

(19) **DANMARK**



Patent- og
Varemærkestyrelsen

(12)

Oversættelse af europæisk patentskrift

(10) **DK/EP 2775936 T3**

-
- (51) Int.Cl.: **A 61 B 17/04 (2006.01)**
- (45) Oversættelsen bekendtgjort den: **2017-04-03**
- (80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: **2016-12-28**
- (86) Europæisk ansøgning nr.: **12813579.5**
- (86) Europæisk indleveringsdag: **2012-11-08**
- (87) Den europæiske ansøgnings publiceringsdag: **2014-09-17**
- (86) International ansøgning nr.: **US2012064053**
- (87) Internationalt publikationsnr.: **WO2013070841**
- (30) Prioritet: **2011-11-09 US 201161557482 P**
- (84) Designerede stater: **AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR**
- (73) Patenthaver: **Easylap Ltd., 30 Ha"ella Street , PO Box 128, 73150 Kfar Truman, Israel**
- (72) Opfinder: **FABIAN, Izhak, 30 Ha'Ella Street, POB 128, 73150 Kfar Truman, Israel**
ALTMAN, Nir, Kibbutz, 90912 Kfar Etzion, Israel
- (74) Fuldmægtig i Danmark: **RWS Group, Europa House, Chiltern Park, Chiltern Hill, Chalfont St Peter, Bucks SL9 9FG, Storbritannien**
- (54) Benævnelse: **SUTURINDRETNING MED AFSTANDSSTYKKE**
- (56) Fremdragne publikationer:
EP-A1- 1 598 017
EP-A2- 2 005 892
WO-A1-95/33408
WO-A1-2007/073931
US-A1- 2003 004 544
US-A1- 2009 264 905

DESCRIPTION

FIELD OF THE INVENTION

[0001] The present invention relates generally to suturing devices such as for the percutaneous closure of body lumens and tissues by means of sutures.

BACKGROUND OF THE INVENTION

[0002] Many suturing devices are known in the art that puncture the skin with needles and percutaneously deliver sutures to the site. For example, PCT Patent Application WO 2009/069119 discloses a suturing assembly 10, which is briefly described here with reference to Figs. 1 and 2.

[0003] Suturing assembly 10 includes a first puncture element 12 including a sharp distal end 14 for puncturing tissue, and a second puncture element 16 including a sharp distal end 18 for puncturing tissue. The distal ends 14 and 18 of first and second puncture elements 12 and 16 are spaced from each other by a gap 20. Preferably, but not necessarily, first and second puncture elements 12 and 16 are parallel to each other.

[0004] First and second puncture elements 12 and 16 are hollow. A suture manipulating assembly 22 that includes a suture thread receiving member 24 and a suture grabber 26, which can be passed into the hollow portions of first and second puncture elements 12 and 16, respectively. First and second puncture elements 12 and 16 are provided with distal funnel cups 28 and 30, respectively, for guiding insertion of suture thread receiving member 24 and suture grabber 26. The funnel cups 28 and 30 also serve as stops to limit movement of suture thread receiving member 24 and suture grabber 26 into first and second puncture elements 12 and 16. Proximal ends of suture thread receiving member 24 and suture grabber 26 are mounted on a handle assembly 32. Suture thread receiving member 24 is mounted on an adjustable block 17 of handle assembly 32. Adjustable block 17 is arranged for moving with respect to a distal block 19 of handle assembly 32.

[0005] Suture thread 38 is placed over a distal end of suture thread receiving member 24. As seen in Fig. 2, the suture grabber 26 is arranged to grab suture thread 38 at the distal end 14 of first puncture element 12 and pull suture thread 38 over the gap to second puncture element 16.

[0006] Briefly, in operation of suturing assembly 10, first and second puncture elements 12 and 16 are first pushed into tissue and the sharp distal ends 14 and 18 puncture a tissue wall. The suture thread receiving member 24 and suture grabber 26 are introduced into the hollow portions of first and second puncture elements 12 and 16, respectively. When the suture thread receiving member 24 is pushed fully up to funnel cup 28, the suture thread 38 passes from a near side of the tissue wall to a far side of the tissue wall. When suture grabber 26 is pushed fully up to funnel cup 30, suture grabber 30 swings out of second puncture element 16 towards the suture thread 38 at the distal end 14 of first puncture element 12. Suture thread 38 is now caught and grabbed by suture grabber 26, as seen in Fig. 2. The suture thread receiving member 24 and suture grabber 26 are then pulled proximally (backwards). This movement pulls suture grabber 26 back into second puncture element 16. As suture grabber 26 moves proximally it brings along with it suture thread 38 over the gap 20, proximally away from the distal end 18 of second puncture element 16, and back through to the near side of the tissue wall. Afterwards, the suture thread 38 may be secured to form a stitch.

[0007] European Patent Application published EP 1 598 017 A1 discloses a suturing assembly according to the preamble of claim 1.

[0008] PCT Patent Application published WO 95/33408 A1 discloses a double needle ligature device including a double needle assembly with a biasing mechanism connecting needle handle or needle separation bar.

[0009] US Patent Application published US 2003/004544 A1 discloses an endoscopic instrument with two needles, two inner sheaths, a needles-coupling member and an inner sheaths-coupling member, according to the preamble of claim 1.

[0010] PCT Patent Application published WO 2007/073931 A1 discloses a medical suturing device comprising a retrieval puncturing needle and an insertion puncturing needle with an upper and lower supporter.

[0011] US Patent Application published US 2009/264905 A1 discloses a medical instrument comprising a puncture needle for surgical suture gripping and a puncture needle for surgical suture insertion, a fixing member to which those two needles are fixed and a flat plate-like member to avoid that the distance between the puncture needle for surgical suture insertion and the puncture needle for surgical suture gripping is changed.

[0012] European Patent Application published EP 2 005 892 A2 discloses a medical device comprising two piercing needle and a storage unit through which a first guide hole and a second guide hole are penetrated in the vertical direction by the piercing needle.

SUMMARY OF THE INVENTION

[0013] The present invention seeks to provide an improved suturing assembly, as described in more detail further below. The present invention is described for convenience with respect to the suturing device of PCT Patent Application WO 2009/069119, but the invention is not limited to such a suturing device, and can be implemented in other suturing devices. The present invention is directed to a spacer that provides further functionality to suturing devices.

[0014] The present invention relates to a suturing assembly in accordance with the disclosure of appended claim 1.

[0015] There is thus provided in accordance with an embodiment of the present invention a suturing assembly including a first puncture element including a sharp distal end for puncturing tissue, a second puncture element including a sharp distal end for puncturing tissue, the distal ends of the first and second puncture elements being spaced from each other by a gap, and a spacer arranged for sliding distally and proximally on at least one of the first and second puncture elements.

[0016] In accordance with an embodiment of the present invention the spacer is arranged to slide distally and proximally on both of the first and second puncture elements.

[0017] In accordance with an embodiment of the present invention the spacer is formed with a first opening through which one of the first and second puncture elements passes through, and a second opening through which the other of the first and second puncture elements passes through.

[0018] In accordance with an embodiment of the present invention the first opening has a closed outer contour.

[0019] In accordance with an embodiment of the present invention the second opening has a closed outer contour; alternatively, the outer contour of the second opening is not completely closed.

[0020] In accordance with an embodiment of the present invention the spacer includes a radially protruding flange.

[0021] In accordance with the present invention the spacer includes a distally protruding protector for protecting a distal tip of at least one of the first and second puncture elements.

[0022] In accordance with the present invention the spacer is arranged for pivoting about one of the first and second puncture elements and the spacer includes a connecting portion that snaps onto the other of the first and second puncture elements.

[0023] In accordance with an embodiment of the present invention, the suturing assembly further includes suture thread disposed along a portion of the first puncture element, wherein the suture thread is arranged to be grabbed at the distal end of the first puncture element, and a suture grabber positioned at the distal end of the second puncture element.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

Figs. 1 and 2 are simplified pictorial illustrations of a prior art suturing assembly, made according to PCT Patent Application WO 2009/069119;

Figs. 3 and 4 are simplified pictorial illustrations of a suturing assembly with a spacer, constructed and operative in accordance

with an embodiment of the present invention, respectively with the spacer at proximal and distal ends of puncture elements;

Fig. 5 is a more detailed illustration of the spacer of Fig. 4;

Fig. 6 is a simplified pictorial illustration of the spacer with a distally protruding protector, constructed and operative in accordance with an embodiment of the present invention; and

Figs. 7 and 8 are simplified pictorial illustrations of the spacer, constructed and operative in accordance with an embodiment of the present invention, respectively before and after pivoting to snap onto one of the puncture elements.

DETAILED DESCRIPTION OF EMBODIMENTS

[0025] Reference is now made to Figs. 3-5, which illustrate a suturing assembly 50, constructed and operative in accordance with a non-limiting embodiment of the present invention.

[0026] Suturing assembly 50 includes a first puncture element 52 including a sharp distal end 54 for puncturing tissue, and a second puncture element 56 including a sharp distal end 58 for puncturing tissue. The distal ends 54 and 58 of the first and second puncture elements 52 and 56 are spaced from each other by a gap 59. A spacer 60 is arranged for sliding distally and proximally on either one or both of first and second puncture elements 52 and 56. In the embodiment illustrated in Fig. 3, spacer 60 is arranged to slide distally and proximally on both of first and second puncture elements 52 and 56.

[0027] As seen best in Fig. 5, in accordance with an embodiment of the present invention, spacer 60 is formed with a first opening 62 through which one of the first and second puncture elements passes through, and a second opening 64 through which the other of the first and second puncture elements passes through. In the embodiments illustrated in Figs. 5 and 6, each of the first and second openings 62 and 64 has a closed outer contour. In the embodiment illustrated in Figs. 7 and 8, the outer contour of second opening 64 is not completely closed.

[0028] Spacer 60 is normally in the distal position (Fig. 4) prior to insertion of the first and second puncture elements 52 and 56 into tissue. The spacer 60 slides to the proximal position (Fig. 3) after insertion into the tissue. Optionally, as seen in Fig. 3, a biasing device 63, such as a coil spring, may be provided for urging spacer 60 from the proximal position to the distal position.

[0029] In accordance with an embodiment of the present invention the spacer includes a radially protruding flange 66, which may serve as a guide, handle or imaging landmark.

[0030] Reference is now made to Fig. 6. In accordance with the present invention, spacer 60 includes one or more distally protruding protectors 68 for protecting one or both of distal ends 54 and 58 of the first and second puncture elements 52 and 56.

[0031] Reference is now made to Figs. 7 and 8. In accordance with the present invention, spacer 60 is arranged for pivoting about one of the first and second puncture elements 52 or 56. Spacer 60 includes a connecting portion 70 that snaps onto the other of the first and second puncture elements.

[0032] In accordance with an embodiment of the present invention, the suturing assembly may combine features of the prior art suturing device. For example, as shown previously in Figs. 1 and 2, the suturing assembly may further include suture thread 38 disposed along a portion of the first puncture element 52, wherein the suture thread is arranged to be grabbed at the distal end of the first puncture element 52, and a suture grabber 26 positioned at the distal end of the second puncture element 54.

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- WO2009069119A [0002] [0013] [0024]
- EP1598017A1 [0007]
- WO9533408A1A1 [0008]
- US2003004544A1A [0009]
- WO2007073931A1A [0010]
- US2009264905A1 [0011]
- EP2005892A2 [0012]

Patentkrav

1. Suturindretning (50), der omfatter:

a. et første punkturelement (52), der omfatter en skarp distal
5 ende (54) til punktur af væv;

b. et andet punkturelement (56), der omfatter en skarp distal
ende (58) til punktur af væv, hvor de distale ender (54, 58)
af det første og andet punkturelement (52, 56) er adskilt fra
hinanden af et mellemrum (59); og

10 c. et afstandsstykke (60), der er indrettet til at glide
distalt og proksimalt på mindst det ene af det første og andet
punkturelement (52, 56),

hvor

afstandsstykket (60) er indrettet til at dreje omkring det ene
15 af det første og andet punkturelement (52, 56), og
afstandsstykket omfatter en koblingsdel (70) der klikker på
det andet af det første og andet punkturelement (52, 56),
hvilken suturindretning er kendetegnet ved, at

afstandsstykket (60) omfatter en distalt udragende
20 beskyttelsesdel (68) til beskyttelse af en distal ende (54,
58) af mindst det ene af det første og andet punkturelement
(52, 56).

2. Suturindretning (50) ifølge krav 1, hvor afstandsstykket
25 (60) er indrettet til at glide distalt og proksimalt på både
det første og det andet punkturelement (52, 56).

3. Suturindretning (50) ifølge krav 2, hvor afstandsstykket
(60) er formet med en første åbning (62), hvorigennem det ene
30 af det første og andet punkturelement (52, 56) passer, og en
anden åbning (64), hvorigennem det andet af det første og
andet punkturelement (52, 56) passerer.

4. Suturindretning (50) ifølge krav 3, hvor den første
35 åbning (62) har en lukket ydre kontur.

5. Suturindretning (50) ifølge krav 3, hvor den anden åbning
(64) har en lukket ydre kontur.

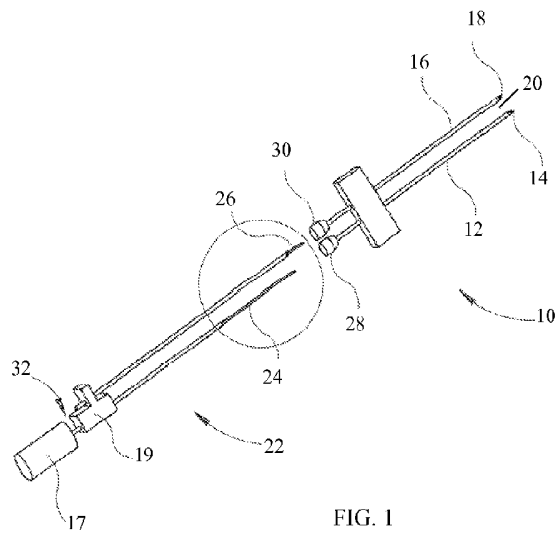
6. Suturindretning (50) ifølge krav 3, hvor en ydre kontur af den anden åbning (64) ikke er fuldstændig lukket.

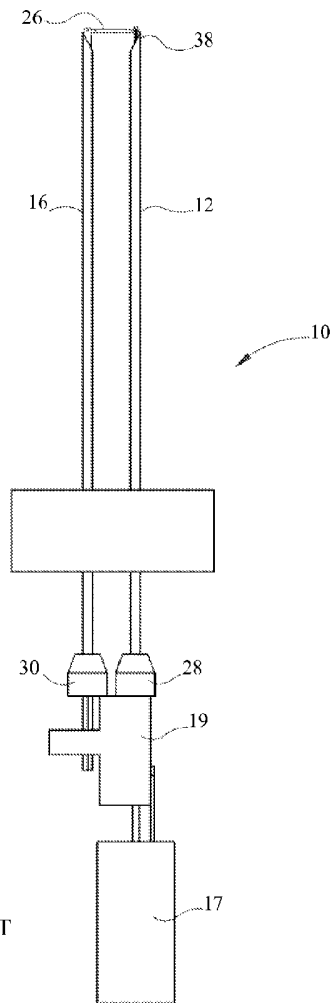
5 7. Suturindretning (50) ifølge krav 1, hvor afstandsstykket omfatter en radialt udragende krave.

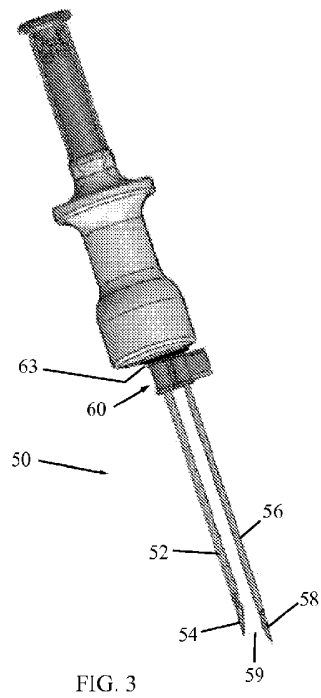
8. Suturindretning (50) ifølge krav 1, der yderligere omfatter en påvirkningsanordning (63) til at drive
10 afstandsstykket (60) fra en proksimal position til en distal position.

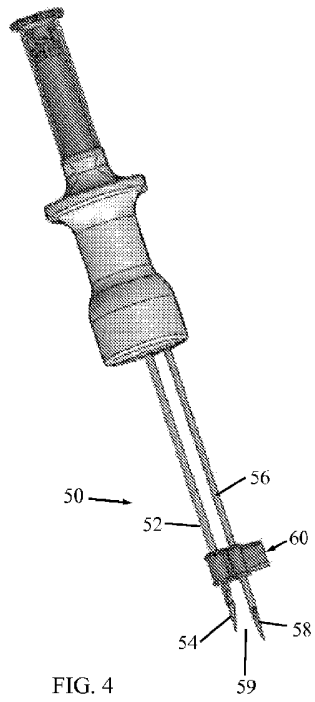
9. Suturindretning (50) ifølge krav 1, der yderligere omfatter en suturtråd (38), der er disponeret langs en del af
15 det første punkturelement (52), hvor suturtråden (38) er indrettet til at blive grebet i den distale ende af det første punkturelement (52), og en suturgriber (26), der er placeret i den distale ende af det andet punkturelement (56).

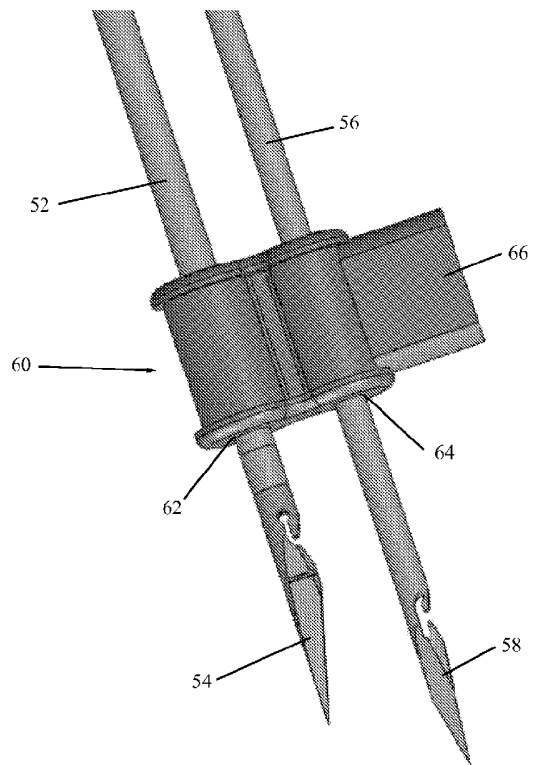
DRAWINGS

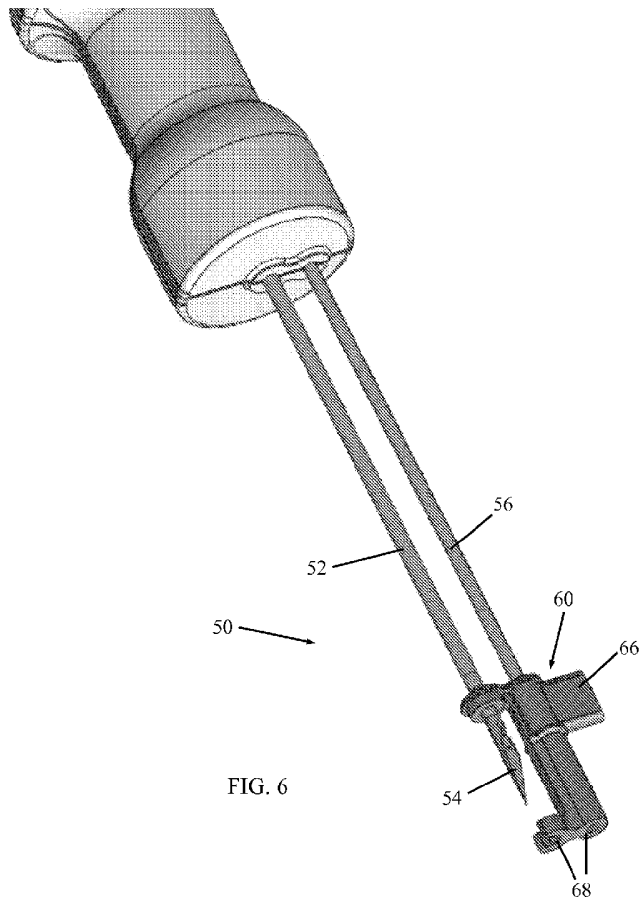












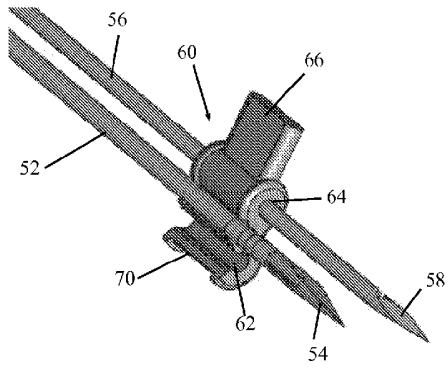


FIG. 7

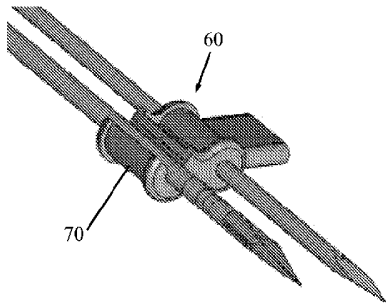


FIG. 8