(19) World Intellectual Property Organization

International Bureau





(43) International Publication Date 3 October 2002 (03.10.2002)

PCT

(10) International Publication Number WO 02/076310 A1

(51) International Patent Classification7: A61B 17/32

(21) International Application Number: PCT/US02/07112

(22) International Filing Date: 8 March 2002 (08.03.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

09/817,633 26 March 2001 (26.03.2001)

(71) Applicant: IEP PHARMACEUTICAL DEVICES INC. [US/US]; 6320 Angus Drive, Raleigh, NC 27617 (US).

(81) Designated States (national): AU, BR, CA, JP.

(84) Designated States (regional): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC,

(74) Agent: SANTUCCI, Ronald, R.; Frommer Lawrence & Haug, LLP, 745 Fifth Avenue, New York, NY 10151 (US).

NL, PT, SE, TR).

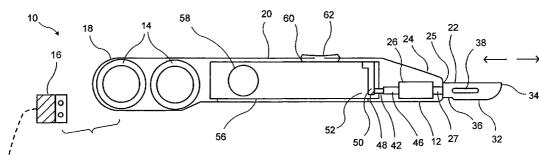
Published:

with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(72) Inventor: JEWETT, Warren, R.; 125 Palace Green, Cary, NC 27511 (US).

(54) Title: ULTRASONIC SCALPEL



(57) Abstract: A light, self-contained, hand held, ultrasonic surgical scalpel having a housing, an ultrasonic power source within the housing, to which ultrasonic vibrations are provided to a blade to which result in cutting features by lateral motion as well as by reciprocating motion imparted to the blades with said cutting action being adjustable.



O 02/076310 AJ

ULTRASONIC SCALPEL

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to a device for performing surgery particularly an ultrasonic scalpel wherein the 5 scalpel is fully self-contained using batteries as a primary source of power with a switch to permit selection between cutting and cautery modes. When operated the ultrasonic scalpel has the ability for lateral motion as well as reciprocating motion of the scalpel blade causing tissue separation along interstitial margins.

Description of the Prior Art

10

15

20

25

In the prior art, it is well known that an ultrasonic surgery avoids the trauma, extensive scarring, and limitations of thermal cutting of electrosurgery and laser surgery. In ultrasonic surgery, the ultrasonic scalpel takes advantage of dissection technology as a result of oscillating motion of the blades. Ultrasonic energy is transmitted through a connection or mount between the ultrasonic energy source and a hand-held coupler which mounts the surgical tool, for example, a surgical blade mounted at the tip of the coupler. This connection facilitates transmission of ultrasonic motion from the energy source through the coupler to the surgical blade in order to generate vibrations in the blade in a reciprocating motion. This ultrasonic motion is then coupled with the tissue to which the blade is applied.

It was generally thought that the same sharp blades used with hand-held surgical scalpels should also be used with ultrasonic scalpels. It was discovered that in

ultrasonic surgical instruments, duller blades achieved exceptional coagulation and cut better than by using sharp conventional scalpel blades. In fact, the duller blade greater transmission of ultrasonic energy is provided to adjoining tissue at the surgical site. This increased transmission was a result of increased blade cutting area in contact with the tissue. Better acoustic coupling as a result of greater transmission of ultrasonic energy enhances cutting capability and capacity for hemostatis.

10 It was found, too, that grinding blades to reduce and modify cross-sectional area enhanced the harmonic "whip" effect.

Existing ultrasonic scalpels can be applied to tissue with a vibrating reciprocating motion. While this reciprocating motion accompanied with dull blades has advantages over ultrasonic scalpels fitted with sharp blades, improved cutting with ease and quality can be achieved if there is lateral motion of the blades as well. Existing ultrasonic scalpels do not have the ability to achieve both ultrasonic lateral and reciprocating motion of the blade.

15

20

25

30

Existing ultrasonic scalpels also have the disadvantage of relying on external power supplies which connect to the surgical device by cord. Connection by cord to a power source can hamper portability of the scalpel as well as being cumbersome in some surgical operations.

Examples of prior art in this field include U.S.
Patent No. 4,587,958 entitled "Ultrasonic Surgical Device" issued to Noguchi et al. on May 13, 1986; U.S. Patent No. 4,832,022 entitled "Cryogenic Ultrasonic Scalpel" issued

to Tjulkov et al. on May 23, 1989; U.S. Patent No. 5,026,387 entitled "Method and Apparatus For Ultrasonic Surgical Cutting and Hemostatis" issued to Thomas on June 25, 1991; U.S. Patent No. 5,167,725 entitled "Titanium" Alloy Blade Coupler Coated With Nickel-Chrome For 5 Ultrasonic Scalpel" issued to Clark et al. on December 01, 1992; U.S. Patent No. 5,254,082 entitled "Ultrasonic Surgical Scalpel" issued to Takase on October 19, 1993; U.S. Patent No. 5,263,957 entitled "Ultrasonic Scalpel 10 Blade and Methods of Application" issued to Davison on November 23, 1993; U.S. Patent No. 5,324,299 entitled "Ultrasonic Scalpel Blade and Methods of Application" issued to Davison et al. on June 28, 1994; and U.S. Patent No. 6,080,175 entitled "Surgical Cutting Instrument and 15 Method of Use" issued to Hogendijk on June 27, 2000.

SUMMARY OF THE INVENTION

20

25

30

It is therefore an object of the invention to provide an ultrasonic scalpel which imparts lateral harmonic motion to the blade and in addition reciprocating motion.

It is therefore a further object of the invention to provide an ultrasonic scalpel which can be used in improved cutting and dissection with ease and quality.

It is therefore a still further object of the invention to provide an ultrasonic scalpel which can be used in incising with superior subsequent wound healing and with minimization of scar tissue.

It is therefore a still further object of the invention to provide an ultrasonic scalpel which can effectively cauterize an incision with minimization of scar tissue.

It is therefore a still further object of the invention to provide an ultrasonic scalpel in a light, self-contained, hand held device thereby improving utility by weight and size advantages.

It is therefore a still further object of the invention to provide an ultrasonic scalpel which is disposable.

To attain the objects described, there is provided an ultrasonic scalpel ideally suited for minimally invasive 10 surgery comprising a housing with a keyed cylinder and a blade coupler having a blade body and a shank extending from the blade body for coupling with a source of ultrasonic energy and transmitting the energy to the blade body. A transducer transmits ultrasonic energy to the 15 blade causing both reciprocating and harmonic lateral motion of the blade. The ultrasonic energy transmitted from the transducer which causes harmonic lateral motion of the blade is due to an offset of approximately one half to two degrees between the drive of the transducer and the 20 armature within the keyed cylinder. In addition the blade may also be subject to reciprocating motion.

The lateral harmonic motion produced is the reason for the ease and quality of a surgical cut and is the preferred embodiment of this invention. Improved cutting by enhanced tissue separation along interstitial margins is demonstrated. In the coagulation mode, the scalpel can operate at lower frequency and higher power providing thermal sealing. The proteinatious nature of tissue breakdown in the region surgerized at cutting frequency causes development of adherent surfaces leading to a

25

30

coagulation effect. This coagulation effect enhances healing with a minimization of scar tissue.

The ultrasonic scalpel of this invention does not require the use of a power cord connected to an external source. A power cord in the close area of surgical operations can be cumbersome and hinder ease of movement of the ultrasonic scalpel. Instead, the power source of the scalpel is batteries in a section of the ultrasonic scalpel housing itself; however, there is capability for an external power source if needed. Also, the weight and size of other required parts of the ultrasonic scalpel such as the electrical actuator and the circuit components with transformer can be reduced. Since the entire ultrasonic scalpel could operate without a separate power supply, the unit is conceivable disposable.

These and other objects and characteristics of the present invention will become apparent from the further disclosure to be made in the detailed description given below.

BRIEF DESCRIPTION OF THE DRAWINGS

5

10

15

The preferred embodiments of the present invention will now be explained in detail with reference to the accompanying drawings, wherein:

Figure 1 is a side view in section of the ultrasonic scalpel of the present invention.

25 Figure 2 is a top plan view showing the scalpel of Figure 1.

Figure 3 is a top plan view of the cylinder/armature arrangement of the present invention illustrating the degree of difference between the armature axis and the

drive axis as well as the wall clearance between the keyed cylinder and the housing of the ultrasonic scalpel.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

5

Referring now to the drawings in detail wherein like numerals refer to like elements throughout the several views, Figure 1 is a side cut-away view of ultrasonic scalpel 10.

Housing 12 of the ultrasonic scalpel 10 of Figure 1 is shaped to be grasped by the surgeon to allow the 10 surgeon to grip and manipulate during surgery. The shape of housing 12 is an elongated rounded body with varying circumferences. At the far end of the body of housing 12, removable sections are located on the housing face to allow for the insertion of a power source, batteries 14 15 and a power cord 16. From the power end 18, the circumference of the body decreases to a gripping area 20 which is the majority of the outside surface area of the housing 12. From the gripping area 20, the circumference of the body decreases to a circumference slightly larger 20 than the width of blade 22, which allows improved sight of the action of blade 22. At the distal end 24 of the body of housing 12, an aperture 25 is provided for insertion of blade 22 to connect with the keyed cylinder 26 of the 25 ultrasonic scalpel 10.

In Figure 2, blade 22 can be one of several special purpose blades pre-fitted for the ultrasonic scalpel for different types of surgery or designed for reciprocating and/or lateral motion of the ultrasonic scalpel. Blade 22

has opposite side faces 28 and 30 and may be made of metal, ceramic, a combination of both or other material suitable for the purpose. For example, when an ultrasonic scalpel is made for lateral motion only, specially shaped and ground blades ensure proper mass and balance throughout the length of the blade.

5

10

25

30

In Figure 1 blade 22 has a side edge 32 and a tip 34 opposite the shank 36. An aperture 38 is provided in the shank face for receiving the extrusion 27 of keyed cylinder 26. As shown in Figure 2, extrusion 27 has a flattened section with a raised surface 40 on one side face sized to fit conformably with the aperture 38 of blade 22.

As shown in Figure 1, blade 22 moves in relation to

the movement of armature 42 in a reciprocating motion as
depicted by the direction arrows. Reciprocating motion is
vibration in the direction of the axis of the blade 22.
Figure 2 depicts the motion of blade 22 in relation to the
movement of armature 42 in a lateral motion as depicted by

the direction arrows. Lateral motion is vibration in a
direction perpendicular to the axis of the blade 22.

It should be understood that in certain circumstances lateral motion alone may be sufficient and desirable without reciprocating motion. Without reciprocating motion imparted to scalpel blade 22, tissue separation occurs only at the nodes of harmonic motion and sugerization occurs as the scalpel blade is manually drawn across the surgical field. The blade 22 and driver 50 assembly may be fabricated in a manner to provide only lateral "whip" motion along the length of blade 22.

In Figure 3, the elongated flattened section 44 of extrusion 27 is the blade attachment section. The tubular section 46 of the armature 42 is the keyed cylinder 26 attachment area. Inside the body of the housing 12 near the aperture 25 is the keyed cylinder 26. The interior of the keyed cylinder 26 confines the armature 42 and transmits the ultrasonic vibration of the armature 42 to blade 22.

5

20

The armature 42 has a solid tubular section 46 which
moves within and impacts the movement of the keyed
cylinder 26. The other end 48 of the body of armature 42
slidably inserts into the driver 50 of transducer 52.
Armature 42 can slidably insert into the driver 50 at an
offset as exaggerated in the illustration of Figure 3.
The driver 50 of the transducer 52 is rounded and has a
recessed area 54 for engaging the armature 42.

The ultrasonic scalpel 10 is energized by a tool tip ultrasonic transducer 52. The transducer 52 vibrates and transmits this vibration through the driver 50 and armature 42 at a controlled frequency to the blade 22, causing reciprocating motion of the blade 22. The blade excursion is a function of electrical power input to the transducer 52.

Ultrasonic vibration for lateral harmonic motion of
blade 22 is caused by the one half to two degree offset of
the driver 50 axis and the armature 42 axis. The keyed
cylinder 26 has a one-thousandth of an inch (0.001")
clearance from the housing 12 to allow whip movement
caused by the lateral harmonic motion. The ultrasonic
scalpel 10 can be limited to transmitting ultrasonic
vibration for solely lateral harmonic motion.

In Figure 4, a piezo beam driver 29 electrically connected to circuit board 56 provides lateral "whip" motion when connected directly to blade 22. An anchor section 45 of driver 29 is the blade attachment section.

5 Driver 29 is preferably a Thunder Beam of Thunder Technology described with transducer 52; however suitable alternatives may be used.

The transducer 52 of Figure 1 has a piezoelectric driver which preferably contains Thunder Technology, which is a high deformation Piezo electrical actuator, 10 (described and illustrated in U.S. Patent 5,632,841 issued May 27, 1997 to NASA; U.S. Patent 5,639,850 issued June 27, 1997 to NASA; and U.S. Patent 6,030,480 issued February 29, 2000 to Face International, the disclosures of which are incorporated herein by reference); however, 15 those skilled in the art will recognize various equivalent substitutions. Operating frequencies of between 40 kHz and 65 kHz have been found to work particularly well. High voltage to the transducer 52 is provided by way of the circuit board 56. The circuit board 56 is a wafer-20 type rectangular shape. At one end of its face, the circuit board 56 connects electrically to the transducer 52.

To provide high voltage to the circuit board 56, a

25 transformer 58 will be connected electrically on the
circuit board face of the end opposite the attached
transducer 52. The transformer 58 will preferably be a
Transoner type (described and illustrated in U.S. Patent
5,834,882 issued to Face International, the disclosure of
30 which is incorporated herein by reference). Transoner is
a multi-layer piezo electric transformer. Of extremely

5

10

15

20

25

30

small size, this device can step up 6 volts to as high as 900 volts; however, those skilled in the art will recognize various equivalent substitutions.

To supply power to the transformer 58, the housing 12 provides interior space for two batteries 14 and an aperture 18 for a connection to an external power source 16. These power sources are connected electrically to the transformer 58. The batteries 14 for the power source can have a lithium core which would enable the ultrasonic scalpel 10 to be operated for 15 minutes. This is adequate because in many surgical procedures, the ultrasonic scalpel 10 is not in continuous use.

The housing 12 has an aperture opening 60 on the exterior gripping section 20 of the body for function switch 62. Function switch 62 comfortably fits in the opening 60 of the exterior of the housing 12 and is attached to the circuit board 56. The function switch 62 is in the form of a sliding button. The function switch 62 allows the operator to control the application of ultrasonic vibrations to the blade 22 for cutting and coagulation modes.

Without the need for but with the ability to use an external power supply, the ultrasonic scalpel 10 can be disposable. Also, the ultrasonic scalpel 10 one can be available in different power and frequency models, for varying surgical application.

While the invention has been described in connection with what is considered to be the most practical and preferred embodiment, it should be understood that this invention is not to be limited to the disclosed embodiment, but on the contrary, is intended to cover

various modifications and equivalent arrangements included within the spirit and scope of the appended claims.

CLAIMS

What is claimed is:

- An ultrasonic scalpel including:
 - a housing having an interior;
- a support piece in said housing;
 - a blade coupled to said support piece;
 - an armature in said support piece;

driver means for applying ultrasonic energy to the blade along its axis through said armature and said support piece to vibrate the blade in a lateral harmonic

motion.

5

- The ultrasonic scalpel of claim 1, wherein said driver means is mounted on said armature and applies
 energy to said blade along its axis through said armature and said support piece to move the blade in a reciprocating motion.
 - 3. An ultrasonic scalpel including:
- 20 a housing having an interior;
 - a support piece in said housing;
 - a blade coupled to said support piece;

driver means for applying ultrasonic energy to the blade along its axis through said support piece to vibrate the blade in a lateral whiplike motion.

4. The ultrasonic scalpel of claim 2 wherein said driver means is mounted at an offset angle on said armature.

5. The ultrasonic scalpel of claim 2 wherein said support piece is a keyed cylinder.

- The ultrasonic scalpel of claim 4 wherein said blades
 are pre-fitted for said keyed cylinder.
 - 7. The ultrasonic scalpel of claim 2 further including a switch attached to said housing.
- 10 8. The ultrasonic scalpel of claim 6 wherein said switch permits selection of cutting and cautery modes.
 - 9. The ultrasonic scalpel of claim 3 further including a switch attached to said housing, wherein said switch activates and de-activates the ultrasonic scalpel.
 - 10. The ultrasonic scalpel of claim 4 wherein the said offset angle is two degrees between the axis of said blade and the axis of said driver.
 - 11. The ultrasonic scalpel of claim 2 or 3 further including a transducer.

15

20

- 12. The ultrasonic scalpel of claim 11 wherein said transducer is a high deformation electrical actuator.
 - 13. The ultrasonic scalpel of claim 2 or 3 further including a transformer.

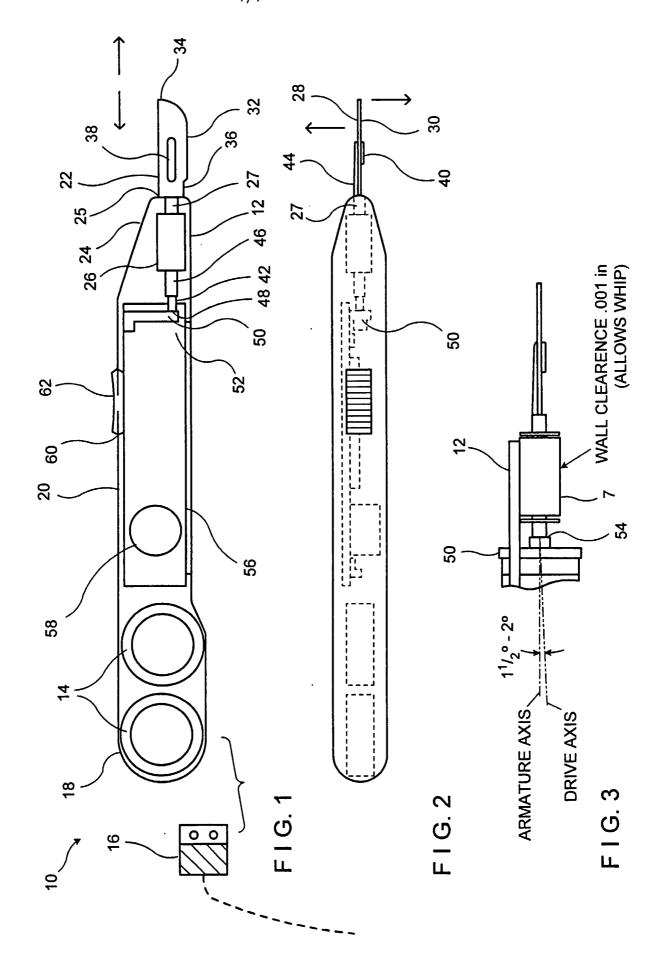
14. The ultrasonic scalpel of claim 13 wherein said transformer is a multi-layer piezo electric transformer.

- 15. The ultrasonic scalpel of claim 14, wherein said transformer can step up six volts to 900 volts.
 - 16. The ultrasonic scalpel of claim 2 or 3 further including a power source.
- 10 17. The ultrasonic scalpel of claim 16, wherein said power source is provided externally.
 - 18. The ultrasonic scalpel of claim 16, wherein said power source is provided by batteries.
- 19. The ultrasonic scalpel of claim 18, wherein said batteries comprise lithium.

15

25

- 20. The ultrasonic scalpel of claim 2 or 3, wherein said scalpel can be adjusted to a plurality of frequency settings.
 - 21. The ultrasonic scalpel of claim 2 or 3, wherein said scalpel can be adjusted to a plurality of power modes.
 - 22. The ultrasonic scalpel of claim 2 or 3, wherein said ultrasonic scalpel is disposable.



INTERNATIONAL SEARCH REPORT

Int onal Application No PCT/US 02/07112

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B17/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7-461B .

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 823 793 A (ANGULO EARL D ET AL) 25 April 1989 (1989-04-25) column 1, line 46 - line 48; figure 1	1,2,7,9, 11,13, 16,17,20
Y	US 5 026 387 A (THOMAS ALAN E) 25 June 1991 (1991-06-25) column 3, line 29 - line 33	1-3,7,9, 11,13, 16-18, 20,21
	column 3, line 29 - line 33 column 3, line 55 - line 68 column 4, line 24 - line 45 figures 1,2	
Υ	US 5 451 220 A (CIERVO DONALD J) 19 September 1995 (1995-09-19) column 1, line 24 - line 39; figure 1	3,18,21

Further documents are listed in the continuation of box C.	γ Patent family members are listed in annex.		
Special categories of cited documents: 'A' document defining the general state of the art which is not considered to be of particular relevance 'E' earlier document but published on or after the international filing date 'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) 'O' document referring to an oral disclosure, use, exhibition or other means 'P' document published prior to the international filing date but later than the priority date claimed	 "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family 		
Date of the actual completion of the international search	Date of mailing of the international search report		
1 July 2002	08/07/2002		
Name and mailing address of the ISA	Authorized officer		
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ducreau, F		

INTERNATIONAL SEARCH REPORT

Inte onal Application No PCT/US 02/07112

C.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category °		Relevant to claim No.
A	US 4 961 424 A (KUBOTA TATSUYA ET AL) 9 October 1990 (1990-10-09) column 3, line 4 - line 12; claim 1; figure 1	1-3
A	US 5 167 725 A (THOMAS ALAN E ET AL) 1 December 1992 (1992-12-01) the whole document	1-3

INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/US 02/07112

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 4823793	Α	25-04-1989	NONE		
US 5026387	Α	25-06-1991	WO US	9113591 A1 5263957 A	19-09-1991 23-11-1993
US 5451220	Α	19-09-1995	NONE		
US 4961424	A	09-10-1990	JP JP JP JP JP DE	1037942 A 1037946 A 1040041 A 1046447 A 1046448 A 3826414 A1	08-02-1989 08-02-1989 10-02-1989 20-02-1989 20-02-1989 16-02-1989
US 5167725	Α	01-12-1992	AU WO US	8441191 A 9202658 A1 5263957 A	02-03-1992 20-02-1992 23-11-1993



专利名称(译)	超声刀		
公开(公告)号	EP1372495A1	公开(公告)日	2004-01-02
申请号	EP2002719166	申请日	2002-03-08
[标]申请(专利权)人(译)	IEP PHARML DEVICES		
申请(专利权)人(译)	IEP制药设备,INC.		
当前申请(专利权)人(译)	IEP制药设备,INC.		
[标]发明人	JEWETT WARREN R		
发明人	JEWETT, WARREN, R.		
IPC分类号	A61B17/3211 A61B17/32 A61B18/	/00	
CPC分类号	를 A61B17/320068 A61B17/3211 A61B2017/320069 A61B2017/320071 A61B2017/320089		71 A61B2017/320089
优先权	09/817633 2001-03-26 US		
其他公开文献	EP1372495B1		
外部链接	Espacenet		

摘要(译)

一种轻型,独立式,手持式超声外科手术刀,具有壳体,壳体内的超声波电源,向刀片提供超声波振动,通过横向运动以及通过往复运动产生 切割特征。具有所述切割动作的刀片可调节。