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Balev et al.

[11] **3,735,764**

[45] **May 29, 1973**

[54] **INSTRUMENT FOR CRUSHING STONES IN URINARY BLADDER**

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[21] Appl. No.: **92,056**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 871,849, Oct. 28, 1969, abandoned, which is a continuation-in-part of Ser. No. 444,681, April 1, 1965, abandoned.

[52] **U.S. Cl.** ....**128/328,** 128/24 A

[51] **Int. Cl.** ...**A61h 21/00,** A61h 29/00, A61b 17/00

[58] **Field of Search** ....128/328, 24 A

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[57] **ABSTRACT**

A method and apparatus for non-surgical removal of concretions in the urinary tract. A lithotrite including a central and outer electrode is connected to electric pulser means including spark discharge members for generation of electrical pulses which result in hydraulic shock waves being emitted from the lithotrite. In operation, the lithotrite is placed adjacent the concretion to be crushed which is surrounded by a dielectric fluid. The frequency and/or intensity of the hydraulic shock wave can be varied until the desired crushing of the concretion is achieved.

21 Claims, 7 Drawing Figures

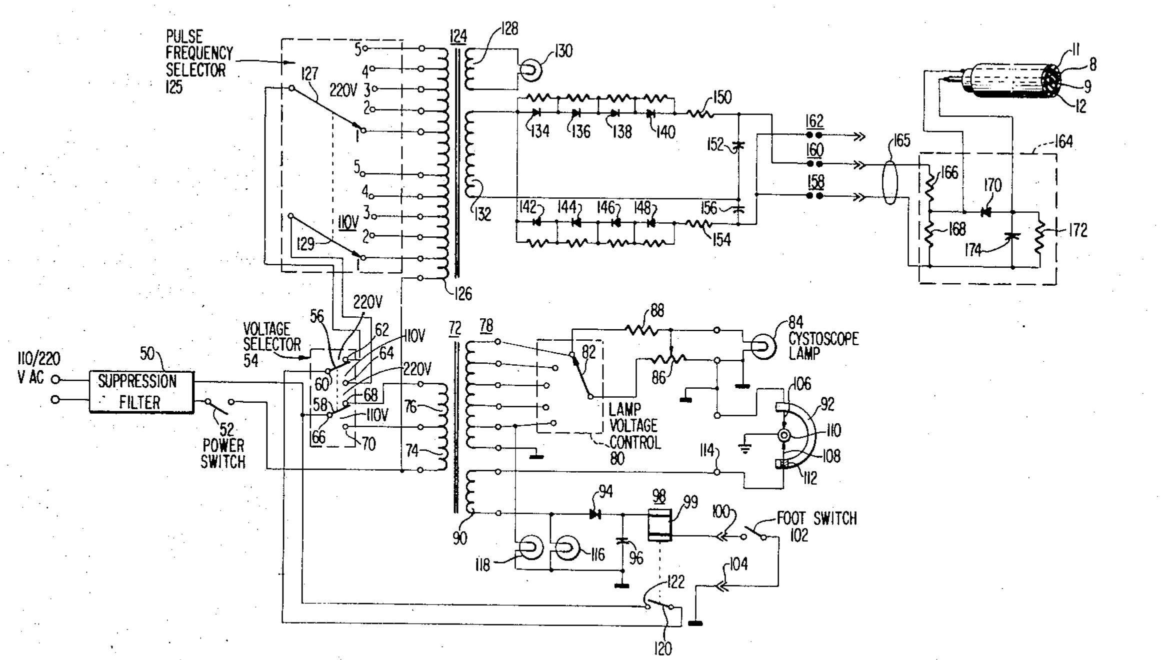
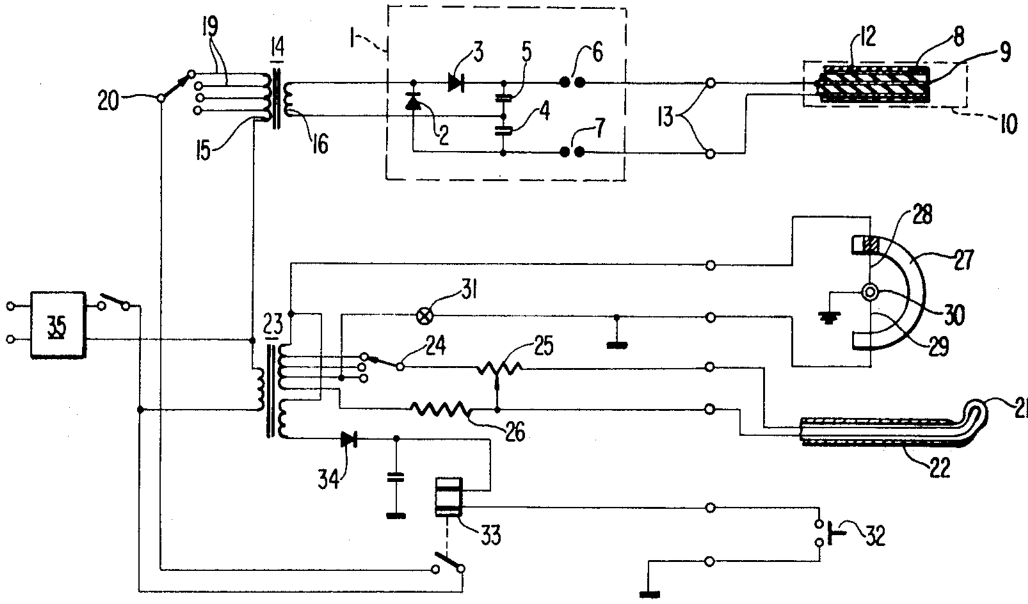


FIG. 1



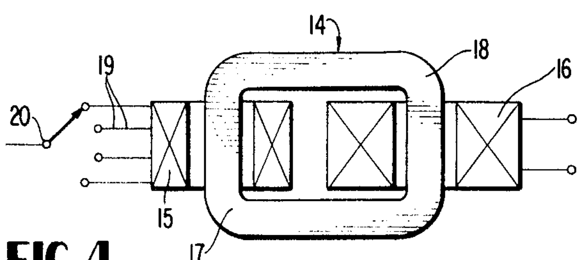


FIG. 4

FIG. 2

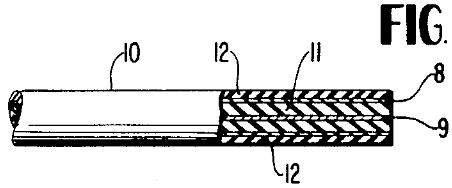
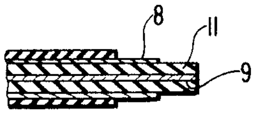


FIG. 3



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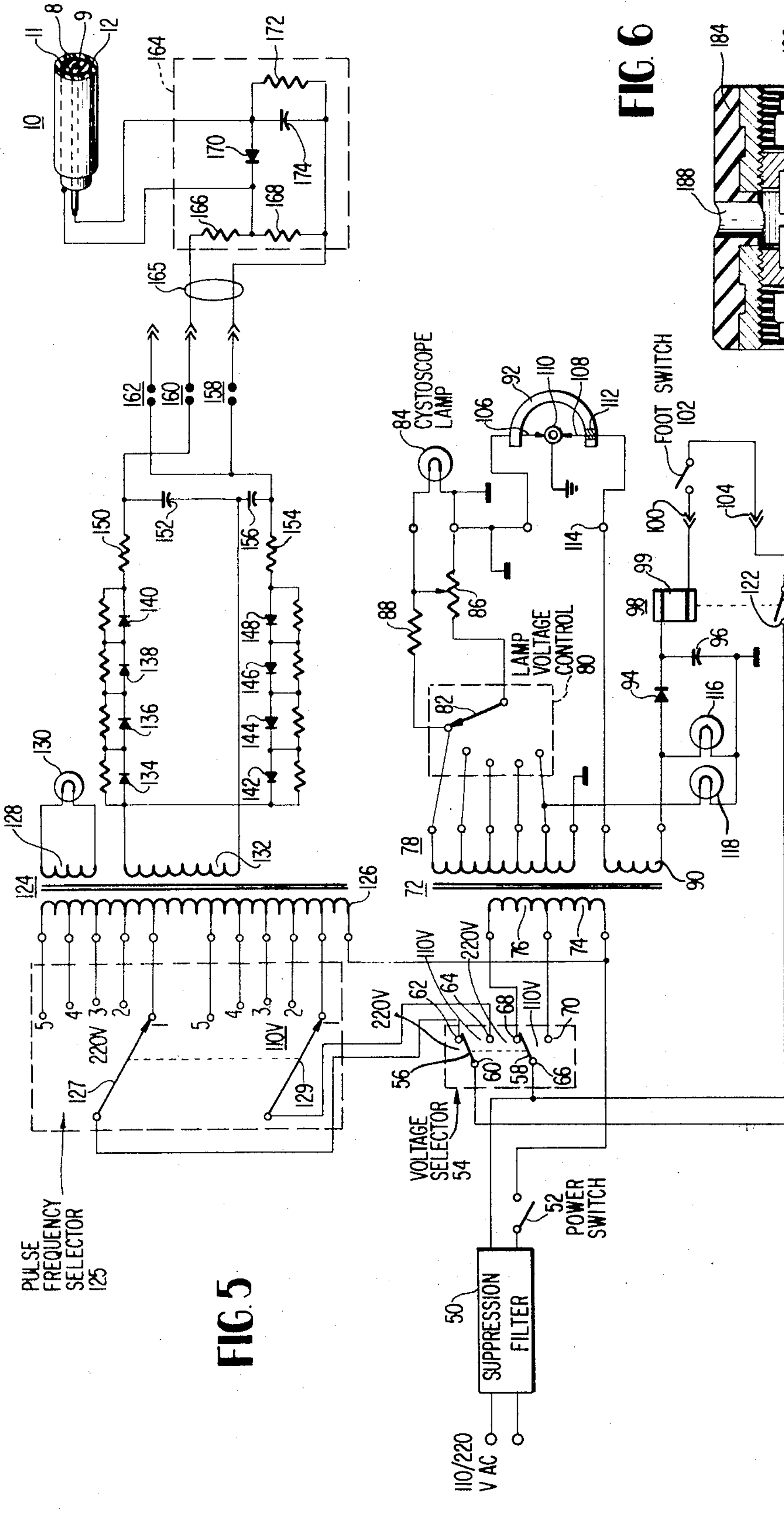

PULSE FREQUENCY SELECTOR 125
VOLTAGE SELECTOR 54
SUPPRESSION FILTER
POWER SWITCH
110/220 V AC
CYSTOSCOPE LAMP
LAMP VOLTAGE CONTROL 80
FOOT SWITCH 102

FIG. 5

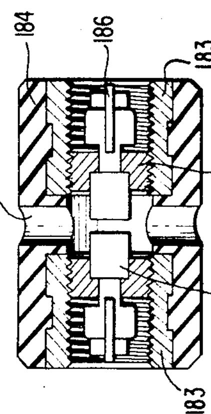
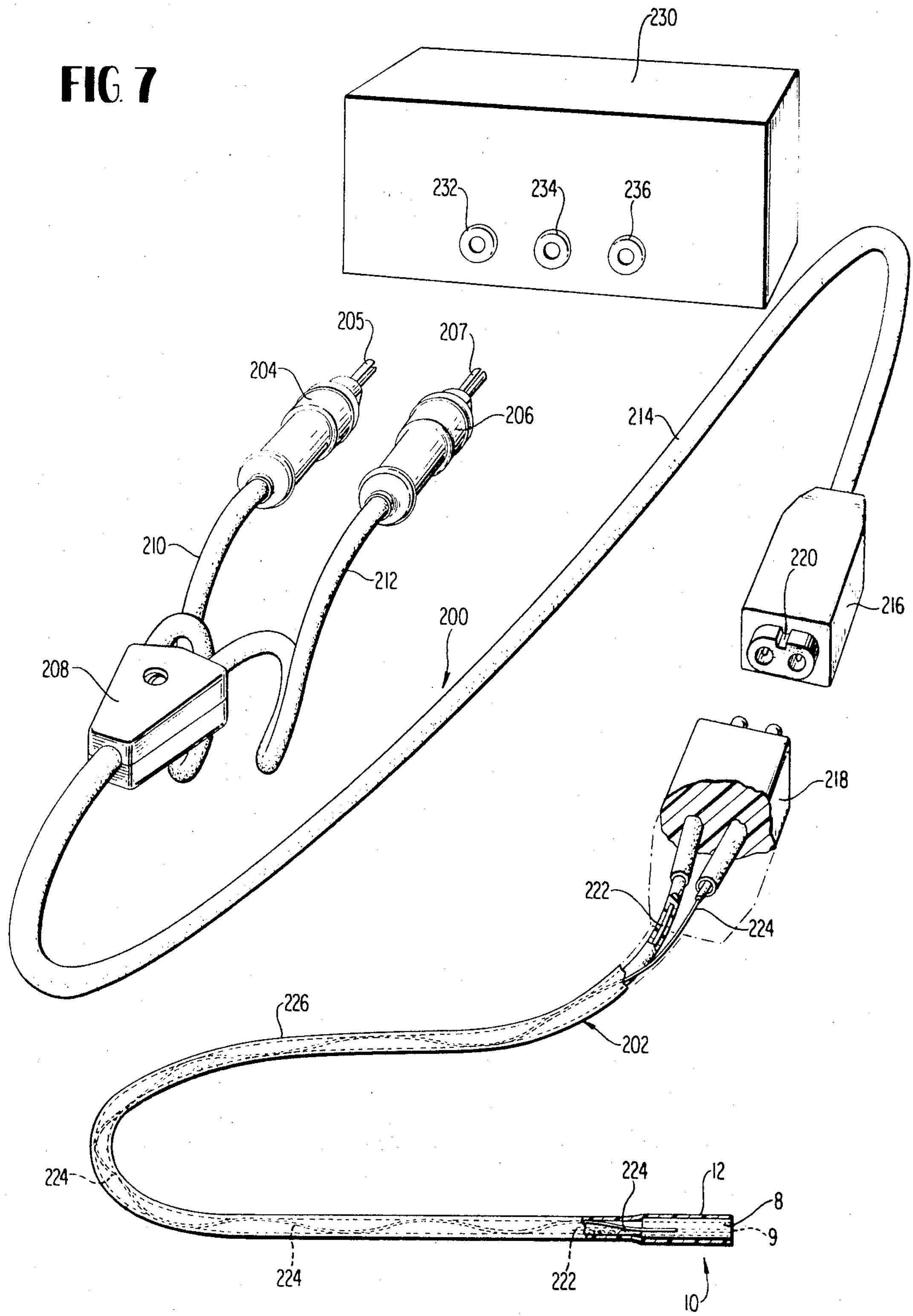


FIG. 6

FIG. 7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INSTRUMENT FOR CRUSHING STONES IN URINARY BLADDER

This application is a continuation-in-part of our application Ser. No. 871,849, filed Oct. 28, 1969, now abandoned which in turn is a continuation-in-part of our application Ser. No. 444,681, filed Apr. 1, 1965, now abandoned.

This invention relates to instruments intended for crushing concretions in the urinary ducts and more particularly to instruments for crushing stones in the urinary bladder.

Mechanical means such as lithotrites and cystoscopes are known in surgery for crushing stones in the urinary bladder, but they are of little efficiency, inconvenient in operation, and do not ensure complete safety to the patient.

Attempts have been made to solve the problem by instruments employing ultrasonic oscillations imparted to the lithotrite introduced into the urinary bladder to contact the stone to be crushed. Said instruments were allowed to control visually the operation of stone crushing and the possibility of trauma to the patient was eliminated. Moreover, the amount of washing fluid in the urinary bladder was comparatively small.

However, in crushing stones of big size (30 mm. and over), and when the number of stones in the urinary bladder is great, the operation might turn out to be time-and labor-consuming.

It is known that with electrical discharges between two spaced electrodes submerged in liquids such as water and electrolytes, hydraulic shock waves of great intensity can be generated in the region between the electrodes. In the generation of such hydraulic shock waves, a high voltage circuit has been used with one or two atmosphere-filled spark gaps in series circuit arrangement with the spacing between the two electrodes, and studies have shown that the intensity can be controlled by varying not only the voltage applied, but also the number and sizes of the various gap and electrode spacings, and sizes and shapes of electrodes. Spark lengths of between 8 and 200 mm. have been used, and numerous electrodes have been used, some in the shape of a cylindrical bore for producing holes from 40 to 50 mm. diameter in rocks of various hardness. Such equipment used air gaps of about 10 mm., a voltage of 25–30 kv., and a capacitance of 0.2 f. While such equipment was found to disintegrate or chisel crystalline, fibrous and certain schistous rocks, it was not adapted for use by the medical profession. Moreover, prior to our invention, it was not evident that this technology could be safely adapted for use in a urinary bladder because of the voltages required and the likelihood of damage to body tissue.

A primary object of the invention is to work out an instrument ensuring effective crushing of stones of most various types encountered in urology.

Another object of the invention is to work out an instrument for crushing stones in the urinary bladder ensuring safe and reliable operation.

The specific object of the invention is to create an instrument for crushing stones in the urinary bladder by producing a hydraulic impact in the liquid medium which surrounds the stone through the use of electrical discharges.

It is a further object of the present invention to provide a novel method for non-surgical crushing of concretions in the urinary tract through the use of hydraulic shock waves generated by electrical discharges.

The problem has been solved, in accordance with the present invention, by an instrument having an elongated lithotrite introduced into the urinary bladder through the operative cystoscope. The novel lithotrite comprises two coaxial, insulated electrodes, i.e., the central and the outer electrode, which are connected to an electric pulser means by a flexible cable adapted to pass through the urinary tract so that the electrodes can be placed immediately adjacent the concretions to be crushed. The lithotrite is insulated up to the butt end portion of the central electrode, the ends of both electrodes can be located either in the same plane, or in different planes.

The electric pulser means comprises, in important part, pulse-forming dischargers connected with the electrodes of the lithotrite and to an accumulating device with capacitors which is fed, for instance, from a power transformer. Component sizes and voltages are selected so as to provide sufficient energy to crush the concretions, but insufficient to cause damage to living tissue when operated properly. Power to the electrodes is controlled by a foot operated switch to provide impulses of electrical energy to the electrodes, and this control is rendered operable only when the instrument is properly grounded to avoid electrical shock to the patient. In the illustrated embodiment, the grounding for the remote control is through a grounding system connected with the cystoscope illuminating lamp supply circuit.

Each of the pulse-forming dischargers can be made as a pair of tungsten cylinders having plane-parallel discharge surfaces whose spacings can be adjusted to control the discharge gap between them, and hence the intensity and/or frequency of the hydraulic shock waves.

Windings of said power transformer should preferably be positioned on separate legs with air gaps between them and the windings.

The following is a detailed description to be read in conjunction with the accompanying drawings, in which:

FIG. 1 shows an electric circuit diagram of the instrument for crushing stones in the urinary bladder;

FIG. 2 shows a lithotrite of the instrument of FIG. 1, having the central and the outer electrodes, whose ends are located in one plane (sectional view);

FIG. 3 shows another embodiment of the lithotrite end of FIG. 2 (in section);

FIG. 4 shows the power transformer for the instrument shown in FIG. 1 (in section);

FIG. 5 is an electrical circuit diagram of a preferred embodiment of an electric pulser for use with the lithotrite of FIGS. 2 and 3;

FIG. 6 is a cross-sectional view of a preferred embodiment of the spark discharge members of FIG. 5; and

FIG. 7 shows the cable arrangement for supplying the electrical pulses to the electrodes which are positioned in the urinary bladder adjacent the concretions to be crushed.

The instrument for crushing stones in the urinary bladder has a device for generating electric pulses, a pulse generator **1** (FIG. **1**) made as a rectifier in accordance with a doubling circuit employing semiconductor elements **2** and **3**. The generator **1** comprises also storage capacitors **4, 5** and two pulse-forming dischargers 6, 7 connected to the coaxial electrodes 8, 9 (the central and the outer) of the lithotrite 10.

Electrodes 8 and 9 are separated from each other with insulating material 11 (FIG. 2).

As the electric pulses of the generator 1 produce a spark in the gap between the ends of the inner and the outer electrodes 8, 9 of the lithotrite, hydraulic shock wave is produced in the liquid medium surrounding the stone to be crushed.

The ends of the inner and the outer electrodes 8, 9 may be located either in one plane (FIG. 2) or in different planes (FIG. 3) which allows control of the character of the percussive hydraulic impact. Whatever the embodiment of the lithotrite 10 may be, the insulating material 11 should extend up to the end of the central electrode 9.

The lithotrite shown in FIG. 2 produces directed hydraulic shock waves, while the lithotrite shown in FIG. 3 produces spherical waves of particularly great percussive strength. In the lithotrite shown in FIG. 3, the insulating material 11 should overlap the end of the outer electrode 8. The outer surface of the lithotrites is also coated by an insulating envelope 12. In the lithotrite shown in FIG. 3, the envelope 12 leaves open a portion of electrode 8. To provide for rapid and convenient replacement of the lithotrites 10, the instrument has a high voltage miniature joint 13 (FIG. 1).

Each of the pulse-forming dischargers 6 and 7 is a pair of tungsten cylinders with plane-parallel discharge end surfaces between which adjustable discharge gaps are formed.

The generator 1 is supplied from a power transformer 14 whose windings, e.g., primary 15 (FIG. 4) and secondary 16, are located on separate legs 17 and 18 and have air gaps between them and the legs.

One of the wires supplying power to the relay 33 and lamp 21 of the cystoscope 22 is also shorted through the grounding bus bar 30 by means of the clamp 27. When there is no contact in the grounding circuit, or else if there is no contact between the contact elements 28, 29 of the clamp 27 through the bus bar, the generator 1 is cut out of operation, the lamp 21 of the cystoscope 22 goes down, and the surgeon cannot proceed with the operation.

Suppression filter 35 is provided in the instrument to eliminate radio interference.

All high potential elements of the pulse generator, i.e., capacitors 4, 5, pulse-forming dischargers 6, 7, semiconductor elements 2, 3, and also other elements not shown in the drawings, such as shunting and additional resistors in the rectifier circuit and sockets for connecting the high voltage cable of the lithotrite 10, should preferably be installed on insulating plates, which are also not shown in the drawings.

The instrument can be powered from 127 V. and 220 V. 50 cps mains.

The operating procedure is as follows:

Into the urinary bladder is introduced the cystoscope 22 in the end of which the illuminating lamp 21 is mounted. The bladder is filled with the washing fluid and the lithotrite 10 is passed into the bladder until it comes in contact with the stones to be crushed. As soon as the instrument is switched on, the illuminating lamp 21 of the cystoscope 22 is lighted up, and the pulse generator 1 starts working when the foot pedal 32 is pressed upon, and the mains voltage is supplied to the primary winding of the power transformer 14 through the contacts of relay 33.

To change the intensity and the repetition frequency of the electric pulses of the generator 1, the primary winding 15 of the transformer 14 has output taps 19 connected to the supply circuit by means of switch 20.

The instrument comprises also a power source for lamp 21 (FIG. 1) of the cystoscope 22. This source is the secondary winding of the step-down transformer 23, whose alternating voltage is supplied to lamp 21 of the cystoscope 22 through switch 24 and resistor 25. The switch 24 is intended to set the voltage corresponding to the rated voltage of the lamp 21 which is used. Resistor 25 serves for a smooth adjustment of the voltage. Resistor 26 provides for the current supply to the lamp 21 of the cystoscope 22 in case of break in the circuits of switch 24 and resistor 25. One of the wires supplying power to the cystoscope lamp 21 is connected to a clamp 27 whose contact elements 28, 29 are mutually insulated and have sharpened points for attachment of the clamp 27 to bus bar 30. One of the contact elements 28 of the clamp 27 is stationary and is insulated from the clamp body, while the other contact 29 is movable and connected to the clamp body through a thread joint (not shown in the drawing).

Parallel to the cystoscope 22 lamp 21 supply circuit, a pilot lamp 31 is connected which is used to detect the circuit break.

The pulse generator 1 is controlled remotely by means of a foot pedal 32 and relay 33 supplied from a rectifier employing diode 34.

Operation of the pulse generator 1 consists in accumulating the charge in capacitors 4, 5 and instantaneous pulsing discharges of this voltage to the circuit of the pulse-forming dischargers 6, 7 and of the lithotrite 10 during the breakdown of the air gaps produced by constant voltage applied from the rectifier.

During the electric breakdown of the discharge cap of the lithotrite, a shock hydraulic wave is formed in the washing liquid which crushes the stone.

FIG. 5 is an electrical circuit diagram of an electric pulser means for supplying pulses to the lithotrite illustrated in FIGS. 2 and 3. The electric pulser means of FIG. 5 includes a suppression filter 50 to filter out radio frequency or other undesirable electrical transients. The input alternating voltage from the power mains is connected directly to the suppression filter 50. The A. C. power is fed from the suppression filter 50 to the electric pulser with one line passing through an on-off power switch 52.

The input power also passes through an input voltage selector switch 54 which includes a pair of movable contact arms 56, 58. Movable contact arm 56 is connected at one end to a stationary contact 60. The other end of the contact arm 56 can be switched between stationary contacts 62 and 64. Similarly, the movable contact arm 58 has one end connected to a stationary contact 66 and the other end is switchable between stationary contacts 68 and 70. The two movable contact arms 56, 58 are mechanically linked together so as to be simultaneously switched from one position to the other.

The movable contact arm 58 is used to select the appropriate operating voltage for a first transformer 72 which has a primary winding having two sections 74, 76. If the input power is 220 volts A.C., the movable arm 58 is moved into connection with fixed contact 68 which is connected to the upper section 76 of the primary of transformer **72.** In this way, if the input A.C. is 220 volts, the entire primary of transformer **72** is used. On the other hand, if the input power is 110 volts A.C., then the movable contact **58** is switched to fixed contact **70** which is connected to the lower portion **74** of the primary of transformer **72.** In this way, only the lower portion **74** of the transformer primary is used when the input voltage is 110 volts.

Transformer **72** supplies the necessary alternating and direct current for various miscellaneous elements of the electric pulser. Transformer **72** has a first secondary winding **78.** Secondary winding **78** has a number of taps which are connected to a lamp voltage control switch **80.** The lamp voltage control switch **80** has a movable member **82** to select the appropriate operating voltage for the cystoscope lamp **84.** In addition to selecting the appropriate voltage for the cystoscope lamp **84,** there is also provided a variable resistor **86** to adjust the brightness of the cystoscope lamp. Finally, a resistor **88** is connected from one tap of the secondary winding **78** directly to the cystoscope lamp **84** so as to assure that there will be some power supplied to the cystoscope lamp at all times in case of a failure in the lamp voltage control switch **80** or the brightness control **86.**

Transformer **72** has an additional secondary winding **90** which is used to provide power for additional functions of the electric pulser. One end of secondary winding **90** is connected to a clamp **92** which is used for grounding the system, as will be explained in detail hereinafter. The other end of secondary winding **90** is fed through a diode **94** and filter capacitor **96** so as to form a D. C. power supply for a control relay **98.** Therefore, the diode **94** is connected to the operating coil **99** of relay **98.** The other side of coil **99** is connected to a plug **100.** Plug **100** may be mounted at a suitable location on the cabinet which encloses the electric pulser.

A manually operable device, such as a foot switch **102,** is provided for activation of the electric pulser. One side of the foot switch **102** is connected to the plug **100** and the other side is connected to a second plug **104** which is also mounted in the cabinet housing the electric pulser. The plug **104** is connected to the chassis or cabinet of the electric pulser, as indicated by the solid square symbol (indicating chassis, as opposed to earth, ground).

Since this instrument is intended for use on living patients, attention to the problem of protecting against electric shock hazards is necessitated. For this reason, safety considerations require that the cabinet and other portions of the electric pulser be securely connected to earth or some type of external electric ground. This may be accomplished by way of clamp **92.** The clamp **92** has two prongs **106, 108** which are shown in firm electrical and mechanical contact with an external electric ground such as, for example, a water pipe **110.** It will be noted that the prongs **106, 108** of clamp **92** are electrically insulated from one another since prong **106** is electrically and mechanically connected to the metallic body of the clamp **92,** whereas the prong **108** is mounted in a block of insulation material **112** which forms a portion of clamp **92.**

The importance of the construction of clamp **92** will be apparent when the circuit for activating the pulser is examined in detail. Note that one end of the secondary winding **90** of transformer **72** is fed by way of terminal **114** to the insulated prong **108** of the clamp **92.** The other end of secondary winding **90** is fed via diode **94** through the coil **99** of control relay **98** to the foot switch **102.** Since the foot switch **102** returns to the cabinet or chassis ground via plug **104,** it will be apparent that the foot switch **102** cannot energize control relay **98** unless the other side of the transformer secondary **90** (that is, the side connected to terminal **114**) is somehow also connected to the chassis ground so as to complete the circuit. As can be seen by examination of FIG. **5,** this is only accomplished when the clamp **92** is securely affixed to an external electric ground. In this way, the clamp **92** acts as a protective means to prevent energization of the electric pulser except when the pulser is securely connected to an external electric ground.

In addition to providing the clamp **92** for rendering the pulser inoperative unless it is externally electrically grounded, there is also provided a ground detector lamp **116** which is connected from the lower end of transformer secondary **90** to the chassis ground. For the same reasons as those set forth above, it will be apparent that the lamp **116** will not be illuminated unless the clamp **92** is securely fastened to an external electric ground.

In addition to the ground detector lamp **116,** there is also provided a power supply monitoring lamp **118** which is connected between one winding of transformer secondary **78** and the chassis ground. Lamp **118** will therefore continuously indicate whether the electrical circuitry for supplying power to the cystoscope lamp **84** is operative.

Assuming that the clamp **92** is firmly fixed to an external electric ground, the operation of the electric pulser following operation of the foot switch **102** will now be explained. Depressing foot switch **102** energizes the coil **99** of relay **98.** This causes a movable contact **120** of relay **98** to be attracted to a fixed contact **122** so as to close the circuit therebetween. The fixed contact **122** is connected to one of the input power lines coming from the suppression filter **50.** The movable contact **120** is connected to the fixed terminal **60** of the voltage selector switch **54.** The movable contact **56** of the voltage selector **54** is placed in the proper position so as to be correlated with the input voltage. This contact is used to relay power from the contacts of relay **98** to the pulse frequency selecting transformer **124.**

Transformer **124** has a number of taps on its primary winding **126.** The upper half of primary winding **126** has a number of taps which will be used if the voltage selector switch **54** is in the **220** volt position, whereas the taps on the lower portion of the primary winding **126** are used if the input voltage is 110 volts. A pulse frequency selector switch **125,** having two ganged movable contact members **127, 129,** is provided to select the desired taps on transformer primary winding **126.**

Transformer **124** has a first secondary winding **128** which is connected to a lamp **130.** When the primary of transformer **124** is energized, lamp **130** will be illuminated and therefore can be monitored to assure that this portion of the electric pulser is operating properly.

Transformer **124** has a second secondary winding **132** which is connected at one end to a plurality of positively poled rectifiers **134, 136, 138** and **140.** Each of these positively poled rectifiers has a bypass resistor so as to assure continuing operation of the system if one of these rectifiers should fail. This same end of the transformer secondary **132** is also connected to a plurality of negatively poled rectifiers 142, 144, 146 and **148**, which are similarly equipped with bypass resistors.

The positively poled series diodes feed through a resistor **150** to a capacitor **152**, whereas the negatively poled diodes feed through a resistor **154** to a capacitor **156**. The junction point of capacitors 152 and 156 is connected back to the other end of the transformer secondary **132** so as to form a conventional rectifier with a voltage doubling circuit of a well-known type.

The output of the voltage doubler is fed to a plurality of spark gaps **158, 160** and **162**, each of which includes a pair of spark discharge members. Spark gaps 158, **162** are connected in parallel to one side of the voltage doubler, whereas the spark gap **160** is connected to the other side of the voltage doubler. In the described embodiment, this provides a selection between a so-called "soft" and "hard" mode of operation. In the "soft" mode of operation, the lithotrite is connected between spark gaps **158** and **160**. The distance between the discharge members forming these two spark gaps may be approximately equal and relatively small so that the amount of voltage required to ionize these two gaps (and thereby generate a pulse for the lithotrite) is relatively small. For this reason, the amount of energy in each pulse can be referred to as being comparatively low, and for this reason, also, this is referred to as the "soft" mode.

On the other hand, connection of the lithotrite in series between spark gaps 160 and 162 is referred to as the "hard" mode because the distance between the discharge members of spark gap 162 is comparatively large with respect to the distance between the discharge members of spark gap **158**. For this reason, the amount of voltage which will be accumulated by the voltage doubler before the spark gap 162 ionizes is larger, and thus the amount of energy transferred to the lithotrite when this gap ionizes is greater than that which was transferred to it in the so-called "soft" mode.

Representative figures for specific types of spark gaps (such as, for example, the spark gaps illustrated and described in detail with respect to FIG. 6) reveal that the distance between the discharge members of spark gaps **158** and **160** should be about 0.3 millimeters, whereas the distance between the discharge members of the spark gap **162** may be as much as 0.7 millimeters. In addition, the separation between the inner and outer electrodes of the lithotrite 10 may be approximately 0.5 millimeters.

The lithotrite **10** may be directly connected to a pair of spark gaps or, alternatively, may be connected to the spark gaps by way of a pulse shaping means 164. The pulse shaping means 164 includes a pair of resistors **166, 168** connected to form a conventional voltage divider. The pulse shaping means 164 also contains a pulse shaping circuit consisting of diode 170, resistor **172**, and capacitor **174**. The lithotrite 10 is then connected across the diode 170.

From the foregoing, it will be apparent that the electric pulser of FIG. **5** can be adjusted in two different ways so as to vary the characteristic of the hydraulic shock wave emitted by the lithotrite 10. By adjusting the position of the pulse frequency selector switch 125, the frequency of the generated electrical pulses can be increased. This is done by advancing the movable contacts 127, 129 from the lower to the higher numbered taps, thereby increasing the voltage out of secondary winding 132. If the pulse frequency is increased without varying the characteristics of the spark gaps, the hydraulic shock waves generated by the lithotrite **10** will increase in frequency and provide a greater destructive force.

In addition to increasing or decreasing the frequency of the hydraulic shock waves, it is also possible to adjust the electric pulser of FIG. 5 so as to vary the intensity of the hydraulic shock waves. As pointed out hereinbefore, this is done by varying the characteristics of the spark gaps, as, for example, increasing the distance between the spark discharge members.

With these variations, the physician operating the instrument comprising the present invention has the ability to work with the lowest force which is effective to crush the concretions and thereby minimize the likelihood of damage to any membranes. If the applied force is not sufficient, small adjustments are possible to gradually increase the force. At its highest setting, the instrument is capable of crushing very hard concretions.

In one particular embodiment of the electrical circuit of FIG. 5, the components shown therein had the following representative values:

Resistor 86	25 ohms
Resistor 88	50 ohms
Resistors 150, 154	2K ohms
Resistor 166	4.7 ohms
Resistor 168	0.3 ohms
Resistor 172	20K ohms
Capacitor 96	200 microfarads
Capacitors 152, 156	0.25 microfarads
Capacitor 174	0.25 microfarads
Gap spacing, spark gaps 158, 160	0.3 millimeters
Gap spacing, spark gap 162	0.7 millimeters

Turning now to FIG. 6, there is shown the details of the spark discharge member assembly which forms part of the electrical pulser of FIG. 5. The spark discharge device of FIG. 6 includes a pair of essentially cylindrical metal members 180 which have their plane-parallel butt ends facing one another so as to form a discharge gap therebetween. The cylindrical metallic members 180 may be constructed of any conductive material which will withstand arcing with minimum adverse effect on the surfaces between which the arcs occur. It has been found that tungsten has particularly desirable characteristics in this device.

The cylindrical metallic members 180 are fitted into externally threaded collets 182. An insulating case **184** is provided with a pair of fixed annular members **183** having internal threads which encase the threads on collets 182. At the opposite end of each of the collets 182 and rigidly secured to the corresponding cylindrical metallic members 180 there is provided an opening **186** which is suited for receiving a tool such as a screwdriver, so as to provide for ready control of the spacing between the facing ends of the two metal cylinders and so as to form the desired size air gap. This particular construction is especially desirable since it also allows the metallic cylinders to be removed from the insulating housing so that the spark gap surfaces may be burnished or otherwise treated to remove any pits that may form therein.

The openings 186 in collets 182 may also serve as connectors to terminals for the high voltage cables **165** that pass from the spark discharge members to the lithotrite and for the internal wiring leading to the spark gap.

Finally, there is provided an opening **188** in the insulated outer case **184** through which the spark gap can be checked and calibrated after the entire spark discharge device is assembled. A spark gap tool having the desired thickness, e.g., 3 mm. or 7 mm., can be inserted through opening **188** to thereby provide a precise measurement of the spark gap spacing.

Turning now to FIG. **7**, a further important feature of the invention resides in the connecting cable which connects the electrical pulser means to the novel electrode, which is illustrated and has been described in connection with FIGS. **2**, **3**, **5**, and also **7**. With reference to FIG. **7**, the preferred cable is divided into two portions, **200** and **202**. Cable **200** has at one end two jacks **204** and **206**, each comprising a central conductor **205** and **207**, and an outer metallic housing as is conventional with a shielded cable. A junction element **208** is conveniently located so that the two separate shielded cables **210** and **212** can be consolidated into one cable **214** which consists of two inner conductors, each with its own insulation, continuing from conductors **205** and **207**, respectively. One outer grounded shield (not shown) is provided under a sheath of insulation in cable **214**.

At plug **216**, the shielding of the cable **200** is terminated, and no part of cable **202**, including the electrode region at **10**, is shielded or connected to ground.

Plug **218**, which is at one end of the lithotrite cable **202**, connects with plug **216**. A suitable key is provided to mate with keyway **220** in plug **216** to thereby assure the proper polarity as different lithotrites are connected to plug **216**. The flexible cable **202** extending from plug **218** should be only as long as essential in order for the electrode to be passed through the cystoscope in the urinary tract of the patient and into the bladder region where the concretions are to be crushed. A length of cable **202** of about one-half meter has been found satisfactory.

Because of the flexibility requirements imposed on cable **202**, and also considering the inside diameter of the cystoscope, severe restrictions are imposed on the outer diameter of cable **202**. At the same time, the two conductors **222** and **224** which carry the electric pulses of high voltage necessary for creating the hydraulic shock wave must be adequately insulated from each other and from outside connections with the hands of the doctor and, of course, the cystoscope extending into the body of the patient.

It has been found that the preferred construction for the cable **202** is to have insulation **226** around the central conductor **222** which is preferably of material other than copper, such as steel. Conductor **224** may be an uninsulated copper wire of about the same diameter as conductor **222** and extend along the outside of the insulation **226** on conductor **222**. As illustrated in dashed lines in FIG. **7**, conductor **224** may follow a helical path. At electrode **10**, conductor **224** is secured to the outer cylinder **9** as by welding.

Insulation **226** needs to have an outer diameter of about **2** to **2.5** mm. to provide adequate insulation, and cannot be materially greater because of the limitations imposed on the maximum diameter of flexible cable **202**, as discussed above. However, at the electrode region **10**, the spacing between the central conductor **9** and the inside of the cylindrical electrode **10** reduces to about 0.35 mm. through a gradual taper adjacent the electrode region **10**. The insulation material between central conductor **9** and cylinder **7** may be a suitable mastic. The cylinder **8** which serves as the outer electrode has a length between about 1 and 1.35 cm., and an outer diameter of about 2.5 mm.

The outer tubing **226** of insulation material forming part of flexible cable **202** is a continuous sheath which extends from plug **218** to cover all or at least the part of the outer electrode **8** containing the connection between wire **224** and electrode **8**. The diameter of tubing **226** of insulation material should be substantially uniform and sufficiently small to pass freely through the cystoscope. A diameter of about 6 mm. has been found to satisfactorily meet all the requirements, including the provision of sufficient insulation over wire **224** to eliminate any sensation of electricity during the operation of the pulser **230** in FIG. **7**.

Three coaxial cable terminals **232**, **234**, and **236** are provided, which are associated with spark gaps **158**, **160**, and **162** of FIG. **5**. Conductor **207** may be made with a larger diameter than conductor **205** so that conductor **207** fits only in terminal **234**, which is associated with spark gap **160**, whereas conductor **205** will fit in either terminal **232** or **236**.

Cable **200**, being a shielded coaxial cable, can be of whatever reasonable length that may be needed since it has reasonably good electrical pulse transmission properties, which means there is no undue attentuation or distortion of the electrical signals. The shielding terminates at plug **216**. Flexible cable **202**, however, cannot have an outer shield of conductive material because of the limitations imposed by the necessity for it to fit within the cystoscope.

The method of using the instruments described in detail above will now be explained. Prior to the actual crushing of urinary concretions, it is necessary to properly prepare the patient. In order to mitigate pain and prevent spasms of the urinary tract, the patient will initially receive a subcutaneous injection, preferably pipolphen or promedol with atropine, 30 to 40 minutes before the operation. Approximately 10 to 15 minutes before the operation, the urethra is anesthetized with either lidocaine or novocaine. If there are spasms of the bladder after the operation commences, the operation should be interrupted and the bladder washed out several times with small volumes of novocaine. This will usually enable resumption and completion of the operation. In certain exceptional situations, it may be necessary to carry out the operation under general anesthesia, particularly in situations where the patient does not properly respond to local anesthesia.

After having completely prepared the patient, a cystoscope (surgical, multi-purpose or model Mackarty urethrocystoscope is introduced into the patient's urinary tract. Selection of the cystoscope can be particularly important in assuring the success of this operation. Preference should be given to the type of cystoscope which has a reverse curvature of the tube and a lower position of the window. In addition, the cystoscope operational channel should be sufficiently large in diameter to allow the passage of fragments after having completed the crushing operation.

After having introduced the cystoscope, the bladder should be filled with a dielectric fluid, preferably boiled water and an antiseptic such as rivanol until the patent has urge to urinate. After having filled the bladder with the irrigation fluid, the optical portion of the cystoscope will then be inserted into the operational channel. As was explained above with respect to FIG. 5, this instrument includes the necessary power supply for the cystoscope lamp **84**. After having determined the appropriate lamp voltage, this voltage is selected on the lamp voltage control switch **80** of FIG. **5** and the intensity of the cystoscope lamp can then be adjusted by way of resistor **86.** At this point, the general condition of the bladder, mucus, membrane, prostate gland, and diverticulum should be examined as well as ascertaining the position, shape and color of the concretion to be crushed.

After having thoroughly examined the bladder and noted the characteristics of the concretion to be crushed, the lithotrite is inserted through the operational channel of the cystoscope. The working end of the lithotrite is then positioned with the aid of an instrument such as an Albarran lingula, until it is pointing toward and in close proximity to the concretion to be crushed. At this point, it is important to assure that the working end of the lithotrite is positioned normal to the surface of the concretion, and it may be placed in contact against the concretion.

Before beginning a crushing operation, it may be preferable to familiarize the patient with the feel of the lithotripsy operation by giving one or two short blasts of hydraulic shock waves (0.1 to 0.2 seconds). After having ascertained that the effect of lithotripsy is not unduly painful to the patient, the actual crushing operation can commence.

Initially, the instrument will be set in the "soft" mode described in detail above with reference to FIG. **5.** Until the physician operating this instrument becomes thoroughly familiar with its capabilities, he will usually begin by setting the pulse frequency selector switch **125** at the number **1** position so as to begin by generating hydraulic shocks of the minimum frequency and intensity. Tests with this instrument have been successful in crushing a variety of concretions including those of phosphate salts and carbonates, oxylates, and urates with polished surfaces. After gaining experience with this instrument, it may be possible, taking into account the characteristics of the concretion, to begin at other than minimum frequency and intensity.

The actual crushing operation is then instituted by depressing the foot switch **102** for a brief period of time (not longer than **1** second). During this interval, a large number of impulses is generated. If the concretion is not fractured (i.e., either cracked or completely broken) by the initial hydraulic burst, it is necessary to wait at least **10** seconds before a further attempt is made.

After having made from three to five unsuccessful attempts at the lowest setting of the instrument, the pulse frequency selector switch **125** may be then advanced to a number **2** position, or higher, and the sequence set forth above is repeated at this setting. Operation continues in this fashion until the number **5** position is reached. If the concretion is still not crushed at this point, it is possible to go into the "hard" mode described above with respect to FIG. **5.** This can be accomplished, for example, by removing the actual high voltage cable **165** which feeds to the lithotrite **10** and inserting it into a different set of plugs. Alternatively, this selection could be accomplished by simple switching arrangements provided with the instrument.

After having changed to the "hard" mode, the pulse frequency selector switch **125** should be returned to a lower setting before lithotripsy is commenced. As was explained above with respect to operation in the "soft" mode, attempts to crush the concretion are carried on with increases in the setting of the pulse frequency selector switch **125** until such time as the concretion is at least cracked, if not completely crushed. At this point, it is desirable to reduce both the power and duration of the hydraulic shocks to a minimum, and to reposition the end of the lithotrite near the surface of the newly formed cavity in the concretion for further applications of impulses.

The technique described above is carried out until such time as the concretion is crushed into fragments which are small enough to pass through the operational channel of the cystoscope.

After having crushed the concretions into fragments which can be removed through the operational channel of the cystoscope, it is then necessary to remove the crushed fragments in some way. The first step is to remove the liquid solution which was injected into the bladder at the beginning. When this liquid is removed, a number of the stone fragments will naturally be withdrawn at that time.

After having removed the dielectric liquid, and having withdrawn the lithotrite from the operational channel of the cystoscope, a Janet's syringe or Bigelow's aspirator can then be connected with the cystoscope tube. An irrigation liquid can then be injected into the bladder, preferably in small, intermittent portions so as to create an eddy. The syringe is then disconnected, and the stone fragments are washed out by the back flow. If the stones are small, it may be possible to wash out all the fragments after a single irrigation. Finally, there may be some very fine particles which will lodge in certain portions of the bladder but these fine particles can be disregarded since they will generally be passed out in a few days following the operation with the normal emission of the urine.

If the concretions are unusually hard, or large in number, it may not be possible to completely crush all of them in one single operation. In this case, the cystoscope can be removed and a catheter introduced into the urinary tract and left there until the next treatment, preferably within two or three days following the first treatment.

While preferred embodiments of the present invention have been illustrated and described, it is, of course, understood that various modifications and changes may be made therein without departing from the true spirit and scope of the invention as defined in the appended claims when accorded a full range of equivalents.

What is claimed is:

1. An instrument for crushing concretions in a urinary tract comprising: an electric pulser means having a pair of output terminals and a power transformer having a high voltage secondary winding, electrical circuitry connected between said high voltage secondary winding and said terminals including capacitor means, spark discharge members forming at least one electrical discharge gap of a predetermined size for breaking down when said capacitor discharges and being connected in series circuit relationship with said terminals and across said capacitor means, and a lithotrite having two electrodes electrically connected to said output terminals and insulated from each other and adapted for being positioned into the urinary tract adjacent a

concretion to be crushed, one of said electrodes being a central conductor and the other electrode being an outer substantially cylindrical conductor coaxially surrounding said central conductor; and a manually operable device for remote control of said pulser means to thereby produce an electrical discharge between said lithotrite electrodes when discharging said capacitor means across said gap.

2. The instrument recited in claim **1** together with lithotrite positioning means comprising a cystoscope having a hollow operational channel through which said lithotrite electrodes are adapted to pass, and means for illuminating the portion of the lithotrite adjacent the concretion to be crushed.

3. The instrument recited in claim **1** further comprising electrical protective means operatively connected between said manually operable device and said pulser means, and protective means comprising a circuit member adapted for connection between an external electric ground conductor and a portion of the circuit in the electric pulser means whereby failure to have such connection prevents operation of said instrument.

4. The instrument recited in claim **1** wherein said coaxial electrodes have butt end portions located in substantially a single plane with an insulative covering on said inner electrode extending up to said butt end portions.

5. The instrument recited in claim **1** wherein said coaxial electrodes have butt end portions located in different planes with said inner electrode and an insulative covering thereon both extending beyond the butt end portion of said outer electrode.

6. The instrument recited in claim **1** wherein said spark discharge members comprise a pair of metallic cylinders having plane-parallel opposed discharge butt end surfaces to form said discharge gap.

7. The instrument recited in claim **6** wherein said cylinders are formed of tungsten.

8. The instrument recited in claim **1** wherein said electrical circuitry includes two pairs of spark discharge members, the members of each pair being separated so as to form an electrical discharge gap and being connected in series circuit relationship between said coaxial electrodes and said capacitor means.

9. The instrument recited in claim **8** wherein said spark discharge members have spacings between about 0.3 and 0.7 millimeters, and the spacing between the coaxial electrodes is approximately 0.5 millimeters.

10. The instrument recited in claim **1** wherein said electrical circuitry includes three pairs of spark discharge members, the members of two of said pairs being separated with substantially equal spacings, and the members of the third pair being separated with a different spacing; and means for controlling the intensity of the discharge between said coaxial electrodes including means for optionally connecting either said two pairs in operative relation with said coaxial electrodes or said third pair and only one of said pairs in operative relation with said coaxial electrodes.

11. An instrument for crushing stones in the urinary bladder comprising in combination: an operative cystoscope having a hollow interior and an illuminating lamp; an elongated lithotrite adapted for introduction through the interior of said cystoscope and having an inner and an outer electrode insulated from each other and adapted to extend beyond one end of the cystoscope, and conductor members adapted to extend through the cystoscope interior and beyond the other cystoscope end; electric pulser means connected to said lithotrite conductor members and comprising a power transformer having windings located on separate legs and air gaps between the windings and the legs; an electrical grounding system connected with said cystoscope lamp; a device for remote control of said transformer connected to it through said grounding system; an accumulating device with capacitors fed from said power transformer and at least one pair of tungsten cylinders connected between said electrodes, the tungsten cylinders having plane-parallel opposed discharge butt end surfaces, and means for changing the discharge gap spacing between said end surfaces.

12. An instrument for crushing stones in the urinary bladder as claimed in claim **11**, wherein the lithotrite electrodes have end portions which are positioned in different planes while the insulation between the electrodes covers the inner electrode up to its end and extends beyond the end of the outer electrode.

13. An instrument for crushing stones in the urinary bladder comprising in combination: an operative cystoscope having a hollow interior; an elongated lithotrite adapted for introduction into a urinary bladder through the interior of said cystoscope and having two coaxial electrodes insulated from each other with each of said electrodes having butt end portions separated by a gap adapted to extend beyond one end of the cystoscope; and electric pulser means connected to said lithotrite for causing an electric breakdown of the gap formed between the butt end portions of said electrodes when the electrodes are immersed in a liquid medium as a result of which a hydraulic shock wave is formed in the liquid medium, said electric pulser means including a pair of spaced discharge members connected in series circuit relationship with said electrode gap.

14. An instrument for crushing stones in the urinary bladder comprising in combination: an operative cystoscope having a hollow interior and an illuminating lamp; an elongated lithotrite adapted for introduction into a urinary bladder through the hollow interior of said cystoscope and having two coaxial electrodes insulated from each other; grounding means for said lithotrite connected with said cystoscope lamp; and electric pulser means connected to said electrodes comprising a power transformer, a device for remote control of said transformer connected with the transformer, an accumulating device including capacitors fed from said power transformer, and pulse-forming dischargers including a pair of spaced discharge members connected with the electrodes of said lithotrite and with said accumulating device.

15. An instrument for crushing concretions in a urinary tract comprising:

two coaxial electrodes insulated from each other, one of said electrodes being a central conductor and the other being an outer conductor surrounding said central conductor, said electrodes having butt end portions located in substantially a single plane with insulation covering the central electrode up to the butt end portion;

means for positioning said electrodes in a urinary bladder adjacent a stone to be crushed; and

electric pulser means connected to said coaxial electrodes and including a power transformer having a high voltage winding, a manually operated device for remote control of said electric pulser means, and an accumulating device including capacitors connected to be energized from said power transformer and two pairs of spark discharge members forming two discharge gaps connected in series with the gap between said electrodes and across the accumulating device, said two discharge gaps being between a pair of plane-parallel, opposed butt end surfaces of said discharge members.

16. A method of crushing concretions in the urinary tract comprising the steps of:

a. providing a cystoscope having an operational channel, an optical portion and an illuminating lamp;
b. inserting said cystoscope into the urinary tract;
c. filling the urinary bladder with a washing fluid;
d. examining the bladder with the optical portion of the cystoscope so as to locate and examine the concretion to be crushed;
e. inserting an electro-hydraulic lithotrite having a working end into the operational channel of the cystoscope;
f. positioning the working end of said electro-hydraulic lithotrite adjacent the concretion to be crushed; and
g. manually operating a remote control device so as to activate an electric pulser connected to the electro-hydraulic lithotrite and generate hydraulic shock waves to crush the concretion.

17. The method recited in claim **16** wherein step (g) comprises the steps of:

a. setting the electric pulser so as to be conditioned to generate hydraulic shock waves of a first intensity and repetition frequency;
b. manually operating said remote control device so as to activate said electric pulser and generate said hydraulic shock waves of said first intensity and repetition frequency;
c. optically examining said concretion to determine whether the concretion has fractured; and
d. in the event that the concretion has not fractured, adjusting the setting of the electric pulser so as to change the intensity and repetition frequency of said hydraulic shock waves, and repeating the above steps (e), (f), and (g).

18. For use with an instrument for crushing stones in the urinary bladder, a cable member having at one end a connector terminal member having a pair of insulated conductors for connection to a mating terminal member supplied with power from said instrument and at the other end two electrodes, one of said electrodes being a central conductor and the other electrode being an outer, substantially cylindrical electrode coaxially disposed relative to said central conductor and separated from said central conductor by insulation material having a thickness of at least about 0.35 millimeters; a flexible cable having a length sufficient to extend through the urinary tract and into the urinary bladder comprising a central insulated wire, a second wire connecting said electrodes to said connector terminal member, and a tubing of insulation material extending as a unitary member of substantially uniform diameter between the connector terminal member and said electrode and covering the outer surface of said outer electrode, said tubing having a thickness sufficient to prevent arcing to other conducting materials and an outside diameter sufficiently small to allow insertion of said electrodes through the urinary tract into the urinary bladder.

19. Apparatus as defined in claim **18** wherein the second wire is an uninsulated single wire of sufficiently small diameter to extend along the other surface of the insulation on the central wire and under the inner surface of said tubing of insulation material to thereby and not materially decrease the flexibility of said flexible cable.

20. Apparatus as defined in claim **19** wherein said flexible cable has a length of approximately one-half meter and an outside diameter of approximately six millimeters, the central insulated wire is not copper, and said second wire is copper.

21. Apparatus as defined in claim **18** together with a second cable having at one end a connector terminal member adapted to mate with the connector terminal member of said lithotrite and at the other end a pair of coaxial terminals, each having an insulated inner conductor and an outer coaxial shield, a junction member for merging said two insulated conductors inside a single outer coaxial shield which extends from said junction member to the vicinity of, but not beyond, said connector terminal member on said second cable.

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