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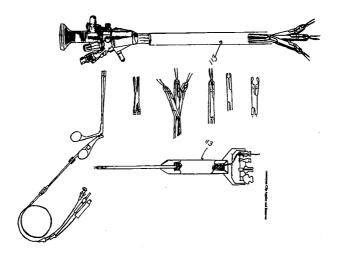
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(54) Title: MAIMANI ANEURYSM CLIP APPLIER AND REMOVER FOR USE WITH NEUROENDOSCOPES AND STERIOTACTIC SYSTEMS



(57) Abstract

A surgical device and method for applying and/or removing intracranial neurosurgical aneurysms clips, includes a direct clip applier and remover having a distal end (105), and having a proximate end (101) designed to fit directly inside both a neuroendoscope (102) and a stereotactic system, both with guidance from known brain scanning means. The device is effective for use with a multi-approach microneurosurgery device (113). This clipping applier and remover is designed to be used directly in neuroendoscopes and stereotactic systems as an alternative to aneurysm clipping methods which are currently used in the treatment of intracranial aneurysms, among other things. A method of the present invention does not require craniotomy, and is specifically useful for both reachable and currently inaccessible and untreatable areas which are found intra-cranially. An aneurysm can easily be accessed by the device owing to its ability to be positioned and to articulate at various angles (108) based upon control by a user.

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TITLE:

MAIMANI ANEURYSM CLIP APPLIER AND REMOVER FOR USE WITH NEUROENDOSCOPES AND STEREOTACTIC SYSTEMS

BACKGROUND OF THE INVENTION

Field of the Invention:

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The present invention relates to apparatus and methods used within surgical contexts, and specifically during neurosurgery. Particularly, the present invention relates to a neurosurgical device for applying and removing intracranial neurosurgical aneurysms clips, which includes a direct clip applier and remover with a multi-approach microneurosurgery tool designed to be housed within at least one of an known neuroendoscope and a known stereotactic system, useful with guidance from known brain scanners without necessarily requiring craniotomy.

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Aneurysm is a swelling out of part of an artery and the forming a sac of which can be life threatening if ruptured. Known to occur in all age groups, medical and general public knowledge of this problem has increased markedly due to a relatively bleak prognosis associated with aneurysm rupture. Generally, a 30 day mortality rate is known to be present in greater than 50% of this population, that is those who have aneurysm.

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Most of the time an aneurysm rupture, any related leakage of these sacs is proceeded by severe headaches, and likewise followed by subarachnoid hemorrhage. Such maladies are known to occur both in accessible and 'unreachable' areas of the brain.

Description of the Prior Art:

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Intracranial arterial aneurysms were first imaged by Egas Moniz in 1933, using angiograms. The first malleable haemostatic clips in neurosurgery were introduced by Cushing in 1911, but they were not appropriate for aneurysms. Concurrently, the first direct surgical treatment of a saccular intracranial aneurysm was reported by Dott, who placed a muscle fragment against the aneurysm. The neck of the aneurysm was first surgically clipped by Dandy in 1938. Schwartz is credited with the first direct attack on an aneurysm in the posterior fossa.

Under the stewardship of neurologists and neurosurgeons, remarkable advances have been made in the context of direct repair of ruptured and symptomatic intracranial aneurysms. Despite the advances during the current microneurosurgical era, the surgical approach to certain areas of the brain continues to be a major challenge.

The use of at least one of rigid and flexible endoscopes and stereotactic systems in approaching the subarachnoid vascular system is indeed a new concept among those having skill in the art. To date, and under current treatment schemes.

aneurysms require performing of either craniotomies or craniactomies which are a major surgery lasting 6-10 hours with high morbidity and mortality rates. They also involve long hospital admission, an increase in complications caused by major surgery, specifically in the elderly population and high risk population. Those patients who are excluded from being operated on conventionally may be helped with the teachings of the device of the present invention, as may neurosurgey patients in general.

It may seem to many at this point in time, that neither the neuroendoscope nor the stereotactic system is capable of providing adequate vision and adequate control to satisfactorily evaluate, dissect, clip and - or remove an aneurysm directly

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Accordingly, to solve this long-standing problem in the instant field of art, the present inventor has diligently searched for mechanisms which would remedy the above situation and ameliorate known pitfalls. The teachings of the present invention are thus offered for consideration to overcome these problems which remain inadequately addressed to date. The mechanisms and teachings of the present invention are the product of the diligent search for solutions to this problem.

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In a review of the art, the only patents which are both available and relevant claim, as their subject matters, either the aneurysm clips proper, or neuroendoscopes, and the like multi-approach microneurosurgery devices. While such apparatus certainly are involved with important aspects of redemption of the above enumerated difficulties, detailed discussions of same are omitted as within the scope of conventional knowledge of those conversant in neurosurgical means and mechanisms.

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For example, U.S. Letters Patent No, 4,360,023 assigned to Mizuho Ikakogyo Company, Limited forms the basis for a least 91 differently sized and shaped aneurysm clips. Such clips are now described by industry standardized terms and expressions, including size and shape

ranging from 'mini' to 'large'

with standard sizing and fitting characteristics also being within the scope of those of skill in the microneurosurgical arts.

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Likewise, U.S. Letters Patent No. 5,437,626 assigned to Neuro Navigational Corporation teaches a shunt with an internal endoscope. While both of these disclosures are readily distinguishable from the instant

teachings, they are incorporated expressly herein by reference, being representative of the state of the art in both aneurysm clips and microneurosurgical devices, such as may be used in accordance with the teachings of the present invention. Once again, detailed discussion and description of both rigid and flexible neuroendoscopes is also omitted, along with any discussion or description of stereotactic systems, as the technical rudiments of same are presumed to be within the knowledge of skilled practitioners.

OBJECTS AND ADVANTAGES OF THE INVENTION

It is an important object of the present invention to provide an improved surgical device and method reducing hospital stay duration, decreasing complications of major surgery, the number of hours required for the same surgery, and morbidity and mortality rates in patients undergoing surgical treatment.

treatment.

Another object of the present invention is to provide an improved surgical device and method which overcomes the drawbacks of the prior art by creating a prophylactic measure for treating patients presently undergoing conservative nonsurgical management of symptomatic lesions.

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Yet another object of the present invention is to substantially shorten the timing of treatment intervals for patients having arterio-venous malformation (AVM), which occur in at least 15% of patients having multiple aneurysms.

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A further object of the present invention is to provide novel enhanced means for applying and removing clips used for treating aneurysms, which means is effective for use with known endoscopes and stereotactic systems.

Briefly stated, advantages of the present invention over

conventional methods include a reduction in hospital stay, a decrease in complications caused by major surgery, a decrease in the number of hours of surgery specifically in the elderly population. Likewise, the instant teachings are useful for high risk cases which cannot be conventionally treated and further facilitate a decrease in overall expenses. It is respectfully proposed that the treatments according to the present invention must be considered first, even in the less straight forward cases.

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According to a feature of the present invention there is provided a direct clipping applier and remover device used with a multi-approach microneurosurgery system housed inside known neuroendoscopes and stereotactic systems.

According to another feature of the present invention, aneurysms can easily be accessed by this new device in both accessible and previously unreachable areas. Another advantage is to be able to operate on multiple aneurysms within short period of time interval. This translates into lower morbidity and mortality, as summarized above.

According to yet another feature of the present invention, neuroendoscopic procedures can be performed through one burr hole, also referred to as a monoportal procedure. This is to be contrasted with a biportal procedure in which two different access apertures are required.

According to yet still another feature of the present invention there is provided apparatus used to manipulate surgical devices for better control.

The instant method likewise provides advantage in situations where there are others who are diagnosed incidentally, i.e., when exams are performed for other problems. With the teachings of the present invention, it is possible to clip an aneurysm prophylactically which would be a life saving measure preventing aneurysm rupture, bleeding and possible death.

The characteristics and advantages of the invention are further

> sufficiently referred to in connection with the accompanying drawings, which represent at least one embodiment. After considering this example, skilled persons will understand that variations may be made without departing from the principles disclosed; and I contemplate the employment of any structures, arrangements or modes of operation that are properly within the scope of the appended claims.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

With the above and related objects in view, the invention consists in the details of the construction and combination of parts, as will be more fully understood from the following description, when read in conjunction with the accompanying drawings and numbered parts, in which:

Fig. 1 is an external view of a microsurgical device as fitted with an anuerysm clip applier according to an embodiment of the present invention, and teachings related to the method of use of same;

Fig. 2 is also an external view of a microsurgical device as fitted with an anuerysm clip remover according to an embodiment of the present invention, and teachings related to the method of use of same;

Fig. 3 illustrates three detailed views of a clip remover and applier according to an embodiment of the present invention and teachings related to the method of use of same;

Fig. 4 is a illustration showing a detailed view of a sagittal section of a shunt end distal view, including a clip remover and applier in a closed position according to an embodiment of the present invention and teachings related to the method of use of same:

Fig. 5 shows two detailed view of an example of a clip used with an embodiment of the present invention, including the clip being shown in an unactuated (first) position, and an actuated (second) position as used with a

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clip remover and applier according to an embodiment of the present invention and teachings related to the method of use of same;

Fig. 6 illustrates an example of one of the different areas of the brain before and after clipping an aneurysm using a device which may be applied or removed or an embodiment of a method according to the present invention;

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Fig 7 shows a neuroendoscopic view of an aneurysm requiring use of a clip applier and remover according to an embodiment of the present invention;

Fig. 8 illustrates a generalized view of a multi-approach microsurgery device effective for use with a clip applier according to an embodiment of the present invention, showing a variety of angular orientations:

Fig. 9 likewise illustrates the same type of view of a clip remover according to an embodiment of the present invention;

Fig. 10 also shows a multi-approach microsurgery device, with a full view of the detailed version shown in Fig. 4, according to an embodiment of the present invention;

Figure 11. illustrates clip appliers and removers, and two view of neuroendoscopes, one rigid, and one flexible as may be used with embodiments of the present invention;

Figure 12. illustrates clip applier and removers in use with the Steriotactic system

Figure 13. a neuroendoscope detailed cross suction to illustrates different port of entry for accesses for different instruments.

DETAILED DESCRIPTION OF THE INVENTION

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The present inventor has discovered that during microneurosurgical procedures lesions, or portions of them, may be hidden behind untraceable structures, requiring novel enhanced access and egress means. Likewise, accessible lesions are within the scope of the present invention, which allows the skilled surgical professional to operate with a higher degree of control, knowledge and awareness of the unique topography and inner workings of the brain of a patient.

The present invention, through combination with known neuroendoscopic and stereotactic systems provides easy accessibility to most aneurysms in the brain and spinal cord. Thus the patient does not have to undergo craniotomy or craniactomy, rather according to the treatments available with the use of the apparatus and methods of the present invention, procedures can be undertaken under visualization of known brain scanning means.

For example, one having a modicum of skill in the art would be aware of the use of systems such as THE LINAC SYSTEM - BRAINSCAN (available through BRAINLAB, USA, Inc., 600 Glen Court, Moorestown, New Jersey 08057, USA) which are employed in conjunction with the instant teachings.

Likewise, instruments for neurosurgery, as detailed in United States Letters Patent No. 5,437,626 - are known to be effective for in vivo placement and removal of devices within the human brain to achieve objects analogous to the teachings of the present invention. Accordingly, after the following brief synopsis, further detail regarding the technical rudiments of said procedures is omitted, as contemplated to be within the scope of knowledge of the averagely skilled practitioner in the art of brain surgery.

Endoscopic devices are known for use in brain surgery which include generally tubular members housing a plurality of image fibers, couplers for video transmission and related cabling, irrigation, and instrument positioning and manipulating means. The present invention contemplates use with both axially rigid stainless steel hypodermic tubular members flexible conduits effective for having the above mentioned means disposed therein within the microsurgical context. Likewise, those of skill in the art will generally realize that known diameters for tubes, fiber, and cabling are used in conjunction with the teachings of the present invention, which also embraces industry standard clips for aneurysms and is designed to matingly engage with same, in addition to clip removers available from at least several known sources. See, for example, SUGITA brand ANEURYSM CLIPS available from Mizuho (TM) Medical Co., Ltd. (Fuse Building 2F 3-30-10, Hongo, Bunkyo-ku, Tokyo 113, Japan) and the 'Malleable Seeing Instruments' of Clarus Medical Systems, Inc., (available from CLARIS MEDICAL, 1000 Boone Avenue N, Minneapolis, MN 55427, USA).

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As discussed herein, a neuroendoscopic device effective for use according to the teachings of the present invention will include an aneurysm clip applier, a clip kehole applier, an aneurysm clip remover, a clip applier forceps and a multipurpose all-angle clip applier.

Likewise, a stereotactic device effective for use according to the teachings of the present invention will include an aneurysm clip applier, a clip kehole applier, an aneurysm clip remover, a clip applier forceps and a multipurpose all-angle clip applier. It is further contemplated that all of the above instruments, components and devices could be composed of Magnetic Resonance Imagery ("MRI") compatible materials.

Referring now to Fig. 1, an outside view of a generalized Endoscopic device includes an aneurysm clip applier, which may be a clip keyhole applier. The clips applier is used with such a multi-approach microneurosurgery device which is shown and know to perform those functions outlined above. The entire systems according to the present invention is housed within a known neuroendoscope.

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Referring now to Fig. 2, a neuroendoscopic device includes an aneurysm clip remover, which may be used as a clip keyhole applier. The clip remover, is used with a multi-approach microneurosurgery device. The entire systems according to the present invention is housed within a known neuroendoscope.

Referring now to Fig. 3, three illustrations show a series of detailed views of a typical operational sequence according to both the device and method of the present invention. Fig. 3(a) shows a clip and an applier in a first (normal) position, prior to application of force. Application of force enables a user to manipulate the attached clip from the first position, as shown in Fig. 3(a), to a second position, as shown in Fig. 3(b). Fig. 3(c) demonstrates that the present inventor also contemplates a variety of angular orientations and arrangement, based upon, among other things, angular rotation about an axis 108.

Likewise, those having skill in the art will readily understand that the aneurysm clip applier and remover is effective for use with any known, and later discovered surgical clips, as the present invention contemplates interchangeable use of appliers and removers for aneurysm clips, as detailed in the claims appended hereto and expressly incorporated by reference herein.

Fig. 4 shows a detailed view of a sagittal section of a shunt end distal view, as would be typical of use of the present invention with at least

one of a neuroendoscope and a stereotactic system. Specifically, a clip remover and applier 105 is shown in a closed position according to an embodiment of the present invention and teachings related to the method of use of same

a view of embodiments of the apparatus of the present invention and a method embodying same with a stereotactic device that consists of an aneurysm clip applier, a clip keyhole applier, an aneurysm clip remover, a

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clip applier forceps and a multipurpose all-angle clip applier. As discussed above for the neuroendoscopic application of the present invention, each of

the above devices could be made up of MRI compatible materials.

Fig. 5 shows two views of a clip, as typically used according to a device and method of the present invention. Namely, the instant teachings used such pre-biased means for clipping to be opened based upon the application of force by a user, within a multi-approach microneurosurgery device, including a neuroendoscope and a stereotactic system.

In reference to Fig. 6 - Fig. 13, those skilled in the art will readily understand that they are designed both to illustrate the typical level of skill of those practicing the instant teachings, and for the purpose of indicating some of the plethoric accessories embraced by the scope of the apparatus and method of the present invention. Accordingly, detailed discussions of same and reference designating numerals are not required in order to teach one having skill how to practice the teachings of the present invention.

It may thus be seen that the objects of the present invention set forth herein, as well as those made apparent from the foregoing description, are efficiently attained. While the preferred embodiments of the invention have been set forth for the purposes of this disclosure, modifications of the disclosed embodiments of the invention as well as other embodiments thereof may occur to those skilled in the art. Accordingly, the appended

claims are intended to cover all embodiments which do not depart from the spirit and scope of the invention.

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111111	<u> </u>									
1.	A clip a	applier	and	remover	which	fits	into	a mici	roneurosurg	ery
apparatus	selected	from	the	group	of de	vices	cons	sisting	essentially	of

neuroendoscopes and stereotactic systems.

WHAT I CLAIM IS:

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2. A device for clipping aneurysms, comprising:

a direct aneurysm clip applier and remover;

said direct aneurysm clip applier and remover is effective for use within a

multi-approach microneurosurgery device, and designed to fit inside of at

least one of a neuroendoscope and a stereotactic system operated under

guidance of the visualization of a brain scanner.

12 13

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3. A device for clipping aneurysms, comprising direct aneurysm clip

14 applier and remover;

said direct aneurysm clip applier and remover

is effective for use within a multi-approach microneurosurgery device, and

designed to fit inside of a neuroendoscope and operated under guidance of the

visualization of a brain scanner.

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4. A device for clipping aneurysms, comprising:

21 a direct aneurysm clip applier and remover;

said direct aneurysm clip applier and remover is effective for use within a

23 multi-approach microneurosurgery device, and designed to fit inside of a

stereotactic system operated under guidance of the visualization of a brain

25 scanner.

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5. A device for clipping aneurysms, comprising:

28 a direct aneurysm clip remover;

1	said direct aneurysm clip applier and remover							
2	is effective for use within a multi-approach microneurosurgery device, and							
3	designed to fit inside of a neuroendoscope.							
4								
5	6. A device for clipping aneurysms, comprising:							
6	a direct aneurysm clip remover;							
7	said direct aneurysm clip applier and remover is effective for use within a							
8	multi-approach microneurosurgery device, and designed to fit inside of a							
9	stereotactic system operated under guidance of the visualization of a brain							
10	scanner.							
11								
12	 A device for clipping aneurysms, comprising: 							
13	a direct aneurysm clip applier;							
14	said direct aneurysm clip applier; is effective for use within a multi-approach							
15	microneurosurgery device, and designed to fit inside of a neuroendoscope							
16	operated under guidance of the visualization of a brain scanner.							
17								
18	8. A device for clipping aneurysms, comprising:							
19	a direct aneurysm clip applier;							
20	said direct aneurysm clip applier is effective for use within a multi-approach							
21	microneurosurgery device, and designed to fit a stereotactic system							
22	operated under guidance of the visualization of a brain scanner.							
23								
24	 A device for clipping aneurysms according to claims 							
25	1,2,3,4,5,6,7,8:							
26	wherein the device is made of an MRI compatible material.							
27								
28	10. Method of using the device of claim 1 further comprising: the step	of inserting the clip						

1	and, clipping an aneurysm.
2	
3	11. Method of using the device of claim 2 further comprising:
4	inserting the clip into a stereotactic system guidance setting; and,
5	clipping an aneurysm.
6	
7	12. Method of using the device of claim 3 further comprising the step
8	of:
9	as inserting the clip remover into a neuroendoscope and removing the clip
10	from an aneurysm.
11	
12	13. Method of using the device of claim 4 further comprising the step of
13	inserting the clip remover into a stereotactic system guidance setting and
14	removing the clip from an aneurysm.
15	
16	14. A device for clipping aneurysms, comprising a tube having a distal
17	segment which has a distal segment fitting inside at least one of a
18	neuroendoscope and a stereotactic system guidance which consists of a
19	clip applier.
20	
21	15. A device for clipping aneurysms according to claim 8,
22	wherein the clip applier is of standard size and fitted with various
23	modifications;
24	and fits directly in a neuroendoscopic setting.
25	
26	16. A device for clipping aneurysms according to claim 8, wherein the
27	clip applier is of a large size with various modifications and fits directly
28	into a neuroendoscopic setting.

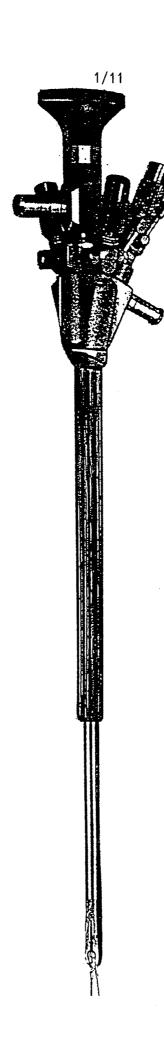
1	17. A devices for clipping aneurysms according to claim 8,					
2	wherein the clip applier is of medium size with various modifications to fit					
3	directly into a neuroendoscopic setting.					
4						
5	18. A device for clipping aneurysms according to claim 8 wherein the					
6	clip applier is of mini size with various modifications to fit directly into a					
7	neuroendoscopic setting.					
8						
9	19. A device for clipping aneurysms, comprising a tube having a distal					
10	segment fits directly inside of at least one of a neuroendoscope and a					
11	stereotactic system guidance which consists of a clip applier having one size					
12	sleeted from the group consisting of:					
13	standard sizes;					
14	large sizes;					
15	medium sizes;					
16	mini sizes;					
17	flexible angle sizes; and					
18	various shapes.					
19						
20	20. A device for clipping aneurysms according to claims					
21						
22	wherein said device is made of an MRI compatible material.					
23						
24	21. Process using the device of claims 1,2,3,4,5,6,7,8,9, 14,15,16,17,					
25	19,					
26	for clipping an aneurysm clip.					
27						
28	22 Process using the device of claims 1 2 3 4 5 6 7 8 9 14 15 16 17 10					

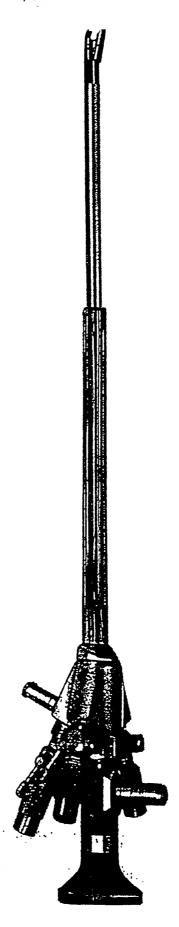
1	for re	moving an aneurysm clip.			
2					
3	23.	A device for clipping aneurysms, comprises a tube having a distal			
4	segme	ent which consists of a clip applier of having a plurality of different			
5	shapes	s with different modifications to be used directly in a stereotactic			
6	setting	<u>,</u>			
7					
8	24.	Device according to claim 23, wherein said clip applier is of			
9	standa	rd size.			
10					
11	25.	Device according to claim 23, wherein said clip applier is of large			
12	size.				
13					
14	26.	Device according to claim 23, wherein said clip applier is of medium			
15	size.				
16					
17	27.	Device according to claim 23, wherein said clip applier is of mini			
18	size.	•			
19	28,	Device according to claim 23, wherein said clip applier is of long			
20	size.				
21					
22	29.	Device according to claim 23, wherein said clip applier further			
23	comp	rises flexible angles.			
24					
25	30.	A device for removing an aneurysm clip from a patient, comprised			
26	of a tube having a distal segment which consists of a clip remover having a				
27	plura	lity of different sizes, flexible angles and shapes with different			
28	modifications to be inserted directly into a neuroendoscopic setting.				

1	
2	31. Device according to claim 30, wherein said clip remover is of
3	standard size.
4	
5	32. Device according to claim 30, wherein said clip remover is of large
6	size.
7	
8	33. Device according to claim 30, wherein said clip remover is of
9	medium size.
10	
11	34. Device according to claim 30, wherein said clip remover is of mini
12	size.
13	
14	35. Device according to claim 30, wherein said clip applier is of long
15	size.
16	
17	36. Device according to claim 30, wherein said clip remover further
18	comprises flexible angles and shapes with different modifications to be used
19	directly within a stereotactic setting.
20	
21	37. Device according to claim 30, wherein said clip remover is of
22	medium size.
23	
24	38. A device for removing an aneurysm clip from a patient, comprised
25	of a tube having a distal segment which consists of a clip remover having a
26	plurality of different sizes, flexible angles and shapes with different
27	modifications to be inserted directly into a stereotactic setting.
28	

1	39.	A device according to claim 38, wherein said clip remover further
2	compris	ses different sizes, flexible angles and shapes with different
3	modific	ations to be used directly within a stereotactic system.
4		
5	40	A device according to claim 38, wherein said clip remover is of large
6	size wit	h different modifications to be used directly in a stereotactic setting.
7		
8	41.	A device according to claim 38, wherein said clip remover is of
9	medium	a size with different modifications to be used directly in a stereotactic
10	setting.	
11		
12	42.	A device according to claim 38, wherein said clip remover is of mini
13	size wit	th different modifications to be used directly in a stereotactic setting.
14		
15	43.	A device according to claim 38, wherein said clip remover is of
16	long siz	ze with different modifications to be used directly in a stereotactic
17	setting.	
18		
19	44.	A device according to claim 38, wherein said clip remover has
20	flexible	angles with different modifications to be used directly in a
21	stereot	actic setting.
22		
23		
24		
25		
26		
27		
28		







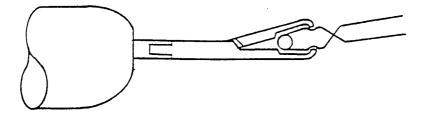


Fig. 3(a)

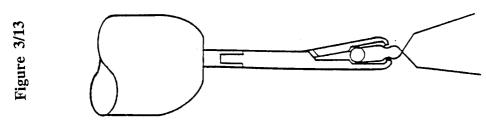


Fig. 3(b)

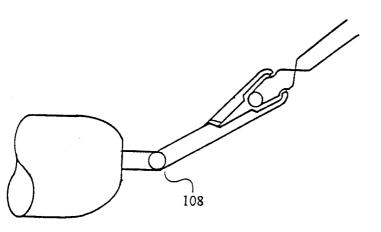


Fig. 3(c)

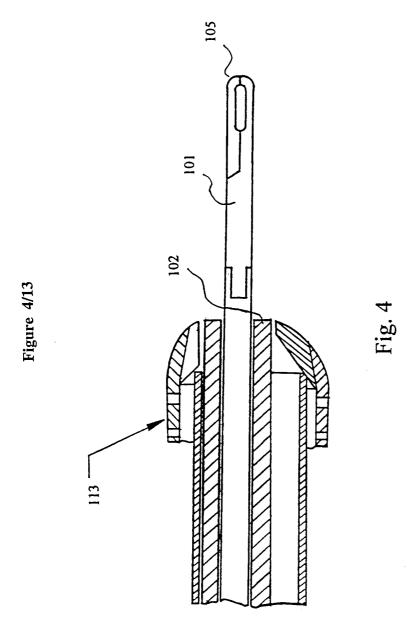


Figure 5/13

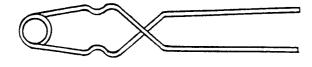
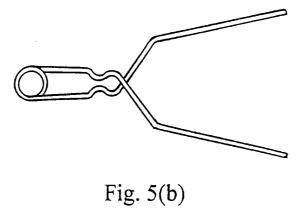
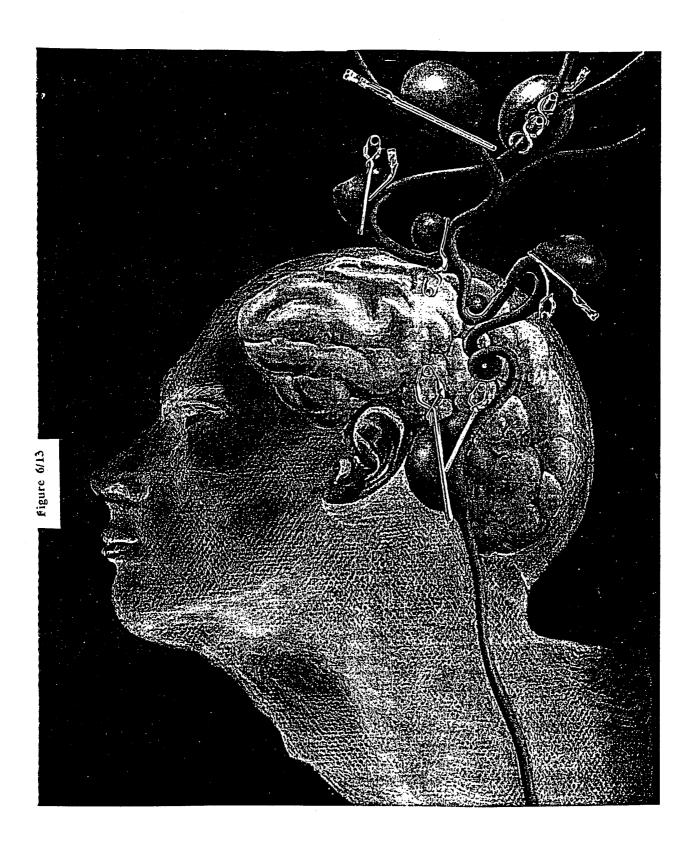


Fig. 5(a)





MINIMALLY INVASIVE THERAPY OF THE BRAIN ENDOSCOPIC CLIPPING ANEURYSM

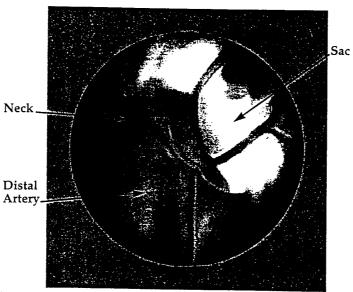


Figure 1. Unclipped Aneurysm.

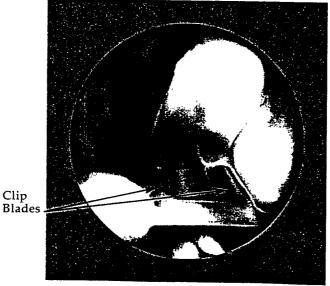


Figure 2. Clipped Aneurysm.

