

PRODUCT TECHNICAL REPORT

EDAP LT-01

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Nephrolithiasis (kidney stones) and cholelithiasis (gallstones) are common diseases with a morbidity rate of approximately 3% for kidney stones and 10% for gallstones of the total U.S. population. Patients with stones which are too large to be naturally eliminated by the human body generally must have extensive surgical procedures with lengthy stays in the hospital.

Extracorporeal shock wave lithotripsy (ESWL) is a noninvasive technique that enables the remote fragmentation of renal and biliary calculi. ESWL uses extracorporeally generated shock waves that are focused on the calculi and causes its fragmentation.

This paper includes a description of the EDAP LT-01 (EDAP International, Boston, MA, USA) piezoelectric extracorporeal shock wave lithotripter and the principles of its operation.

The EDAP LT-01 extracorporeal shock wave lithotripter is a compact system that uses 320 piezoelectric transducers activated by electronic generators to produce the shock wave. This is a monofocal system, i.e., the energy produced by the piezoelectric elements is not reflected before its convergence on the focal point and the renal stone. The piezoelectric elements are dispersed across the surface of a spherical cup that has a single focal point. All of the piezoelectric elements generate pulses simultaneously and in phase (coherent source). The energy waves produced by the piezoelectric elements are concentrated onto the focal point by the spherical shape of the cup. The spherical cup is part of a maneuverable treatment head that can be positioned so that the focal point of the spherical cup coincides with a target calculus. The converging pressure waves produced by the piezoelectric elements causes the destruction of the stone.

In addition to generating the shock waves, the EDAP LT-01 uses ultrasound imaging for stone localization instead of x-ray imaging. A 3.5 MHz sectorial ultrasound imaging probe is an integral

part of the EDAP LT-01 treatment head. Its imaging field includes the focus of the treatment head. The operator is able to use the ultrasound image to locate the calculus and maneuver the treatment head so that its focus precisely coincides with the target stone. In addition, the destruction of the stone can be monitored continuously, in real time, on the screen of the ultrasound scanner.

The shock waves and the imaging acoustic waves are transmitted through an adjustable level water pocket covered by an elastic membrane above the spherical cup. The membrane is placed in contact with the patient and efficient coupling is assured by using conducting gel between the membrane and the patient's skin.

Generation of shock waves with the EDAP LT-01 can be precisely adjusted so that the treatment can be individualized for each patient. The shock wave generation system of the EDAP LT-01 allows the shock wave energy per pulse and the frequency of the pulses to be easily adjusted by the operator.

Functional Description

The EDAP LT-01 lithotripter, pictured in Figure 1, consists of the following major components:

- Treatment head and support
- Electronic generator
- Ultrasound scanner
- Control console
- Treatment table
- Power supply
- Optional peripheral equipment

Treatment Head and Support

The treatment head, illustrated in Figure 2, is a major element of the EDAP LT-01 system and

