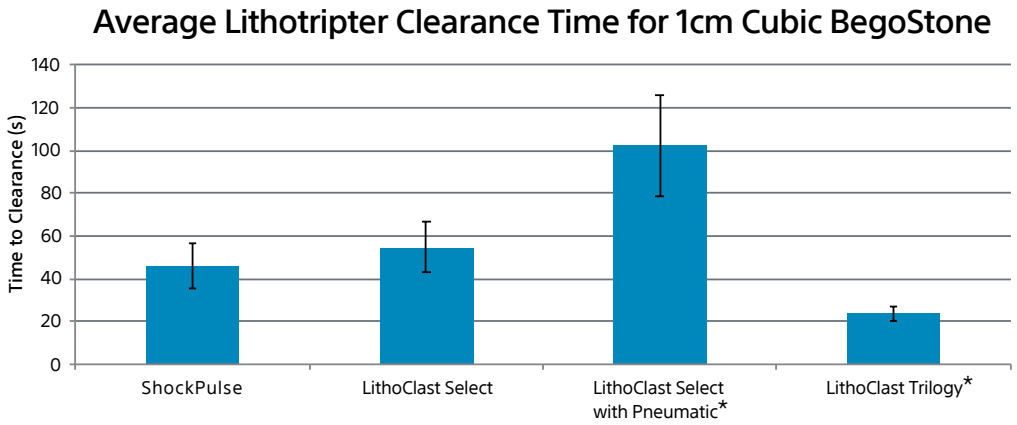

Figure 1: Average Lithotripter Clearance Time for 1cm Cubic BegoStone
(*, significantly different from all other devices, $p < 0.01$)

Conclusions

In an *in vitro* setting that mimics clinical percutaneous renal surgery, the novel single-probe, dual-energy LithoClast Trilogy was significantly more efficient than current generation dual-energy devices. However, further clinical testing is needed to ensure safety and efficacy in patients.

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Boston Scientific Corporation
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Marlborough, MA 01752
www.bostonscientific.com

Ordering Information
1.888.272.1001

URO-520111-AA FEB 2018

PRESENTED AT

WORLD CONGRESS OF ENDOUROLOGY

ANNUAL CONGRESS

September 12–16, 2017 ▪ Vancouver, Canada

Presentation Title: ENDOSCOPIC CLEARANCE LITHOTRIPSY DEVICES: BENCH COMPARISON OF STONE ELIMINATION CAPACITY AND DRILLING SPEED

Author Block: MJ Bader, F Strittmatter, A Alghamdi, T Pongratz, M Eisel, C Stief, R Sroka
– UroClinic München and Department of Urology, University of Munich, Germany

Introduction

Several endoscopic stone fragmentation and clearance lithotripsy systems are currently available. The Swiss LithoClast™ Master (EMS Switzerland) offers standalone ultrasonic lithotripsy and ultrasonic / pneumatic combination lithotripsy with 2 coaxially mounted probes to transmit ultrasonic vibration and impact generated compression waves. The ShockPulse-SE (Olympus Germany) transmits ultrasonic vibration and an ultrasonically generated shock through the same hollow probe. The latest development is the Swiss LithoClast Trilogy (EMS Switzerland) employing an electromagnetic impactor and an ultrasonic lithotripter to deliver ultrasonic vibration and ballistic impact compression waves through the same hollow probe.

Objective

The objective of this study was to compare stone elimination and drilling speed.

Materials and Methods

Cubical BegoStone (15:3) phantoms of 10mm size were used for clearance testing. Ten fragmentation and clearance tests were performed in an underwater hemisphere by 5 different operators (50 test runs per device). The average stone removal time per operator and per device was recorded and statistical analysis was performed. For the drilling speed test, a free-hand set-up was used. Stones of 15mm size were positioned on one side of an underwater balance and lithotripter probes were vertically mounted in direct contact. A weight of 450g was placed on the other side of the balance to ensure a constant contact pressure. Ten test runs per device were performed. The drilling time until breakthrough or, if no breakthrough occurred, the achieved drilling depth after 1 minute was measured and the resulting drilling speed was calculated.

Results

The Swiss LithoClast Trilogy was clearing the stone phantoms significantly faster than all other devices (Trilogy: 28 sec, ShockPulse: 39 sec, LithoClast Master ultrasound (US) only: 37 sec, LithoClast Master combined: 44 sec.). There was no significant difference between the ShockPulse and LithoClast Master with either ultrasound only or combined function. A significant difference ($p < 0.004$) was found between LithoClast Master used in combination mode vs. ultrasound standalone. A similar pattern was seen for the drilling speed, where the LithoClast Trilogy outperformed all other lithotripters (Trilogy: 0.65 mm/sec, ShockPulse: 0.46 mm/sec, LithoClast Master combined: 0.47 mm/sec and LithoClast Master US only: 0.18mm/sec). ($p<0.05$).

Conclusions

The Swiss LithoClast Trilogy was significantly faster than the other lithotripters. Since the other devices use comparable probe sizes and lumen, it seems that the clearance and drill speed advantage of the LithoClast Trilogy is based on the better performance of the electromagnetic impactor.

Boston Scientific
Advancing science for life™

Boston Scientific Corporation
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Ordering Information
1.888.272.1001

URO-520110-AB JUL 2018

PRESENTED AT

WORLD CONGRESS OF ENDOUROLOGY

ANNUAL CONGRESS

September 12–16, 2017 ▪ Vancouver, Canada

Presentation Title: COMPARATIVE EVALUATION OF TISSUE DAMAGE INDUCED BY ULTRASOUND AND IMPACT DUAL MODE ENDOSCOPIC LITHOTRIPSY VERSUS CONVENTIONAL SINGLE MODE ULTRASOUND LITHOTRIPSY

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Introduction and Objective

The EMS LithoClast™ Trilogy, a combined ultrasonic / impact lithotripter, was compared to the established ultrasound lithotripter Storz Calcuson™. The safety test simulated the accidental direct contact between lithotripter probes and the urothelium which can occur when sliding off a stone during lithotripsy or drilling through a stone.

The purpose of this study was to investigate the tissue safety of a new ultrasound and impact dual mode lithotripsy transmitted through a single probe in an in vivo animal model.

Materials and Methods

Testing was performed in pigs on bladder tissues. Six female pigs (German Landrace) were allocated into 2 groups. Cystoscopic access to the pig bladder was established through a conventional cystoscope with straight working channel. The bladder tissue was exposed to direct lithotripter probe contact at maximum power during 10 seconds to produce visible tissue lesions. Small and large diameter probes (1.5 / 3.4 re. 3.5 mm) were tested. Acute tissue trauma was evaluated using a scoring model. After 7 days, all animals were sacrificed, necropsied and examined post mortem. Histological examinations of the urinary bladder were performed with each animal. The study was performed under a GLP compliant protocol and approved by the federal ethical committee of Bavaria, Germany.

Results

Irrespective of the lithotripter used, no systemic signs of toxicity were observed up to 7 days after the intervention. All lesions were set successfully and the acute and 7 days' post-op scoring could be performed in all animals. The evaluation did not reveal any relevant differences between the lesions set with either the small or large probes. Lack of intense leucocyte and other inflammatory cells infiltration confirmed the absence of aggressive systemic reactions and was confirmed as well by the absence of effects on hematological parameters. The documented minimal to mild vascular congestion at surgery as well as 7 days post-operatively is to be considered a normal finding in response to trauma. Histologically, signs of normal ongoing healing were observed on the urinary bladder mucosa.

Conclusions

The single probe combined ultrasonic and impact lithotripsy application with the LithoClast Trilogy device showed comparable tissue safety as conventional ultrasonic lithotripsy alone.

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Reimbursement Guide

Is the Swiss LithoClast Trilogy Lithotripter reimbursable by insurance?

The procedures in which Trilogy is used are reimbursable. Billing guides with respective coding and estimated Medicare reimbursement for relevant stone management procedures are available online at www.bostonscientific.com/en-US/reimbursement/urology.html.

For additional coding and reimbursement information, contact your local Urology and Pelvic Health Territory Manager or the Urology and Pelvic Health Reimbursement Help Desk at UroPH.reimb@bsci.com or 1-508-683-4022.

Is this device patient chargeable?

"Patient chargeable" is a colloquial term used by hospitals to convey that a device/supply is appropriately charged to the patient's account (i.e. as a distinct line item on the patients claim) in the hospital/facility's patient accounting or AR system. It does not mean that the patient is actually charged directly for the device/supply nor would an insured patient ever pay an additional amount "out of pocket" for the device/supply. The fact that a hospital/facility chooses to designate certain devices/supplies (e.g., single-use devices) as "patient chargeable" will not in and of itself result in immediate increased reimbursement for the hospital/facility. It will allow CMS to better factor the true cost of the procedure into future Medicare reimbursement rate setting. It may also help in negotiations with private payers by more clearly demonstrating novel device costs that have been introduced to a procedure.

The designation of a given device/supply as "patient chargeable" is entirely up to the discretion and policy of the individual hospital/facility. Section 2202.8 of the Medicare Provider Reimbursement Manual dealing with Ancillary Services (e.g., operating room) does not specifically address which items are part of the basic (routine) charge and which are charged in addition to the basic charge (non-routine). Medicare is on record that it is up to the individual hospital to determine whether to and how to itemize the charge for a specific device/supply or alternatively, incorporate it into overhead (e.g., via the OR charge). However, Medicare does require that whatever method is chosen be applied consistently. They also require that charges billed on the CMS-1450 form (aka UB-04) be aggregated under the appropriate Revenue Code.

The appropriate Revenue Code is 272 - Medical/Surgical Supplies and Devices-Sterile Supply.

For additional coding and reimbursement questions please contact our Urology and Pelvic Health Reimbursement Help Desk at UroPH.reimb@bsci.com OR 1-508-683-4022.

Relevant Reimbursement Codes:

GUIDEPOINT Reimbursement Resources

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

CPT Codes	
50080	Percutaneous nephrostolithotomy or pyelostolithotomy, with or without dilation, endoscopy, lithotripsy, stenting, or basket extraction; up to 2 cm
50081	Percutaneous nephrostolithotomy or pyelostolithotomy, with or without dilation, endoscopy, lithotripsy, stenting, or basket extraction; over 2 cm
50395	Introduction of guide into renal pelvis and/or ureter with dilation to establish nephrostomy tract, percutaneous
50430	Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (e.g., ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; new access
50431	Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (e.g., ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; existing access
50432	Placement of nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation
50433	Placement of nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, new access
50561	Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus
52005	Cystourethroscopy, with ureteral catheterization, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service
52332	Cystourethroscopy, with insertion of indwelling ureteral

ICD-10-PCS Codes (Inpatient Procedure Codes)	
0T9030Z	Drainage of Right Kidney with Drainage Device, Percutaneous Approach
0T9130Z	Drainage of Left Kidney with Drainage Device, Percutaneous Approach
0TC03ZZ	Extirpation of Matter from Right Kidney, Percutaneous Approach
0TC13ZZ	Extirpation of Matter from Left Kidney, Percutaneous Approach
0TC43ZZ	Extirpation of Matter from Left Kidney Pelvis, Percutaneous Approach
0TC33ZZ	Extirpation of Matter from Right Kidney Pelvis, Percutaneous Approach
0TC14ZZ	Extirpation of Matter from Left Kidney, Percutaneous Endoscopic Approach
0TC04ZZ	Extirpation of Matter from Right Kidney, Percutaneous Endoscopic Approach
0TC44ZZ	Extirpation of Matter from Left Kidney Pelvis, Percutaneous Endoscopic Approach
0TC34ZZ	Extirpation of Matter from Right Kidney Pelvis, Percutaneous Endoscopic Approach
0T9140Z	Drainage of Left Kidney with Drainage Device, Percutaneous Endoscopic Approach
0T9040Z	Drainage of Right Kidney with Drainage Device, Percutaneous Endoscopic Approach
0T9340Z	Drainage of Right Kidney Pelvis with Drainage Device, Percutaneous Endoscopic Approach
0T9430Z	Drainage of Left Kidney Pelvis with Drainage Device, Percutaneous Approach
0T9440Z	Drainage of Left Kidney Pelvis with Drainage Device, Percutaneous Endoscopic Approach
0TF43ZZ	Fragmentation in Left Kidney Pelvis, Percutaneous Approach
0TF44ZZ	Fragmentation in Left Kidney Pelvis, Percutaneous Endoscopic Approach
0TF33ZZ	Fragmentation in Right Kidney Pelvis, Percutaneous Approach
0TF34ZZ	Fragmentation in Right Kidney Pelvis, Percutaneous Endoscopic Approach

ICD-10-CM (Diagnoses Codes)	
N20.0	Calculus of kidney
N20.1	Calculus of ureter
N20.9	Urinary calculus, unspecified

Possible DRG Assignments	
659	Kidney and ureter procedures for non-neoplasm with major complication or comorbidity (MCC)
660	Kidney and ureter procedures for non-neoplasm with complication or comorbidity (CC)
661	Kidney and ureter procedures for non-neoplasm without (CC/MCC)

ExpertCare Capital Equipment Technical Service Plan

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Swiss LithoClast® Trilogy

Lithotripter

ExpertCare Capital Equipment Technical Services

We are dedicated to maximizing your lithotripsy investment and delivering peace of mind with unlimited remote support and world-class replacement coverage options for your capital and reusable LithoClast® Trilogy components. Boston Scientific's **ExpertCare** Trilogy programs help to preserve your lithotripsy equipment uptime with hassle-free priority care and predictable cost of ownership. Our knowledgeable team of technical experts genuinely care and will provide prompt resolution to enable the highest quality performance out of your system.

	EssentialCare	TotalCare
Service Plan Features		
Unlimited technical support calls	●	●
24/7/365 access to technical support	●	●
Unlimited repair exchanges	●	●
Coverage of reusable components (handpieces, torque wrench)	◒ 50% off list price	●
Preventative maintenance	◒ 50% off list price*	●
Priority designation		●

● **100% Coverage**

◒ **Partial Coverage**

* Applies to Preventative Maintenance Kit

ExpertCare
Capital Equipment Technical Services

Swiss LithoClast® Trilogy

Lithotripter

Online, on the phone, or onsite, we're here for you.

We're here to provide continuing support and lasting peace of mind with service plans that meet every budget and need. With **ExpertCare**, we take care of you – so you can take care of your patients.



Technical Assistance Center: (800) 949-6708

For more information, please contact your **Boston Scientific Urology Sales Representative.**

*The information in this brochure is descriptive. Please see your service plan quote and terms and conditions for details.

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Manufactured by:
EMS Electro Medical Systems SA
Ch. de la Vuarpillière 31
CH-1260 Nyon - SWITZERLAND

Distributed by:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752

www.bostonscientific.com

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Ordering Information

Manufacturer	E.M.S. Electro Medical Systems S.A.
Distributor	Boston Scientific Corporation
Distributor Tax ID Number	04 269 5240
Will this product replace or supplement a current in-house product?	This product can replace or supplement your existing intracorporal lithotripter
Is this item/technology on contract with GPOs and/or IDNs?	Please speak to your Boson Scientific sales representative for the contract status of specific GPOs and IDNs.
Ship unit	1 UOM each*
Mode of transportation	FedEx® delivery
Minimum order quantity?	No
Lead time in working days?	1-2 days
What are the dimensions of the shipping carton container?	The Trilogy Probe Kit box is 9 1/4" (L) x 3 1/2" (D) x 31 1/7 " (H) The carton for the capital kit is 25 1/2" (L) x 23 3/10" (D) x 16 1/2" (H)
What is the list price per each unit or unit of utilization?	Please speak to your Boson Scientific sales representative for the price per each unit.
Method of purchase	Please speak to your Boson Scientific sales representative regarding sales programs for this purchase
Probes, Stone catcher, Fluid Management system storage considerations	Temperature: -29°C to +38°C / Relative humidity: max 85%
Handpiece storage considerations	Temperature: -29°C to +38°C / Relative humidity: max 85%
Console and its accessories storage conditions	Temperature: +5°C to +38°C / Relative humidity: max 85%
Is this a dated product?	Yes, the Trilogy System sterile products have a 2-year shelf life
What department(s) will use and/ or be affected by this product?	Operating Room, Cysto Suite, Urology Suite and purchasing.
Will there be additional implementation costs, such as installation, cost of education, impact on equipment or additional space?	No, however a brief in-service by a BSC representative is suggested prior to use.
Will this product require evaluation by any of the following departments?	Epidemiology/Infection Control? No Safety and Security? No Bio Engineering Maintenance? Yes Pathology/Labs? No
Can this device transmit or maintain electronic Protected Health Information (ePHI)?	No
Will this device connect to the facility's network?	No

* Trilogy Probe Kits include a Trilogy Single-Use Probe and Stone Catcher for Trilogy.

Swiss LithoClast Trilogy System Kit

UPN	GTIN	Description
M0068402000K0	7613353123994	Swiss LithoClast Trilogy System Kit
Included in Kit:		
M0068402010	7613353125707	Swiss LithoClast Trilogy Console
M0068402030	7613353125776	Swiss LithoClast Trilogy Handpiece Kit
M0068402050	7613353125806	Swiss LithoClast Trilogy Foot Switch
M0068403590	7613353133351	Trilogy Reusable Torque Wrench
M0068401810	7613353125820	Stone Catcher Holder
M0068401800	7613353125769	HDMI-VDI Cable (10m)
M0068401820	7613353125837	Filling Bottle
M0068401830	7613353125844	Bottle of Demineralized Water (2.5l)
M0068401850	7613353125721	Power Cord (US - 6m)
M0068401860		Swiss LithoClast® Trilogy System IFU
M0068401890		Quick Guide
M0068401620	7613353125851	Cleaning Rod for Trilogy Probes (3.4mm and 3.9mm)

Swiss LithoClast Trilogy Single-Use Probe Kits*

UPN	GTIN	Description	Color Code
M0068403550	7613353123703	3.9mm x 440mm Trilogy Probe Kit	
M0068403540	7613353123697	3.9mm x 350mm Trilogy Probe Kit	
M0068403530	7613353123727	3.4mm x 445mm Trilogy Probe Kit	
M0068403520	7613353123710	3.4mm x 340mm Trilogy Probe Kit	
M0068403510	7613353123734	1.9mm x 341mm Trilogy Probe Kit	
M0068403500	7613353162702	1.5mm x 440mm Trilogy Probe Kit	
M0068403470	7613353123758	1.1mm x 425mm Trilogy Probe Kit	
M0068403480	7613353123765	1.1mm x 520mm Trilogy Probe Kit	
M0068403490	7613353123772	1.1mm x 625mm Trilogy Probe Kit	

* Single-Use Probe Kits include a probe and Stone Catcher.

Swiss LithoClast® Trilogy System Accessories

UPN	GTIN	Description
M0068402030	7613353125776	Swiss LithoClast Trilogy Handpiece Kit*
M0068402050	7613353125806	Swiss LithoClast Trilogy Foot Switch
M0068403590	7613353133351	Trilogy Reusable Torque Wrench
M0068401610	7613353125790	Cleaning Rod for Trilogy Handpiece
M0068401810	7613353125820	Stone Catcher Holder
M0068401800	7613353125769	HDMI-VDI Cable (10m)
M0068401820	7613353125837	Filling Bottle
M0068401830	7613353125844	Bottle of Demineralized Water (2.5l)
M0068401850	7613353125721	Power Cord (US - 6m)
M0068401860		Swiss LithoClast® Trilogy System IFU
M0068401890		Quick Guide
M0068401620	7613353125851	Cleaning Rod for Trilogy Probes (3.4mm and 3.9mm)
M0068401630	7613353125868	Cleaning Rod for Trilogy Probes (1.9mm)
M0068401790	7613353125899	Trilogy Handpiece Suction Connector

Swiss LithoClast Trilogy Single-Use Accessories (Optional)

UPN	GTIN	Description
M0068402981	7613353126384	Stone Catcher for Trilogy (Bx5)
M0068402061	7613353132118	Double Suction Bags Set (Bx5)
M0068402071	7613353133931	Suction Bag 5l (Bx10)

Swiss LithoClast Trilogy Cart

UPN	GTIN	Description
M0068401760	7613353125912	Swiss LithoClast Trilogy Cart

* Swiss LithoClast Trilogy Handpiece Kit includes a Trilogy Reusable Torque Wrench, shipped separately.

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Bench test results may not necessarily be indicative of clinical performance.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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