MODULITH® SLX-F2
UROLOGICAL WORKSTATION

STORZ MEDICAL

Our philosophy:
humane technology – technology for people

Rather than expecting people to adapt to new technologies, we must ensure that technical progress is adapted to the requirements of people.

Our objective: better therapies through new technologies. Established in 1987, STORZ MEDICAL AG is a Swiss member company of the KARL STORZ Group. The objective pursued by our physicists and engineers is to continuously improve shock wave technology and to develop new system concepts.

Our products have proved their efficacy in urology in millions of cases.

Man is the measure of all things (Protagoras)

MODULITH® SLX-F2 – more than just a lithotripter

Urological stone therapy is no longer an isolated discipline in medicine. Today, it embraces a wide spectrum of minimally invasive and extracorporeal procedures. While extracorporeal shock wave lithotripsy (SWL) is, of course, the method of choice for most urological stone treatments, it is complemented by transurethral and percutaneous procedures for stone fragmentation. Recent progress in flexible ureterorenoscopy and percutaneous techniques extend the range of therapy options available today.

The MODULITH® SLX-F2 is the perfect solution for multi-mode stone therapy. The integrated StorM-Touch central control platform ensures true centralized control of all instruments constituting this highly flexible, multi-functional workstation and provides maximum ease of use.

StorM-Touch is the common control platform for the plurality of different procedures that can be performed with the MODULITH® SLX-F2, from SWL and endourological techniques to PCNL, X-ray and acquisition of medical data.

StorM-Touch uses the SCB communication system developed by KARL STORZ. This ensures perfect system compatibility with a wide variety of KARL STORZ instruments and enables a customized layout of the workstation to suit specific requirements.

MODULITH® SLX-F2

Innovation and experience

The MODULITH® SLX-F2 is the result of over 20 years of experience in the design of lithotripters and of millions of cases of successful stone fragmentation in different parts of the human body. The MODULITH® SLX-F2 is an exceptional lithotripter, but it is much more than that: it is the core component of a fully integrated stone therapy system with a wide spectrum of general endourological and diagnostic features.

Integrated high-quality X-ray and ultrasound systems not only facilitate lithotripsy applications, but also turn the MODULITH® SLX-F2 into a versatile diagnostic and therapeutic workstation.

Everything under control

STORZ MEDICAL has implemented a new pioneering control concept which enables central control of the most diverse system components. All devices in the network can be easily controlled from a central touch screen, irrespective of whether stone therapy, contrast medium imaging or percutaneous procedures are performed.

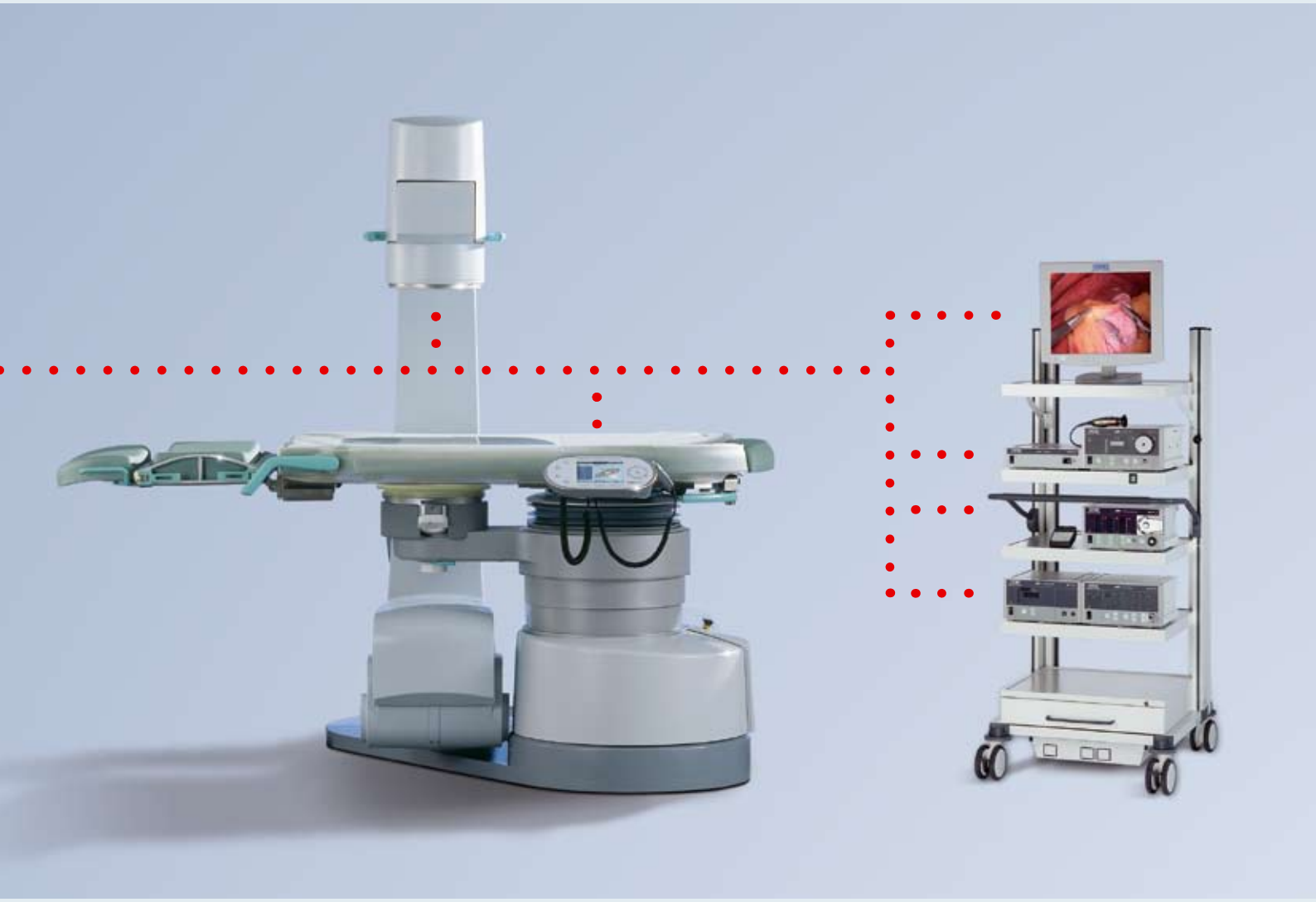
The on-screen Realistic User Interface (RUI) shows an actual picture of what the user interfaces of the individual devices look like and thus helps to avoid user errors. With StorM-Touch, the user always has everything under control, no matter whether the equipment is controlled from the local touch screen directly at the workstation or from the remote control panel behind lead-glass windows. The central control platform provides full-range functionality, including control of the lithotripter, X-ray system, endoscopic and other devices.

The workstation thus presents itself as a true fully integrated and harmonious system, rather than as a mere assembly of separate components.

StorM-Touch control platform

The StorM-Touch central control platform for urological workstations is based on the OR1 fully integrated operating room concept successfully launched by KARL STORZ GmbH & Co. KG a few years ago. All networked devices are linked with each other through the Storz Communi-

StorM-Touch

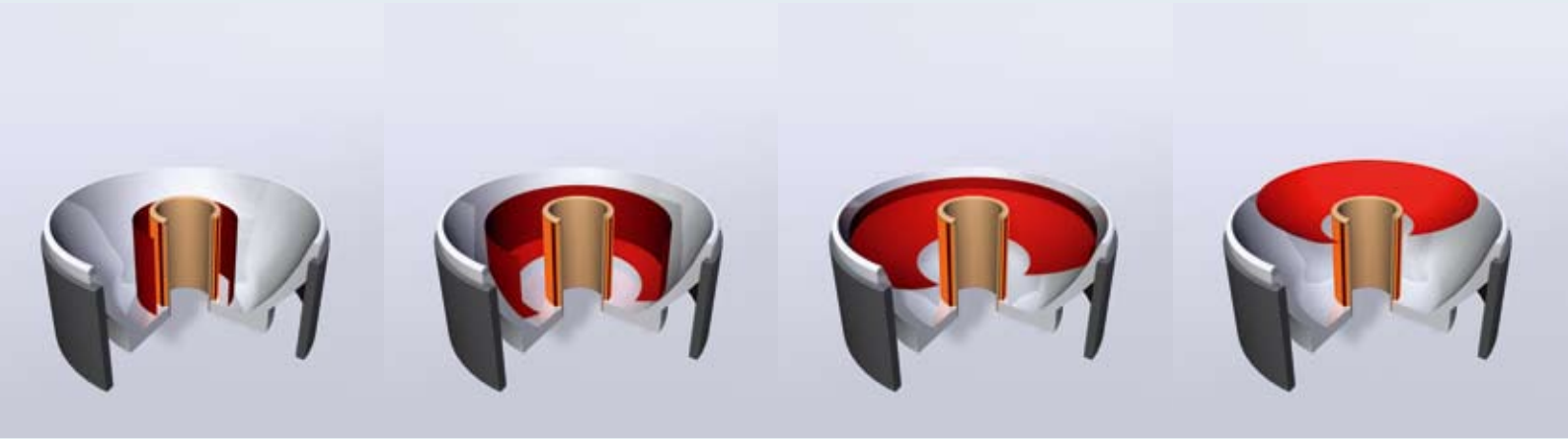


cation Bus (SCB) and can be controlled centrally. The range of systems that can be included in this suite is continuously extended. StorM-Touch is complemented by a variety of useful options:

- **LithoPos®:** automatic stone positioning system facilitates and accelerates shock wave therapy.
- **StorM-Base:** all relevant treatment parameters, patient information and X-ray images can be stored in a database for later evaluation.
- **DICOM modules:** for long-term archiving in a PACS system.

These features are described in detail under »Options«.

Cylindrical source

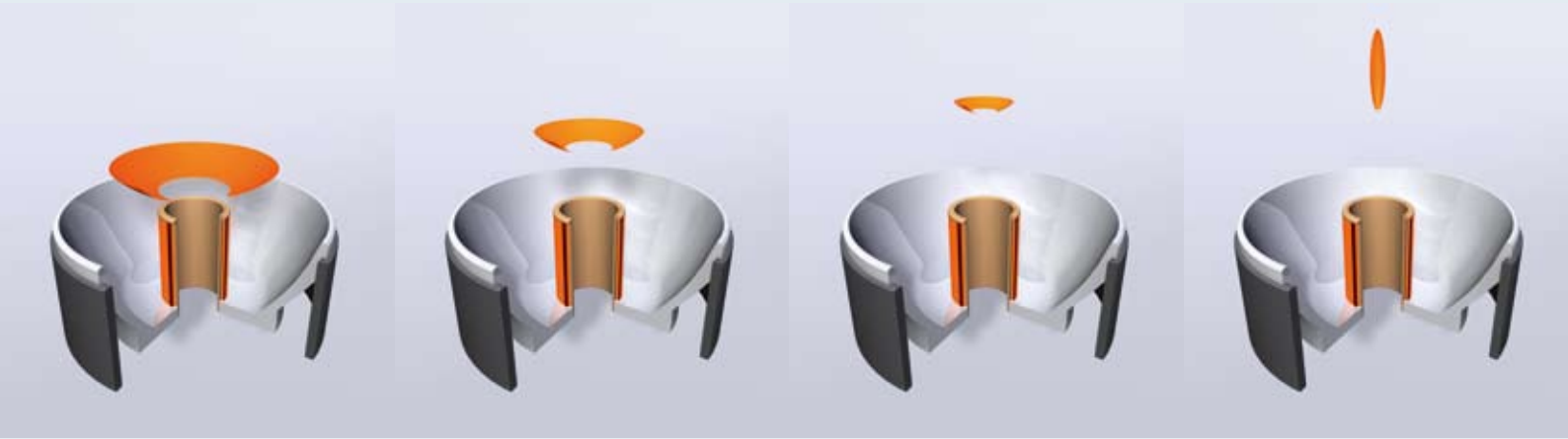


The therapy source is the core component of any lithotripter. It determines not only the stone disintegration efficiency, but also the localization systems that can be integrated into the lithotripter.

Shock waves are extremely short pressure pulses with peak pressures between approx. 10 and over 150 MPa. This is equivalent to 100 – 1500 times the atmospheric pressure.

This form of acoustic energy can be introduced into the body without any significant side effects to effectively disintegrate minimally elastic structures such as kidney stones.

Unique shock wave generator



With its patented cylindrical source, STORZ MEDICAL is the only manufacturer worldwide to have developed its own shock wave generator for exclusive use in all STORZ MEDICAL shock wave systems.

Cylinder geometry – the key to success

The specific geometry of the cylindrical shock wave source developed by STORZ MEDICAL has allowed to eliminate the drawbacks of spark gap systems and to decisively improve electromagnetic shock wave generation methods. Electromagnetically generated shock waves provide excellent dosing capability and can be triggered without any significant fluctuations at low energy levels and high pressures. One of the most crucial medical requirements is thus reliably met, which means that the pain produced by shock waves and the need for anaesthesia can be controlled in an optimum manner.

The use of reflectors with extremely large diameters (30 cm) allows the shock wave energy at the skin entry point to be distributed over a large surface area to substantially reduce any discomfort. Moreover, the cylindrical source is designed for exceptional penetration depths of up to 165 mm (optionally up to 180 mm). Even in obese patients, shock waves can thus be reliably focused on almost any stone to ensure effective fragmentation.

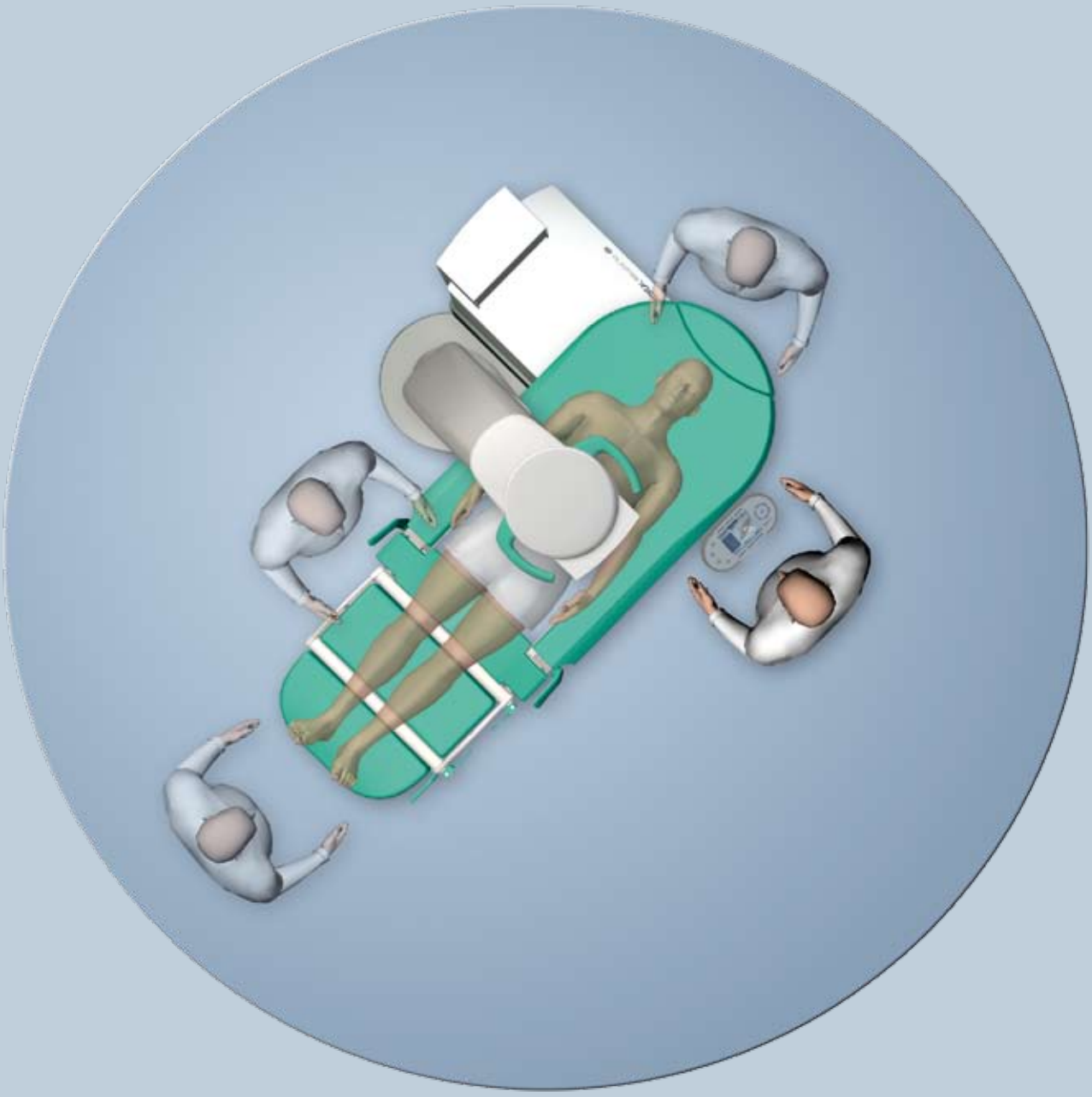
The STORZ MEDICAL cylindrical source provides excellent values for all major parameters:

- high fragmentation efficiency*
- minimum side effects
- large penetration depth for obese patients
- constant energy emission
- good dosing capability
- long service life
- low operating costs

*J. M. H. Teichman, A. J. Portis, P. P. Cecconi, W. L. Bub, R. C. Endicott, B. Denes, M. S. Pearle and R. V. Clayman: In vitro comparison of shock wave lithotripsy machines; The Journal of Urology, Vol. 164, 1259-1264, October 2000

Ergonomic design for maximum ease of use

The MODULITH® SLX-F2 was developed with a focus on ergonomic design and the requirements of the daily medical routine. Fundamental design objectives included easy access to patients from all sides, especially in the head area, and an innovative control concept to relieve users of many routine tasks and enable them to concentrate on the essentials.



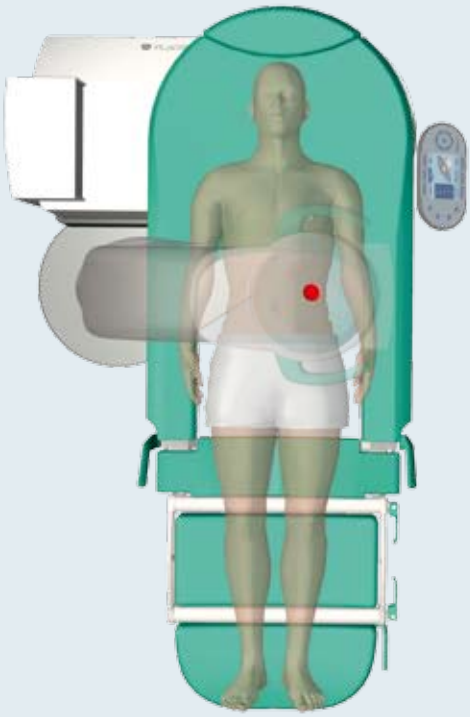
No patient repositioning required

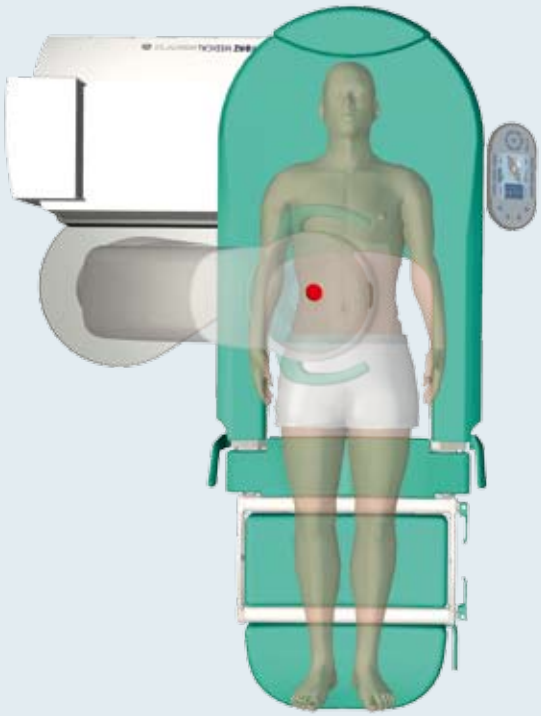
The central arrangement of the therapy source in the vertical (AP) direction adds to the highly ergonomic and user-friendly design of the MODULITH® SLX-F2. No patient repositioning is required. The left or right kidney and ureter can be treated without having to move the patient.

This means that the patient's head is always in the same position and that monitoring of vital parameters is greatly facilitated. This is of crucial importance in the rare cases in which anaesthesia is required.

The MODULITH® SLX-F2 can be equipped with mobile C-arcs from various manufacturers or with an integrated X-ray system developed by STORZ MEDICAL. The patient table is radiotransparent over the entire abdominal region so that unlimited imaging of the urogenital tract is possible from the upper kidney pole to the bladder. During this process, the shock wave source is swivelled into parking position to remove it from the X-ray path.

Fluoroscopic projections and localization in the commonly used vertical (AP) direction are based on the known standards of urological diagnostics to ensure clear orientation in the usual form. Ultrasound examinations can be performed by means of various ultrasound transducers. Even in-line transducers, which are integrated into the therapy head, can be used.

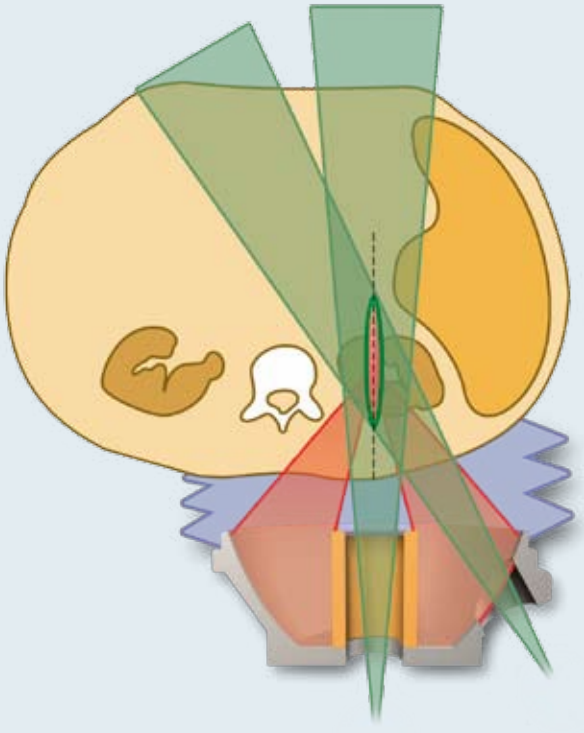


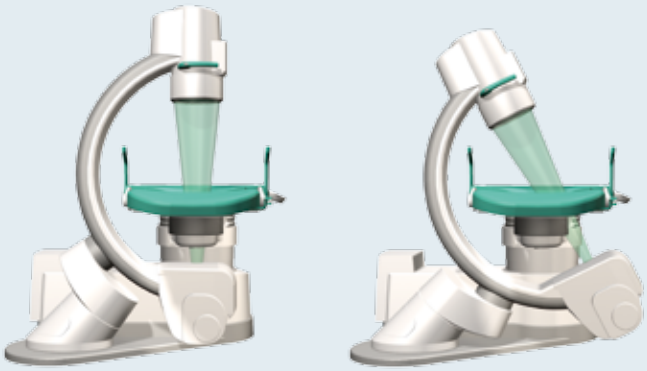


MX X-ray for localization and diagnostics

Three-dimensional stone localization requires fluoroscopic projections to be performed in two directions, i.e. at 0° and 30° relative to the vertical axis. Most lithotripters use X-ray systems that are swivelled in cranio-caudal direction as this solution is technically less complex than the lateral (orbital) swivel. However, AP and lateral projections provide better image quality than cranio-caudal projections and ensure easy and reliable identification of the stone position.

STORZ MEDICAL has developed an isocentric mechanism for lateral swivels to ensure continuous fluoroscopy during the swivelling movement. The target area can thus be reliably controlled while the X-ray system is swivelled to change between AP and lateral projection. Positioning errors can thus be avoided.





The benefits of lateral projections over cranio-caudal projections for stone localization

There are two decisive reasons why kidney stones should be localized by means of lateral projections:

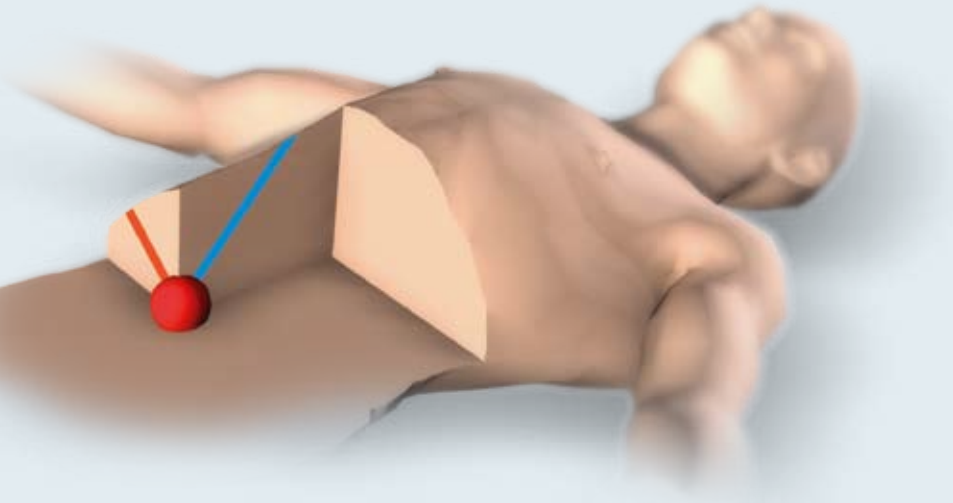
1. Respiration-induced movements of kidney and stone mostly occur along the body's longitudinal axis, i.e. in cranio-caudal direction. Precise positioning of the kidney stone in the therapy focus in the third dimension requires 30° projections. Owing to respiration-induced movements, this method inevitably leads to localization errors. These errors can be eliminated almost entirely when performing lateral projections.
2. When projections are made in cranio-caudal direction, the fluoroscopic distance in the human tissue is several centimetres longer than with lateral projections. This increases exposure to radiation both for doctors and for patients and reduces the image quality.

Airbags provide a free view

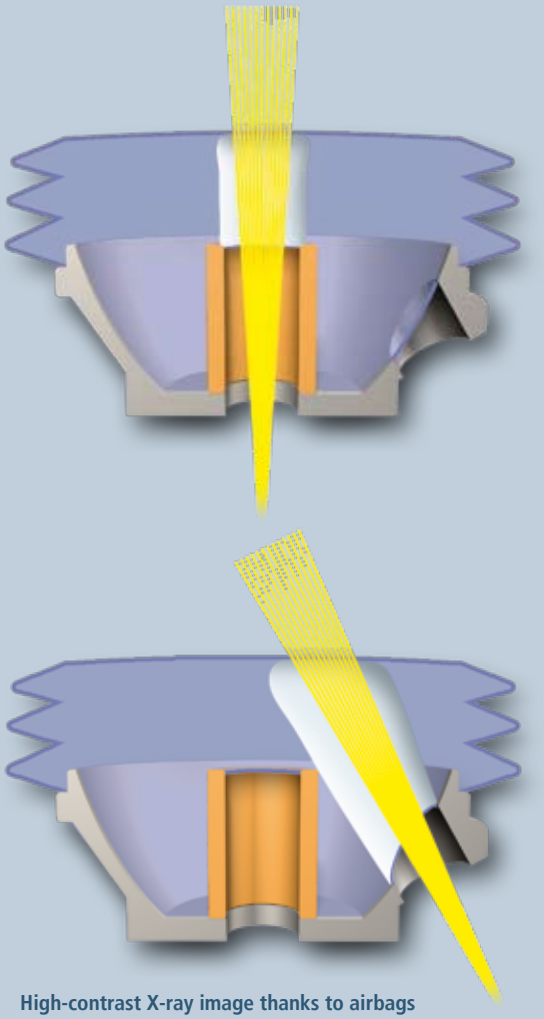
The therapy source can be completely removed from the X-ray path to ensure an unhindered view of the therapy field during X-ray fluoroscopy.

With the patented geometry of the STORZ MEDICAL cylindrical shock wave source, direct (in-line) monitoring of the therapy field through the cylindrical source is also possible while the source is coupled to the patient's body. The water cushion required for shock wave transmission and application interferes with the transmission of the X-rays due to scattering and absorption.

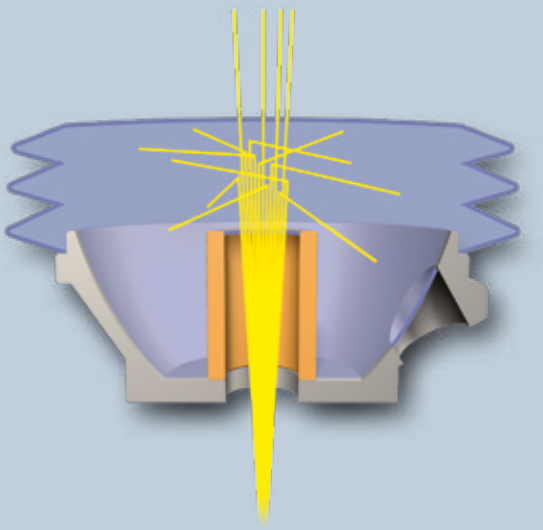
In order to eliminate these effects, airbags are used which force the water located between the shock wave source and the patient out of the X-ray path during fluoroscopy. High-contrast fluoroscopic images can thus be produced even when the therapy source remains coupled to the patient's body. A second airbag is available for 30° lateral projections.



Comparison of fluoroscopic distances
lateral
cranio-caudal



High-contrast X-ray image thanks to airbags

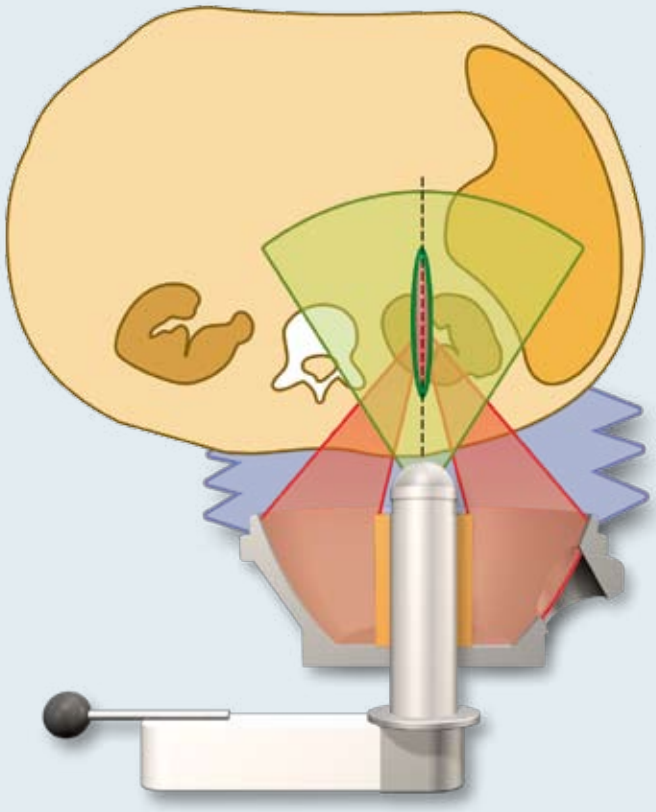


Reduced contrast due to scattered radiation in the absence of airbags

In-line ultrasound localization

Ultrasound localization concept

Stone localization can be performed by means of ultrasonography whenever the patient's specific anatomical conditions allow reliable visual stone identification. This requirement is generally fulfilled in the case of kidney stones. If ultrasound is used for localization and treatment control, the stone position can be continuously monitored without exposure to radiation. This may prove beneficial in the presence of strong respiration-induced movements or in restless patients. The cylindrical design of the STORZ MEDICAL therapy source allows the ultrasound transducer to be installed in the centre of the therapy head so that the ultrasound image shows the stone on the central therapy head axis.



This in-line arrangement ensures that obstacles such as ribs or the iliac wing are directly visible in the ultrasound image. Moreover, sensitive regions such as the lungs, heart or gas-filled organs can be reliably identified and by-passed during shock wave application. This allows even children to be treated with maximum care and without any significant risks.

In-line localization for maximum precision

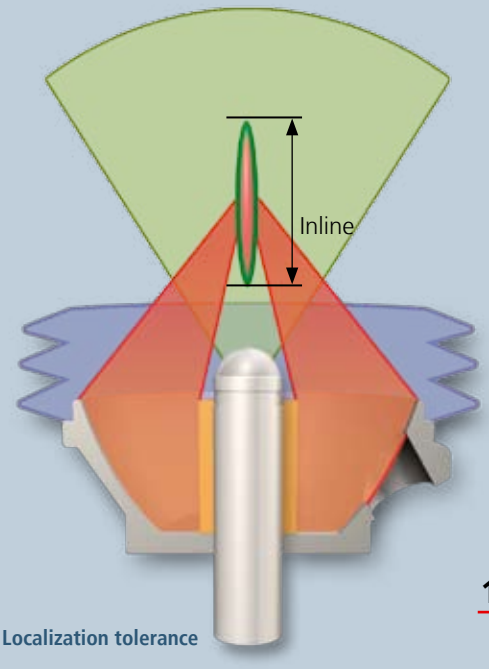
On their way from the skin surface to the stone, shock waves and ultrasound waves slightly deviate from the linear direction of propagation due to the effects of refraction at the boundary layers between neighbouring tissues. However, the co-axial (in-line) arrangement of the diagnostic ultrasound transducer and therapeutic shock wave source ensures that shock waves and ultrasound waves pass through the same tissue regions so that only minimum deviations occur with respect to their directions of propagation. This ensures optimum correspondence between the localized target area position and the shock wave focus.

In order to determine the depth of the stone to be fragmented, a precise measurement of the propagation time of the ultrasound signal is necessary. As the specific properties of tissues such as skin, fat, muscle tissue or kidney tissue are different in each patient, minor deviations in the stone depth measurements cannot be avoided. If the in-line system arrangement is used, these deviations are limited to the linear extension of the cigar-shaped focus.

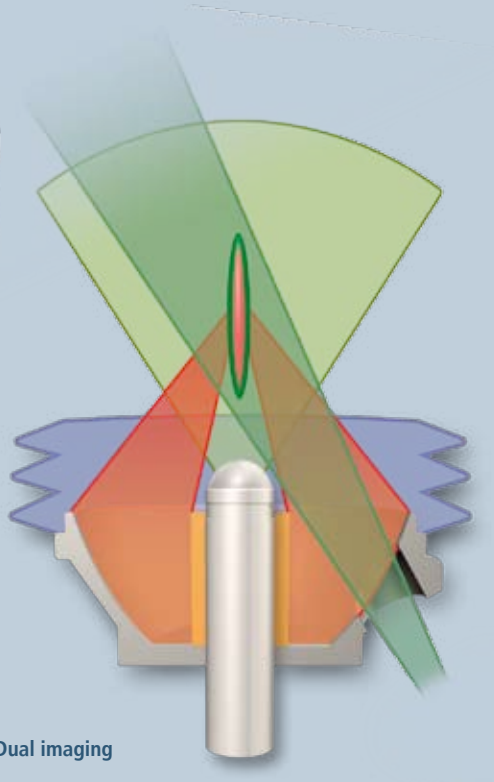
This ensures maximum targeting accuracy and fragmentation efficiency. Minor deviations in the focus depth are insignificant, and lateral shifts beyond the focal area caused by respiration-induced movements, for example, are immediately visible in the ultrasound image and can be corrected on-line.

Dual imaging

The combination of X-ray and ultrasound localization enables the doctor to choose the localization method best suited to a specific application or to use both localization systems simultaneously. The in-line ultrasound and X-ray images display the degree of stone fragmentation and clearly show whether the calculus is still located in the therapy focus. Unparalleled reliability and precision during localization and treatment are thus guaranteed.



Localization tolerance



Dual imaging

Extension capability and modular design

Modular design

The modular design of the MODULITH® SLX-F2 allows the workstation to be tailored to specific system requirements. The lithotripter can be used with different X-ray systems, for example, to create an ergonomically optimized workstation. In addition to permanently installed, stationary solutions, it is also possible to choose a »quasi-stationary« concept with mobile C-arc for localization. This quasi-stationary arrangement of the workstation devices allows direct system access without having to readjust the system components. Since no installation measures are necessary, the workstation can be easily transferred to a different room.

A mobile version is available for temporary use of the workstation at different locations. This solution provides excellent flexibility to ensure fast and easy transfer. Only minimal adjustments are necessary before treatment can be started.

Variants

MODULITH® SLX-F2 stationary system with integrated MX/1000 X-ray system

The MODULITH® SLX-F2 with integrated C-arc is designed as a stationary system for permanent installation. It is perfectly tailored to all requirements of urological treatments and includes high-resolution diagnostic imaging and storage features. In addition to fluoroscopy and digital radiography with image intensifiers, this system concept can also be supplied with a conventional radiography option using large film cassettes.

MODULITH® SLX-F2 stationary system with integrated MX/Flex X-ray system

The MODULITH® SLX-F2 with MX/Flex X-ray system is designed for stationary use. Daily adjustments are not necessary. This system concept enables fluoroscopic imaging for diagnosis and localization and offers a digital snapshot function by means of image intensifiers.

The two system concepts with integrated X-ray system (MX/1000 and MX/Flex) both use the StorM-Touch platform for X-ray and lithotripter control. Various additional software options such as LithoPos® and StorM-Base can be easily included.

MODULITH® SLX-F2 semi-stationary system with mobile C-arc

The semi-stationary version of the MODULITH® SLX-F2 is a fully featured urological workstation. It can be transferred to other rooms without requiring any significant installation work. Mobile C-arcs are used for X-ray diagnostics and X-ray localization. These C-arcs can also be used separately and independently of the lithotripter to perform other types of examinations.

MODULITH® SLX-F2 mobile system with mobile C-arc

The fully mobile version of the MODULITH® SLX-F2 has a built-in undercarriage to allow frequent and easy transport between different treatment locations. When used in combination with mobile C-arcs, the mobile variant of the MODULITH® SLX-F2 is a fully functional workstation for lithotripsy applications and endourological procedures. This solution requires only minimal installation and adjustment time.

MODULITH® SLX-F2
MX/1000 / MX/Flex stationary version

MODULITH® SLX-F2 semi-stationary version

MODULITH® SLX-F2 mobile version

OPTIONS

Dual focus

The benefits of a small focus

During lithotripsy treatment, the forces transmitted to the calculus by the shock waves exceed the limits of elasticity of the stone material, thus causing the stone to be disintegrated into tiny sand-like fragments. Depending on the type and consistency of the stone to be broken up, high forces may be required to ensure reliable stone fragmentation. Although extracorporeally induced lithotripsy is generally free from any serious side effects, tissue injury in the focal zone cannot be completely avoided. In order to minimize tissue damage in the regions surrounding the focus, the focal zone should be confined to the stone as such. However, the shock wave energy in the focus should still be high enough to ensure efficient fragmentation even of hard and impacted stones. Featuring a small focal zone with a precisely concentrated pressure field, the long-proven STORZ MEDICAL cylindrical source provides the perfect solution to meet these requirements. In physical terms, a small focus is conditional upon a large aperture of the shock wave source (diameter approx. 30 cm). Owing to technical constraints, many shock wave generators using different methods of shock wave generation are not able to produce precise focal zones in an optimum manner.

The benefits of a large focus

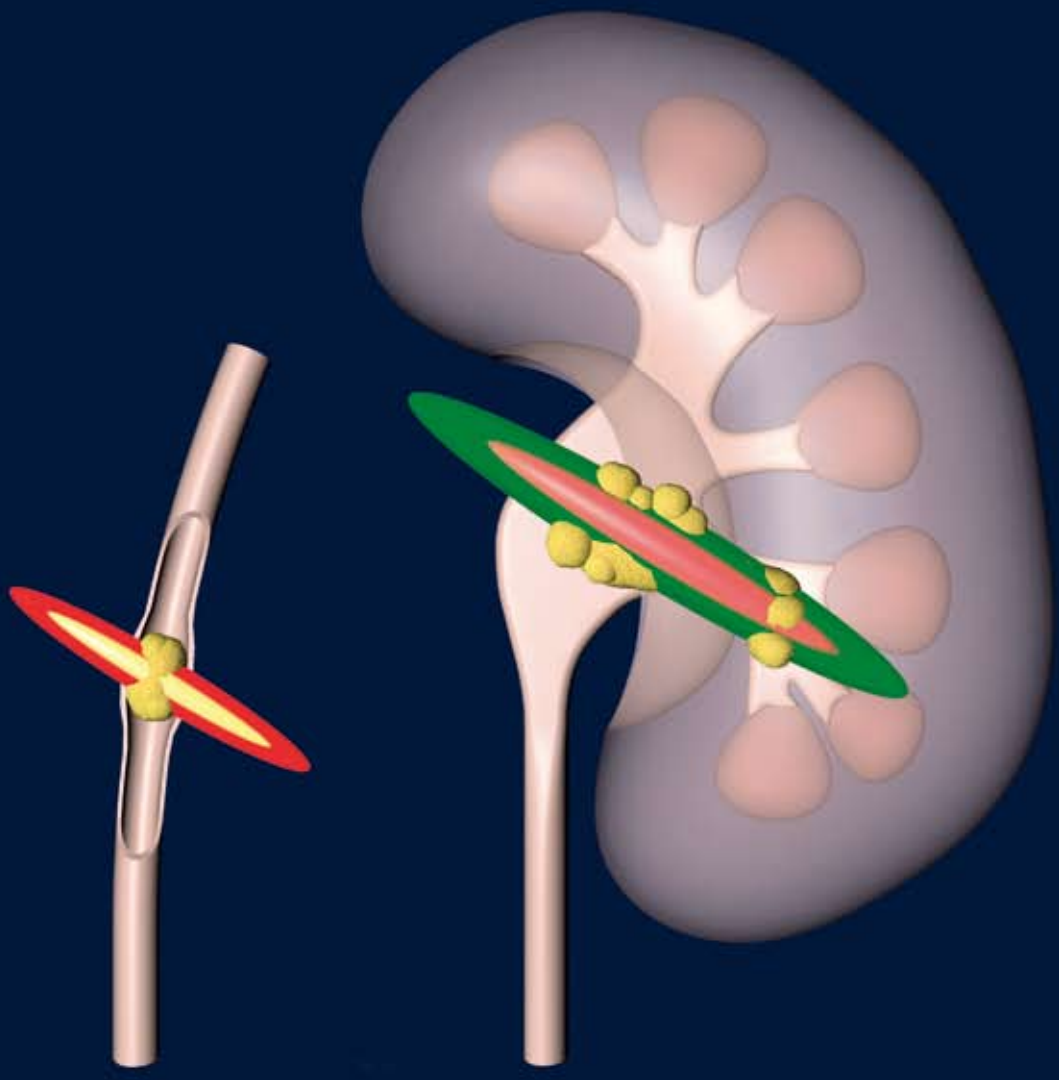
In clinical routine, precise stone positioning in the therapy focus is often not possible. Unlike with ureter stones, respiration-induced movements of the kidney, for example, cause renal stones to shift out of the focal zone periodically. Broken off concrements can thus move away from the stone into the renal pelvis or other calyces so that they can no longer be localized together with the main target concrement if a small focus is used.

Dual focus – the choice is yours!

With a simple press of a button you can change between a small focus and a large focus or vice versa – even during the therapy session. In this way, you are free to select the treatment strategy best suited to the patient's specific indication and anatomical conditions. A ground-breaking solution in the history of lithotripsy.

Dual focus

No two stones or anatomies are the same. Hence, different focal zones are required to accommodate for different stone sizes and positions. Higher pressures and precise energy concentration are necessary for the disintegration of impacted ureter stones, whereas lower pressures and larger focal zones can be used in the treatment of large stones located in the renal pelvis. The dual focus of the MODULITH® SLX-F2 enables you to perfectly adapt shock wave parameters to specific indications and to develop your own treatment strategies. To underline this decisive new system feature, »F2« has been appended to the name of the MODULITH® SLX.



Left:
Precise focus for ureter stones

Right:
Enlarged focus for kidney stones

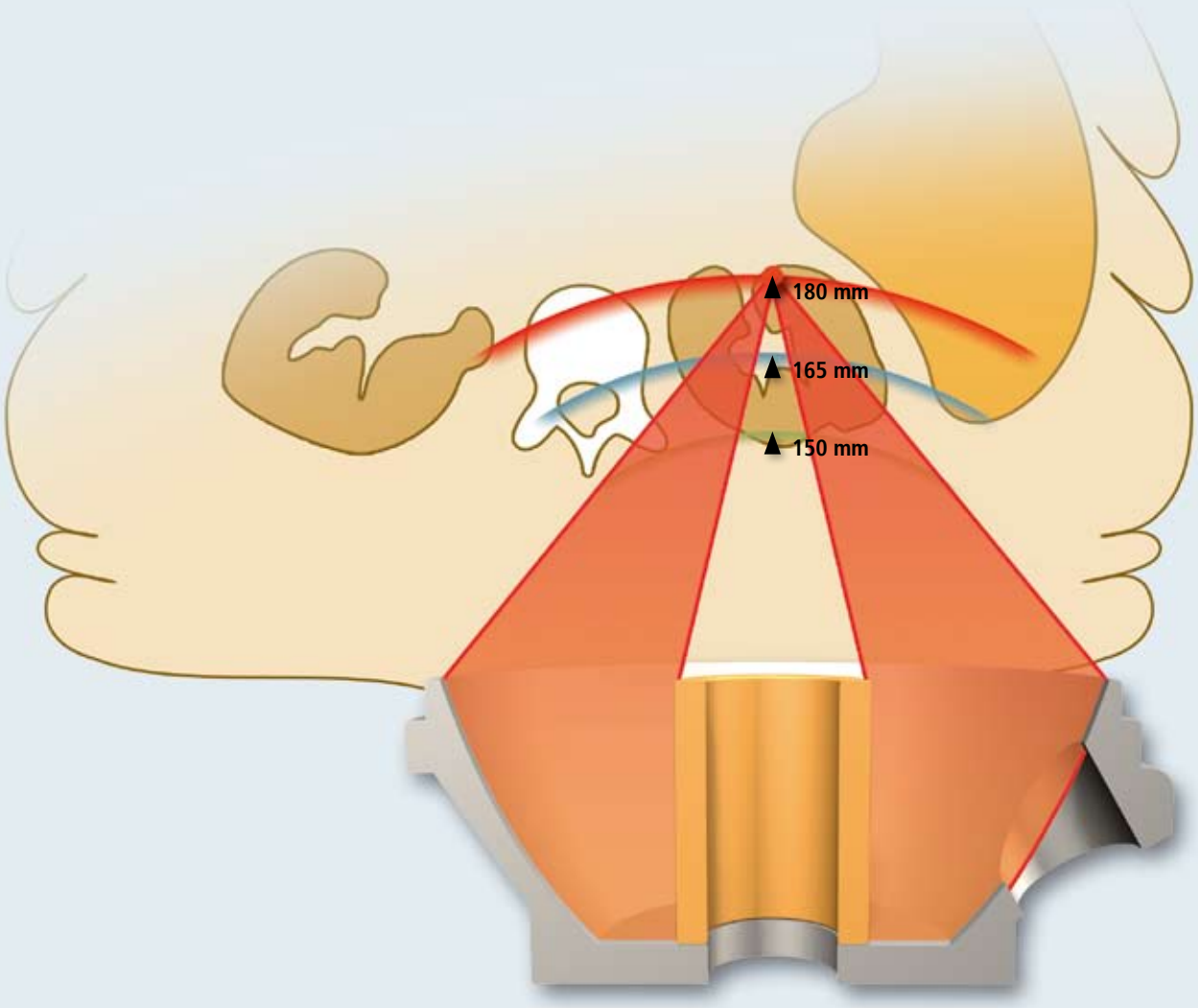
180 mm focus depth

A new world record!

During the last few decades, there has been a general trend of increasing obesity in many parts of the world. This alarming development inevitably means that the weight limits of medical devices need to be increased and that shock wave sources with higher penetration depths are required.

The MODULITH® SLX-F2 has an exceptionally high weight limit of 225 kg and can be equipped with an optional therapy source with a hitherto unparalleled penetration depth of up to 180 mm. These features enable reliable fragmentation of deep stones even in extremely obese patients and under difficult conditions.

STORZ MEDICAL has set new standards in extracorporeal shock wave lithotripsy, offering a system with a 180 mm penetration depth for the fragmentation of stones that could not be reached with conventional lithotripters.



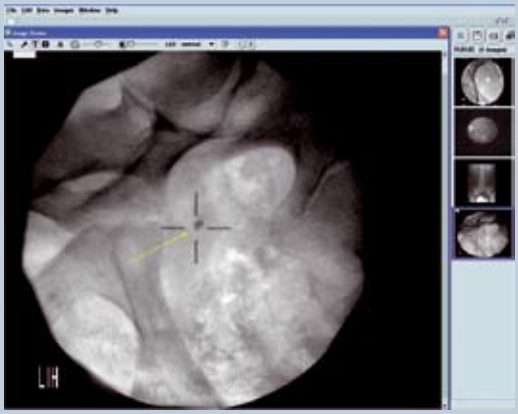
LithoPos® – automatic stone positioning

With its LithoPos® option, STORZ MEDICAL has reinvented the automatic stone positioning method. LithoPos® significantly accelerates and facilitates stone positioning. The stone merely needs to be tapped on the touch screen and is then automatically moved into the shock wave focus.

This solution offers users maximum simplicity and convenience and substantially reduces fluoroscopy times for patients.

OPTIONS

Communication/Documentation



StorM-Base – lithotripsy database with extensive functionalities

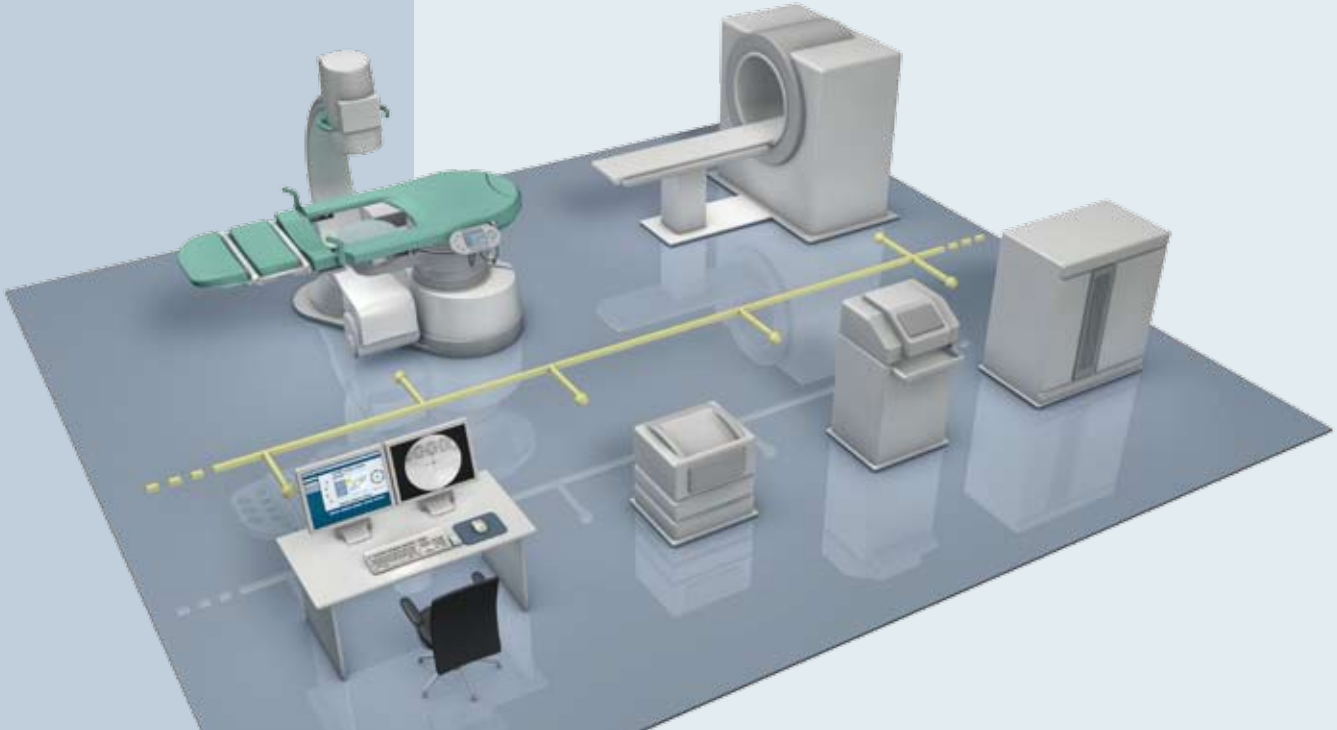
The StorM-Base software package has been specially developed for therapy and image archiving applications. It offers a multitude of features both for lithotripsy treatments and for scientific purposes.

Data can be retrieved according to user-defined combinations of criteria. Retrospective evaluation of data collected over several years is thus possible within seconds.

DICOM

With the DICOM imaging module of the StorM-Base lithotripsy database, image data can be archived locally or sent into a PACS system. Various DICOM modules are available to suit different requirements.

Patient information can be retrieved from the hospital information system (DICOM Worklist Management).

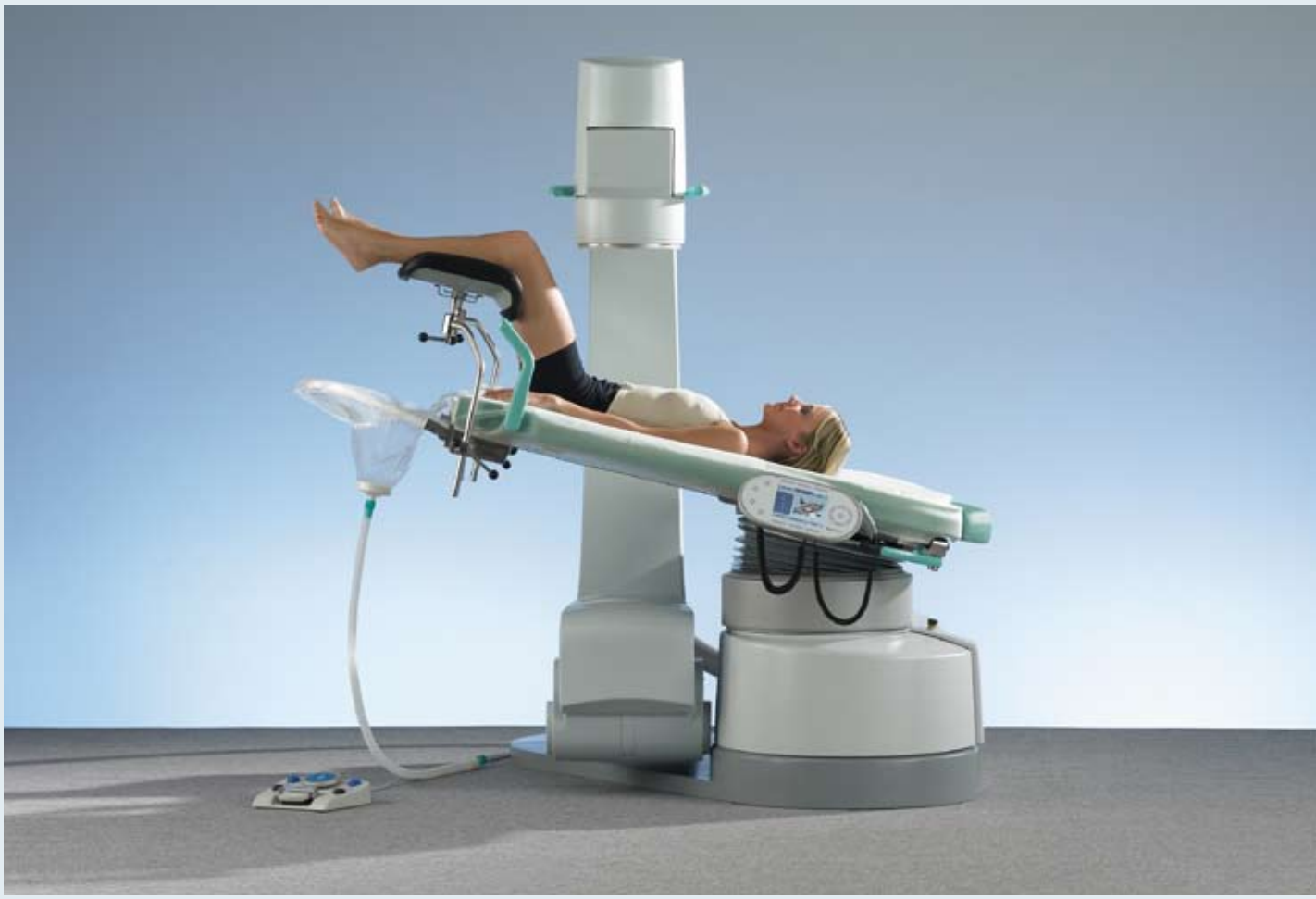


Endourological workstation

SCB-linked endoscopic devices

In addition to being a fully integrated workstation for extracorporeal lithotripsy and diagnostic X-ray, the MODULITH® SLX-F2 can be complemented by various endourological devices to cover the entire spectrum of therapy options for successful stone fragmentation. With the help of a dedicated software solution, all endourological devices currently available from KARL STORZ can be controlled directly from the StorM-Touch user interface.

STORZ MEDICAL demonstrates once again how simple it is to keep everything under control. The user-friendly central touch screen enables easy management of the complex interaction between separate system components.



OPTIONS

Radiation protection and therapy monitoring

Remote control

Remote control of the workstation from behind lead-glass windows provides perfect radiation protection of operators. However, this should not be achieved at the expense of ease of use and therapy monitoring.
This is why the remote control option of the MODULITH® SLX-F2 enables 100 percent control of all movements and all therapy and X-ray functions.
The remote control panel is used exactly in the same way as the touch screen located at the workstation. Thanks to the central control of all components via the StorM-Touch platform, the remote control panel requires only minimal space and ensures maximum user-friendliness even in space restricted environments.
This solution guarantees excellent ease of use and perfect operator protection.

Unique highlights of the MODULITH® SLX-F2:

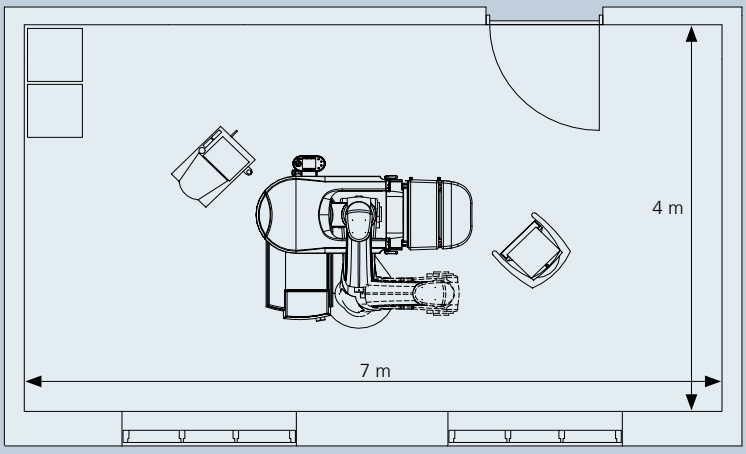
- Highly effective extracorporeal shock wave lithotripsy combined with state-of-the-art endourology – the perfect solution for the entire spectrum of minimally invasive stone therapies.
- Innovative StorM-Touch control platform – centralized control of all system functions for maximum ease of use.
- Stone therapy and diagnosis with a single system.
- STORZ MEDICAL cylindrical source for lithotripsy treatments with the most advanced technology.
- Modular design – solutions tailored to specific requirements.
- Useful software options to round off the urological workstation.

Service – always by your side

- ***Site planning***
- ***Installation***
- ***Application training***
- ***Service training***
- ***Exchange of experience among users***
- ***Maintenance***
- ***Hotline***
- ***Repair***

The services offered by STORZ MEDICAL AG range from pre-installation consultation right up to prompt assistance during everyday operation.

Extensive user training and application support are, of course, included in the scope of supply. STORZ MEDICAL also organizes technical training sessions so that minor problems can be rectified immediately by in-house hospital technicians. The MODULITH® SLX-F2 is characterized by its excellent reliability. But should any faults be encountered, our global service network ensures that qualified help is always near at hand.



Site planning

Easy installation
Minimum room size 4 m x 5 m

STORZ MEDICAL
Tägerwilen, Switzerland

Technical specifications

Stationary concept:	MODULITH® SLX-F2 (stationary):	for stationary use with integrated X-ray system
	System dimensions (L x W x H):	216 cm x 187 cm x 202 cm
	Overall system weight:	885 kg
Stationary & mobile concept:	MODULITH® SLX-F2 (mobile):	for stationary or mobile use with mobile X-ray C-arc
	Lithotripter dimensions (L x W x H):	169 cm x 89 cm x 124 cm
	Lithotripter weight:	695 kg
Shock wave source:	Shock wave generator:	electromagnetic cylindrical source
	Penetration depth:	0 – 165 mm, optionally 180 mm
	Shock wave focus:	dual focus (optional), changeover possible during therapy session
Integrated X-ray system:	Projections:	in-line AP/PA and 30° lateral (isocentric)
	X-ray generator:	50 kW (other types optional)
	X-ray modes:	fluoroscopy, film radiography, digital radiography
System with X-ray C-arc:	Projections:	in-line AP/PA and 30° lateral
	X-ray C-arc:	recommended types
	X-ray modes:	fluoroscopy and digital radiography
Ultrasound system:	Projections:	in-line localization
	Ultrasound system:	black/white (optional colour Doppler imaging)
Patient table:	Applications:	lithotripsy, endourology and urological diagnostics
	Table movement:	motorized X–Y–Z movements and Trendelenburg tilt (optional)

HUMANE TECHNOLOGY – TECHNOLOGY FOR PEOPLE

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