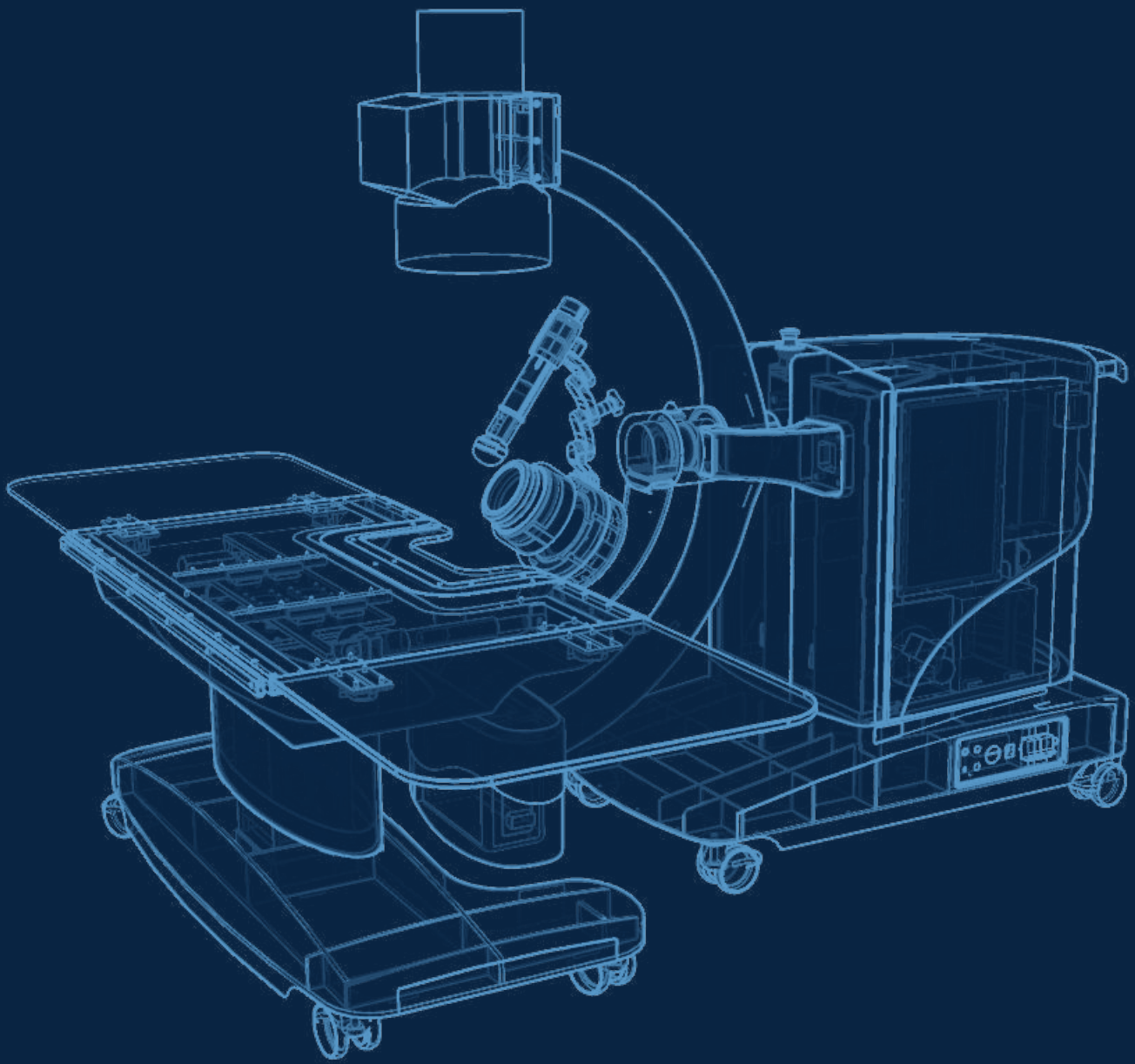
SPARK
EM ESWL



ELECTROMAGNETIC/ELECTROHYDRAULIC LITHOTRIPSY SYSTEM

CAT.1.4.1, First Release Date: 30.11.2023
Rev.01, Revision Date: -

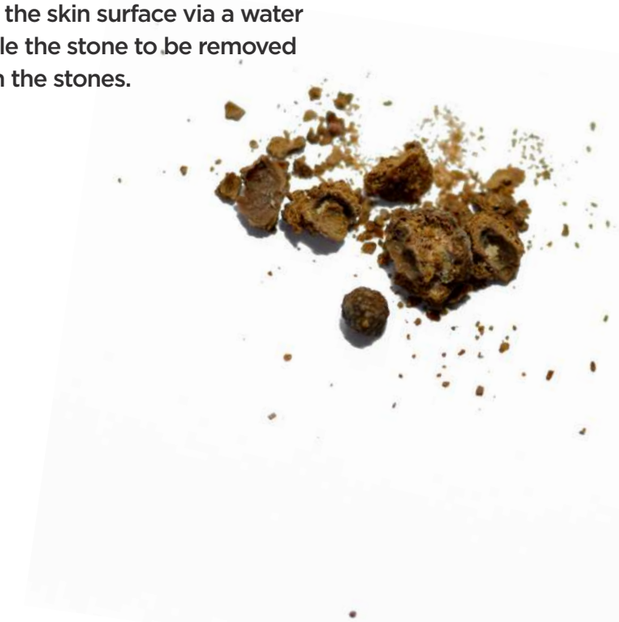
NEler medikal ltd.

SPARK EM ESWL
ELECTROMAGNETIC LITHOTRIPSY SYSTEM

SPARK EM ESWL
COMFORTABLE STONE CRUSHING EXPERIENCE!

ESWL is a non-invasive (non-surgical) procedure that is using focused shock waves to crush stones located in kidneys and ureters.

The shock waves produced by the high voltage generator are transmitted directly into the human body by contact from the skin surface via a water cushion. These transmitted shock waves enable the stone to be removed from the body with its disintegrating effect on the stones.



SUPERIOR FOCUSING SYSTEM

X-RAY AND ULTRASONIC LOCALIZATION

SPARK EM ELECTROMAGNETIC LITHOTRIPSY SYSTEM

DUAL IMAGING TECHNOLOGY!
Combines the advantages of X-Ray and Ultrasonography!

ULTRASOUND SYSTEM
Superior image processing software for Urology

Spark EM ESWL

DATABASE SYSTEM
Superior image processing software for Urology

HAND REMOTE CONTROL UNIT
Possibility of all device features control by multi-functional comprehensive remote control unit

FLEXIBLE THERAPY HEAD
Allows various stone treatment by advanced shock head movement capacity

PATIENT TABLE
Comfortable Treatments with motorized Patient Table

Superior System Efficiency

High Precision and Control

Advanced Performance

Ergonomic Design Effective Use

SPARK EM ESWL
ELECTROMAGNETIC LITHOTRIPSY SYSTEM

SPARK EM ESWL, works with its electromagnetic working principle supported by an optical lens, provides high accuracy and low precision values, with minimum pain and other complications.

The shock therapy head of **SPARK EM** has a design that is completely compatible with the patient's body. Thanks to the improved water cushion design, maximum coupling with the patient's body and treatment efficiency are provided.

With its special degassing feature, **Spark EM ESWL** decomposes the gas inside the liquid of generator to the minimum level (1-1,5 mgr/Lt) and provide best shock wave transmission with least pain on the patient.

“ İnceler Medikal has gained experience by providing technical service to various brands and models of ESWL devices for more than 20 years. Spark ESWL systems, which it developed based on this knowledge, are designed in accordance with the needs of the users and demand of the world market. ”

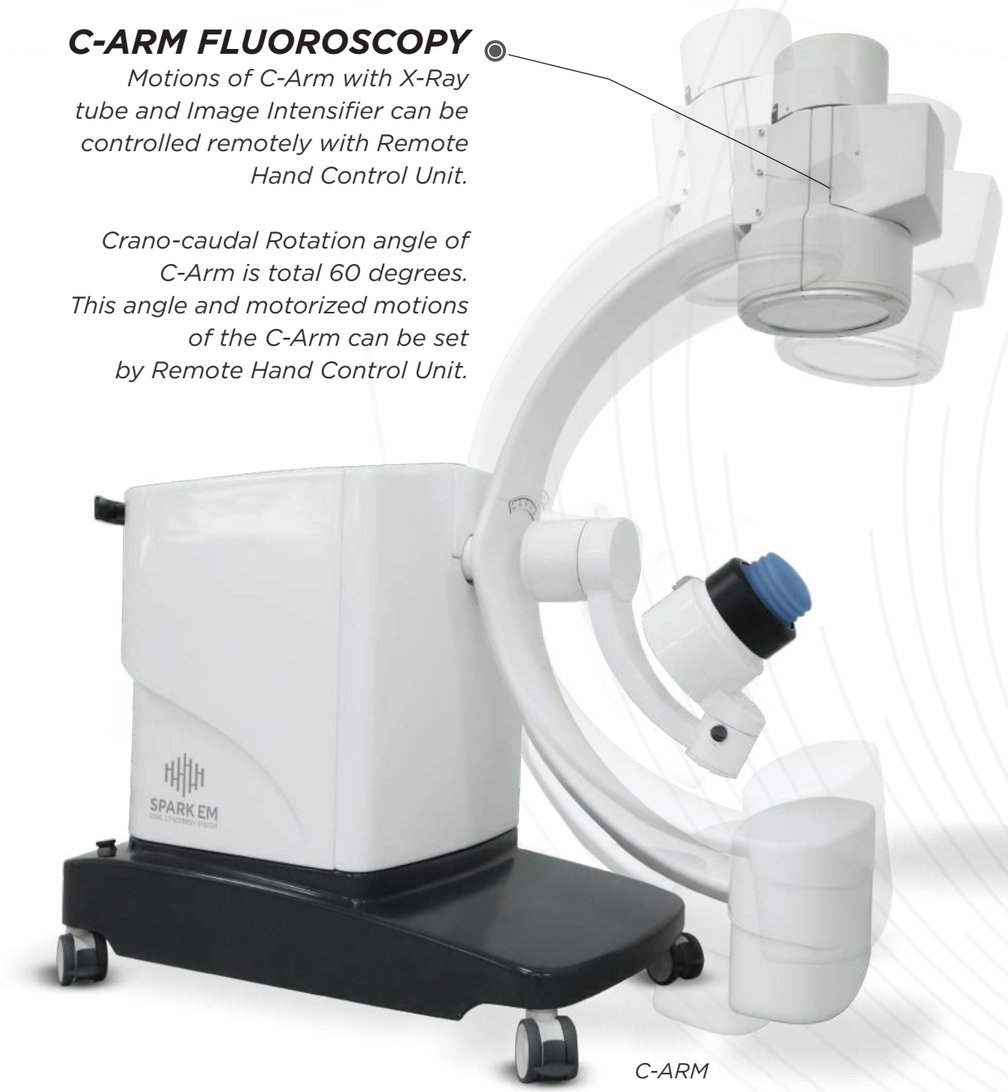
SPARK EM ESWL
ELECTROMAGNETIC LITHOTRIPSY SYSTEM

MOTION FEATURES

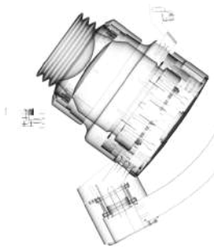
C-ARM FLUOROSCOPY

Motions of C-Arm with X-Ray tube and Image Intensifier can be controlled remotely with Remote Hand Control Unit.

Crano-caudal Rotation angle of C-Arm is total 60 degrees. This angle and motorized motions of the C-Arm can be set by Remote Hand Control Unit.



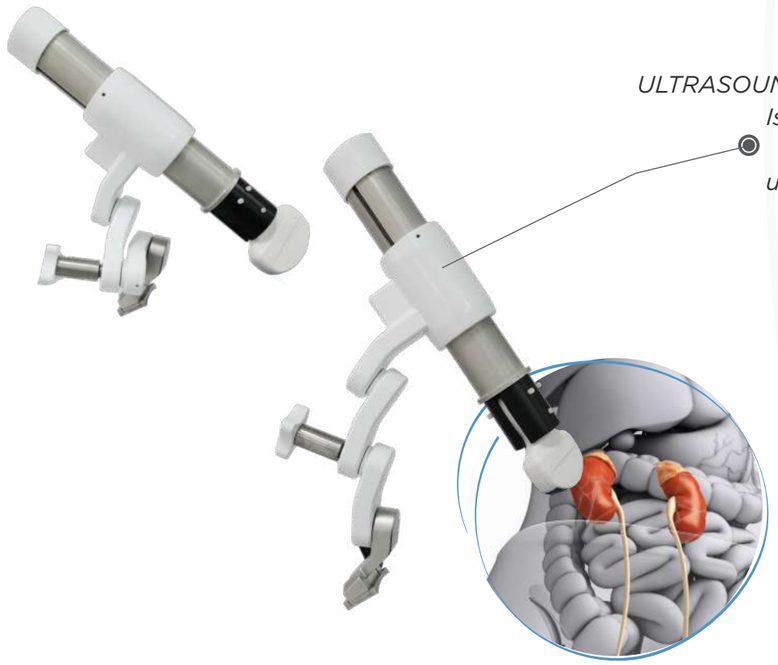
C-ARM
±30° Rotation capability of C-Arm on both directions.



Patient lays on the back for the best cushion coupling, stone targeting and shock transmission.

> ***İnceler Medikal ESWL Systems can be easily transported thanks to its semi-compact design and provides the opportunity to use in narrower areas with the Fluoroscopy unit integrated into the ESWL generator.***

ULTRASOUND IMAGING AND LOCALIZATION TECHNOLOGY



ULTRASOUND LOCALIZATION ARM
Iso-centric Designed and compatible with various ultrasonography devices.

> The external ultrasound localization system allows the ultrasound probe to have a longer life comparatively to linear localization systems.

> An optional ultrasound focusing system detects all types of stones and transmits the image in high resolution format instantenously.

> With X-ray and Ultrasound combined and separate imaging options, Spark EM ESWL systems offer the user the most comprehensive stone imaging opportunity.

> While the X-Ray Fluoroscope feature enables the patient to be positioned quickly at the initial of the operation, the Ultrasound imaging system allows the tracking of the instantaneous movements and fragmentation of the stone. In addition, in pediatric patients and in the treatment of non-opaque stones, it is possible to detect and break stones only by ultrasonography, without using X-Ray, with Spark ESWL systems.

SPARK EM ESWL
ELECTROMAGNETIC LITHOTRIPSY SYSTEM

DATABASE SYSTEM
SUPERIOR IMAGE PROCESSING SOLUTION!

Patient information, medical history, stone details, disintegration parameters, laboratory results, X-ray dosage and statistical data can be exported by software. The software not only archives the data, but also stores the patient's images in DICOM format. These recordings can be written to CD/DVD.

PATIENT TABLE
EXPERIENCE OF
COMFORTABLE TREATMENT

The multi-functional Patient Table can be used as an operating table. It has a low height feature where the patient can easily lie down without any assistance.

CAN BE MOVED AND TRANSPORTED TO ANY PLACE EASILY

All three parts of the SPARK EM system are equipped with reinforced solid wheels. The device can be used in any desired location in the hospital. It can be moved from room to room without the need for a lift or similar carrier vehicles.

SPARK EM ESWL
ELECTROMAGNETIC LITHOTRIPSY SYSTEM

REMOTE CONTROL UNIT TO CONTROL LITHOTRIPSY

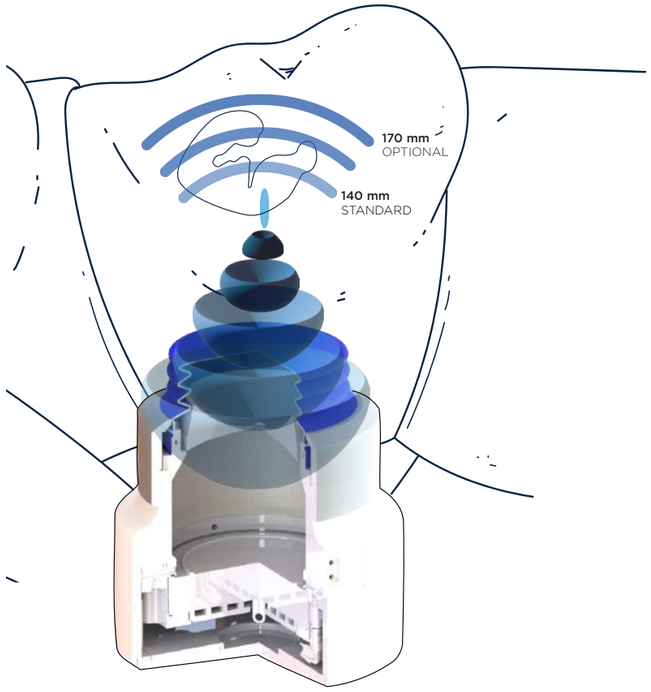
All functions can be set with a remote control unit during, before and after operations.

The Spark Em system is designed to reduce the focal point deviation to zero. The Fluoroscopy System can be used in combination with the ESWL unit and is produced with high resolution imaging standards.

> Ergonomic, lightweight and exclusive design
> Availability of ease of use remotely

PENETRATION DEPTH FEATURES OF
SPARK EM ESWL

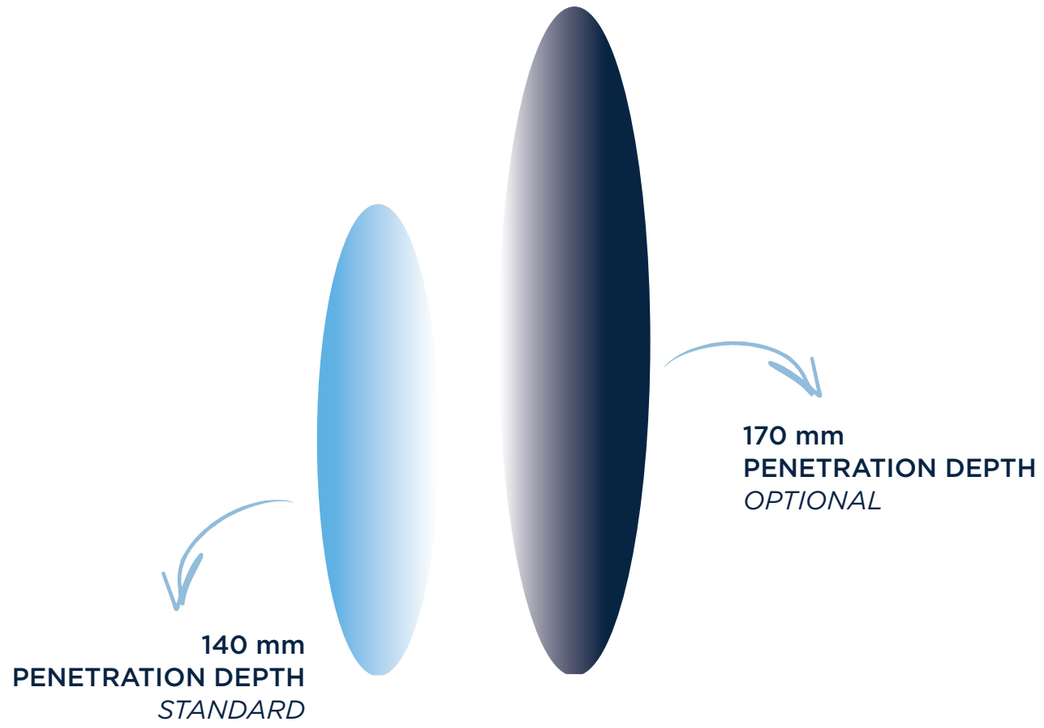
The **Spark EM ESWL** System stands out with its high penetration depth. This feature helps overweight patients achieve more effective results while responding to their treatment needs. At the same time, the system's precise determination of clear focal points plays a decisive role in the stone breaking process. In this way, the treatment is carried out more successfully with the correct targeting and fragmentation of the stones. **Spark EM ESWL** offers a more sensitive and effective approach to stone treatment by combining these features with its advanced technology.



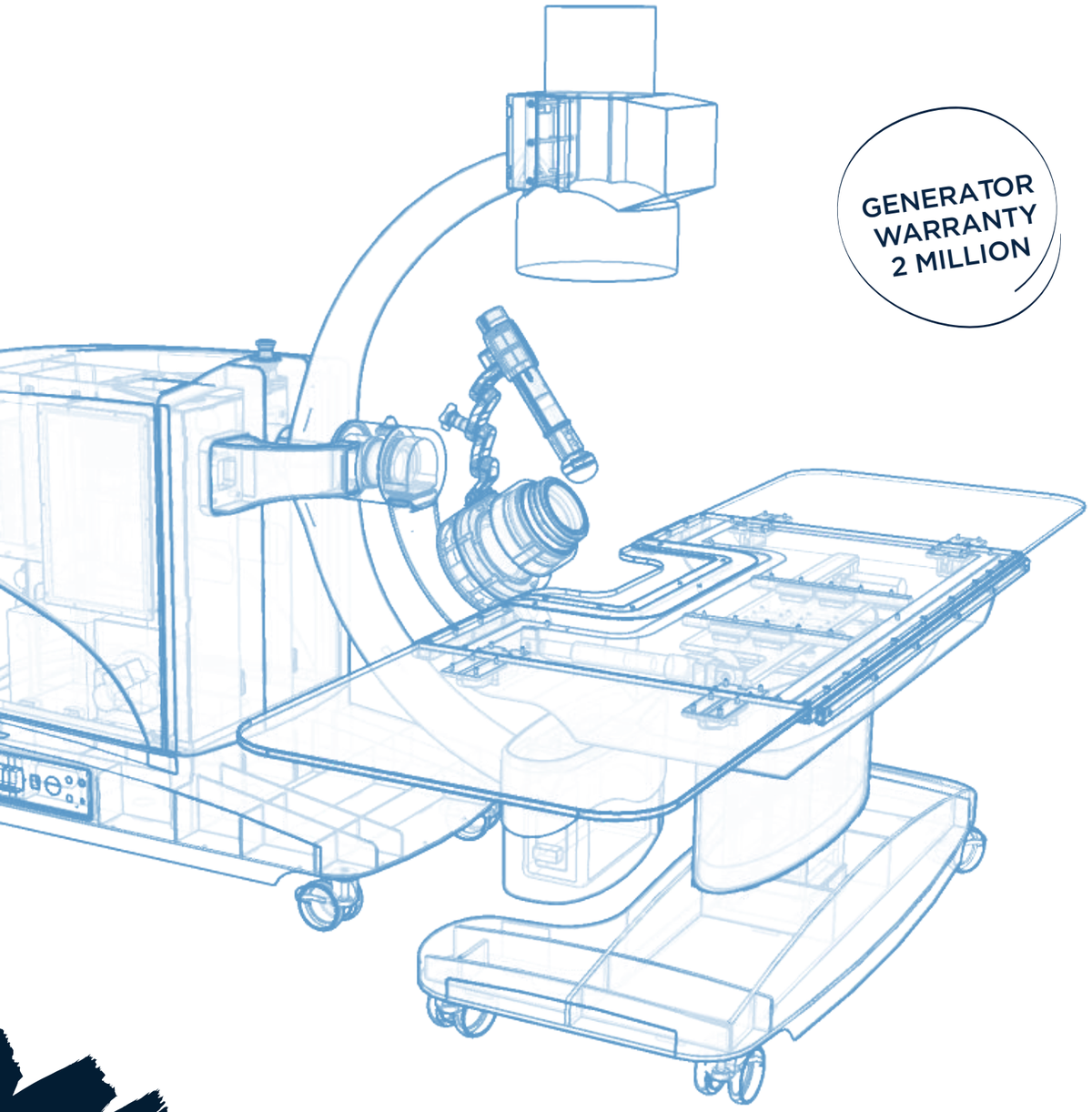
SPARK EM ESWL
ELECTROMAGNETIC LITHOTRIPSY SYSTEM

Spark EM ESWL device offers its users 2 different options for penetration depth. These options allow to customize the treatment process according to the needs of the patients and the location of the stones. The standard focusing option offers a depth of penetration of **140mm**, targeting typical stone formations, while the focusing option provides a deeper focus of **170mm**, allowing more complex or deep stones to be effectively broken.

Advanced **170 mm** depth option of the **Spark EM ESWL** device facilitates the work of medical professionals who want to achieve more precise and successful results in the field of kidney stone treatment.



SPARK EM ESWL
ELECTRMAGNETIC LITHOTRIPSY SYSTEM
TECHNICAL SPECIFICATIONS



GENERATOR WARRANTY 2 MILLION

TECHNICAL DATA/ MAIN UNIT

Manufacturer	İnceler Medikal Sağlık Hizmetleri San. Tic. Ltd. Şti.
Model	İnceler Medikal -Spark EM ESWL
Quality and Electrical Safety Classification	According to EN 60601-1 Class I Type B According to EN 93/42 MDD Class IIb
Energy Source(Working Principle)	Electromagnetic
Focusing	Acoustic lens
Patient Touch	Membrane (Dry Touch)
Localization	Fluoroscopy and/or Ultrasound
Focal Penetration	140 mm (170mm optional)
Unit Control	Hand Control Unit
Focal Pressure	Up to 700 Bar
Shockwave Generating Voltage	Variable 7 – 22 KV MAKS
Device Sturcture	Semi Compact(ESWL & Fluoroscopy)
Main Unit Dimensions	1775mm x 670mm x 1750mm
Water System	Closed system with water cushion touch. Pressure regulation and 9 lt. Water capacity
Main Body Weight	285 kg
Height	1175 mm
Length	1750 mm
Width	670 mm
General Rules for Basic Safety and Required Performance of Electrical Medical Equipment	IEC 60601-1
Electrical Medical Equipment - Part 1-2: General Requirements for Basic Safety and Required Performance - Supplementary Standard: Electromagnetic Disturbances	IEC 60601-1-2

PATIENT TABLE

Movement Height/Horizantal/Vertical	300mm/150mm/150mm
Patient Table Dimensions (wl,h)	2400mm X 740mm X 760mm
Weight	200 kg
Lifting Capacity	250 kg

X-RAY FLUOROSCOPY

Fluoroscopy Voltage	40–110 KV (Automatic Brightness Control)
Fluoroscopy Power	Max. 3,5 kW
Fluoroscopy Current	0.2–3.5 mA (ABC) two main selection
Image Intensifier	9” (12” optional)
X-Ray Tube	0,6 mm – 1,5 mm (1,8 mm optional), focal spot, fixed anode tube 40.000 H.U.
TV Camera	High resolution CCD camera
Monitor	(19”–21” optional)

GENERAL

Main Power Supply	230 ±% 10 VAC & 50/60 Hz & Single Phase
The System Complies With	According to EN 60601-1 Class I, Type B According to 93/42/MDD, Class IIb
Warranty	24 Months

SPARK EM ESWL
C-ARMLESS SYSTEM

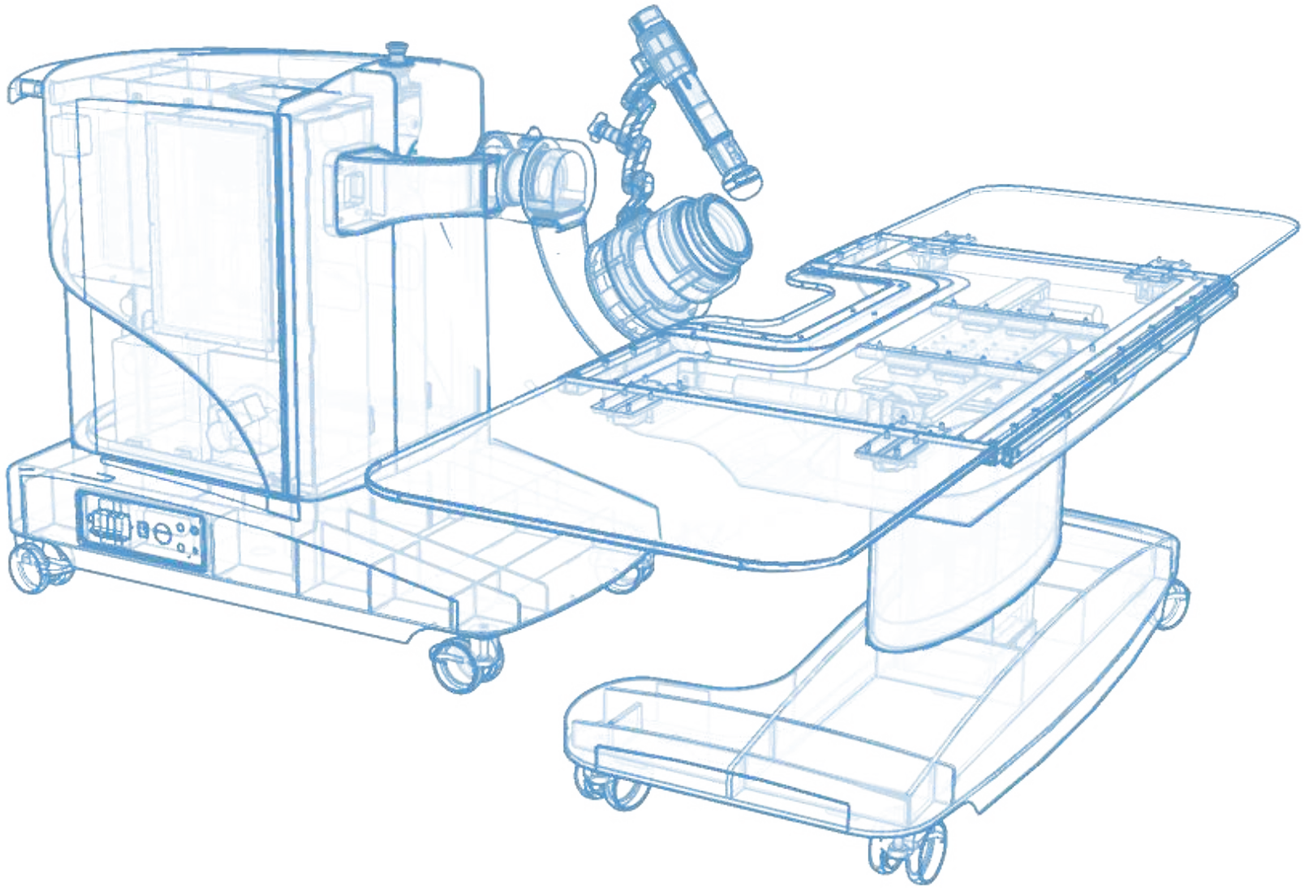
C-Armless versions of the **Spark EM ESWL** and **Spark ESW**L Systems are also available for use in combination with external C-Arm Fluoroscopy Units and/or Ultrasonography.

SPARK EM ESWL
ELECTROMAGNETIC LITHOTRIPSY SYSTEM

SPARK EM ESWL
C-ARMLESS SYSTEM

TECHNICAL SPECIFICATIONS

GENERATOR WARRANTY 2 MILLION



TECHNICAL DATA/ MAIN UNIT

Manufacturer	**İnceler Medikal Sağlık Hizmetleri San. Tic. Ltd. Şti.**
Model	**İnceler Medikal -Spark EM ESWL**
Quality and Electrical Safety Classification	**According to EN 60601-1 Class I Type B** **According to EN 93/42 MDD Class IIb**
Energy Source(Working Principle)	**Electromagnetic**
Focusing	**Acoustic lens**
Patient Touch	**Membrane (Dry Touch)**
Localization	**Fluoroscopy and/or Ultrasound**
Focal Penetration	**140 mm (170mm optional)**
Unit Control	**Hand Control Unit**
Focal Pressure	**Up to 700 Bar**
Operating Voltage	**Variable 7 – 22 KV MAKS**
Device Sturcture	**Semi Compact(ESWL & Fluoroscopy)**
Main Unit Dimensions	**1775mm x 670mm x 1750mm**
Water System	**Closed system with water cushion touch.** **Pressure regulation and 9 lt. Water capacity**
Main Body Weight	**285 kg**
Height	**1175 mm**
Length	**1750 mm**
Width	**670 mm**
General Rules for Basic Safety and Required	**IEC 60601-1**
Performance of Electrical Medical Equipment Electrical Medical Equipment - Part 1-2: General Requirements for Basic Safety and Required Performance - Supplementary Standard: Electromagnetic Disturbances	**IEC 60601-1-2**

PATIENT TABLE

Movement Height/Horizantal/Vertical	**300mm/150mm/150mm**
Patient Table Dimensions (wl,h)	**2400mm X 740mm X 760mm**
Weight	**200 kg**
Lifting Capacity	**250 kg**

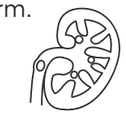
GENERAL

Main Power Supply	**230 ±% 10 VAC & 50/60 Hz & Single Phase**
The System Complies With	**According to EN 60601-1 Class I, Type B** **According to 93/42/MDD, Class IIb**
Warranty	**24 Months**

Spark ESWL®
Electrohydraulic Lithotripsy System

SPARK ESWL
ELECTROHYDRAULIC LITHOTRIPSY SYSTEM

In the **SPARK ESWL** system, all operations can be done with a remote control. During lithotripsy, the focus of the device can be controlled from any desired location. Any brand of ultrasonography device can be added to our system through the uniquely designed ultrasound localization arm.



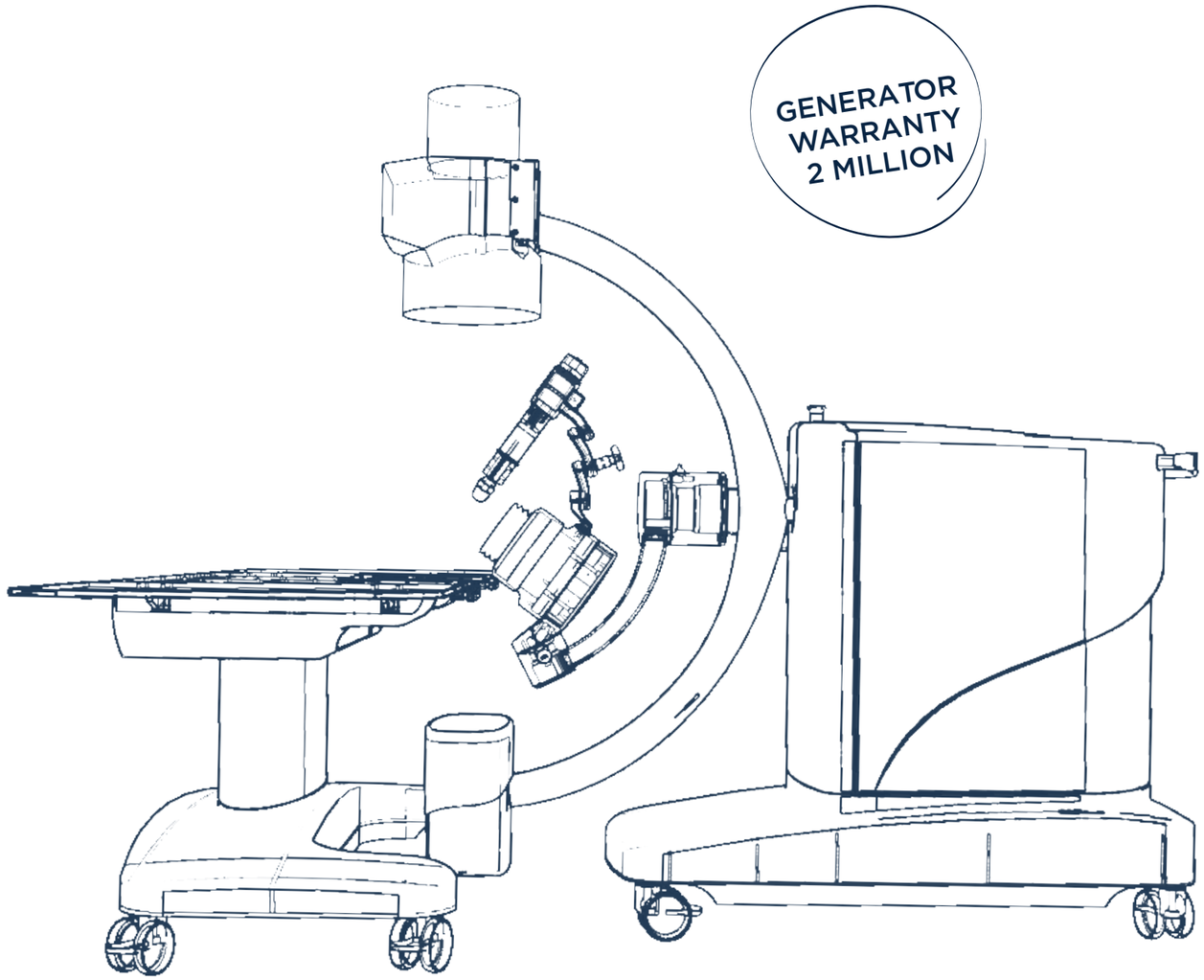
“SPARK ESWL System is designed and produced on the basis of comfortable use and easy technical service for users. Especially low after-sales operating costs are taken as a basis.”

SPARK ESWL
ELECTROHYDRAULIC LITHOTRIPSY SYSTEM

SPARK ESWL

ELECTROHYDRAULIC LITHOTRIPSY SYSTEM

TECHNICAL SPECIFICATIONS



TECHNICAL DATA/ MAIN UNIT

Manufacturer	**İnceler Medikal Sağlık Hizmetleri San. Tic. Ltd. Şti.**
Model	**İnceler Medikal -Spark ESWL**
Quality and Electrical Safety Classification	**According to EN 60601-1 Class I Type B** **According to EN 93/42 MDD Class IIb**
Energy Source(Working Principle)	**Electrohydraulic**
Focusing	**Ellipsoid reflector**
Patient Touch	**Membrane (Dry Touch)**
Localization	**Fluoroscopy and/or Ultrasound**
Focal Penetration	**130 mm**
Unit Control	**Hand Control Unit**
Focal Pressure	**Up to 700 Bar**
Electrode Type	**Long Life (40 sessions = 80.000 shocks)**
Shockwave Generating Voltage	**Variable 7 – 24 kV max**
Device Sturcture	**Semi Compact(ESWL & Fluoroscopy)**
Main Unit Dimensions	**1775mm x 670mm x 1750mm**
Water System	**Closed loop circuit with water cushion** **Pressure regulation and 9 lt. Water capacity**
Main Body Weight	**285 kg**
General Rules for Basic Safety and Required Performance of Electrical Medical Equipment	**IEC 60601-1**
Electrical Medical Equipment - Part 1-2: General Requirements for Basic Safety and Required Performance - Supplementary Standard: Electromagnetic Disturbances	**IEC 60601-1-2**

PATIENT TABLE

Movement Height/Horizantal/Vertical	**300mm/150mm/150mm**
Patient Table Dimensions (wl,h)	**2400mm X 740mm X 760mm**
Weight	**200 kg**
Lifting Capacity	**250 kg**

X-RAY FLUOROSCOPY

Fluoroscopy Voltage	**40–110 KV (Automatic Brightness Control)**
Fluoroscopy Power	**Max. 3,5 kW**
Fluoroscopy Current	**0.2–3.5 mA (ABC) two main selection**
Image Intensifier	**9” (12” optional)**
X-Ray Tube	**0,6 mm – 1,5 mm (1,8 mm optional), focal spot, fixed anode tube 40.000 H.U.**
TV Camera	**High resolution CCD camera**
Monitor	**(19”–21” optional)**

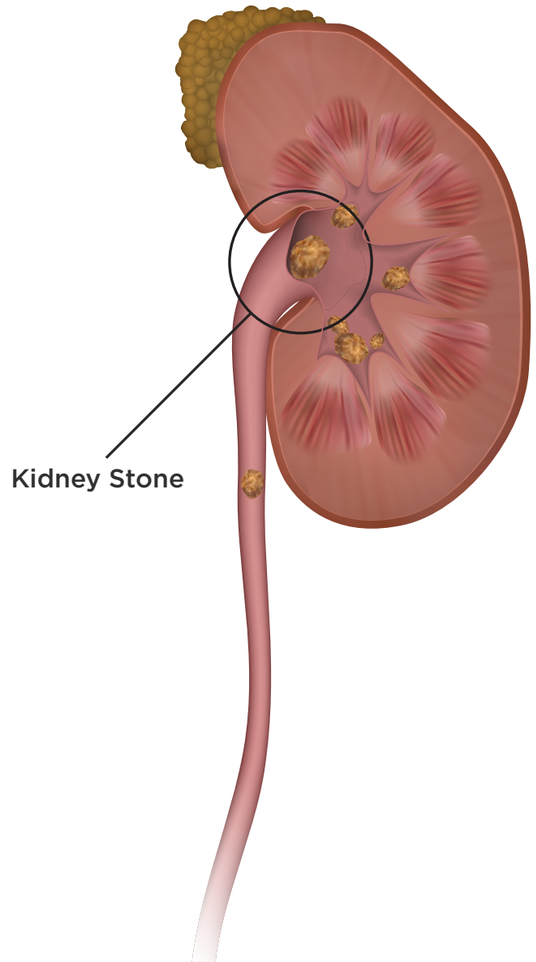
GENERAL

Main Power Supply	**230 ±% 10 VAC & 50/60 Hz & Single Phase**
The System Complies With	**According to EN 60601-1 Class I, Type B** **According to 93/42/MDD, Class IIb**
Warranty	**24 Months**

SPARK EM ESWL

ELECTROMAGNETIC/ELECTROHYDRAULIC LITHOTRIPSY SYSTEM

Spark EM ESWL is a system that aims to perform the stone breaking process in the most effective and comfortable way. This method divides large stones into smaller pieces and then allows the patient to excrete the pieces through urine by drinking plenty of water and moving the patient over time. Thanks to this method, patients are able to be cured without the need for surgical intervention.

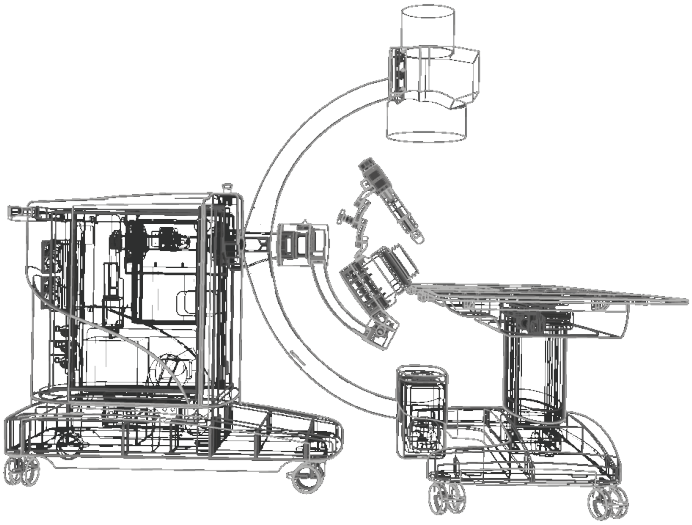


SPARK EM ESWL®
ELECTROMAGNETIC LITHOTRIPSY SYSTEM

COMFORTABLE LITHOTRIPSY TECHNOLOGY!

Üroloji

SPARK EM ESWL



Technology For Health

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SPARK EM ESWL

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