

MODULITH SLX-F2 Dual Focus

a report by

STORZ MEDICAL AG

Advanced Shock Wave Technology

Medically used shock waves are high-energy pressure waves that break kidney stones within the body without injuring the surrounding tissue. Most elegantly, the shock waves are generated outside the body, passed through the skin and focused onto the target stone. This procedure is called extracorporeal shock wave lithotripsy (ESWL).

ESWL was established in clinical routine in the early 1980s. First-generation machines made use of an open water bath requiring patients to be submerged into a water tub. Shock waves were generated by underwater sparks, driven by a high voltage electrical discharge. Although effective, the disadvantage was the stochastically fluctuating energy delivery and frequent replacement of worn out electrodes. Second- and third-generation machines are based on alternative shock wave technologies such as piezo-electric and electro-magnetic principles, featuring precisely reproducible energy delivery and life-cycles of a million shocks or more. The open water bath was replaced by 'dry coupling' via a water-containing coupling cushion. Further progress was made regarding implementation of different localisation modalities such as ultrasound and/or fluoroscopy.

STORZ MEDICAL AG is the only company who has developed a proprietary shock wave technology. Based on the electromagnetic principle, the STORZ MEDICAL AG shock wave source has a cylindrical configuration with a large parabolic reflector offering several technical advantages:

- high fragmentation efficiency;
- low pain sensation at skin level;
- large focal depth (0–16.5cm);
- precisely adjustable and reproducible pulse delivery; and
- in-line integration of fluoroscopy or ultrasound.

Tests of independent institutions confirmed outstanding performance with respect to fragmentation efficiency, as well as low analgesia requirements due to the extremely wide aperture of 300mm.

Having access to a superior shock wave source also has an impact on the possibility to realise favourable device concepts. Frequent change of electrodes, common with spark gap machines, usually prevents the implementation of in-line localisation systems. In-line fluoroscopy, and/or in-line ultrasound, improve precision of localisation as well as ease of orientation and therefore improve performance and operation safety.

The STORZ MEDICAL AG cylinder source offers the in-line option by design, without any restrictions.

Once again, STORZ MEDICAL AG is setting the pace by introducing innovative shock wave technology. Based on the proven cylinder configuration, STORZ MEDICAL AG now offers switchable focus geometry – the Dual Focus feature. Whereas previous machines provided either a smaller or bigger focus, the new MODULITH SLX-F2 features a dual focus, selectable according to individual clinical needs. Depending on the specific indication, the operating doctor may select the appropriate focal size.

Dual Focus – Adjustable Focus Size

The size and consistency of human kidney stones cover a wide range from bulky stag horn stones to tiny, hard cystine stones trapped in the ureter. For efficient fragmentation some require the highest shock wave pressures concentrated on a precisely defined target area whereas others need extended treatment areas with moderate pressure values. Until now, lithotripsy devices could only provide one single focus configuration. In order to match with different stone configurations, individual anatomical conditions and selected treatment strategies, adaptation of focal size is requested.

Why and Where to Use a Small Focus

During lithotripsy treatment, the forces transmitted by the shock waves to the calculus exceed the limits of elasticity of the stone material, therefore causing the stone to be fragmented 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 minimise tissue damage in the regions surrounding the focal zone, the focal zone should be confined to the stone as such. However, the shock wave energy in the focus should still be enough to ensure efficient fragmentation even of hard and impacted stones. Featuring a small focal zone with narrow pressure field, the long proven STORZ MEDICAL AG cylinder source provides the perfect solution for meeting these requirements. In physical terms, a small focus is conditional upon the large aperture of the shock wave source (diameter 300mm). Owing to technical limitations, many shock wave generators using different methods for shock wave generation are not able to provide small focal zones in an optimum manner.

Why and Where to Use a Large Focus

In clinical routine, precise stone positioning in the therapy focus is often not possible. Unlike the situation with ureter stones, respiration-induced movements of the kidney, for example, cause renal stones to shift out of the focal zone at regular intervals. Broken off concretions can therefore move away from the stone into the renal pelvis or other calyces so that they can no longer be localised together with the main target concretion if a small focus is used. Moreover, the renal parenchyma, which is inevitably located in the shock wave path, is much more sensitive to high-intensity shock waves than the ureter, so that minor vascular damage cannot be avoided. Depending on the patient's specific anatomical conditions, it may be appropriate to use a larger focus with lower shock wave pressure.

Dual Focus – The Intelligent Solution

STORZ MEDICAL AG developed the shock wave technology offering the 'switch-option' to select either one of the focal zones by simply pushing a button. Treatment strategies can now be switched between following patients or even within a treatment of a single patient. This is a groundbreaking solution in the history of lithotripsy.

Innovative Lithotripter Design

Based on the previously described proprietary shock wave technology STORZ MEDICAL AG is in the favourable position to develop superior lithotripsy devices. The new model MODULITH SLX-F2 is the result of over 20 years of experience in the design

of lithotripters and the millions of successful lithotripsy treatments performed. Characteristic features include ergonomic patient positioning, easy accessibility and, above all, easy and reliable localisation. These are essential requirements to ensure that the excellent stone disintegration quality of the MODULITH SLX-F2 applies effectively with outstanding therapy efficiency. The MODULITH SLX-F2 is more than just a lithotripter. With high-quality integral X-ray and ultrasound components, it can be used as a diagnostic and therapeutic workstation. The many different patient positioning options and the Trendelenburg tilt feature (0-15° head down tilt) speak for themselves.

Patient Positioning

When positioning immobile patients, doctors and nursing staff are required to use extreme caution and care. Likewise, helping sedated patients to get on or off the patient table is a situation that is often critical and difficult to handle. STORZ MEDICAL AG has again underscored its commitment to innovation to improve the ergonomic design of its systems and increase patient safety. The patient table of the MODULITH SLX-F2 is equipped with a tilting device with a 30° swivelling angle to help patients sit up on the patient table or lie down horizontally for treatment, therefore making patients feel safer and easing the physical strain on personnel. Once supported safely, the patient may be precisely adjusted in all three spatial dimensions by motorised controls. The central arrangement of the therapy source in vertical (anterior posterior (AP)) direction adds to the highly ergonomic and user-friendly design. No patient repositioning is required. The left or right kidney/ureter can be treated independently of the patient's alignment. This means that the patient 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.

In-line Localisation

The unique design of the shock wave source enables both ultrasound and alternating X-ray to be implemented 'in-line' (in-line means on the axis of the shock wave source). Comparable to targeting with an aiming device of a rifle, target stones can be straightly aligned with the shock wave path. Targeting is precise and easy to perform either with ultrasound or fluoroscopy. The dual imaging option is available and may be selected according to the individual conditions. Even during a single treatment, the different localisation modalities may be activated alternatively as required. No other shock wave device offers in-line fluoroscopy and in-line ultrasound in the same machine.

Multifunctionality

Facing the limited budgets of current healthcare systems, most economic solutions are requested. Since one or two imaging systems are mandatory for stone visualisation and targeting, some extra effort will provide additional use of the device beyond stone fragmentation. The modular concept of the MODULITH SLX-F2 offers implementation of different imaging devices. According to the specific needs of individual clients, high quality X-ray and/or ultrasound systems with diagnostic capabilities may be integrated. For a number of endourology procedures or other treatment options, the MODULITH SLX-F2 is well prepared. Extraordinary effort was put into the ergonomic

design of the stretcher, which not only allows for easy patient access but for special positioning such as motorised Trendelenburg inclination, three-dimensional (3-D) shifts and a sealing cover of the top of the stretcher for work in a wet environment.

Ergonomics and Mobility

Above all, the system is designed in a very compact and elegant manner. A new man-machine interface was developed to ease operation of the machine by implementing several automatic control sequences and operator guidance as well as several safety functions. The whole system can be offered as mobile unit either for transport within the hospital or for transportation from one hospital to another, serving multiple users. ■