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[54] **METHOD AND APPARATUS FOR DISINTEGRATION OF URINARY CALCULI**

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[73] Assignee: **Blackstone Corporation**, Jamestown, N.Y.

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[52] **U.S. Cl.** .... **128/328**, 128/24 A
[51] **Int. Cl.** **A61b 17/22**
[58] **Field of Search** .... 128/24 A, 328

[56] **References Cited**

UNITED STATES PATENTS

2,227,727	1/1941	Leggiadro	128/328 X
3,517,665	6/1970	Sheldon	128/24 A
3,543,757	12/1970	Balaev et al.	128/328
3,570,476	3/1971	Gregg	128/24 A
3,584,327	6/1971	Murry	128/24 A

FOREIGN PATENTS OR APPLICATIONS

1,218,112	6/1961	Germany	128/328

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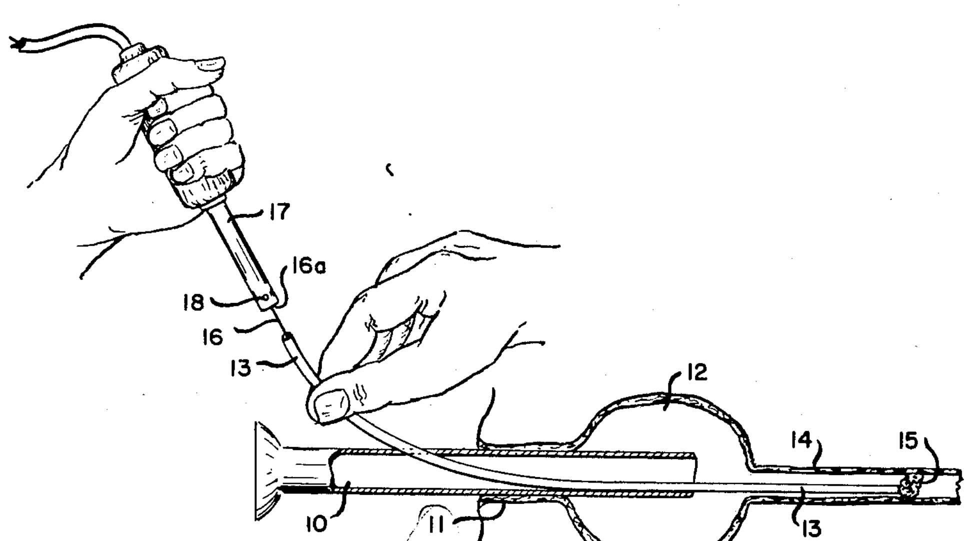
[57] **ABSTRACT**

A method and apparatus are provided for disintegrating urinary calculi by subjecting the urinary calculi to ultrasonic forces transmitted transversely of a wave guide in a catheter.

10 Claims, 13 Drawing Figures



C Urethra 2/29

Fig. 1.

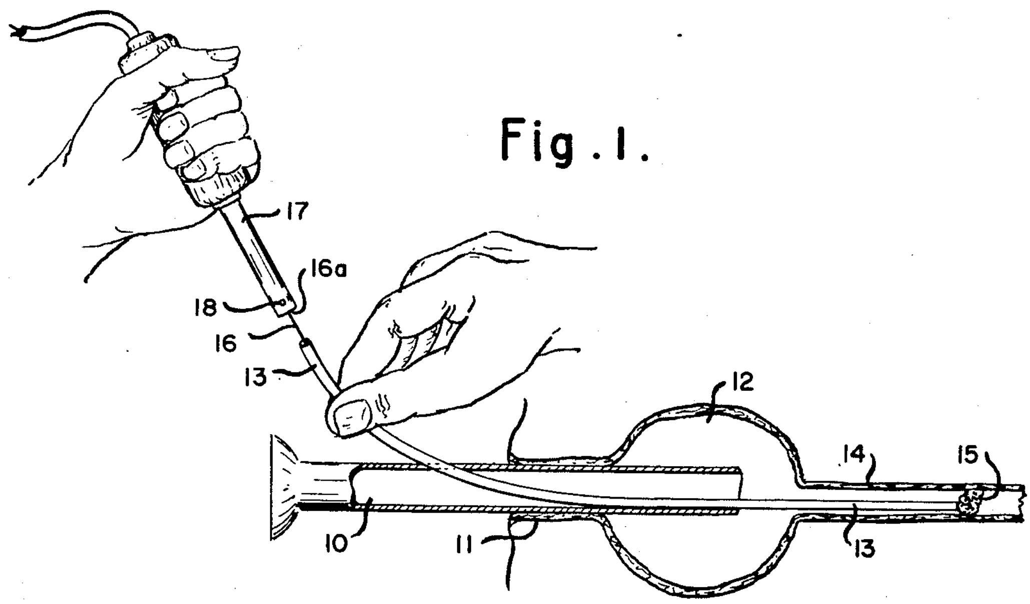


Fig. 2A.

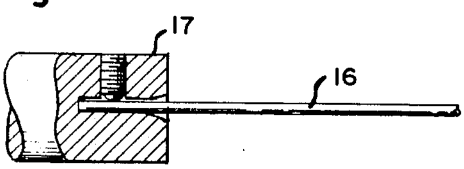


Fig. 2B.

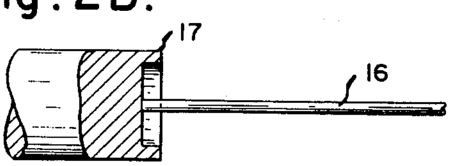


Fig. 2C.

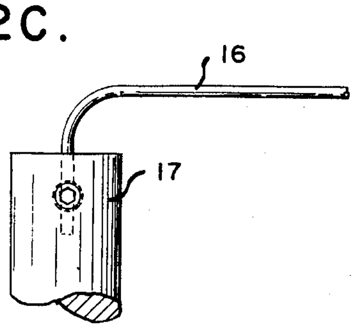


Fig. 2D.

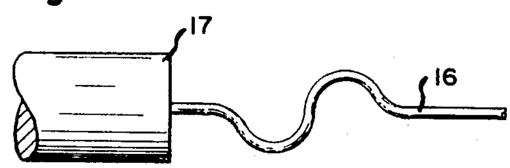


Fig. 2E.

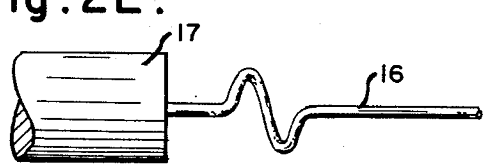
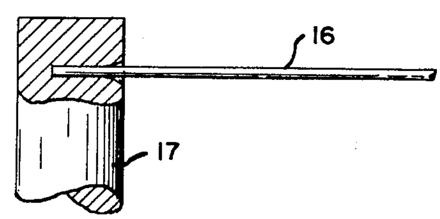


Fig. 2F.



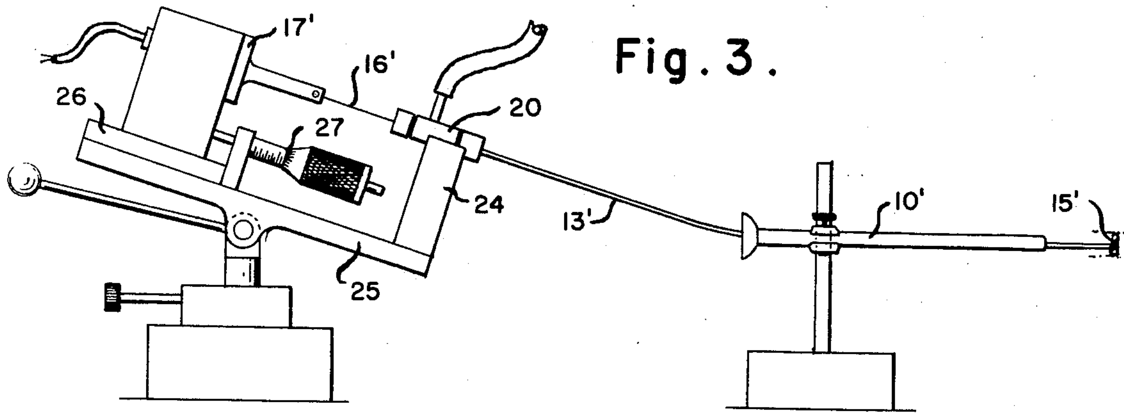


Fig. 3.

Fig. 4.

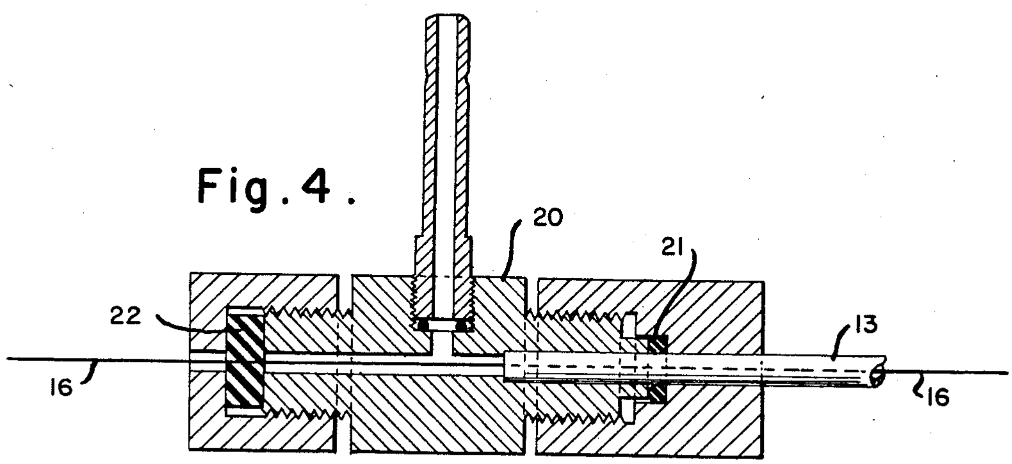


Fig. 5A.

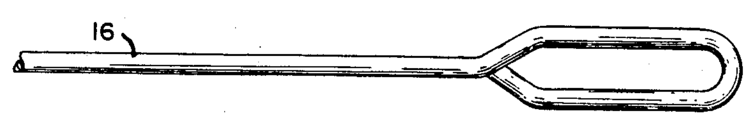


Fig. 5B.

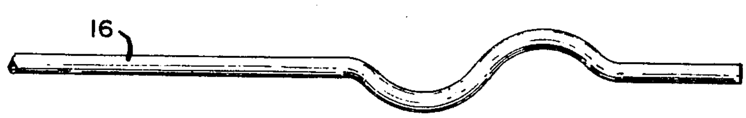


Fig. 5C.

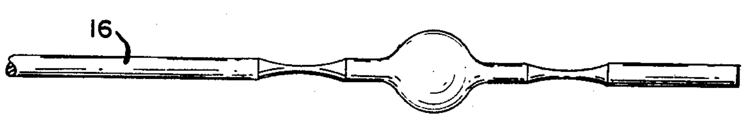
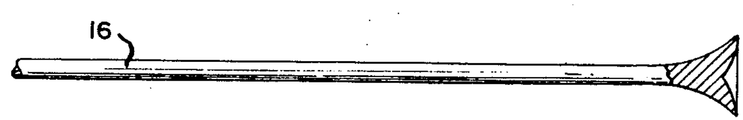


Fig. 5D.



METHOD AND APPARATUS FOR DISINTEGRATION OF URINARY CALCULI

This invention relates to methods and apparatus for disintegration of urinary calculi and particularly to an ultrasonic method and apparatus for fragmenting or drilling through urinary calculi.

It is well known that the average number of hospital admissions for removal of urinary calculi or stones is about 1 per 1,000 of population per year. This means that there are in excess of 200,000 cases of urinary calculi requiring hospital care. Stones which are quite small may in some cases be passed without hospitalization. However, all stones and particularly larger stones, especially if associated with obstruction or infection, must be removed from the urinary tract to prevent renal damage. Stones which are lodged low in the ureter may often be removed by manipulation using devices which are passed through the ureter up to the stone where they engage the stone for mechanical extraction. When the stone is high in the ureter or remains in the kidney, then it must be removed with open surgery in present practices.

The present invention eliminates the need for surgical removal of urinary calculi and reduces the hazards of mechanical manipulation in removing stones from the urinary tract.

The idea of vibratory impact machining of urinary calculi is not new. At least as early as 1946 proposals for vibratory impact machining of stones obstructing urinary tracts were made. Thereafter many investigators worked on techniques for ultrasonic disintegration of such urinary calculi. Focused beam techniques on distal stones were difficult to control and results were questionable. Impact machining techniques by transmitting longitudinal vibrations through wire wave guides were found to be effective to some degree but much too slow to be practical. Moreover, such methods were difficult to control and greatly restricted in utility because of excessive heat generation along the wave guide and the very large size of the wire used in order to provide longitudinal vibration.

We have found that urinary calculi can be quickly fragmented or drilled through if a wave guide or coupling member is passed through the lumen of a catheter in the ureter so that both catheter and wave guide touch the calculi to be fragmented and the relative size of the wave guide with respect to the catheter in such that lateral motion of the wave guide within the catheter at the stone is possible. We have found that with such an arrangement large urinary calculi can be quickly fragmented and removed, usually in 2 to 60 seconds.

In the practice of our invention a catheter is passed cystoscopically to the side of the stone in the urinary tract, a wave guide is passed through the lumen of the catheter and both are made to contact the stone, the wave guide being of such size as to provide lateral motion of the guide within the catheter. An ultrasonic transducer is attached to the wave guide and energized setting the guide into longitudinal and transverse vibration thereby causing an impaction and scraping action of the free end of the guide on the stone resulting in fragmentation or drilling of the stone. Preferably the wave guide is a wire. The cutting area may be irrigated or cooled by passing flushing fluid through the catheter around the wave guide. Preferably the apparatus consists of hollow catheter means adapted to enter the ureter and contact the stone, wave guide means having a diameter smaller than the hollow portion of the catheter means and adapted to pass through said hollow catheter means to contact the stone, and transducer means engaging the wave guide at the end opposite the stone and imparting both lateral and transverse motion to the wave guide at the end contacting the stone.

In the foregoing general description of our invention we have set out certain objects, purposes and advantages. Other objects, purposes and advantages will be apparent from a consideration of the following description and the accompanying drawings in which:

FIG. **1** illustrates the apparatus of this invention, partly in section in place in a human urinary system for removing a stone;

FIG. **2** (a) through **2** (f) illustrates fragmentarily several embodiments of coupling between transducer and wave guide;

FIG. **3** is a side elevational view of an apparatus for controlled fragmentation of stones;

FIG. **4** is a section through a connector for a catheter and wave guide for introducing flush solution into the catheter; and

FIG. **5** (a) through **5** (d) illustrates in side elevation several embodiments of wave guide cutting and fragmenting ends.

Referring to the drawings we have illustrated a cystoscope **10** inserted through a urethra **11** into a bladder **12.** A catheter **13** is inserted through the cystoscope **10,** the bladder **12** and into a ureter **14** until its end contacts stone **15.** At this point a wave guide in the form of wire **16** is inserted through the catheter until its end contacts the stone **15.** The wire **16** must be of substantially smaller diameter than the lumen diameter of the catheter, preferably less than two-thirds of the lumen diameter. The free end **16***a* of the wire **16** is attached to a transducer **17** by a set screw **18** or it may simply be abutted against the transducer with the transducer being urged toward the stone to put pressure on the wave guide.

With the catheter and wave guide in fixed position against the stone, the cystoscope is moved to the position which provides the least amount of curvature in the catheter and wave guide. An X-ray picture of the urinary tract is preferably taken at this point to assure contact of the catheter and wave guide with the stone. At this point with contact assured the transducer is energized and the catheter and wave guide are both pushed gently toward the stone until the wave guide has moved a distance equal to the estimated thickness of the stone.

We have found that coupling of the transducer **17** with the wire **16** can take various forms. The transducer can be directly mechanically connected as shown in FIG. **2**(a) using a set screw or similar means. This is in general our preferred connection. Due to the high slenderness ratio of the guide (wire), this coupling will, above a threshold ultrasonic displacement velocity lead to instability resulting in conversion of longitudinal motion into transverse motion of the guide, which is desired in the practice of this invention. The same is true of the embodiment of FIG. **2**(b) where there is no mechanical attachment between the transducer and wire and coupling is achieved by the force pushing against the wire end to force the wire into contact with the stone. The connections shown in FIGS. **2**(c), **2**(d) and

2(e) provide indirect conversion of the transducer motion into combined longitudinal and transverse, longitudinal and transverse torsional and longitudinal and transverse ellipsoidal motion respectively at the free end of the wire when it contacts the stone. The connection shown at 2(f) converts the longitudinal motion of the transducer into transverse motion.

In order to better control the position of the catheter and wave guide at the distal point which may be 40 cm. from the transducer we provide a control apparatus shown in the modification of FIG. **3.** In this embodiment those elements which are identical with elements of FIG. **1** bear like reference numerals with the addition of a prime sign. Referring to FIG. **3,** the catheter **13'** and wave guide **16'** are positioned at the stone **15'** as described in connection with FIG. **1** above. The exposed ends of the catheter and wire guide are fixed in a "T" connector **20** provided with an O-ring **21** to seal around the catheter **13** without collapsing the catheter end. A puncturable rubber diaphragm **22** is placed at the opposite end of the "T" and the wire **16** is passed therethrough. A viscous grease such as silicon vacuum grease seals the puncture in the diaphragm through which the wire passes so that gases or liquids may be pumped through the side arm of the T to cool or flush the stone area. The T member **20** is fixed in a clamp **24** mounted on a tilting base **25** which carries a slide **26** on which is mounted transducer assembly **17'**. The slide **26** is controlled by micrometer feed **27** to apply pressure through the transducer **17'**, the wire **16'** to the stone **15'**. The micrometer **27** allows a fixed controlled feed of wire against the stone and reduces the chance of the wire going through the stone and accidentally penetrating the ureter.

In order to obtain the maximum efficiency while reducing the likelihood of accidental penetration of the ureter, the wire end illustrated in FIG. **5** have been used by us with success. These ends are designed to center the wire end in the catheter to prevent by-passing the stone. In addition, some of these ends by rotation after drilling through the stone can be used to reverse drill and thus create a better chance of breaking the stone or they may be used to pull the stone out of the ureter.

We have also found that an expandable catheter aids in centering the wire and in preventing accidental penetration of the ureter. Such a catheter can be provided with a double wall construction, the outer wall being relatively thin and elastic and enlarged by introducing air or gas between the two walls after the catheter is placed in contact with the stone.

In the foregoing specification we have set out certain preferred practices and embodiments of our invention, however the invention may be otherwise practiced within the scope of the following claims.

We claim:

1. An apparatus for fragmenting and drilling urinary calculi comprising a catheter adapted to be inserted into a ureter to abut the calculi to be removed, a coupling member extending lengthwise of the lumen of said catheter and having a diameter less than the diameter of said lumen whereby said coupling member may vibrate transversely within the catheter and ultrasonic means acting on the coupling member to cause transverse vibration of the end thereof adjacent the calculi.

2. An apparatus as claimed in claim **1** wherein the diameter of the coupling member is less than two-thirds the diameter of the lumen.

3. An apparatus as claimed in claim **1** wherein the coupling member is a wire.

4. A method for fragmenting and drilling urinary calculi comprising th steps of:

a. placing a catheter in a ureter containing a calculi to be removed with one end abutting the calculi and the other end free,

b. inserting a coupling member through the lumen of said catheter until one end abuts the calculi while the other end extends out of the free end of the catheter, said coupling member having a smaller diameter than the lumen diameter,

c. subjecting the coupling member to ultrasonic vibrations such that transverse vibrations are produced at the end abutting the calculi, and

d. moving the coupling member into the catheter to cause it to fragment and drill the calculi.

5. A method as claimed in claim **4** wherein the coupling member is a wire whose diameter is less than two-thirds of the diameter of the lumen of the catheter.

6. A method as claimed in claim **4** wherein a cystoscope is inserted in the urinary tract to at least the bladder and the catheter is inserted through the cystoscope into the bladder and from thence into the ureter.

7. A method as claimed in claim **4** wherein flushing fluid is introduced into the catheter whereby the catheter is irrigated with fluid during fragmenting and drilling.

8. An apparatus as claimed in claim **1** wherein the coupling member has a wave form adjacent the point when the ultrasonic means acts upon it.

9. An apparatus as claimed in claim **1** wherein the coupling member has a spiral form adjacent the end where the ultrasonic means acts upon it.

10. An apparatus as claimed in claim **1** wherein the ultrasonic means acts on the coupling member transversely to its length.

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