UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Micro-Tech (Nanjing) Co., Ltd and Micro-Tech Endoscopy USA, Inc.,

Petitioners

v.

Boston Scientific Scimed, Inc.,

Patent Owner

U.S. Patent 7,094,245
Issue Date: August 22, 2006
Title: Device and Method for Through the Scope Endoscopic Hemostatic Clipping

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CASE: Unassigned

Petition for *Inter Partes* Review of U.S. Patent 7,094,245

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Ex. 1014 - Thomas J. Wang, et al., *Choosing the Right Through-the-Scope Clip: A Rigorous Comparison of Rotatability, Whip, Open/Close Precision, and Closure Strength (with Videos)*, 89 Gastrointestinal Endoscopy 77 (2019)

Ex. 1015 - Stefan K. Goelder, et al., *Endoscopic Hemostasis State of the Art – Nonvariceal Bleeding*, 8 World J. Gastrointestinal Endoscopy 205 (2016)

Ex. 1016 - Kenneth F. Binmoeller, et al., *Endoscopic Hemoclip Treatment for Gastrointestinal Bleeding*, 25 Endoscopy 167 (1993)

Ex. 1017 - Gottumukkala S. Raju, Comment, 123 Gastroenterology 1400 (2002)

Ex. 1018 - Complaint, *Boston Scientific Corp. v. Micro-Tech Endoscopy USA Inc.*, No. 1:18-cv-01869-CFC (D. Del. Nov. 26, 2018)

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I. INTRODUCTION

Petitioners Micro-Tech (Nanjing) Co., Ltd and Micro-Tech Endoscopy USA Inc. respectfully request *inter partes* review and seek cancellation of claims 1-15 of U.S. Patent No. 7,094,245 (the "'245 Patent") under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*.

II. 37 C.F.R. § 42.8(b): MANDATORY NOTICES

A. 37 C.F.R. § 42.8(b)(1): Real Party In Interest

Petitioners Micro-Tech (Nanjing) Co., Ltd and Micro-Tech Endoscopy USA Inc. are the real parties in interest.

B. 37 C.F.R. § 42.8(b)(2): Related Matters

The '245 Patent is the subject of the following actions brought by Patent Owner against Petitioners that may affect or be affected by a decision in this proceeding: U.S. District Court for the District of Delaware Case No. 1:18-cv-01869-CFC.

The '245 Patent has at least fourteen child applications, some of which are still pending. Several of these related applications are involved in proceedings before the Board (*see, e.g.*, IPR2017-00132, 133, and 134) as well as district court proceedings including District of Delaware civil action no. 15-980-LPS-CJB.

C. 37 C.F.R. § 42.8(b)(3) and (4): Notice Of Counsel And Service Information

Petitioners provide the following designation of counsel:

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Christopher J. Higgins 0CHPTABDocket@orrick.com Reg. No. 66,422 ORRICK, HERRINGTON & SUTCLIFFE LLP 1152 15th Street, N.W. Washington, DC 20005-1706 Telephone: (202) 339-8400 Facsimile: (202) 339-8500 Customer No. 34313	T. Vann Pearce TVPPTABDocket@orrick.com Reg. No. 58,945 ORRICK, HERRINGTON & SUTCLIFFE LLP 1152 15th Street, N.W. Washington, DC 20005-1706 Telephone: (202) 339-8400 Facsimile: (202) 339-8500 Customer No. 34313

Petitioners submit Powers of Attorney with this Petition. Please address all correspondence to lead and backup counsel. Petitioners consent to service by email at: 0CHPTABDocket@orrick.com and TVPPTABDocket@orrick.com.

III. REQUIREMENTS FOR INTER PARTES REVIEW

This Petition meets and complies with all requirements under 37 C.F.R. § 42.104 for *inter partes* review.

A. 37 C.F.R. § 42.104(a): Ground For Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioners certify that the ’245 Patent is available for *inter partes* review and Petitioners are not barred or estopped from

requesting *inter partes* review challenging the claims of the ’245 Patent on the grounds identified herein.

B. 37 C.F.R. § 42.104(b): Identification of Challenge

Pursuant to 37 C.F.R. § 42.104(b), Petitioners request that the PTAB invalidate the challenged claims of the ’245 Patent.

1. 37 C.F.R. § 42.104(b)(1) Challenged Claims

Petitioners challenge claims 1-15 of the ’245 Patent.

2. 37 C.F.R. § 42.104(b)(2): The Prior Art and Statutory Grounds.

The one-year time bar under pre-AIA 35 U.S.C. §102(b) is measured from the effective U.S. filing date of the ’245 Patent, which is no earlier than October 5, 2001. The prior art references relied upon herein are:

Patent/Publication	Priority Date	Publication Date	Prior Art	Ex. No.
U.S. Patent No. 6,808,491 (“Kortenbach I”)	May 21, 2001	Feb. 20, 2003	102(e)	1004
U.S. Patent No. 6,569,085 (“Kortenbach II”)	August 16, 2001	Nov. 21, 2002	102(e)	1006
U.S. Patent No. 5,766,184 (“Matsuno”)	Nov. 2, 1995	May 17, 1996	102(b)	1007
U.S. Patent No. 5,569,274 (“Rapacki”)	Feb. 2, 1993	Oct. 29, 1996	102(b)	1008
U.S. Patent No. 4,733,664 (“Kirsch”)	Oct. 15, 1985	Mar. 29, 1988	102(b)	1009

Both Kortenbach references and Matsuno were neither cited nor relied upon during prosecution of the ’245 patent. Kirsch and Rapacki are cited by the ’245 patent but are not cumulative because they are being used in combination with other primary references under grounds not considered during prosecution.

Below are the specific statutory grounds under 35 U.S.C. §§ 102 and 103 (pre-AIA) on which the claims are challenged:

Ground 1: Claims 1, 4-5, 7, 9, 10, 12, 13, and 15 are anticipated under 35 U.S.C. §102(e) by Kortenbach I.

Ground 2: Claims 1, 3-5, 7, 9, 10, 12, 13, and 15 are obvious under 35 U.S.C. §103(a) over Kortenbach I.

Ground 3: Claims 1, 7, 9, 12, 13, and 15 are anticipated under 35 U.S.C. §102(e) by Kortenbach II.

Ground 4: Claims 1, 7, 9, 12, 13, and 15 are obvious under 35 U.S.C. §103(a) over Kortenbach II.

Ground 5: Claims 1, 3-7, and 9-15 are anticipated under 35 U.S.C. §102(b) by Matsuno.

Ground 6: Claims 1, 3-7, and 9-15 are rendered obvious under 35 U.S.C. §103(a) by Matsuno in view of the knowledge of a POSITA and/or Kirsch.

Ground 7: Claims 1, 3-13, and 15 are rendered obvious under 35 U.S.C. §103(a) by Matsuno in view of the knowledge of a POSITA and/or Rapacki.

Ground 8: Claim 2 is rendered obvious under 35 U.S.C. §103(a) by Kortenbach I in view of Kirsch.

3. Level of Ordinary Skill in the Art

A person of ordinary skill in the field, as of the '245 patent's effective filing date, would have possessed the knowledge and skill known by an engineer or similar professional with at least a bachelor's degree in engineering, or a physician having experience with designing medical devices. This person would also have an understanding of engineering or medical device design principles. Ex. 1002, ¶¶34-37.

4. Supporting Evidence

Supporting evidence relied upon includes the declaration of Dr. Morten Jensen and other supporting evidence in the Exhibit List filed herewith.

IV. INSTITUTION SHOULD BE GRANTED

Petitioner has established a reasonable likelihood of success on the merits and all other requirements for IPR have been met. The Board should institute IPR.

Petitioner's primary references were never considered during prosecution. Thus, no ground presented here was considered by the Examiner.

While there is a parallel district court proceeding involving the '245 patent, no preliminary injunction motion has been filed, and the district court has not been presented with or invested any time in the analysis of prior art invalidity issues. *Bos. Sci. Corp. v. Micro-Tech Endoscopy USA Inc.*, No. 1:18-cv-01869-CFC/CJB

(D. Del. Nov. 26, 2018). Petitioners also timely filed their petition within the statutorily prescribed 1-year window. Declining to institute IPR here in view of the co-pending district court litigation would essentially render nugatory the 1-year filing period of § 315(b). Notably, § 315(b) originally contained only a 6-month filing window which was amended to 1-year prior to passage of the America Invents Act to "afford defendants a reasonable opportunity to identify and understand the patent claims that are relevant to the litigation" before having to file an IPR petition. 157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl). Moreover, making the status of the district court litigation a threshold consideration before institution ignores the common scenario, contemplated by Congress, of obtaining a district court stay based on institution. *Cf.* 157 Cong. Rec. S1363 (daily ed. Mar. 8, 2011) (statement of Sen. Chuck Schumer); H. Rep. No. 112-98, Part I, at 48 (2011). For these reasons, and those explained below, the instant petition should be instituted.

V. THERE EXISTS A REASONABLE LIKELIHOOD THAT THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. The '245 Patent.

The '245 patent generally relates to the use of compression clips in endoscopic procedures. Ex. 1001 at 1:7-10, Ex. 1002, ¶27. The compression clips are used to cause the hemostasis of blood vessels, typically located along the gastrointestinal tract. *Id.* The clips are applied to stop internal bleeding by

applying a sufficient constrictive force to the bleed site. Ex. 1001 at 2:17-24; Ex. 1002, ¶27. As admitted by the specification, endoscopic clip devices were well-known in the art prior to the '245 patent. Ex. 1001 at 2:25-36.

Endoscopic clips were first described for use in endoscopic procedures in 1975 by a group of Olympus scientists. Ex. 1011 at 1; Ex. 1012 at 1; Ex. 1002, ¶28. The basic underlying technology exists today. Ex. 1002, ¶¶28-29. That is, a device with a handle, sheath, control wire, clip assembly, and a detachable clip that could both open and close were well-known in the art for decades. Ex. 1011 at 1; Ex. 1012 at 1; Ex. 1016 at 1-4; Ex. 1019 at 5 figs.1, 2, 3, 4, 5 & 7, 6 figs.10 & 11; *see also* Ex. 1017 at 2-3.

The basic function of a hemostatic clip device was described in numerous publications years before the '245 patent was filed, including in 1999 in Gastrointestinal Endoscopy:

> The procedural steps of endoclip application are straightforward. A stainless steel clip, each prong 6 mm in length and 1.2 mm in width, is loaded onto a clip application device and retracted into a protective Teflon sheath (HX-3L; Olympus Corp, Tokyo, Japan). The application device is inserted through the working channel of a standard endoscope. Sliding the sheath backwards using the handle extends the clip from the sheath. Retracting the clip approximately 1 mm maximally opens the prongs. When fully open, the distance between the clip prongs measures 12

> mm. The orientation of the clip prongs can be adjusted by rotating the handle clockwise. The clip is closed by fully retracting the clip. For hemostasis, the clip is used to grasp, compress, and ligate a bleeding vessel. The hemostatic effect is immediate and should be permanent if the vessel is properly ligated.

Ex. 1012 at 1; Ex. 1002, ¶30. The claimed device in the '245 patent operates in the same manner and accomplishes the same purpose. For example, the '245 patent explains that "medical devices of the present invention include: a compression clip used to cause hemostasis of blood vessels and a mechanism for deploying the clip…a mechanism for closing the clip…a control wire connected to the clip and able to be disconnected from the clip…a trigger enclosed within the handle." Ex. 1001 at 2:47-60; Ex. 1002, ¶31.

The '245 patent expressly describes what the "goal of the invention is:" to provide a device with: 1) a high success rate, 2) easier set-up as compared to the Olympus EndoClip, and 3) easier to deploy than the Olympus EndoClip. Ex. 1001 at 2:41-46; Ex. 1002, ¶32. Yet, the characteristics of a device that allegedly lead to these improvements are not recited in the claims of the '245 patent.

B. Prosecution History of the '245 Patent

The prosecution history of the '245 patent included a restriction requirement and several prior art rejections, all of which necessitated amendment of the claims.

In a restriction requirement, the examiner required the applicants to elect "one figure and the corresponding claims." Ex. 1010 at 150. In particular, the applicants were required to restrict the claims to one species of "clip applier devices" out of the 14 embodiments in the specification and drawings and then select a subspecies of "different clip legs" and "clip engagement means." *Id.* at 150-51. In response, the applicants elected the clip applier device from "Figures 2-7" and a corresponding clip arrangement from Figure 8. *Id.* at 145. While applicants' election imposes limits on the scope of the claims, for purposes of this IPR, it does not make a difference with respect to the prior art.

Following the election, the claims were rejected as anticipated by U.S. Patent No. 5,304,183 to Gourlay and claims 1 and 2 were rejected as anticipated by U.S. Patent No. 5,340,360 to Stefanchik. Attempting to overcome the rejections, the applicants amended the claims to include the limitation of a "breakable link." *Id.* at 132; Ex. 1002, ¶33. In argument, the applicants distinguished the prior art, which the examiner found to disclose "inherently" breakable links, from that of the claims in the '245 patent, which are "adapted to be broken by a predetermined tensile force." Ex. 1010 at 132; Ex. 1002, ¶33. The applicants further explained that the Gourlay reference did not specifically disclose that its "movable arms 20 are breakable." Ex. 1010 at 103; Ex. 1002, ¶33. The fact that the prior art did not

disclose a linkage that could be broken into pieces served as the basis for allowance. Ex. 1010 at 62.

C. Proposed Claim Construction

1. Preamble (Claims 1 and 14) – "A medical device for causing the hemostasis of a blood vessel for use through an endoscope, said medical device comprising"

The preambles of claims 1 and 14 are not limitations because they merely state an intended use of the claimed "medical device," which is defined in the body of claims 1 and 14. Ex. 1002, ¶¶54-55. "As a general rule preamble language is not treated as limiting." *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1347-48 (Fed. Cir. 2012).

A preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Acceleration Bay, LLC v. Activision Blizzard Inc.*, 908 F.3d 765, 770-71 (Fed. Cir. 2018); *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808-09 (Fed. Cir. 2002) ("a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention"). For example, a preamble is not limiting when it "is reasonably susceptible to being construed to be merely duplicative of the limitations in the body of the claim (and was not clearly added to overcome a

[prior art] rejection)." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358-59 (Fed. Cir. 2010).

Here, the term "medical device" is used only to put a collective name to the components in the body of the claim. Ex. 1002, ¶56. Thus, it is not a limitation. *See, e.g.*, *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1434 (Fed. Cir. 2000) ("control apparatus" in the preamble was not limiting because it "merely gives a descriptive name to the set of limitations in the body of the claim that completely set forth the invention" – claims 1 and 7 recited different elements but had the same preamble). The body of claims 1 and 14 define a structurally complete apparatus, and the term "medical device" was not added during prosecution to overcome a prior art rejection. Accordingly, the term "medical device" does not limit either claim 1 or claim 14. *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1327-29 (Fed. Cir. 2019) (noting that, in the context of a preamble, when a term is a name for "structure of which the body-recited module is a part," it does not serve to limit the claim).

The remainder of the preamble is also not a limitation because it merely states an intended use for the claimed apparatus. Here, the language of the preamble contains two separate statements of intended use. First, the preamble states that the claimed apparatus is "***for causing*** the hemostasis of a blood vessel." In other words, if the claimed apparatus, as defined in the body of the claims, is

used in a particular way, then it can cause hemostasis of a blood vessel. Yet, this *use* cannot serve as a limitation to either of apparatus claim 1 or 14. *Acceleration Bay, LLC*, 908 F.3d at 770-71.

Second, the remainder of the preamble recites that the claimed apparatus is "***for use*** through an endoscope." Thus, the apparatus defined in the body of the claims *may or may not* be used through an endoscope, but because it is an apparatus claim, how the claimed device is ultimately used cannot serve as a limitation of the claim. *Arctic Cat Inc.*, 919 F.3d at 1327-29. This is no clearer than, when as here, the claim specifically recites the words "for use," thus is signaling to those skilled in the art that this is a non-limiting intended use of the claimed apparatus. Ex. 1002, ¶56.

2. "a breakable link….adapted to be broken"

A break is a specific type of mechanical failure in which one component fractures. Ex. 1002, ¶57. Here, the '245 patent claims a component that is "adapted to be broken" based upon the application of a "tensile force." Accordingly, a "breakable link…adapted to be broken" means "a component of the device that is designed to mechanically fail by fracturing at a predetermined tensile load." Ex. 1002, ¶57.

The claims further confirm that a "breakable link" is a type of "frangible link," which is a link designed to fail mechanically when subjected to a certain

tensile strength during operation. *See id.*, ¶58. For example, dependent claim 12 recites that a frangible link is either of a "wire reversibly formed into a j-hook and the breakable link." It then further specifies the type of mechanical failure each requires. The j-hook must deform (i.e., straighten) and the breakable link must break (i.e., fracture). A breakable link may not be read broadly so as to encompass any frangible link because the claims specifically disclaim that scope. *Wright Med. Tech., Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1445 (Fed. Cir. 1997) ("we must not interpret an independent claim in a way that is inconsistent with a claim which depends from it").

Moreover, a POSITA would understand that the common meaning of a component "adapted to be broken" means that the component is designed to fracture at a specific tensile load. Ex. 1002, ¶59. As Dr. Jensen explains, a fracture does not require a component to separate into two or more pieces, but it does require that the component undergo a brittle or ductile fracture in which a complete separation of the material occurs. *Id.* Thus, while a fracture does include the scenario when a component breaks into two or more pieces, it also encompasses the scenario in which a circle or loop is "broken" or "fractured" such that it is no longer a loop or circle. *Id.*, ¶60.

The specification further aligns with the requirements of the claim language and common meaning regarding a breakable link. When the applicants intended

for something to "break," they stated as much, and when the applicants intended for something to "deform," that was recited. *See id.*, ¶¶61-62. For example, with respect to Figure 10, "the frangible link 1005 is a taper in control wire 1006, enabling the link to be broken at a specific position…with a predetermined tensile load." Ex. 1001 at 9:24-27. Similarly, the embodiment of Figure 18 uses an elastic band as the breakable link and pulling the control wire "has the effect of breaking the second elastic band 1804." *Id.* at 13:3-5. Also, in Figure 21 a "frangible link is implemented in this embodiment by a breakable link 2105." *Id.* at 13:62-64. Thus, "[a]t a predetermined tensile load, the breakable link 2105 breaks." *Id.* at 14:21-22.

Contrary to the embodiments described as "breaking," the specification explains that a frangible link in the form of a j-hook may be designed to "deform" and release the clip. The specification explains that "where the j-hook is formed, must deform when a predetermined tensile load is applied. The device's ability to release the clip is dependent on this property." *Id.* at 14:40-47. Accordingly, the patentee distinguished between a link that deforms compared to one that breaks. Indeed, the patent describes the "breakable" embodiments above as "alternatives" to the straightening j-hook embodiment of Figures 1-7. *Id.* at 8:62-64, 13:55-56.

The Board previously observed that the '245 patent's specification "discloses *several distinct embodiments* that may be used to detach a clip from a

delivery device." IPR2017-00132, Paper No. 71, at 6 (discussing the child '048 patent) (emphasis added). Patent Owner claimed various of these distinct embodiments in the different applications and patents in this family; that is, the '245 patent's claims do not encompass *all* of the specification's distinct embodiments.

The prosecution history of the '245 patent, as well as its child applications, confirm that breakable means to fracture into pieces. *See* Ex. 1002, ¶63. During prosecution, the applicants amended the claims to include the limitation of a "breakable link." Ex. 1010 at 132. The applicants attempted to distinguish the prior art Gourlay reference, which the examiner found to disclose "inherently" breakable links, from that of the claims in the '245 patent, which are "adapted to be broken by a predetermined tensile force." *Id.* The applicants argued that the Gourlay reference did not specifically disclose that its "movable arms 20 are breakable." *Id.* at 103. The fact that the prior art did not expressly recite that a physical component was broken into pieces gained allowance of the claims. *Id.* at 62. The applicant's arguments also confirm that "adapted to be broken" means something "designed" to be broken, and not merely any physical component that could, in some circumstance, be broken. This aligns with the usual meaning of "adapted to" in patent claims as "made to, designed to, or configured to." *In re Man Mach. Interface Techs. LLC*, 822 F.3d 1282, 1286 (Fed. Cir. 2016).

Similarly, during prosecution of application no. 15/091,147 the applicants argued that "one skilled in the art would understand that a mechanical failure constitutes a deforming, breaking, etc. of at least one of several mechanically coupled components." Ex. 1020 at 166. Thus, the applicants made clear, that in the context of the '245 patent specification, a physical component that is coupled together must mechanically fail. *Id.* And in the case of a breakable link, that mechanical failure is the fracturing of a component.

When read in light of the plain language of the claims, the specification, and the prosecution history, a "breakable link…adapted to be broken" means "a component of the device that is designed to mechanically fail by fracturing at a predetermined tensile load." Ex. 1002, ¶64.

D. Ground 1: Kortenbach I Anticipates Claims 1, 4-5, 7, 9, 10, 12, 13, and 15

1. Kortenbach I

U.S. Patent No. 6,808,491 ("Kortenbach I") was filed on May 20, 2002 and claims priority to provisional patent application no. 60/292,419, which was filed on May 21, 2001 and is substantively identical to the application filed on May 20, 2002.[1] Ex. 1002, ¶40. Accordingly, Kortenbach I is prior art as of May 21, 2001

[1] Kortenbach I also claims priority to a provisional patent application 09/730,911 filed on December 6, 2000. Whether and to what extent Kortenbach I is entitled to

and is prior art to the ’245 patent under 102(e). Kortenbach I is not cited by the ’245 patent and was not discussed during prosecution.

Kortenbach I is directed to an endoscopic hemoclip device in which the hemoclip is coupled to the device via a breakable link. Ex. 1004 at 7:56-8:51, Ex. 1002, ¶41. As is typical with endoscopic hemoclip devices around 2002, the endoscope hemoclip device of Kortenbach I includes the basic structure shown in Fig. 1 below.

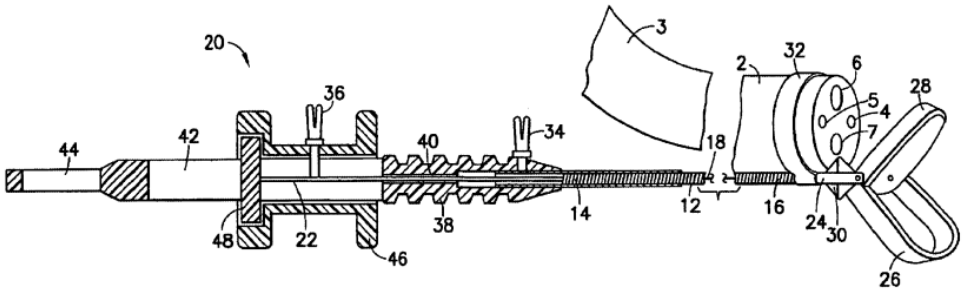

FIG. 1

The actuation device 20 includes a coil sheath 12 and a pull wire 18 within the coil sheath. It further includes other “conventional components” such as a shaft 38 and a thumb ring, or handle, 44. Ex. 1002, ¶42. To operate the jaws and control the clip, the device includes a spool, or actuator, 46.

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this priority date need not be considered as priority to the May 2001 provision predates the ’245 patent.

Although Fig. 1 describes and depicts the common and conventional components of the endoscopic hemoclip device in Kortenbach I, Figs. 15-20 disclose and describe an embodiment that, while using the same conventional components shown above from the sheath back to the proximal end of the device at the handle, utilizes a breakable link to leave a hemoclip within a patient's body. Ex. 1002, ¶43.

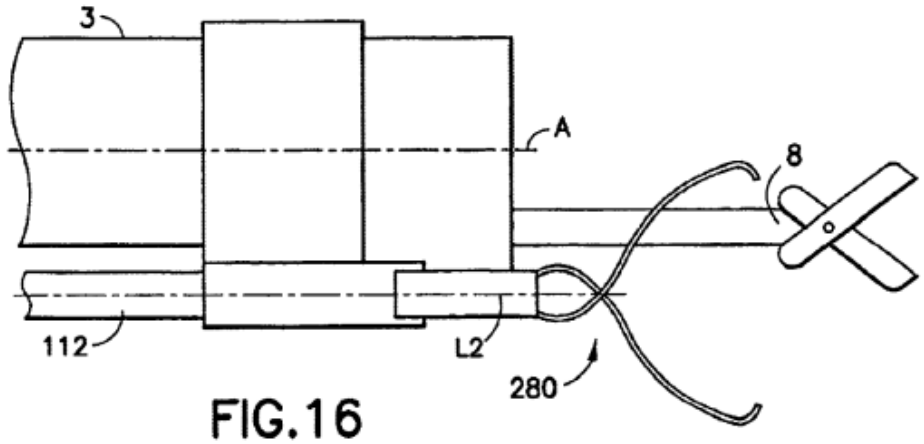


FIG.16

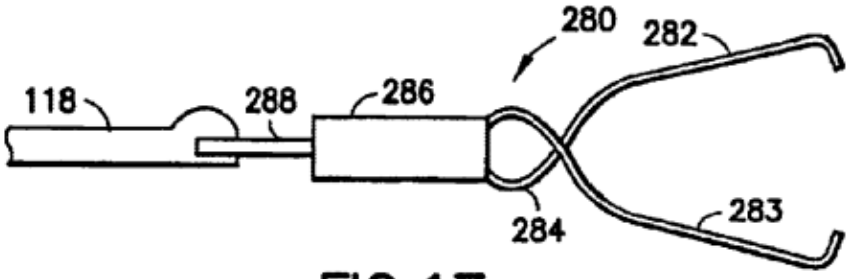


FIG.17

As shown above in Figs. 16 and 17, the hemoclip assembly attaches to control wire 118, which extends through coil sheath 112. The clip 280 includes a bridge portion 284 and two clip legs 282 and 283. Ex. 1002, ¶44. The control wire

118 is coupled to the clip 280 via a breakable link 288 inside of tube 286. *Id.* During operation, when the control wire 118 is pulled in the proximal direction, the clip legs are caused to be closed by the tube 286, and when a sufficient amount of force is applied to control wire 118, the frangible link is broken so that the hemoclip separates from the endoscope device and remains on the tissue in the patient. *Id.*

a. The Kortenbach Provisional Provides Written Description Support for at Least One Claim

The chart below demonstrates that the Kortenbach I provisional patent provides written description support for claim 1, and therefore, Kortenbach I is entitled to the filing date of its provisional application. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015); *See Cisco Sys., Inc. v. Capella Photonics, Inc.*, IPR2016-01276, 2016 WL 783545, at *9-11 (PTAB Feb. 17, 2016). Here, Petitioners show that the provisional filing discloses "(1) the subject matter Petitioner relies upon in [Kortenbach I] to show the unpatentability of the challenged claims [] and (2) the invention of [Kortenbach I]." *Cisco Sys., Inc.*, IPR2016-01276, 2016 WL 783545, at *9-11. The provisional application discloses, nearly verbatim, the subject matter relied up on by Petitioners in Kortenbach I at page 10, line 21 through page 11, line 17 and page 21, line 17 through page 22, line 24. Moreover, the table below demonstrates that the provisional filing provides written description support for at least one claim in

Kortenbach I. Ex. 1002, ¶45. Accordingly, Kortenbach I is entitled to a priority date of at least May 21, 2001. *Id.*, ¶46.

Kortenbach I Claim 1	**Written Description Support in Provisional**
1. A surgical system for performing surgery on tissue, comprising: a) an endoscope having a lumen and a distal end;	Ex. 1005 at Fig. 1, pages 4:4-20, 10:21-11:17.
b) a surgical tool coupled to said distal end of said endoscope in a longitudinally fixed manner, said surgical tool including, i) a first end effector, and ii) actuation means for actuating said first end effector; and	Fig. 1, pages 4:22-5:16, 12:10-17, 13:1-14:2, 18:1-19:17, 19:19-21:3.
c) an instrument extendable through said lumen of said endoscope, wherein said instrument includes a second end effector axially extendable through and beyond said first end effector and adapted to axially pull the tissue between said first end effector for manipulation of the tissue by said first end effector.	Figs. 1, 10-12, 4:22-5:16, 13:1-14:2, 18:1-19:17, 19:19-21:3.

2. Claim 1

a. Claim 1 [preamble] – "A medical device for causing the hemostasis of a blood vessel for use through an endoscope, said medical device comprising"

The preamble of claim 1 is not a limitation. *See supra* Section V.C.1. To the extent the preamble is found to be a limitation, it is nevertheless disclosed by Kortenbach I, which teaches a medical device that causes hemostasis of a blood vessel when used with an endoscope. *See, e.g.*, Ex. 1004 at Abstract, 1:14-57, 2:7-23, 7:55-8:23, Figs.1, 7-9, & 15-20; Ex. 1002, ¶65. The endoscopic hemoclip device in Kortenbach I may be used "within a suction and/or irrigation lumen, or one working channel of a multichannel endoscope." Ex. 1004 at 9:15-20; Ex. 1002, ¶66. Accordingly, Kortenbach I discloses a medical device that can be used through an endoscope and cause the hemostasis of a blood vessel as recited in the preamble of claim 1.

b. Claim 1[a] – "a clip, the clip having at least two clip legs"

Kortenbach I discloses a clip (280) with at least two clip legs (282 and 283). Ex. 1004 at 8:11-23, Figs. 8F, 17; Ex. 1002, ¶67. The clip legs in Kortenbach I are designed to be pulled together and compress tissue between them when closed, as shown below in Fig. 17 and annotated Fig. 17, which shows the clip legs when closed in a parallel horizontal configuration. Ex. 1004 at 8:11-23; Ex. 1002, ¶¶68-69.

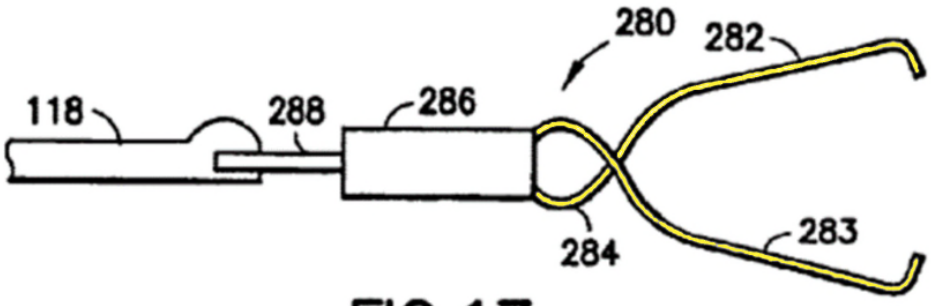


FIG.17

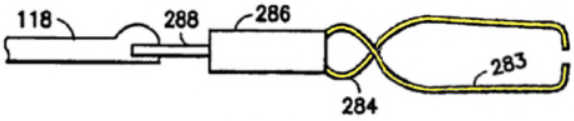


FIG.17

c. Claim 1[b] – "a breakable link adapted to couple a control wire to the clip and adapted to be broken by a first predetermined tensile force applied by the control wire"

Kortenbach I discloses a control wire (pink) coupled to the clip (yellow) via a breakable link (blue) (288). Ex. 1004 at 7:55-8:23; Ex. 1002, ¶70.

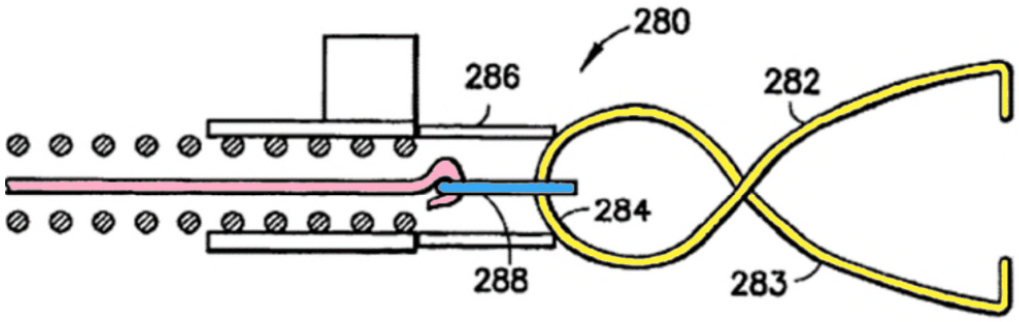


FIG.20

Kortenbach I describes the operation of the device such that when the control wire is pulled, the frangible link is broken and the clip is released.

> The hemoclip is then closed about the tissue by pulling the pull wire 118 relative to the coil 112 such that proximal portions of the jaws 282, 283 are pulled into the tubes 285, 286 and effect closure of the jaws about the tissue. The grasper 8 is operated to release the tissue, and ***the pull wire 118 of the hemoclip assembly 280 is then pulled further to break the frangible link 288 such that the hemoclip separates from the endoscope 3 and remains on the tissue***.

Ex. 1004 at 7:55-8:23. Thus, in Kortenbach I, the breakable link (288) is a physical component that links the control wire to the clip and, as opposed to simply being designed to deform under a tensile load, is designed to "break" and separate the control wire from the clip. Ex. 1002, ¶¶71-75. Under the proper claim construction in which the breakable link is a component of the device that is designed to mechanically fail by fracturing, Kortenbach I discloses this claim element.

d. Claim 1[c] – "the control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs when the control wire is coupled to the clip"

Kortenbach I discloses that the control wire reversibly opens the two clip legs and closes the two legs. Ex. 1002, ¶¶76-78; Ex. 1004 at 7:55-8:23. As shown below in multiple Figures, when the control wire (or rod) is pulled in the proximal direction, the clip legs are caused to open and close. *Id.* First, as shown in Fig. 15,

when the control wire is extended distally, the clip legs are closed. *Id.* Then, as shown in Fig. 16, when the control wire is pulled proximally, the clip legs are caused to open. *Id.* As the control wire is pulled more proximally, the clip and clip legs contact the sides of the tube, and the clip legs begin to close towards each other. *Id.* Should the control wire (or rod) be released or pushed distally, the clip legs will return to the open state, or all the way to the initial closed state depicted in Fig. 15. *Id.* This operation may continue until the clip is pulled all the way into the tube, which locks it into place so that the breakable link can be broken to separate the clip from the control wire. *Id.*; Ex. 1004 at 7:55-8:23.

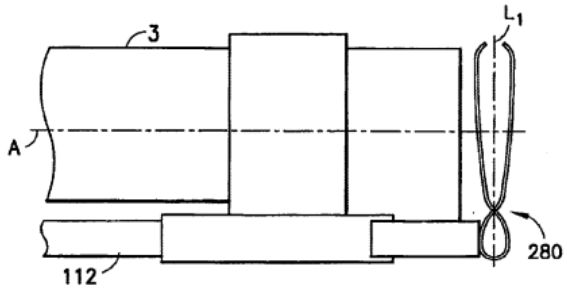


FIG.15

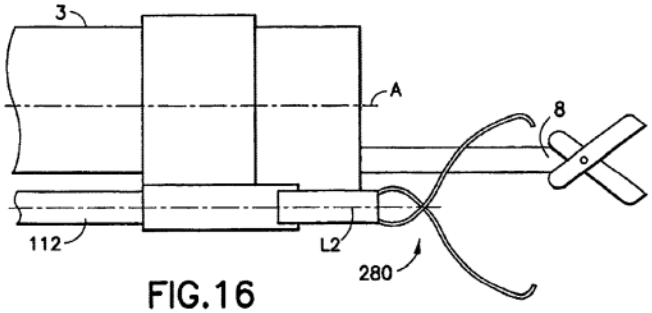


FIG.16

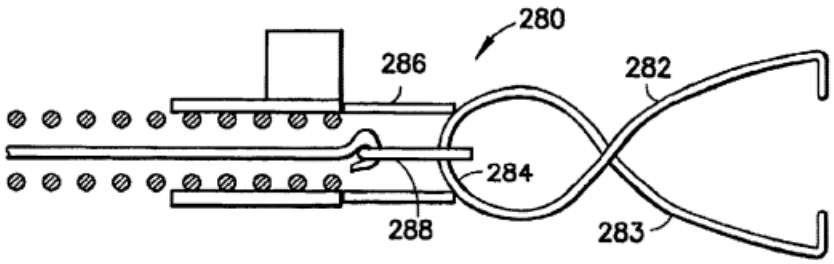


FIG.20

Accordingly, Kortenbach I discloses a clip assembly that can reversibly move from a closed, to an open, and back to a closed position. *See, e.g.*, Ex. 1004

at 2:57-61; Ex. 1002, ¶79. The claim language does not require the capability to open and close the clip arms an unlimited number of times, nor does the claim specify the degree of opening and closing that the clips legs are required to undergo. Nevertheless, a POSITA would understand that the clip can be opened and closed as many times as desired and can move from fully open to fully closed positions as well. Ex. 1002, ¶79. Accordingly, Kortenbach I discloses this limitation.

e. Claim 1[d] – "an axially rigid sheath enclosing the control wire, the sheath able to communicate a first force opposing a second force of the control wire"

Kortenbach I discloses an axially rigid sheath enclosing the control wire. The control wire 18/118 is enclosed by the coil sheath 12/112. Ex. 1002, ¶¶80-81. The coil (i.e. sheath) and the pull wire move in opposite directions to one another (i.e., communicating opposing forces to each other) in response to a force from the actuating device. *See, e.g.*, Ex. 1004 at 6:1-9, 13-15 (showing that when pull wire moves distally the coil moves proximally and vice versa); Ex. 1002, ¶¶80-81.

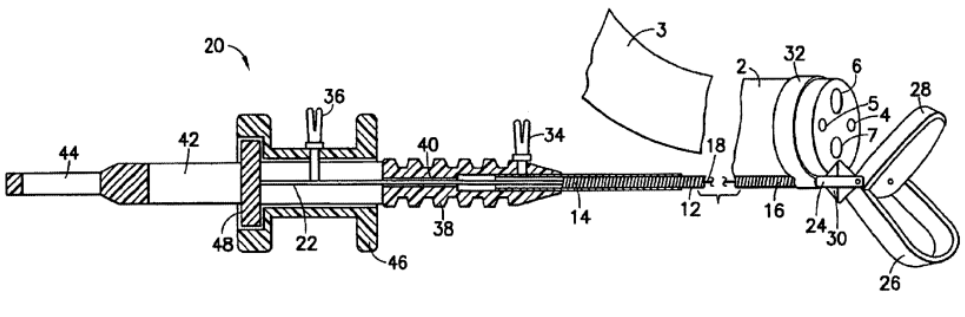


FIG. 1

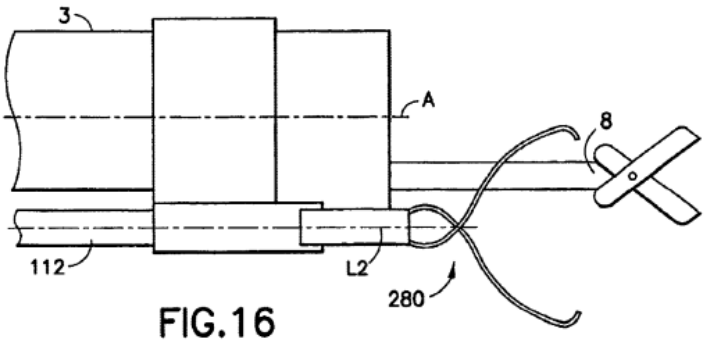


FIG.16

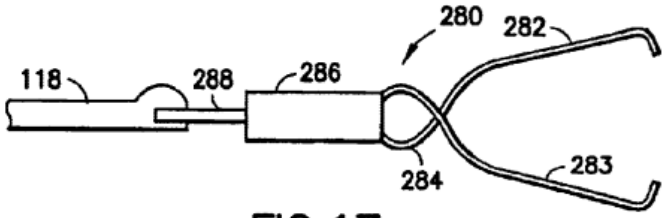


FIG.17

f. Claim 1[e] – "a handle coupled to the axially rigid sheath"

Kortenbach I discloses a handle (orange) (including 44, 42, 40, 38) coupled to the sheath (purple) (12). Ex. 1002, ¶82. Kortenbach I refers back to the first embodiment as disclosing the same handle and actuator structure for all later embodiments. Ex. 1004 at 5:25-29, 5:66-6:1; 8:5-9; Ex. 1002, ¶82.

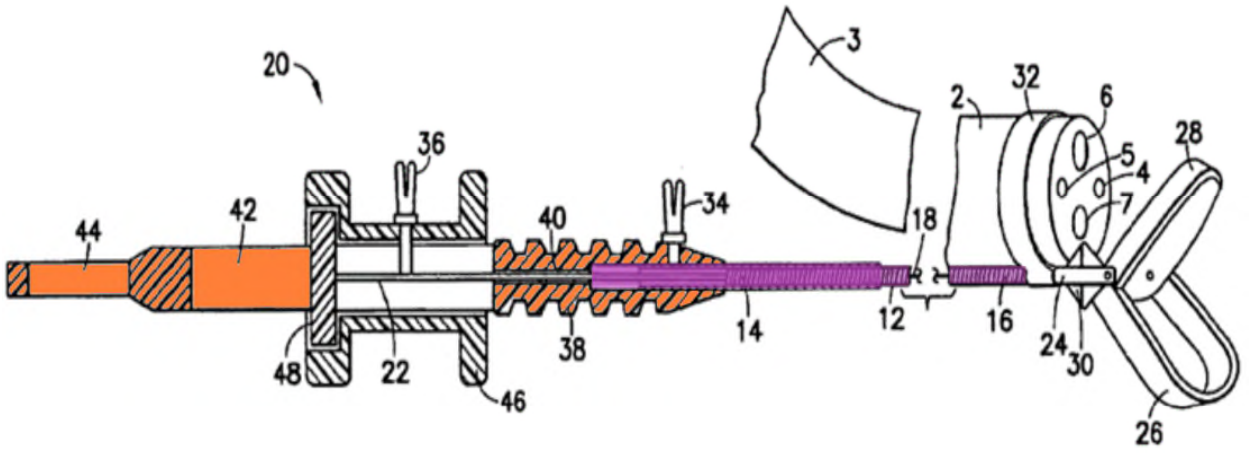


FIG. 1

g. Claim 1[f] – "an actuator coupled to the control wire, the control wire engageable by the actuator to open the at least two clip legs, to close the at least two clip legs, and to uncouple the control wire from the clip"

Kortenbach I discloses an actuator (green) coupled to the control wire (pink) (18, 22 (proximal end of control wire)). The control wire is engageable by the actuator and opens the two legs and closes the two clip legs and uncouples the wire from the clip. Ex. 1004 at 6:1-33, 8:5-9, 16-23; Ex. 1002, ¶83.

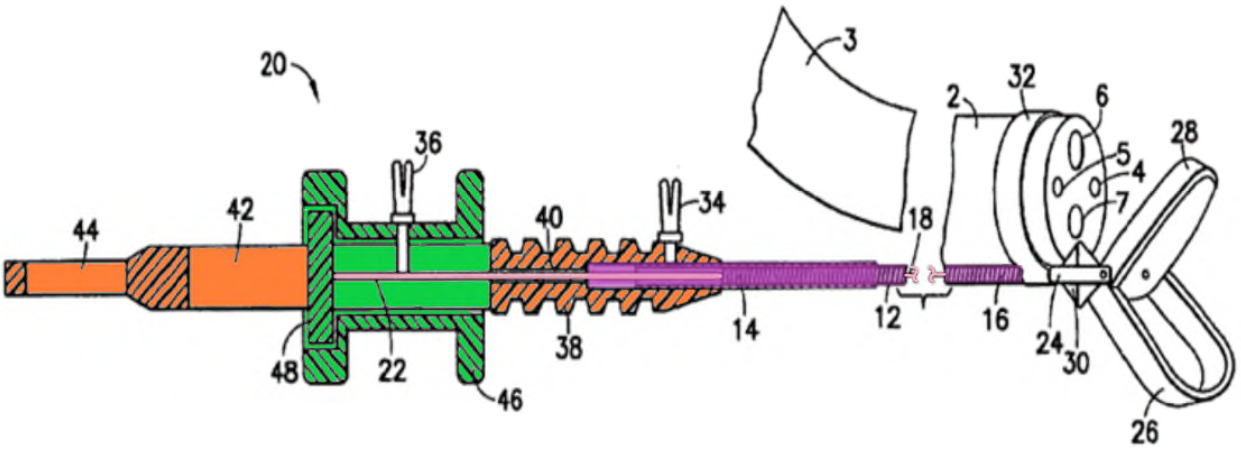


FIG.1

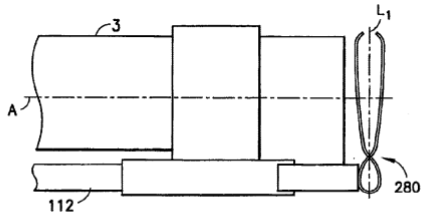


FIG.15

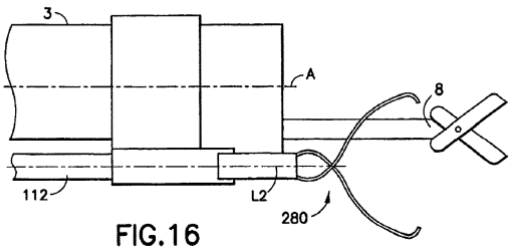


FIG.16

h. Claim 1[g] – "wherein when the breakable link is broken, the control wire uncouples from the clip"

As noted above for claim element 1[b], Kortenbach I discloses the use of a breakable link, which breaks to separate the clip from the control wire.

> The grasper 8 is operated to release the tissue, and the pull wire 118 of the hemoclip assembly 280 is then pulled ***further to break the frangible link 288 such that the hemoclip separates from the endoscope 3*** and remains on the tissue.

Ex. 1004 at 7:55-8:23; Ex. 1002, ¶84. Kortenbach I anticipates claim 1.

3. <u>Claim 4 – "further comprising a lock sleeve, wherein the control wire is able to be pulled in a proximal direction to pull the clip through the lock sleeve, thereby closing the clip legs"</u>

Kortenbach I discloses that the tubes (285/286) act as a lock sleeve so that when the wire pulls the clip assembly into the tubes, the legs of the clip assembly close. Ex. 1004 at 7:55-8:23; Ex. 1002, ¶85.

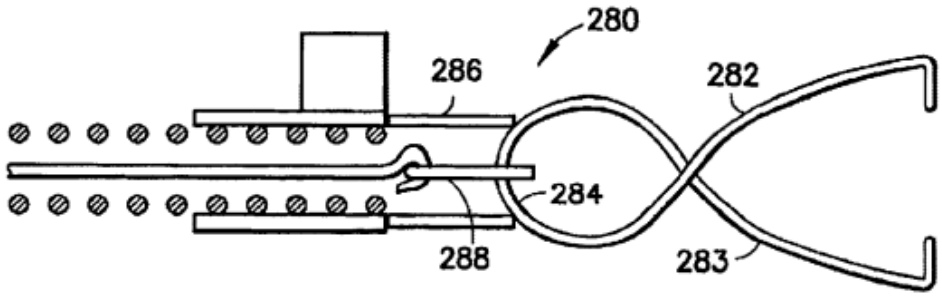


FIG.20

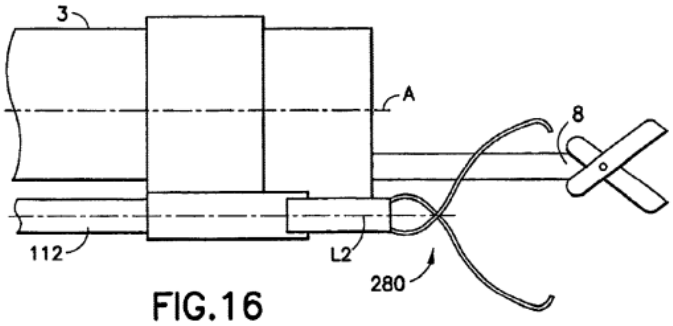


FIG.16

4. Claim 5 – "The medical device of claim 4, wherein the control wire is able to be pushed in a distal direction to push the clip out of the lock sleeve, thereby opening the clip legs."

Kortenbach I discloses that the wire is able to both open and close the clip legs via the tubes. *See* Figs. 1 and 16-20; Ex. 1002, ¶86. Specifically, exerting proximal force on (i.e. pulling) the pulling wire such that the proximal ends of the jaws (i.e. the arms) are pulled into the closing tubes (i.e. lock sleeves) causes the jaws to close because of compressive forces of the walls of the closing tubes being exerted on the proximal portions of the jaws. Ex. 1002, ¶87. It follows that pushing the pulling wire distally, causing the jaws to be pushed out of the closing tube, would relax/remove the compressive forces on the proximal ends of the jaws that were exerted by the walls of the closing tube, thereby causing the jaws to open. *Id.*

5. Claim 7 – "further comprising a lock arrangement for locking the at least two clip legs in a closed position."

Kortenbach I discloses a lock arrangement, including at least tubes 285 and 286, which effect closure of the clip arms and hold them closed after being released. Ex. 1004 at 8:11-23; Ex. 1002, ¶88.

6. Claim 9 – "wherein the axially rigid sheath is torsionally rigid, the sheath transmitting a rotational force from the handle to the clip at a ratio of approximately 1 to 1"

Kortenbach I teaches that the sheath is torsionally rigid and that the clip is "rotatably coupled" to the pull wire. Ex. 1004 at 4:16-20; Ex. 1002, ¶89.

7. Claim 10 – "The medical device of claim 1, further comprising: a lock sleeve, the lock sleeve radially surrounding the clip legs; wherein a distal compressive force applied to the lock sleeve moves the lock sleeve relative to the at least two clip legs, causing the at least two clip legs to close."

Kortenbach I discloses that the tubes (285/286) act as a lock sleeve so that when the wire pulls the clip assembly into the tubes, the legs of the clip assembly close. Ex. 1004 at 7:55-8:23; Ex. 1002, ¶90. Thus, the clip legs and lock sleeve move relative to one another when a distal compressive force is applied, which causes the clip legs to close. *Id.*

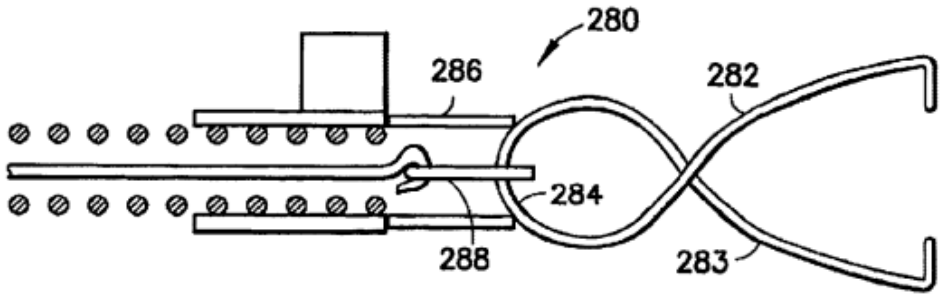


FIG.20

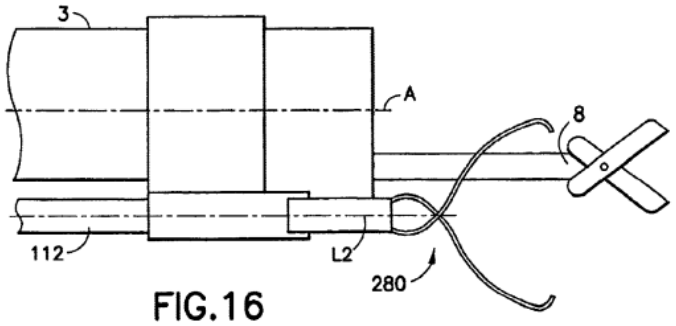


FIG.16

8. Claim 12 - "The medical device of claim 1, wherein a distal termination of the control wire comprises: a frangible link, wherein the frangible link is at least one of a wire reversibly deformed into a j-hook and the breakable link, wherein the j-hook is able to be straightened by the first predetermined tensile force; and wherein the breakable link is able to be broken by the first predetermined tensile force."

To the extent claim 12 does not impermissibly broaden independent claim 1, Kortenbach I discloses at least the breakable link as described above for claim elements 1[b] and 1[g].[2] Ex. 1002, ¶91.

9. Claim 13 – "wherein the device is disposable"

The hemoclip device in Kortenbach I is disposable, such that it may be disposed of after use, or is otherwise not reusable. Ex. 1001 at 3:19-21; Ex. 1002, ¶92.

Claim 13 refers to the "medical device of claim 1" as being disposable. The "medical device of claim 1" is every element of claim 1, which includes the clip, the breakable link, and multiple other components. The clip in Kortenbach I is left in a patient's body when it is deployed. Moreover, the "breakable link" in

[2] If claim 12 is interpreted as taking the breakable link element of claim 1 and substituting it with a frangible link, that, according to claim 12 can be either a j-hook or the breakable link from claim 1, then claim 12 impermissibly broadens claim 1. *Zircon Corp. v. Stanley Black & Decker, Inc.*, 452 F. App'x 966, 976 n.8 (Fed. Cir. 2011) ("It seems that [plaintiff] believes that a dependent claim can provide a new limitation that acts as a substitute for a limitation contained in the independent claim. The law does not support that position.").

Kortenbach I is "broken." Accordingly, the "medical device of claim 1" as disclosed by Kortenbach I is not reusable because at least a portion of its device (as defined by '245 patent claim 1 to include at least the clip and the tube) has been permanently detached and another component has been broken. Thus, it is not reusable. Ex. 1002, ¶93.

To the extent this limitation is not expressly recited in Kortenbach I, a POSITA would find it inherent that any endoscopic device may be disposed of after use on a patient. Ex. 1002, ¶94.

10. Claim 15

Claim 15 is a method claim that corresponds to the exact same structural components recited in the body of independent claim 1. *See* Ex. 1002, ¶¶95-96. Method step (i) is no more than "providing a medical device comprising" five elements of claim 1. *Id.*, ¶97. Accordingly, these elements are met for the same reasons explained above in Sections V.D.2.a-h. *Id.*

Method step (ii) is no more than using the hemoclip device according to its well-known purpose. Nonetheless, Kortenbach I teaches that its hemoclip device is "delivered to the surgical site," which is the claimed deployment location. *Id.*, ¶98.

Method step (iii) corresponds to the same functional limitations from independent claim 1 regarding the actuator and the breakable link. *Id.*, ¶99. These limitations are disclosed as described above for claim elements 1[b], 1[f], and 1[g].

Accordingly, Kortenbach I discloses claim 15. *Id.*, ¶100.

E. Ground 2: Kortenbach I Renders Claims 1, 3-5, 7, 9, 10, 12, 13, and 15 Obvious

1. Claims 1 and 15

To the extent Patent Owner argues that Kortenbach I does not expressly disclose claim limitations 1[c] and 15[i], which require a "control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs when the control wire is coupled to the clip," a POSITA would find this limitation obvious over Kortenbach I. *In re Black*, 778 F. App'x 911, 917-19 (Fed. Cir. 2019); Ex. 1002, ¶101.

First, the claim element requires that the control wire open and close the clip legs "when the control wire is coupled to the clip." Accordingly, there is no requirement that once the clip legs are locked into position and the control wire is uncoupled from the clip, that it still be possible to open and close the clip legs. Ex. 1002, ¶102.

Second, Kortenbach I repeatedly discusses moving the clip between closed to open to closed positions. A POSITA would understand that Kortenbach I teaches, and at a minimum strongly suggests, the ability to reversibly operate the

clip arms via the control wire. Ex. 1002, ¶103. Indeed, Kortenbach I expressly notes that "relative movement of the coil and pull wire causes opening and closing of the jaws." Ex. 1004 at 2:15-18; Ex. 1002, ¶103. A POSITA would understand this to mean that the clip may be opened and closed based on the movement of the control wire by the operator. Ex. 1002, ¶103. Kortenbach I further suggests this result when it notes that only when the control wire is pulled "further to break the frangible link" is the clip fixed in position and no longer able to be manipulated. Ex. 1004 at 8:11-23. The mere possibility that a minor difference in the opening and closing of the clip arms between the '245 patent and Kortenbach I may exist is not enough to defeat obviousness. *Dann v. Johnston*, 425 U.S. 219, 229-30 (1977) ("[T]he mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness. The gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art.").

Accordingly, claims 1 and 15 are obvious over Kortenbach I. Ex. 1002, ¶104.

2. Claim 3 – "the control wire is able to be coupled to the clip by a j-hook; the j-hook is able to be straightened by the first predetermined tensile force; and when the j-hook is straightened, the control wire uncouples from the clip"

To the extent dependent claim 3 does not impermissibly broaden independent claim 1,[3] Kortenbach I discloses a control wire coupled to the clip via a j-hook, as shown below in Fig. 20. Ex. 1002, ¶105.

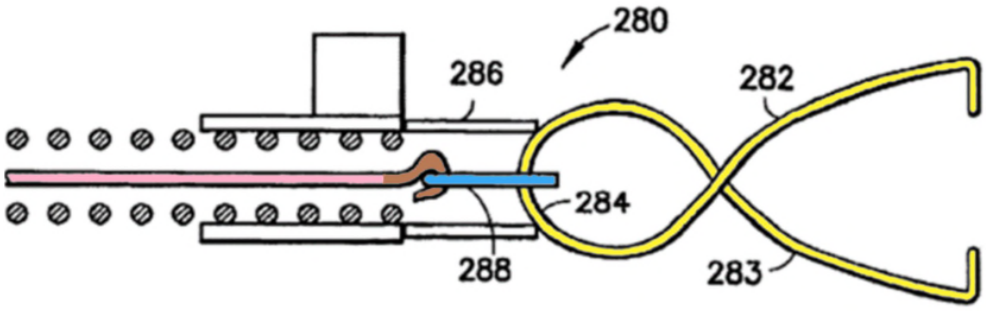


FIG.20

[3] As the examiner noted during prosecution, "Regarding claim 3, the applicant has not positively claimed a j-hook." Ex. 1010 at 110 (Final rejection). If Claim 3 is read to impose any limitation at all, then it must be read to require both a j-hook and a breakable link that are separate components. Otherwise, claim 3 serves to eliminate the "breakable link" limitation in independent claim 1, which requires the "breakable link" to "couple a control wire to the clip." If claim 3 is read to permit a j-hook to be an alternative to a breakable link to couple the control wire to the clip, then claim 3 impermissibly broadens independent claim 1. *Zircon Corp.*, 452 F. App'x at 976 n.8.

Kortenbach I does not expressly disclose that the j-hook straightens when applied with a tensile force. However, a POSITA would find it obvious to implement a metal j-hook that deforms under a predetermined tensile strength as this was well-known in the art at the time of the '245 patent. *Id.*, ¶106. And once straightened, the hook would disengage the control wire from the clip. *Id.* Accordingly, claim 3 is obvious over Kortenbach I.

The remainder of the claims (4, 5, 7, 9, 10, 12, and 13) are obvious for at least the same reasons discussed above in Section D in that Kortenbach I expressly discloses each of them, and they are dependent upon claim 1 which Kortenbach I at least renders obvious.

F. Ground 3: Kortenbach II Anticipates Claims 1, 7, 9, 12, 13, and 15

1. Kortenbach II

U.S. Patent No. 6,569,085 ("Kortenbach II") was filed on August 16, 2001. Ex. 1002, ¶47. Accordingly, Kortenbach II is prior art to the '245 patent under at least 102(e). Kortenbach II is not cited by the '245 patent and was not discussed during prosecution. *Id.*

Kortenbach II is directed to a device for minimally invasive endoscopic surgery procedures. *Id.*, ¶48. The device in Kortenbach II includes a clip attached to the control wire of an endoscope via a frangible link. Ex. 1006 at 4:43-5:31.

Figure 1 of Kortenbach II shows a typical endoscope device for applying a hemostatic clip. Ex. 1002, ¶48.

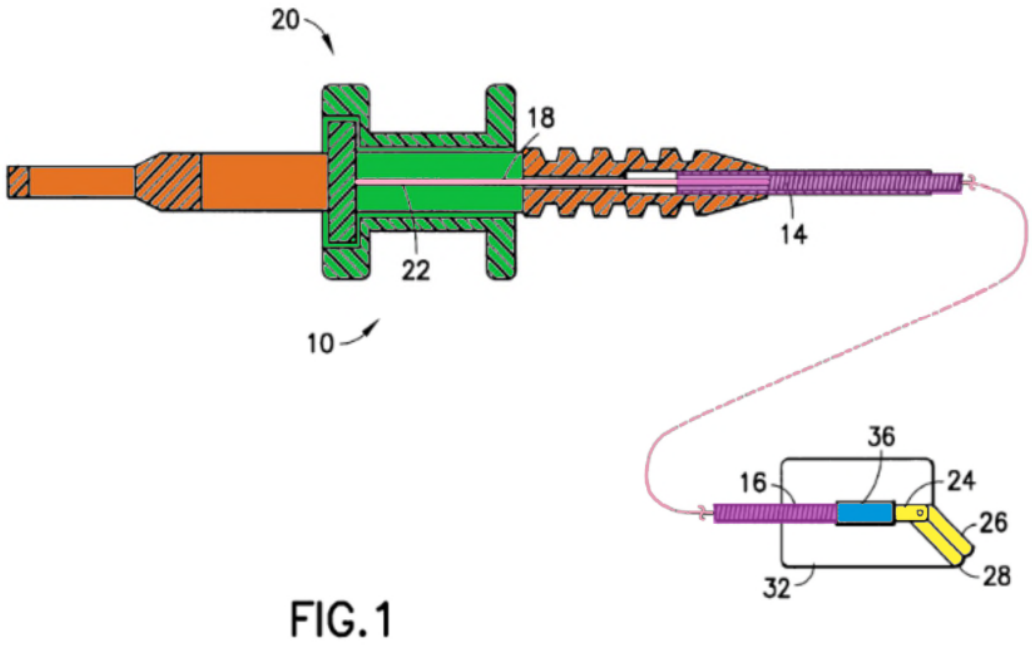


FIG. 1

The hemoclip device shown above in annotated Figure 1 includes an actuator 20 (green), a handle (orange), sheath (purple), control wire (pink), link (36), and clip/clip arms 24-28 (yellow). Ex. 1002, ¶49.

2. <u>Claim 1</u>

a. <u>Claim 1 [preamble] – "A medical device for causing the hemostasis of a blood vessel for use through an endoscope, said medical device comprising"</u>

The preamble of claim 1 is not a limitation. *See supra* Section V.C.1. To the extent the preamble is found to be a limitation, it is nevertheless disclosed by Kortenbach II. Kortenbach II discloses a medical device that causes hemostasis of

a blood vessel when used with an endoscope. *See, e.g.*, Abstract, col. 1:31-45; 2:48-3:63; 5:1-31; Ex. 1002, ¶107.

b. Claim 1[a] – "a clip, the clip having at least two clip legs"

Kortenbach II discloses a clip with at least two clip legs (26 and 28). Kortenbach II explains that "[t]he jaws **26**, **28** in the first embodiment are configured as a hemostasis clip." Ex. 1006 at 4:43-5:31; Ex. 1002, ¶108. The clip legs in Kortenbach II are designed to be compressed together in order to grasp tissue at a target site. Ex. 1006 at 5:1-31; Ex. 1002, ¶108.

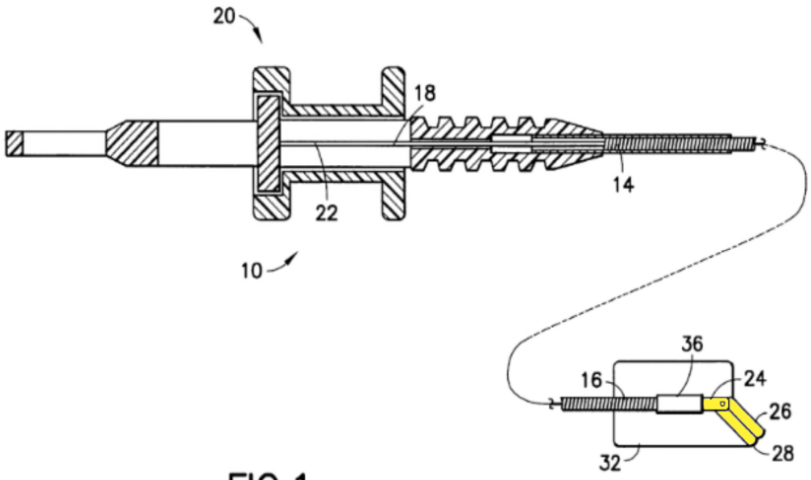


FIG. 1

c. Claim 1[b] – "a breakable link adapted to couple a control wire to the clip and adapted to be broken by a first predetermined tensile force applied by the control wire"

Kortenbach II discloses a control wire (18) coupled to the clip via a breakable link (blue)(36). Ex. 1002, ¶109. The breakable link (blue)(36) couples

the control wire (pink) (18) to the clip (yellow). *Id.* Kortenbach II describes element 36 as a quick release that includes a breakable link within. Ex. 1006 at 5:23-31; Ex. 1002, ¶109. Once the jaws are locked shut, and cannot be further opened and closed, a breakable link "between the pull wire 18 and the jaw 26" can be broken to decouple the control wire from the clip. *Id.* Kortenbach II explains that the breakable link can be part of a "force limiting feature, i.e. a thinned down portion of one of the jaws or wires which yields to the limit force." Ex. 1006 at 5:19-22.

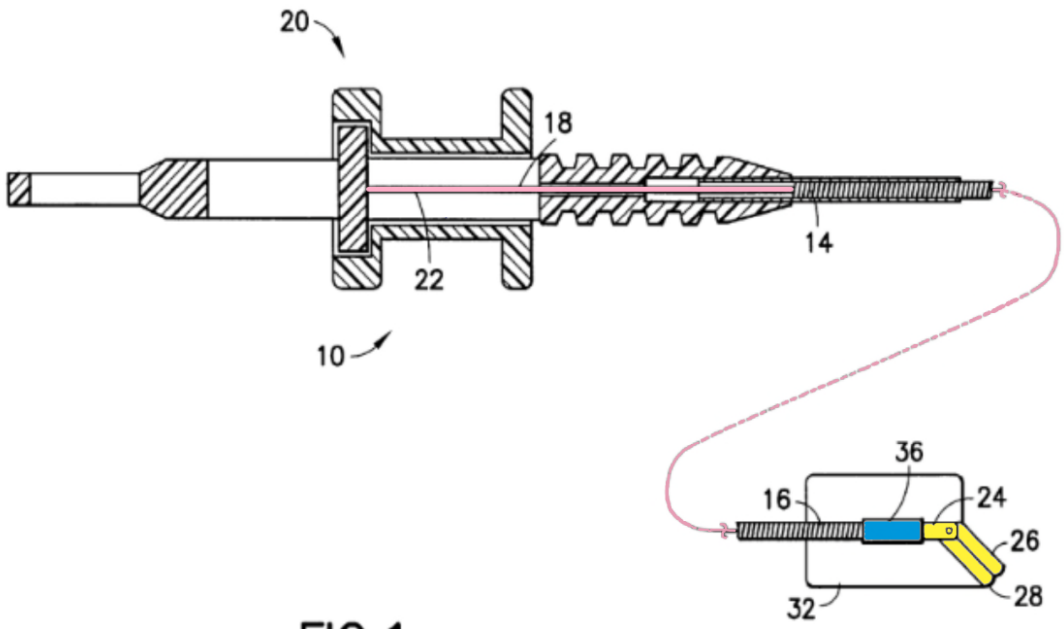


FIG. 1

d. Claim 1[c] – "the control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs when the control wire is coupled to the clip"

Kortenbach II discloses that the control wire opens the two clip legs and closes the two clip legs. Ex. 1006 at 4:43-5:31; Ex. 1002, ¶110. For example, Kortenbach II teaches that "the jaws 26, 28 are also coupled to the distal end (not shown) of the pull wire 18 such that movement of one of the pull wire of the coil relative to the other causes the jaws to open or close." Ex. 1006 at 4:52-55; Ex. 1002, ¶110. Kortenbach II further explains that the jaws may be open and closed until they are "locked shut" by the cam lock. Ex. 1006 at 5:1-31; Figs.4 & 5; Ex. 1002, ¶111.

e. Claim 1[d] – "an axially rigid sheath enclosing the control wire, the sheath able to communicate a first force opposing a second force of the control wire"

Kortenbach II discloses an axially rigid sheath enclosing the control wire. Ex. 1002, ¶112. In Kortenbach II, a sheath (purple) (12) encloses the wire and presents an opposing force to the control wire. *Id.* The coil 12 is axially rigid and can assert a force opposing that of the control wire at least because when the control wire is pulled proximally, it moves "reciprocally" to the sheath (12). Ex. 1006 at col. 3:6-20, 4:43-5:31 (as shown in the Figure, 14 is the proximal end of coil 12 and 16 is the distal end of the same coil 12); Ex. 1002, ¶112. Were the

sheath (12) not axially rigid, it would not move reciprocally to the control wire (18). Ex. 1002, ¶112.

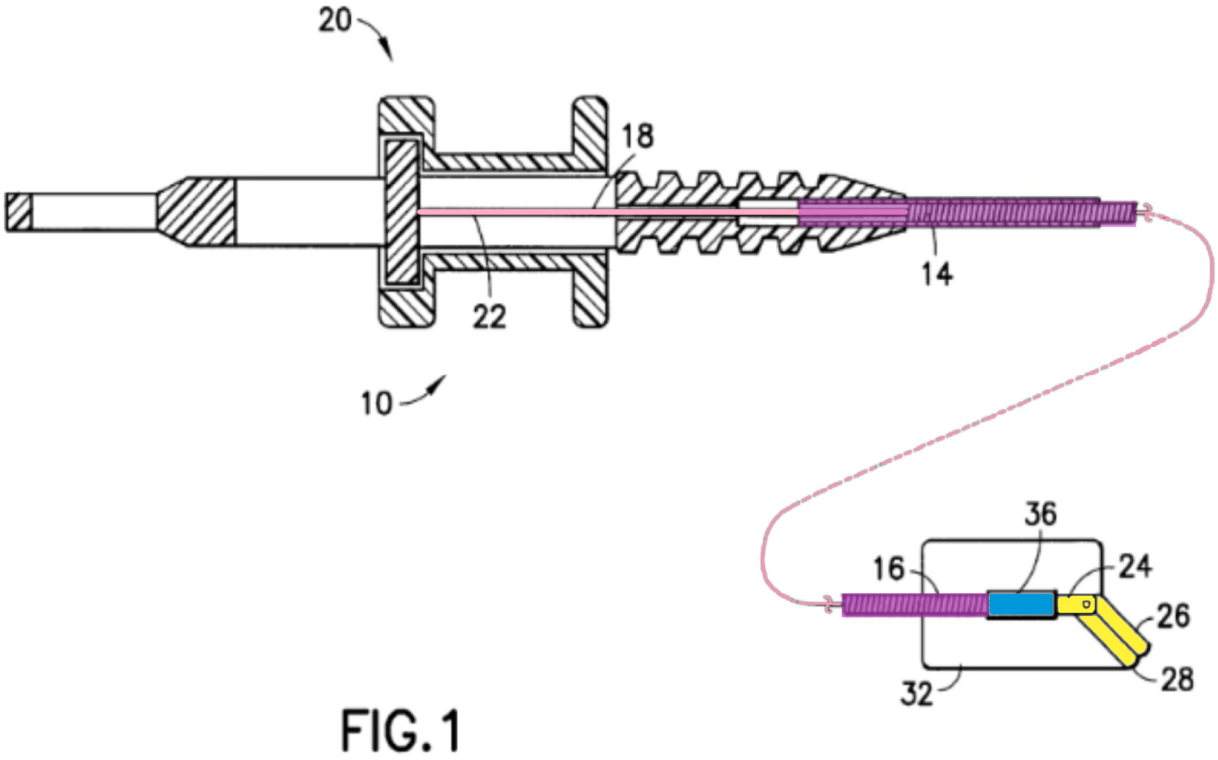


FIG. 1

f. Claim 1[e] – "a handle coupled to the axially rigid sheath"

Kortenbach II discloses a handle (orange) coupled to the sheath (proximal end 14). Ex. 1006 at Fig. 1; 4:43-5:31; Ex. 1002, ¶113.

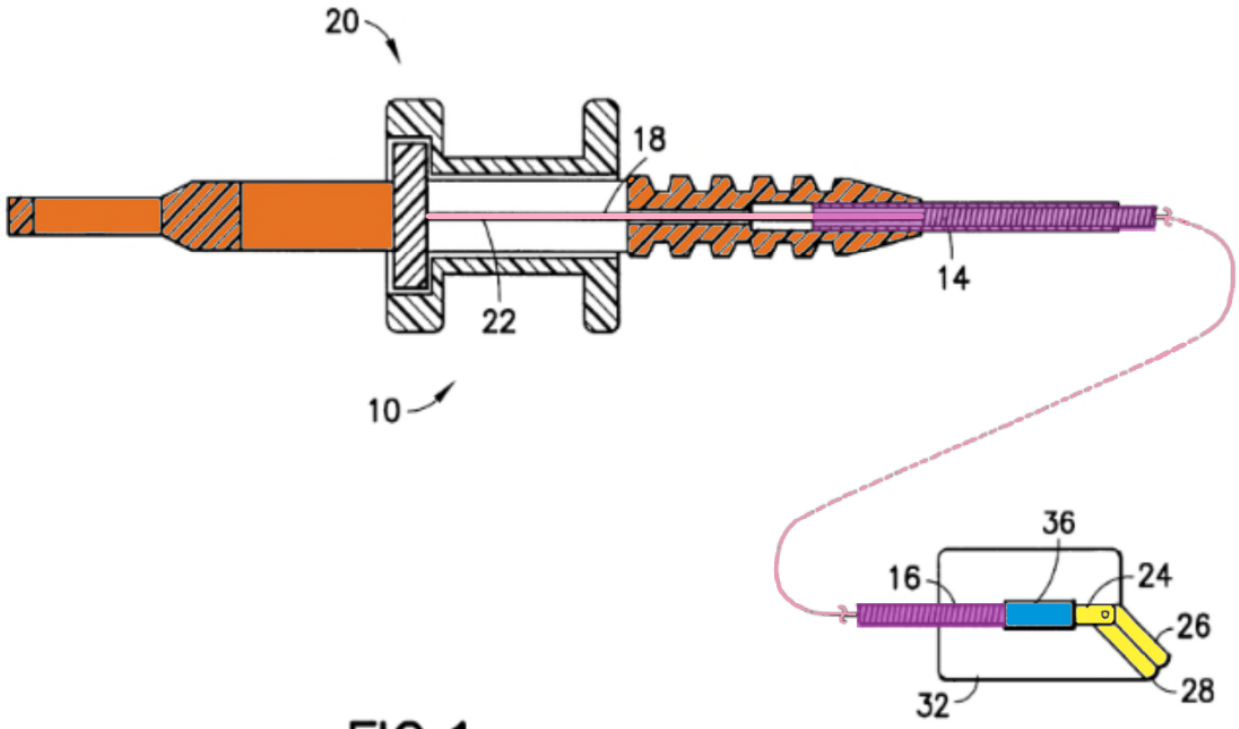


FIG. 1

g. Claim 1[f] – "an actuator coupled to the control wire, the control wire engageable by the actuator to open the at least two clip legs, to close the at least two clip legs, and to uncouple the control wire from the clip"

Kortenbach II discloses an actuator (green) (20) coupled to the control wire (18 and proximal end 22). Pulling the actuator causes the control wire to open the two clip legs and to close the two clip legs and uncouple the wire from the clip. Ex. 1006 at 3:12-17, 4:43-5:31; Ex. 1002, ¶¶114-15.

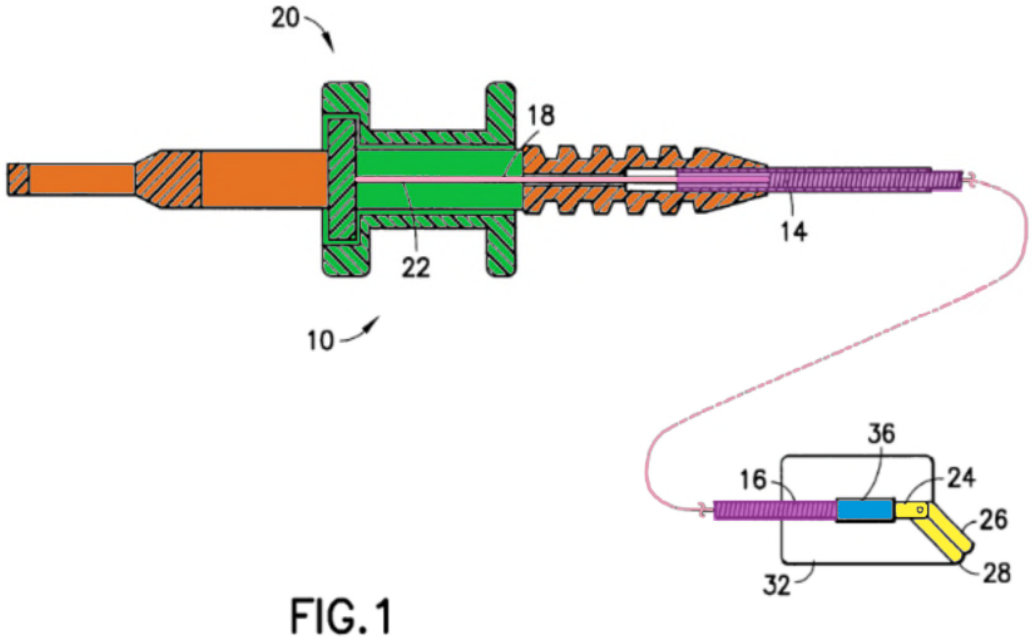


FIG. 1

h. Claim 1[g] – "wherein when the breakable link is broken, the control wire uncouples from the clip"

As noted above in claim element 1[b], Kortenbach discloses the use of a breakable link, that when broken, separates the clip from the control wire. Ex. 1002, ¶116. Kortenbach II anticipates claim 1.

3. Claim 7 – "further comprising a lock arrangement for locking the at least two clip legs in a closed position."

Kortenbach II discloses a locking arrangement for locking the two clip legs. For example, Kortenbach II teaches a cam lock 35 that "locks the jaws in the closed position…" Ex. 1006 at 5:1-31; Ex. 1002, ¶117. In addition, claim 3 of Kortenbach II requires that "said jaws have a locking cam such that they can be locked in the closed position." Accordingly, Kortenbach II discloses claim 7.

4. Claim 9 – "wherein the axially rigid sheath is torsionally rigid, the sheath transmitting a rotational force from the handle to the clip at a ratio of approximately 1 to 1"

Kortenbach II teaches that the sheath is torsionally rigid and that the clip is "rotatably coupled" to the clevis. Ex. 1006 at 4:50-52; Ex. 1002, ¶118.

5. Claim 12

To the extent claim 12 does not impermissibly broaden independent claim 1, Kortenbach II discloses at least the breakable link as described above for claim elements 1[b] and 1[g]. Ex. 1002, ¶119.

6. Claim 13 - "wherein the device is disposable"

The hemoclip device in Kortenbach II is disposable, such that it may be disposed of after use. Ex. 1001 at 3:19-21; Ex. 1002, ¶120.

In addition, claim 13 refers to the "medical device of claim 1" as being disposable. The "medical device of claim 1" is every element of claim 1, which includes the clip. The clip in Kortenbach II is left in a patient's body when it is deployed. Accordingly, the "medical device of claim 1" as disclosed by Kortenbach II is not reusable because a portion of its device (as defined by '245 patent claim 1 to include at least the clip and the tube) has been permanently detached. Thus, it is not reusable. Ex. 1002, ¶121.

To the extent this limitation is not expressly recited in Kortenbach II, a POSITA would find it inherent that any endoscopic device may be disposed of after use on a patient. *Id.*, ¶122.

7. Claim 15

Claim 15 is a method claim that corresponds to the exact same structural components recited in the body of independent claim 1. *See* Ex. 1002, ¶¶123-24. Method step (i) is no more than "providing a medical device comprising" five elements of claim 1. *Id.*, ¶125. Accordingly, these elements are met for the same reasons explained above in Sections V.F.2.a-h. *Id.*

Method step (ii) is no more than using the hemoclip device according to its well-known purpose. Nonetheless, Kortenbach I teaches that its hemoclip device is "delivered to the surgical site," which is the claimed deployment location. *Id.*, ¶126.

Method step (iii) corresponds to the same functional limitations from independent claim 1 regarding the actuator and the breakable link. *Id.*, ¶127. These limitations are disclosed as described above for claim elements 1[b], 1[f], and 1[g].

Accordingly, Kortenbach II discloses claim 15. *Id.*, ¶128.

G. Ground 4: Claims 1, 7, 9, 12, 13, and 15 Are Obvious Over Kortenbach II

1. Claims 1 and 15

To the extent Patent Owner argues that Kortenbach II does not expressly disclose claim limitations 1[c] and 15[i], which requires a "control wire reversibly operable both to open the at least two clip legs and to close the at least two clip

legs when the control wire is coupled to the clip," a POSITA would find this limitation obvious over Kortenbach II. Ex. 1002, ¶129.

First, the claim element requires only that the control wire open and close the clip legs "when the control wire is coupled to the clip." Accordingly, as in the '245 patent, there is no requirement that once the clip legs are locked into position and the control wire is uncoupled from the clip, that it still be possible to open and close the clip legs. *Id.*, ¶130.

Second, Kortenbach II repeatedly discusses moving the clip between closed to open to closed positions. A POSITA would understand that Kortenbach II teaches and at a minimum strongly suggests the ability to reversibly operate the clip arms via the control wire. *Id.*, ¶131. Indeed, Kortenbach II expressly notes that "movement of one of the pull wire or the coil relative to the other causes the jaws to open or close." Ex. 1006 at 4:52-55; Ex. 1002, ¶132. A POSITA would understand this to mean that the clip may be open and closed based on the movement of the control wire by the operator. Ex. 1002, ¶132. Kortenbach II further suggests this result when it notes that only when the control wire is pulled enough so as to "lock shut" the clip arms is the clip fixed in position and no longer able to be manipulated. Ex. 1006 at 5:1-31; Figs.4 & 5; Ex. 1002, ¶132.

Accordingly, claims 1 and 15 are obvious over Kortenbach II. Ex. 1002, ¶133. The remainder of the claims (7, 9, 12, and 13) are obvious for at least the

same reasons discussed above in Section F in that Kortenbach II expressly discloses each of them, and they are dependent upon claim 1 which Kortenbach II at least renders obvious.

H. Ground 5: Matsuno Anticipates Claims 1, 3-7, and 9-15

1. Matsuno

U.S. Patent No. 5,766,184 ("Matsuno") was filed on November 2, 1995 and claims priority to a PCT application filed on July 1, 1996 and two Japanese applications dating back to November 2, 1994. Ex. 1002, ¶50. Matsuno is prior art to the '245 patent at least under 102(b). Matsuno is not cited by the '245 patent and was not discussed during prosecution. *Id.*

Matsuno "relates to an endoscopic treatment tool inserted into the body cavity through an endoscope for performing a treatment or the like." Ex. 1007 at 1:5-7; Ex. 1002, ¶51. In Matsuno, the clip assembly can be detached from the control wire after an attachment link (51) is deformed.

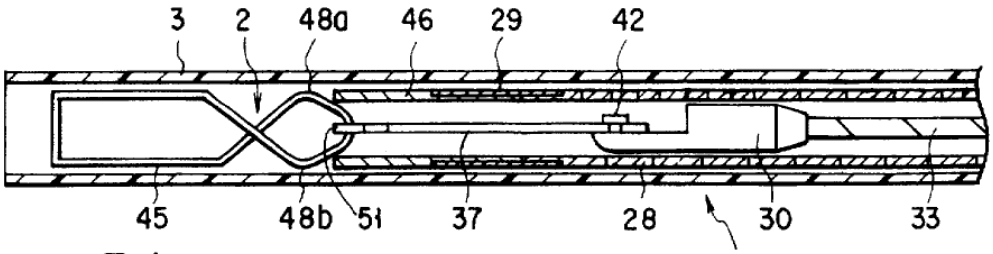


FIG. 1A

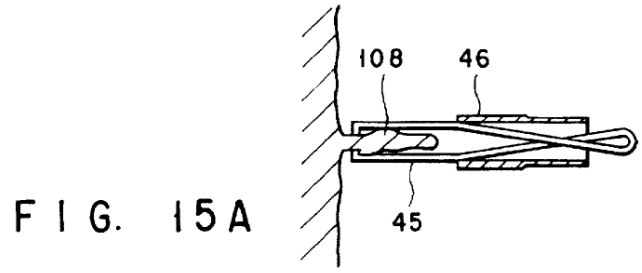


FIG. 15A

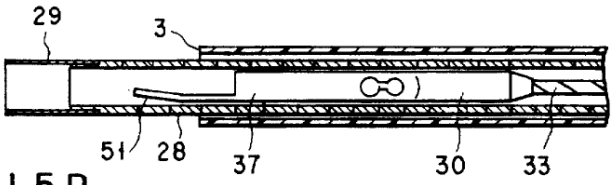


FIG. 15B

During operation, when a clip is closed on the target area, the clip may be deployed when a tensile force is applied by the actuator to the control wire. Ex. 1002, ¶¶52-53. In this instance, the link 51 between the clip assembly 2 and the control wire 33 is broken. *Id.* This is demonstrated by first looking to Figure 1B, which shows the link 51 in its attached state. *Id.* Subsequently, the link 51 is bent open and the link between the clip 2 and control wire 3 is decoupled. *Id.*

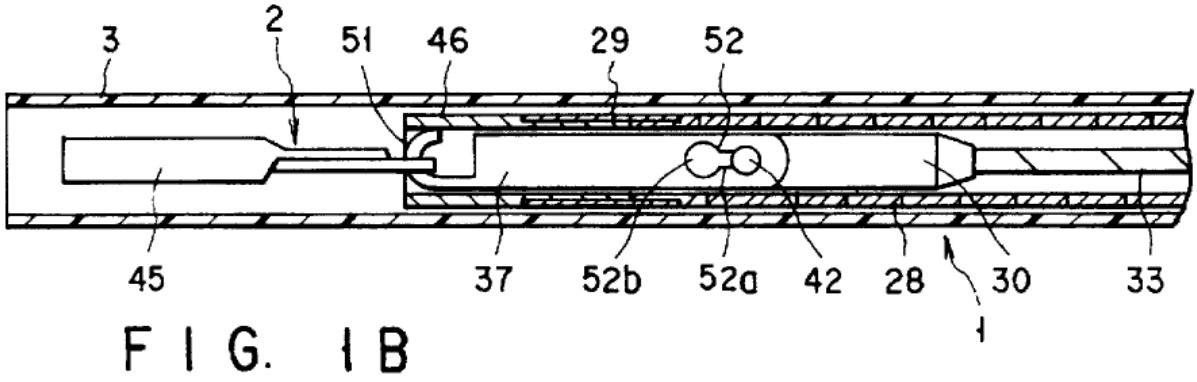


FIG. 1B

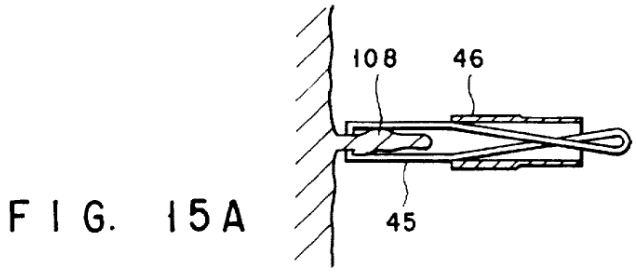


FIG. 15A

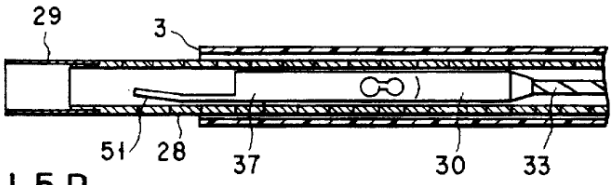


FIG. 15B

2. Claim 1

a. Claim 1 [preamble] – "A medical device for causing the hemostasis of a blood vessel for use through an endoscope, said medical device comprising"

The preamble of claim 1 is not a limitation. *See supra* Section V.C.1. To the extent the preamble is found to be a limitation, it is nevertheless disclosed by Matsuno. The clip device of Matsuno is for hemostasis and can be introduced to the body through an endoscope tube. Ex. 1007 at Abstract, 1:5-7, 1:59-2:5; Ex. 1002, ¶¶134-36.

b. Claim 1[a] – "a clip, the clip having at least two clip legs"

Matsuno discloses a clip (45) (yellow) with two clip legs in a parallel horizontal configuration. Ex. 1007 at 4:64-5:7, 23-27, 12:11-61; Ex. 1002, ¶¶137-38.

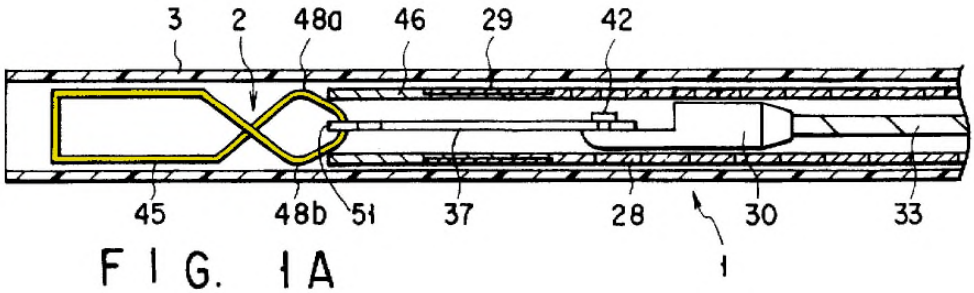


FIG. 1A

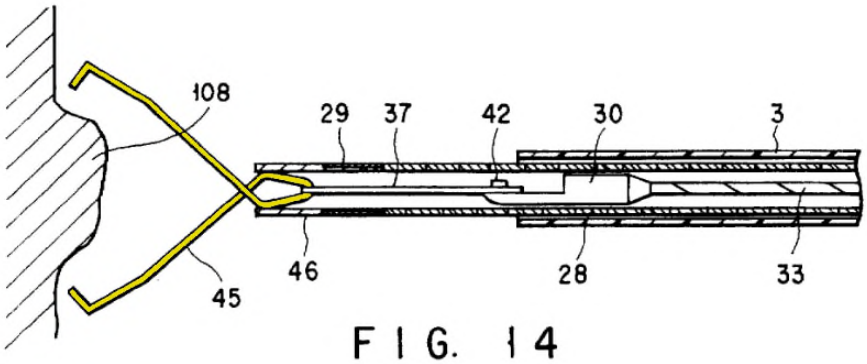


FIG. 14

The clip legs in Matsuno are compression clips legs that, when compressed together, pinch the target tissue. *Id.*

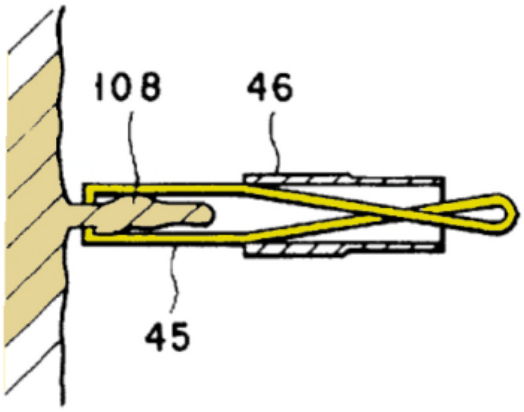


FIG. 15A

c. Claim 1[b] – "a breakable link adapted to couple a control wire to the clip and adapted to be broken by a first predetermined tensile force applied by the control wire"

Matsuno discloses a j-hook (51)(blue) that uncouples the clip from the control wire (33)(pink) when a predetermined tensile load is applied.

> Pulling the operating wire 33 further toward the operator, the clip 45 is struck deep into the vital tissue 108 as shown in FIG. 15A. At the same time, the hook 51 of the coupling plate 37 is extended as shown FIGS. 15B and 15C and the clip 45 comes off from the coupling plate 37. By the way, the clip-fastening ring 46, which presses the arms 49a, 49b of the clip 45, does not come off from the clip 45 as shown in FIG. 15A and is retained in the body together with the clip 45.

Ex. 1007 at 12:53-61; *see* Figs. 1A, 5A, 5B, 14, 15A-C; Ex. 1002, ¶139.

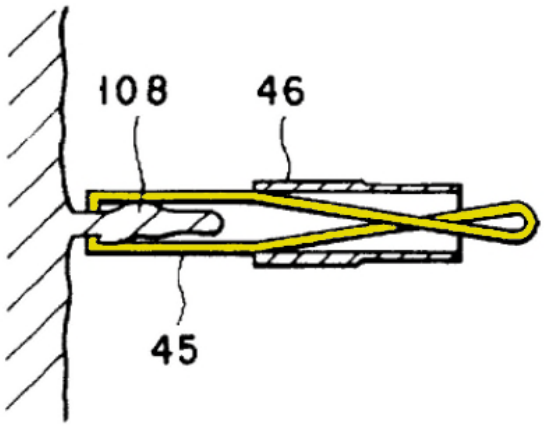


FIG. 15A

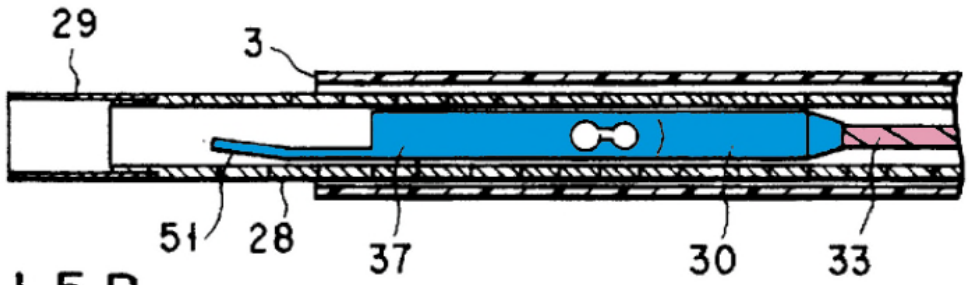


FIG. 15B

Petitioner's note that, for Matsuno to anticipate claim 1, the Board would need to adopt Patent Owner's apparent interpretation of the "breakable link" element of claim 1. That is, the j-hook of Matsuno is not designed to "break" into pieces upon a predetermined tensile load being applied. Rather, it is "deformed" and the "link" between the clip and the j-hook no longer exists, but no physical component exists that can be called a breakable link. Ex. 1002, ¶140.

There are accordingly two scenarios in which Patent Owner's arguments render claim 1 anticipated by Matsuno. *Id.*, ¶141.

First, Petitioner's accused product in the co-pending district court case includes a j-hook that couples the control wire to the clip assembly. When a tensile load is applied to the control wire, the j-hook is designed to slightly deform (not fracture), thus uncoupling the clip assembly from the control wire. Indeed, in its Complaint, Patent Owner made the following allegation:

> The SureClipTM Hemostasis Clip products contain a pair of J hooks that extend distally from the distal end of a control wire; the J hooks are releasably connected to the proximal pin of the clip assembly, ***such that application of a sufficient predetermined force will release the J hooks from the clip assembly, thereby forming a breakable link that, when broken, uncouples the control wire from the clip.***

Ex. 1018, ¶ 41; *see also* Ex. 1021 (Infringement Contentions) at 1-2, 6 (alleging that a deformed j-hook meets the breakable link element).

Accordingly, if Patent Owner maintains that the accused SureClip device meets claim 1, then Matsuno anticipates based on its disclosure of a j-hook. Ex. 1002, ¶¶142-44.

Second, to the extent that Patent Owner argues that claim 3 is not invalid as impermissibly broadening independent claim 1, then Matsuno's disclosure of the j-hook that meets each and every element of dependent claim 3 must necessarily invalidate claim 1. That is, if Patent Owner argues that the j-hook of dependent claim 3 is a type of "breakable link" in claim 1, then the disclosure of a j-hook required by claim 3 must meet the broader element of claim 1. *Id.*, ¶145.

If Patent Owner agrees with Petitioner's construction that a "breakable link…adapted to be broken" means "a component of the device that is designed to mechanically fail by fracturing," then Petitioner will agree to address Matsuno under obviousness, as described below in Section V.I. In other words, if Patent Owner agrees that a j-hook does not meet the "breakable link" element of claim 1, then Petitioner agrees that Matsuno does not anticipate. *Id.*, ¶146.

d. Claim 1[c] – "the control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs when the control wire is coupled to the clip"

Matsuno discloses that the control wire is reversibly operable such that it both opens and closes the clip legs. Ex. 1007 at claim 1, 12:11-61; Ex. 1002, ¶147. Matsuno explains that the clip legs can be closed when in contact with the outer

sheath (3) as shown in Fig. 1A, then opened when extending beyond the sheath as shown in Figure 14, and then can be closed again when the legs come into contact with the tube as the control wire is pulled in the proximal direction. *Id.* This is demonstrated at least by the figures below.

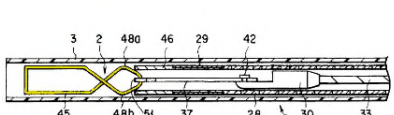


FIG. 1A

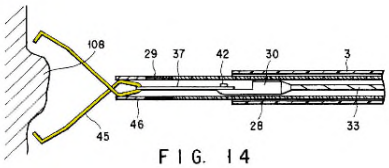
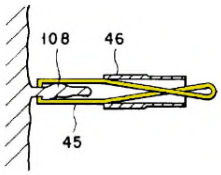


FIG. 14

FIG. 15A



In addition, Matsuno explains that the control wire 33 is prevented from "buckling" when it is moved back and forth to control the clip legs opening and closing. *See, e.g.*, Ex. 1007 at 9:7-26, 11:61-12:61; Ex. 1002, ¶148. Matsuno further explains that the control wire 33 can be "tensioned" in either direction to pull the clip legs into or out of the ring 46, which may allow for easier control of the rotation of the clip legs. *See, e.g.*, Ex. 1007 at 12:23-52; Ex. 1002, ¶148. Accordingly, Matsuno discloses a control wire that reversibly operates the clip legs to open and close.

e. <u>Claim 1[d] – "an axially rigid sheath enclosing the control wire, the sheath able to communicate a first force opposing a second force of the control wire"</u>

Matsuno includes an axially rigid sheath (28/32) (purple) that encloses the control wire (33) (pink). Ex. 1007 at 4:42-59, 5:48-6:12, 8:54-9:35; Ex. 1002,

¶149. This sheath communicates an opposing force to the control wire, thus allowing the clip assembly to be pulled into the tube. Ex. 1002, ¶150.

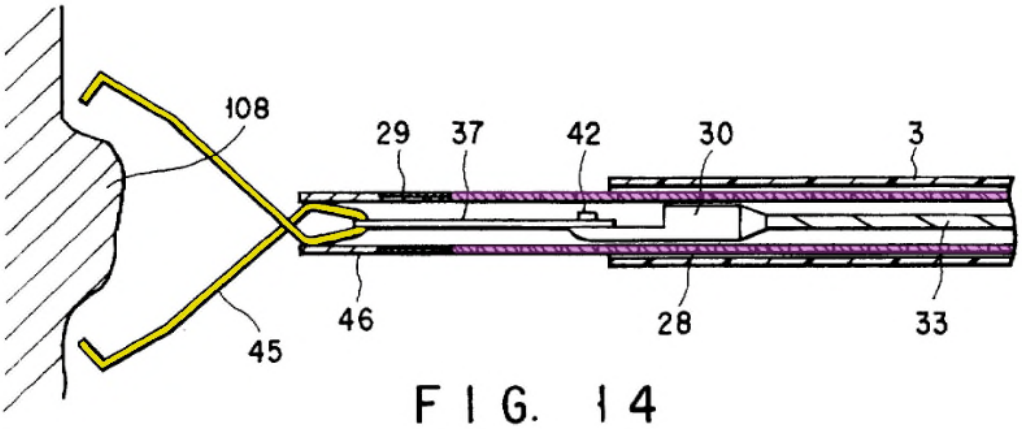


FIG. 14

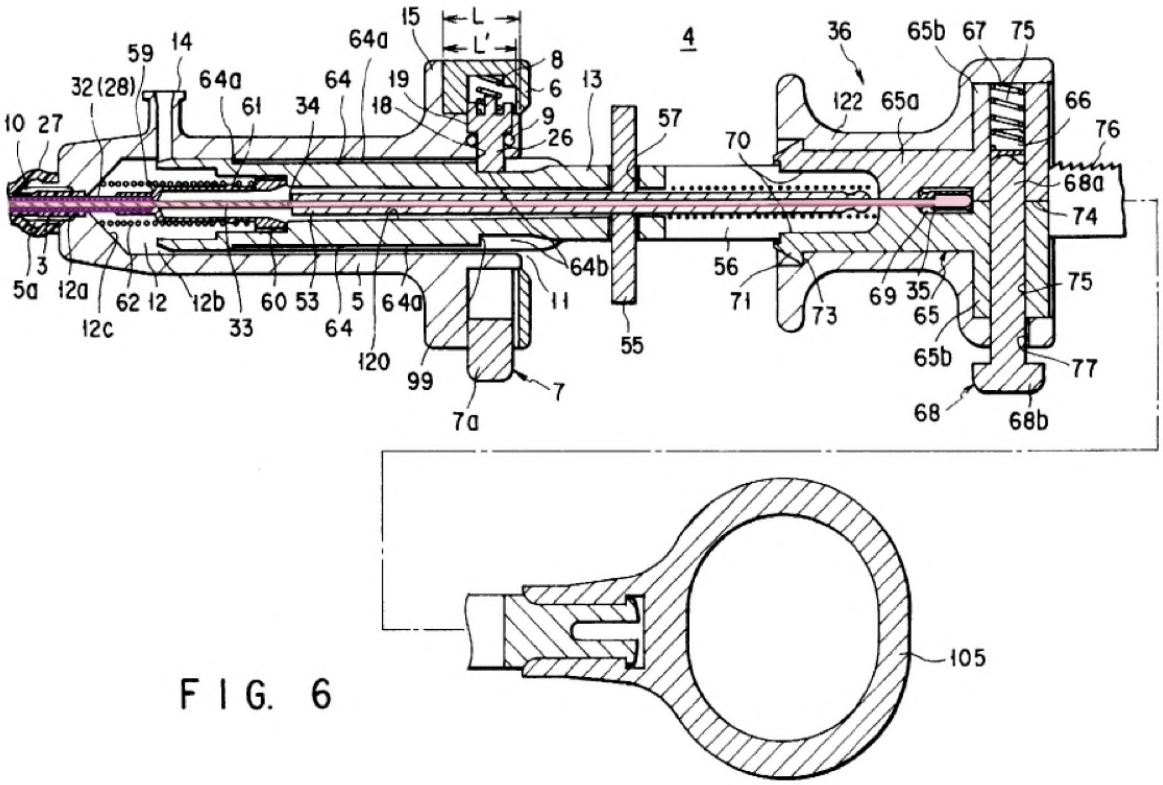
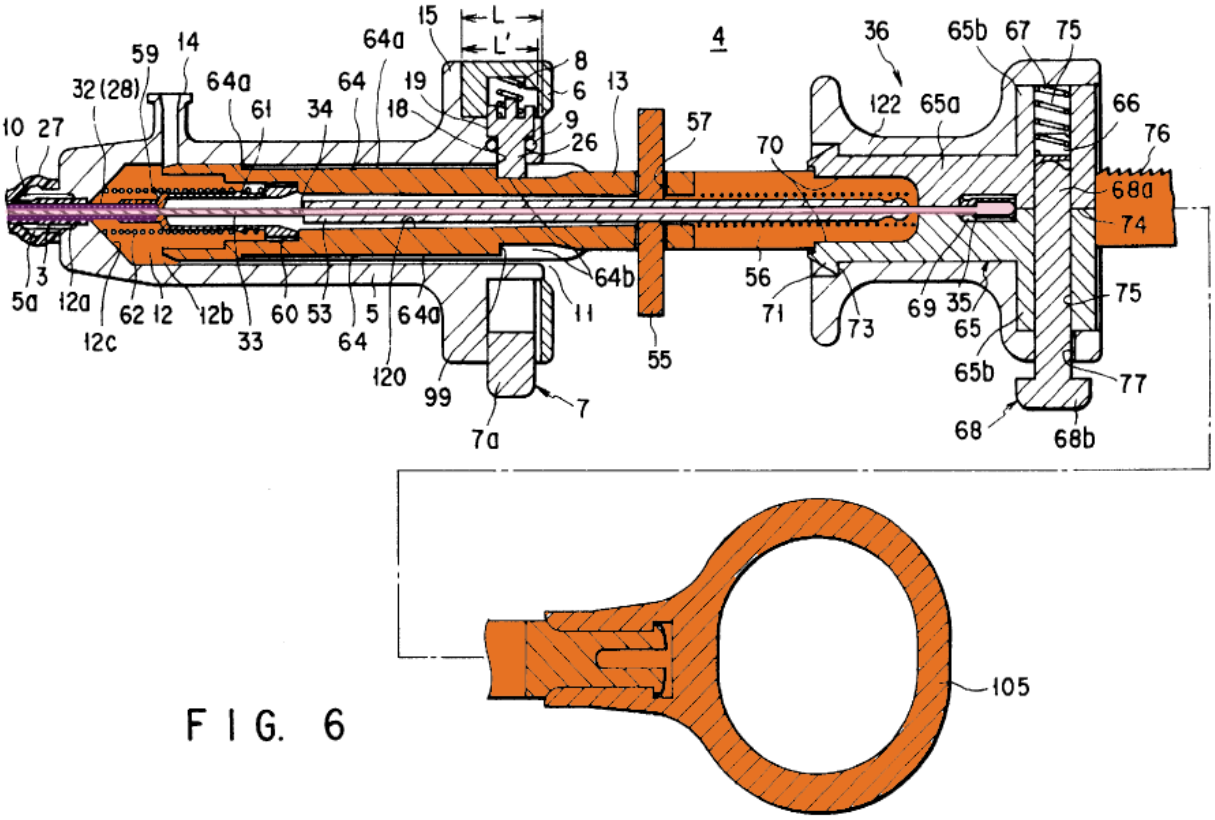


FIG. 6

f. Claim 1[e] – "a handle coupled to the axially rigid sheath"

Matsuno discloses a handle as shown in Figure 6 highlighted in orange. The handle (orange) is coupled to the sheath (purple). Ex. 1002, ¶151.



F I G. 6

g. Claim 1[f] – "an actuator coupled to the control wire, the control wire engageable by the actuator to open the at least two clip legs, to close the at least two clip legs, and to uncouple the control wire from the clip"

Matsuno discloses an actuator (36), shown in green, coupled to the control wire (33) (pink). Ex. 1007 at 4 fig.6; Ex. 1002, ¶152. The actuator (called a slider 36 by Matsuno) is coupled to the control wire such that when the actuator is pulled in a proximal direction, it pulls the control wire and causes the two clip legs to

close. Ex. 1007 at 10:17-12:61; Ex. 1002, ¶152. When the actuator is pulled even further, the tensile load causes the control wire to uncouple from the clip. Ex. 1007 at 12:23-27, 53-61; Ex. 1002, ¶152.

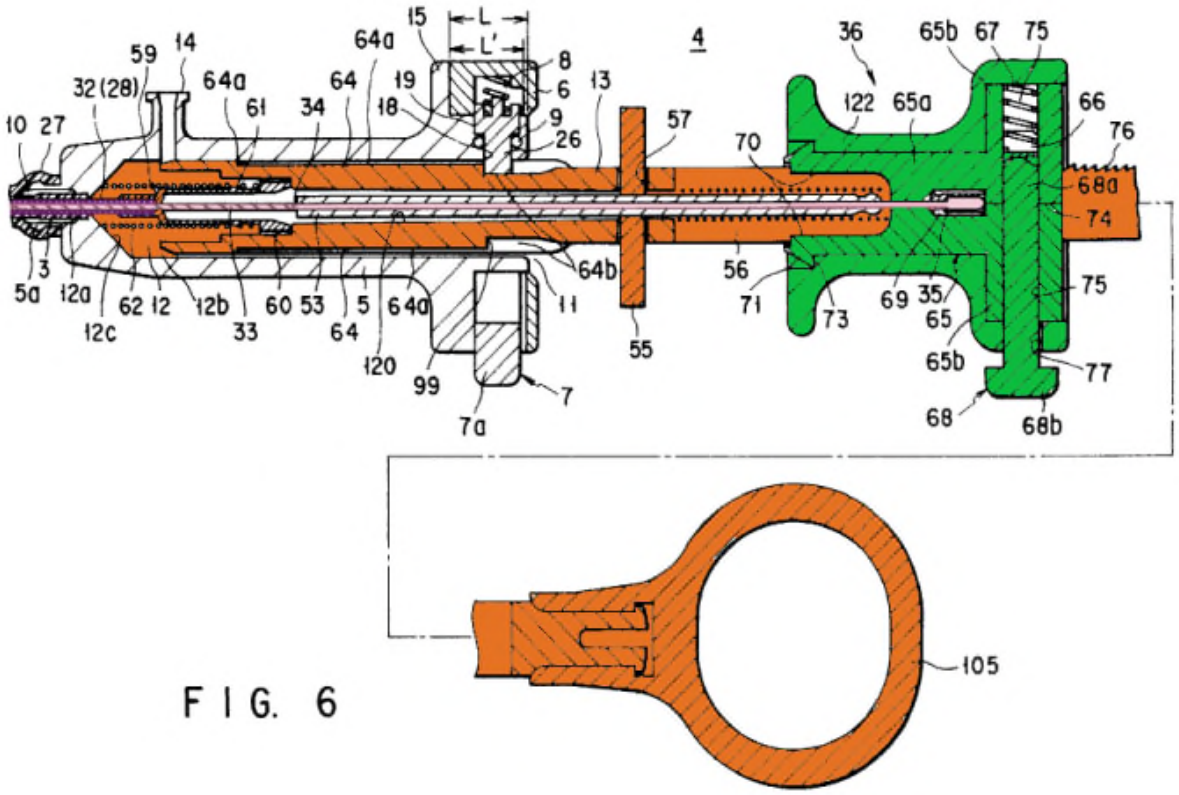


FIG. 6

h. Claim 1[g] – "wherein when the breakable link is broken, the control wire uncouples from the clip"

Matsuno discloses a breakable link that uncouples the clip from the control wire, as described above with respect to claim element 1[b]. Ex. 1002, ¶153. Thus, Matsuno anticipates claim 1.

3. Claim 3 - "the control wire is able to be coupled to the clip by a j-hook; the j-hook is able to be straightened by the first predetermined tensile force; and when the j-hook is straightened, the control wire uncouples from the clip"

To the extent dependent claim 3 does not impermissibly broaden independent claim 1, Matsuno discloses a j-hook as shown in Figure 1B below. *See* claim 1[b]; Ex. 1002, ¶154.

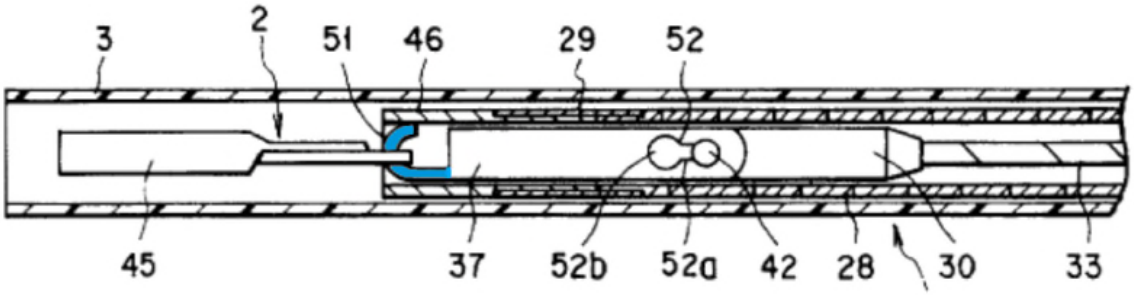


FIG. 1B

The j-hook in Matsuno is able to be straightened, which uncouples the control wire from the clip. The figure below from Matsuno shows the j-hook in a substantially straightened position. Ex. 1002, ¶¶51, 53.

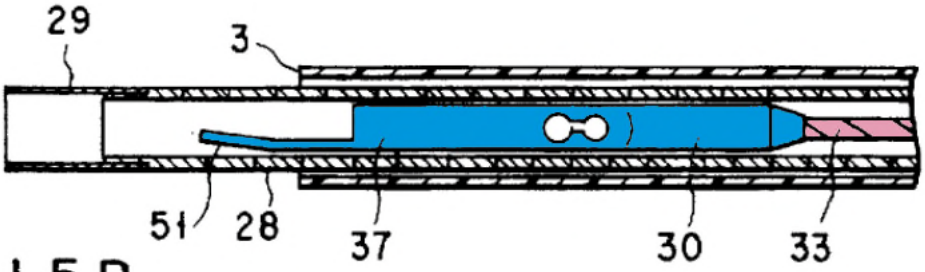


FIG. 15B

4. Claim 4 – "further comprising a lock sleeve, wherein the control wire is able to be pulled in a proximal direction to pull the clip through the lock sleeve, thereby closing the clip legs"

Matsuno discloses that the clip legs (yellow) are closed when the control wire pulls the clip through the lock sleeve (46) (red). Ex. 1007 at 12:43-52; Ex. 1002, ¶155.

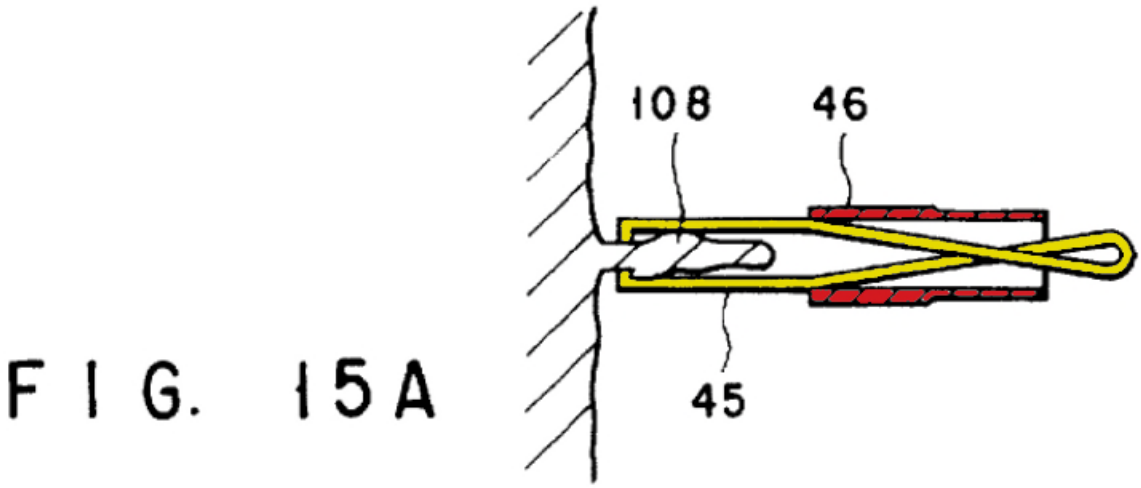


FIG. 15A

5. Claim 5 – "The medical device of claim 4, wherein the control wire is able to be pushed in a distal direction to push the clip out of the lock sleeve, thereby opening the clip legs"

Matsuno discloses that the clip legs are opened when the control wire pushes the clip out of the lock sleeve. Ex. 1007 at 11:53-12:61; Ex. 1002, ¶¶156-59.

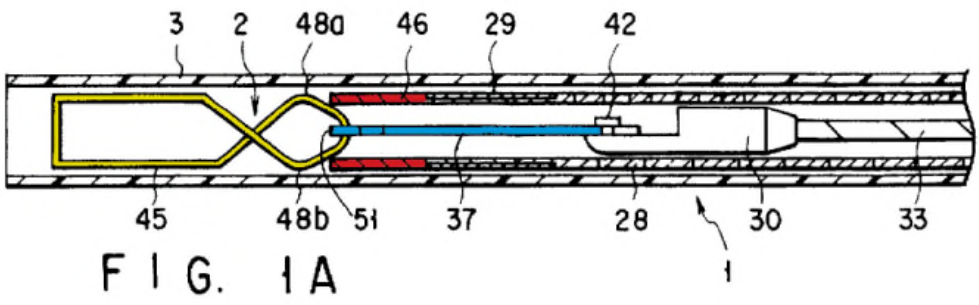


FIG. 1A

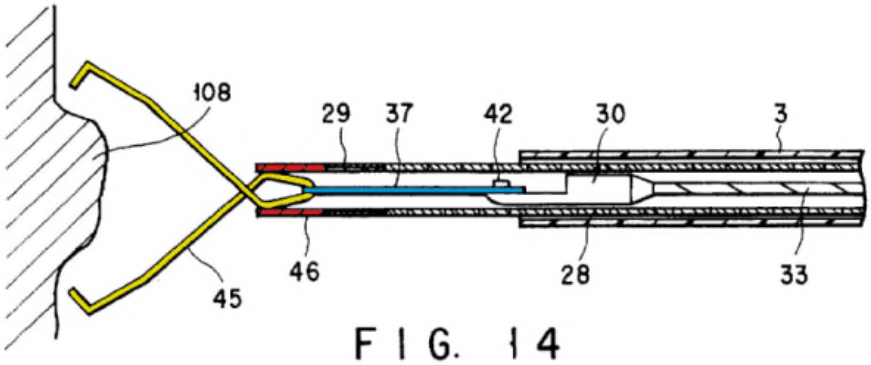


FIG. 14

6. Claim 6 – "The medical device of claim 4, further comprising: a retainer, the retainer release ably coupled to the lock sleeve; and a retainer release arrangement, the retainer release arrangement able to engage the retainer to uncouple the retainer from the lock sleeve."

Matsuno discloses a retainer (29) (brown) that is coupled to the lock sleeve (46) (red) and a retainer release arrangement that is able to separate the retainer from the lock sleeve. Ex. 1002, ¶160. As described by Matsuno and as shown in the two annotated figures below, when the clip is pulled into the lock sleeve, the arrangement of the retainer at the end of the sheath (purple) allows for the release from the lock sleeve. Accordingly, Matsuno discloses claim 6. Ex. 1007 at 12:57-61; Ex. 1002, ¶160.

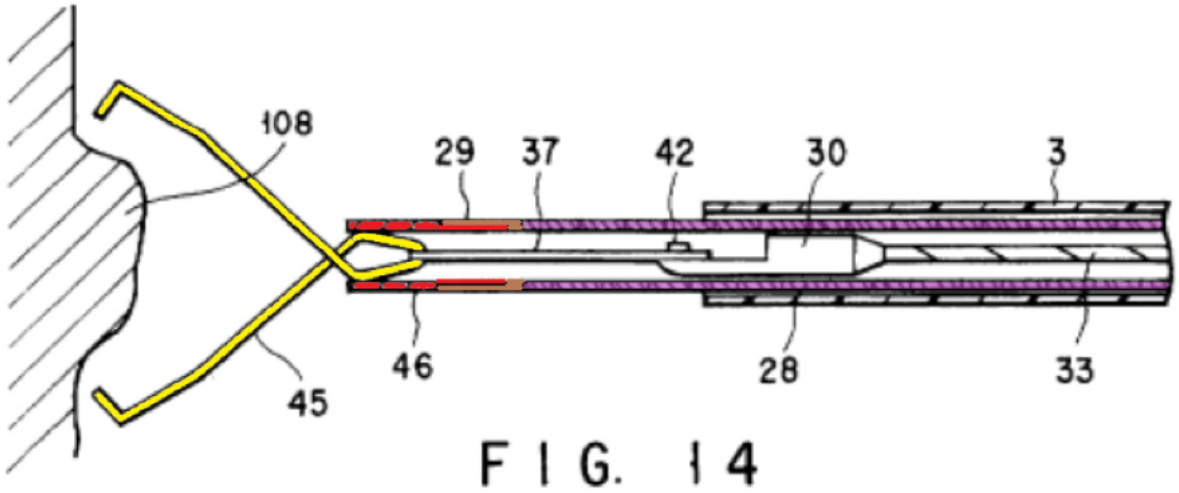


FIG. 14

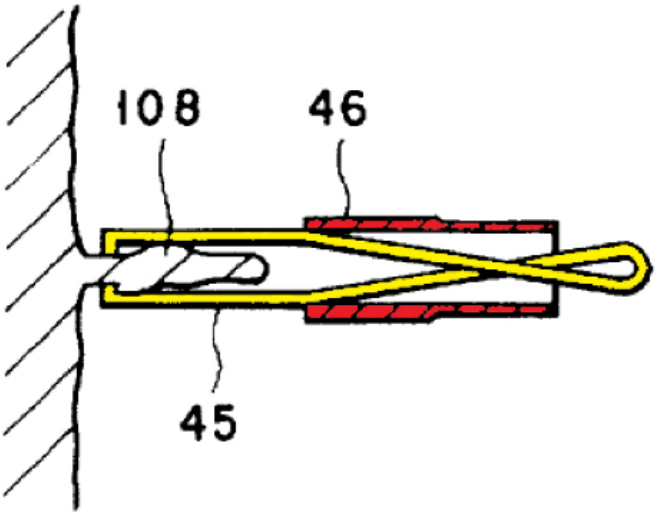


FIG. 15A

7. Claim 7 – "further comprising a lock arrangement for locking the at least two clip legs in a closed position."

Matsuno discloses a lock arrangement (46) (red) that locks the two clips legs closed. Ex. 1007 at 12:43-52; Ex. 1002, ¶161.

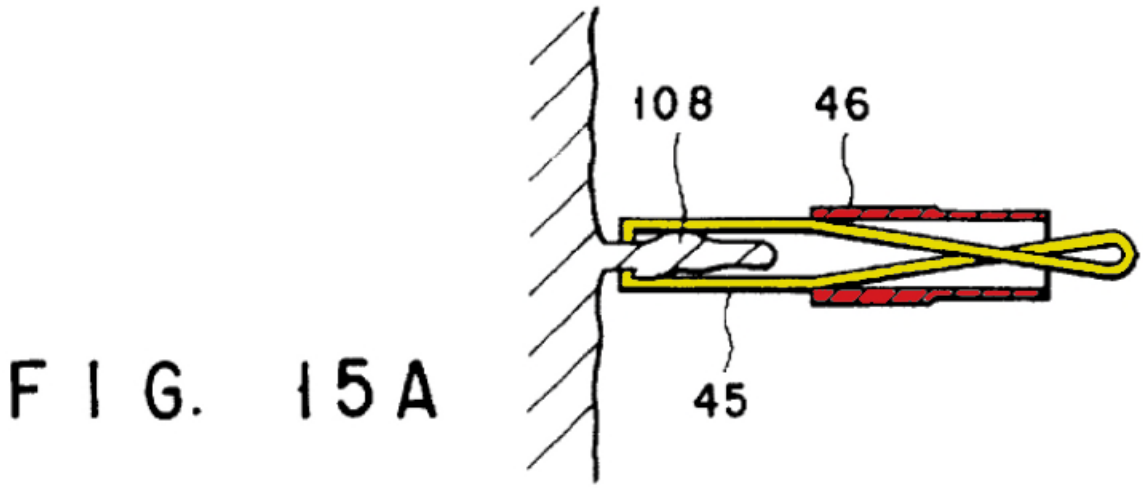


FIG. 15A

8. Claim 9 - "wherein the axially rigid sheath is torsionally rigid, the sheath transmitting a rotational force from the handle to the clip at a ratio of approximately 1 to 1"

Matsuno discloses a torsionally rigid sheath that allows the operator to rotate the clip at the surgical site. Ex. 1007 at Abstract, 9:2-10:21; Ex. 1002, ¶162. The rotational force is transmitted at approximately a 1 to 1 ratio such that "by rotating the rotative operation member 55 with the clip device led into the body cavity by way of the endoscope, the direction in which the clip 45 of the cassette-type clip 2 is opened can be remotely controlled from outside the body." Ex. 1007 at 10:12-16; Ex. 1002, ¶162. Accordingly, Matsuno discloses claim 9.

9. Claim 10 – "The medical device of claim 1, further comprising: a lock sleeve, the lock sleeve radially surrounding the clip legs; wherein a distal compressive force applied to the lock sleeve moves the lock sleeve relative to the at least two clip legs, causing the at least two clip legs to close."

Matsuno discloses that the clip legs (yellow) are closed when the control wire pulls the clip through the lock sleeve (46) (red). The pulling of the control wire and the clip pressing against the lock sleeve is a distal compressive force that causes the clip legs to close. Ex. 1002, ¶163.

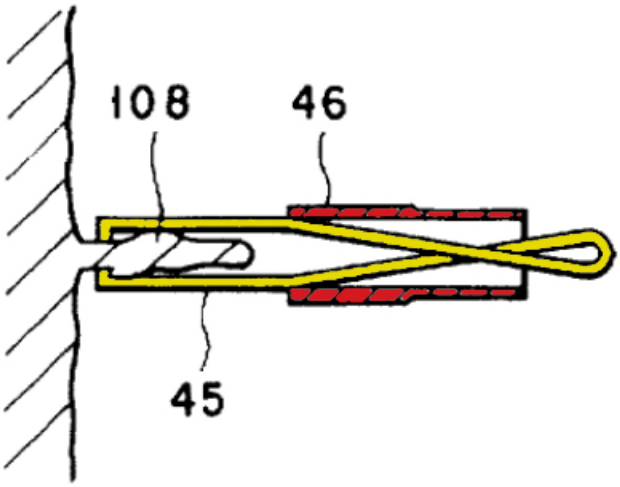


FIG. 15A

10. Claim 11 – "The medical device of claim 1, wherein a proximal tensile force on the control wire is opposable by a distal compressive force on the outer sheath, the distal compressive force on the outer sheath able to close and lock the at least two clip legs."

The term "outer sheath" lacks antecedent basis and therefore, claim 11 is indefinite. Assuming "outer sheath" refers to the "axially rigid sheath" of claim 1

and not an "outer sleeve" as is included in claim 14, Matsuno discloses claim 11. As shown below, when the control wire is pulled in the proximal direction and creates a tensile force, that force is opposed by the sheath, which creates a compressive force on the two clips legs by its coupling to the lock ring 46, causing the clip legs to close. Ex. 1002, ¶¶164-65.

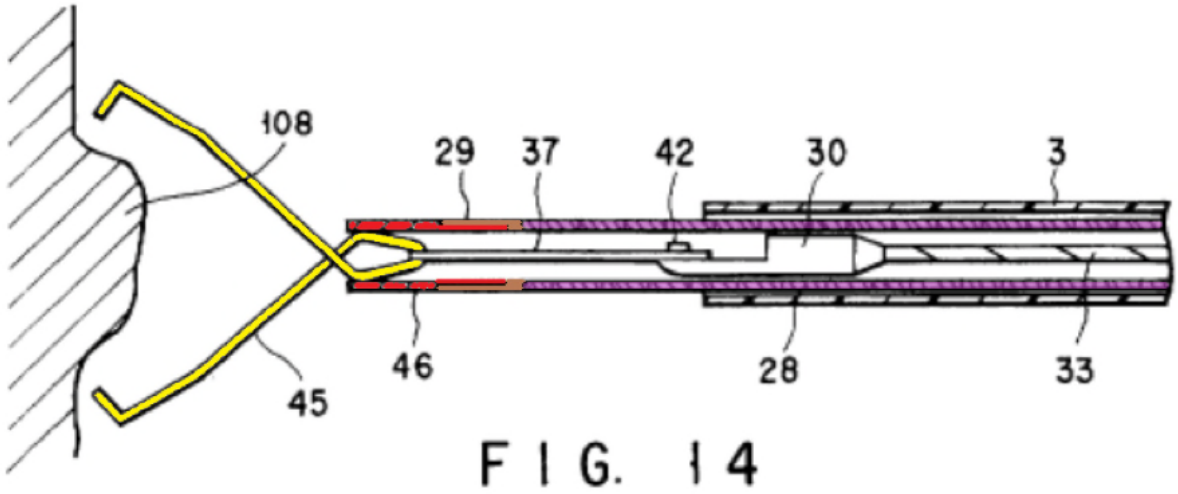


FIG. 14

11. Claim 12

To the extent claim 12 does not impermissibly broaden independent claim 1, Matsuno discloses at least the j-hook and/or the breakable link as described above for claim elements 1[b] and 1[g]. Ex. 1002, ¶166.

12. Claim 13 - "wherein the device is disposable"

The hemoclip device in Matsuno is disposable, such that it may be disposed of after use. Ex. 1002, ¶167.

In addition, claim 13 refers to the "medical device of claim 1" as being disposable. The "medical device of claim 1" is every element of claim 1, which

includes the clip and the breakable link. The clip in Matsuno is left in a patient's body when it is deployed. Accordingly, the "medical device of claim 1" as disclosed by Matsuno is not reusable because a portion of its device (as defined by '245 patent claim 1 to include at least the clip and the tube) has been permanently detached. The breakable link in Matsuno is also physically deformed and cannot be reused. Thus, it is not reusable. *Id.*, ¶168.

To the extent this limitation is not expressly recited in Matsuno, a POSITA would find it inherent that any endoscopic device may be disposed of after use on a patient. *Id.*, ¶169.

13. Claim 14

a. Claim 14 [preamble] – "A medical device for causing the hemostasis of a blood vessel for use through an endoscope, said medical device comprising"

See claim 1[preamble]; Ex. 1002, ¶170.

b. Claim 14[a] – "a clip, the clip having at least two clip legs"

See claim 1[a]; Ex. 1002, ¶171.

c. Claim 14[b] – "an outer sleeve, the outer sleeve reversibly movable with respect to the clip both to open the at least two clip legs and to close the at least two clip legs"

Matsuno includes an outer sleeve (3) (light green), which is reversibly movable with respect to the clip (45) (yellow). Ex. 1002, ¶¶172-74. As shown

below in Fig. 1A, when the outer sleeve (3) is distally extended, the clip legs are caused to close. *Id.*

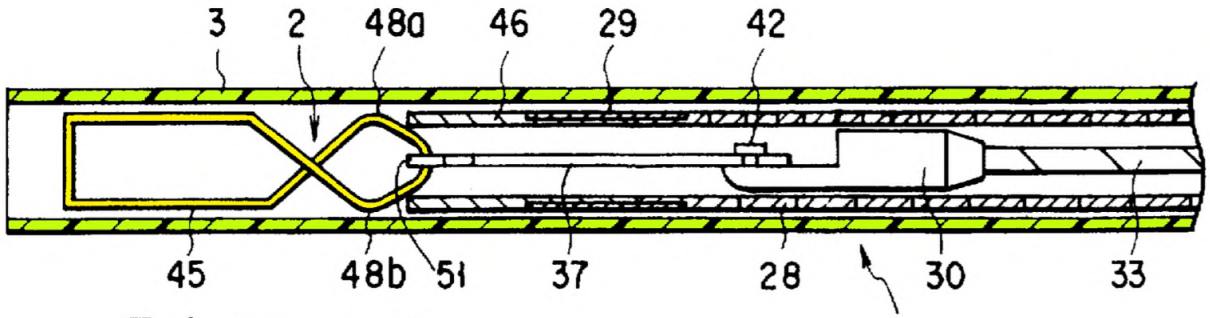


FIG. 1A

When the outer sleeve is retracted and the clip is extended, the clip legs are caused to open because they are no longer held closed by the outer sleeve. *Id.*

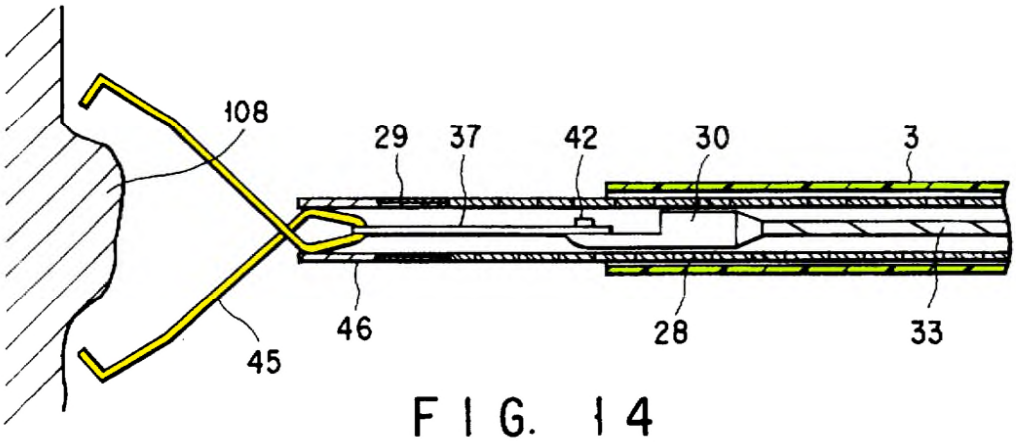


FIG. 14

d. Claim 14[c] – "a control wire coupled to the outer sleeve for moving the outer sleeve relative to the clip"

The control wire (33) (pink) in Matsuno is coupled to the outer sleeve (3) (light green). The control wire causes the outer sleeve to move relative to the clip

as demonstrated above for claim element 1[b]. Ex. 1007 at 12:11-52; Ex. 1002, ¶175.

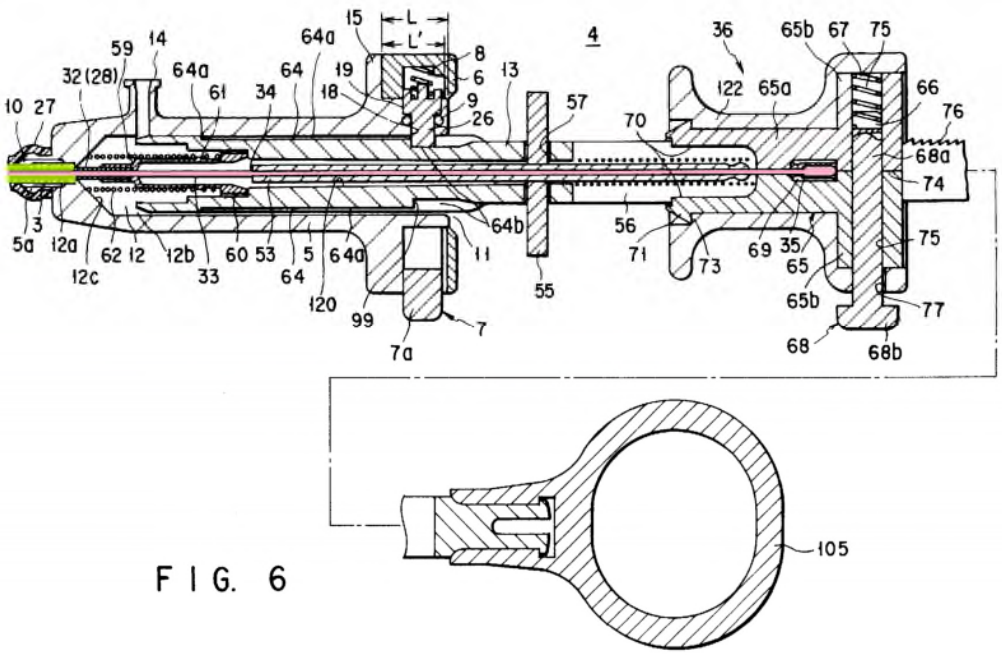


FIG. 6

e. Claim 14[d] – "an axially rigid sheath enclosing the control wire, the sheath couplable with, and uncouplable from, the clip"

Matsuno includes an axially rigid sheath (28/32) (purple) that encloses the control wire (33) (pink). Ex. 1007 at 4:42-59, 5:48-6:12, 8:54-9:35; Ex. 1002, ¶176.

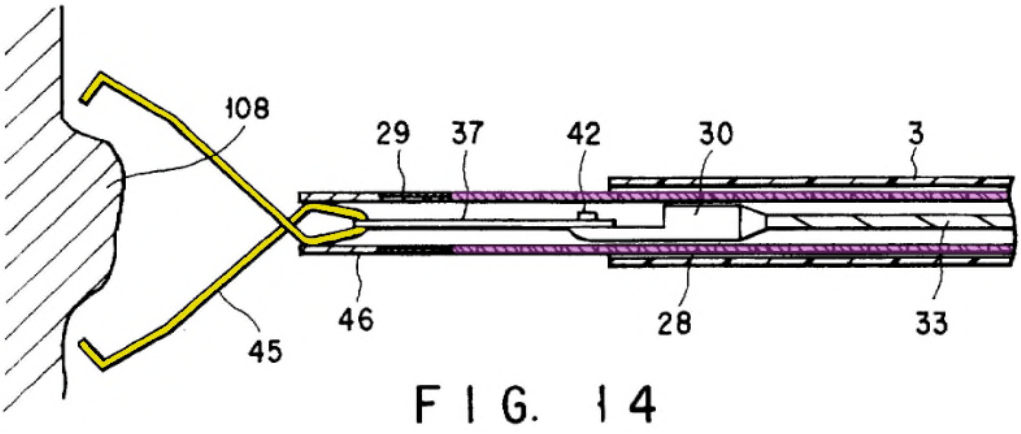


FIG. 14

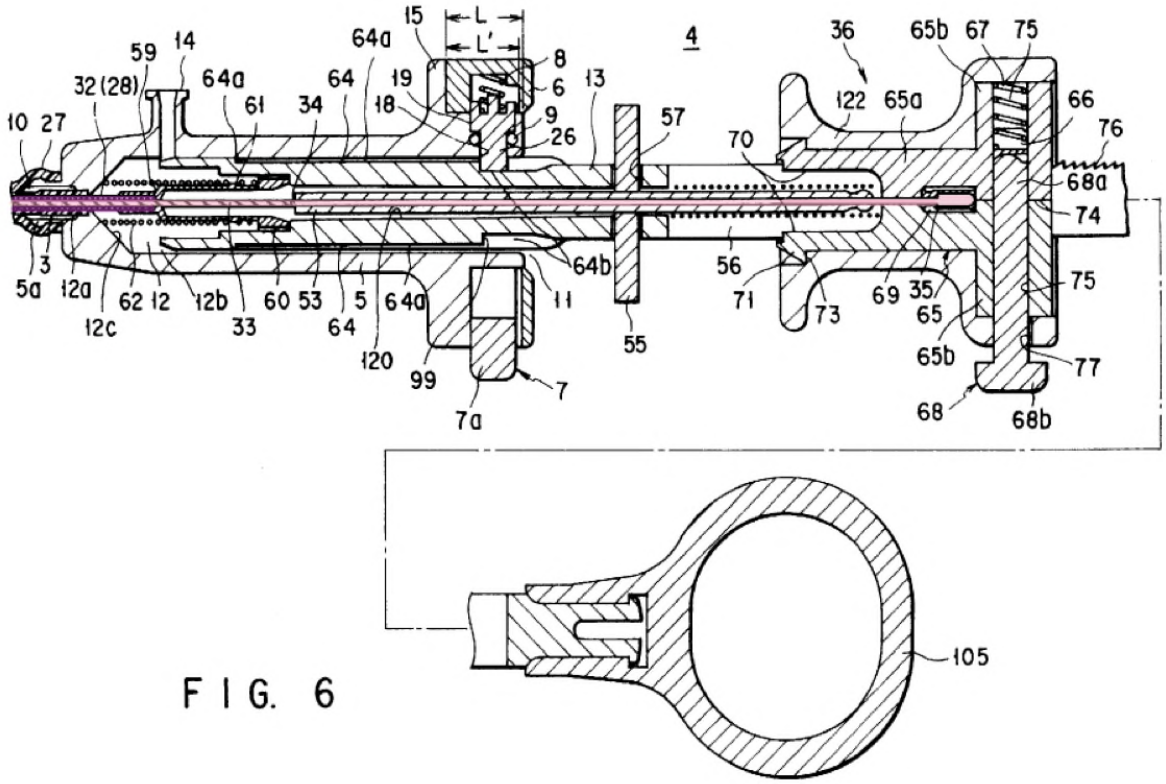


FIG. 6

f. Claim 14[e] – "a handle coupled to the axially rigid sheath"

See claim 1[e]. Ex. 1002, ¶177.

g. Claim 14[f] – "an actuator coupled to the control wire, the control wire engageable by the actuator to move the outer sleeve to open the at least two clip legs, to close the at least two clip legs, and to uncouple the clip from the sheath"

Matsuno discloses an actuator (36), shown in green, coupled to the control wire (33) (pink). Ex. 1007 at 4 fig.6; Ex. 1002, ¶178. The actuator (called a slider 36 by Matsuno) is coupled to the control wire such that when the actuator is pulled in a proximal direction, it pulls the control wire and causes the two clip legs to close. Ex. 1007 at 10:17-12:61; Ex. 1002, ¶178. When the actuator is pulled even further, the tensile load causes the control wire to uncouple from the sheath. Ex. 1007 at 12:53-61; Ex. 1002, ¶178.

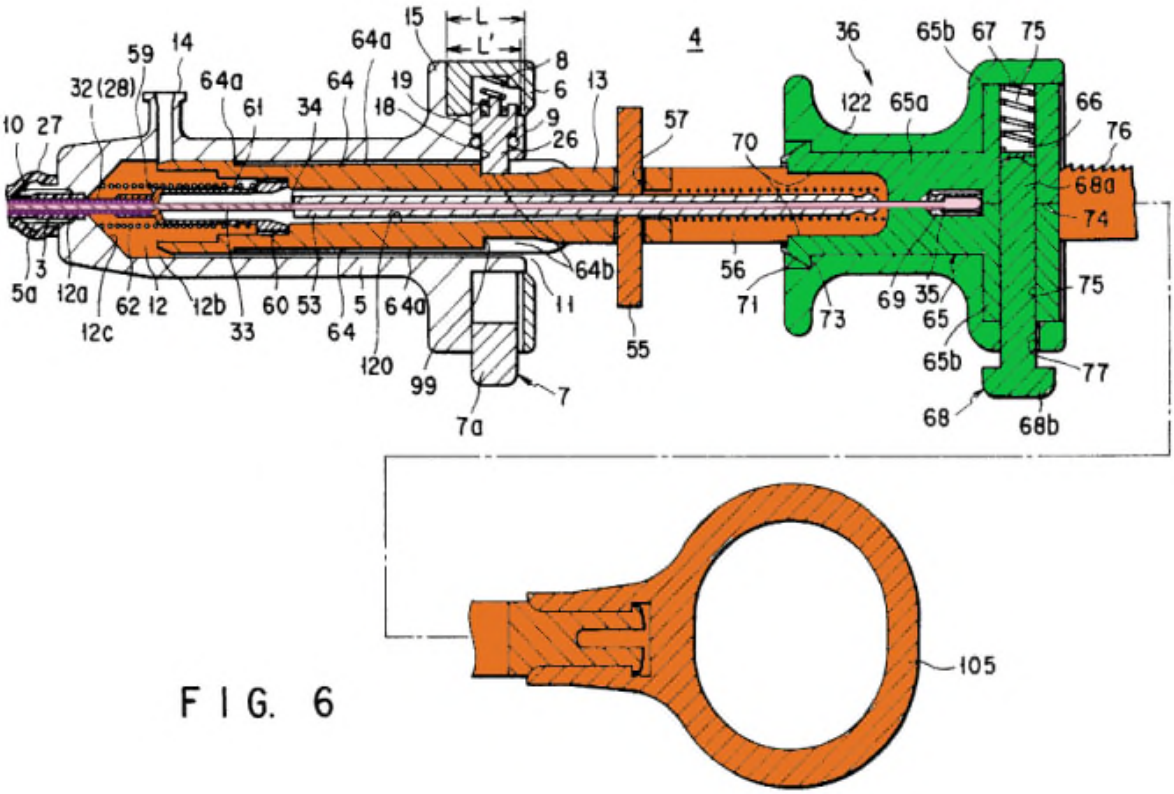


FIG. 6

h. Claim 14[g] – "a breakable link adapted to be broken by a predetermined tensile force applied by the control wire, wherein when the breakable link is broken, the control wire uncouples from the clip"

See claim elements 1[b] and 1[g]; Ex. 1002, ¶179.

14. Claim 15

Claim 15 is a method claim that corresponds to the exact same structural components recited in the body of independent claim 1. *See* Ex. 1002, ¶¶180-81. Method step (i) is no more than "providing a medical device comprising" five elements of claim 1. *Id.*, ¶182. Accordingly, these elements are met for the same reasons explained above in Sections V.H.2.a-h. *Id.*

Method step (ii) is no more than using the hemoclip device according to its well-known purpose. Nonetheless, Matsuno teaches that its hemoclip device is "led into the body through the endoscope channel." Ex. 1007 at Abstract, 1:5-7, 1:59-2:5; Ex. 1002, ¶183.

Method step (iii) corresponds to the same functional limitations from independent claim 1 regarding the actuator and the breakable link. Ex. 1002, ¶184. These limitations are disclosed as described above for claim elements 1[b], 1[f], and 1[g].

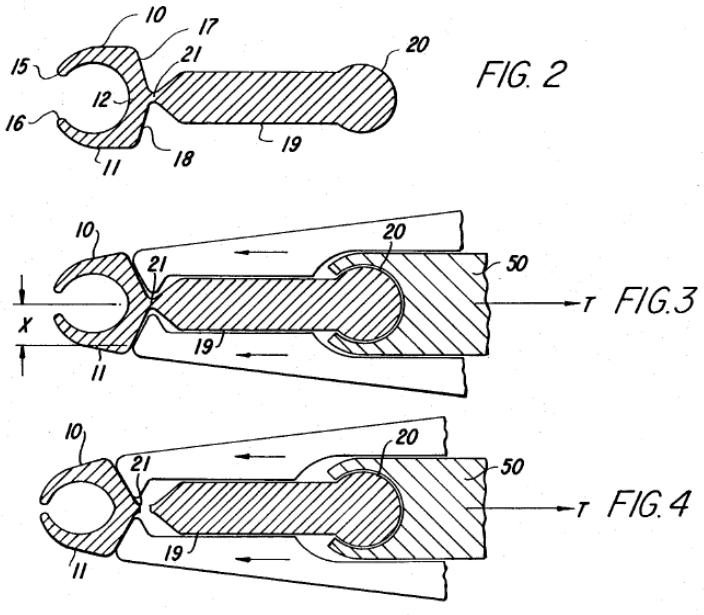
Accordingly, Matsuno discloses claim 15. *Id.*, ¶185.

I. Ground 6: Claims 1, 3-7, and 9-15 Are Rendered Obvious by Matsuno in View of the Knowledge of a POSITA and/or Kirsch

Matsuno anticipates claims 1, 3-7, and 9-15 as described above under Patent Owner's apparent interpretation of the "breakable link" element. To the extent Patent Owner argues that Matsuno does not expressly disclose certain elements of independent claims 1, 14, or 15, or dependent claim 13, including the breakable link element, it would have been obvious to combine Matsuno with the well-known knowledge of a POSITA as evidenced by, for example, U.S. Patent No. 4,733,664 ("Kirsch"). In particular, it would have been obvious to implement the breakable link from Kirsch into the device of Matsuno. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1 (1966); Ex. 1002, ¶186. Kirsch is in the same field of art as Matsuno (endoscopic devices) and a POSITA would have a high-level of working knowledge of the devices in Kirsch and Matsuno. Ex. 1002, ¶188. Moreover, both Matsuno and Kirsch are directed to solving the same alleged problems as the '245 patent – namely providing a device that allows an operator to accurately and easily apply a clip during an endoscopic procedure. *Id.* Both Matsuno and Kirsch, in fact, solved the same problem many years earlier. *See id.*

Kirsch was filed on October 15, 1985 and issued on March 29, 1988. *Id.*, ¶187. It is prior art under at least 102(b). *Id.* Kirsch is directed to an endoscopic surgical clip applier. Ex. 1009 at Abstract, 1:9-20; Ex. 1002, ¶188. In particular, the point of Kirsch is to provide a clip that remains in the body after application.

Ex. 1009 at 2:23-34 ("A further object of the invention is to provide a permanently implantable surgical clip for use in place of microvascular suturing."); Ex. 1002, ¶188. To accomplish this goal, Kirsch provides a set of clip arms that are attached to a bridge portion, which is attached to a body via a breakable link. Ex. 1009 at 2:35-42, figs.2, 3, & 4; Ex. 1002, ¶188. Kirsch notes that "the connection point is a neck 21 of reduced cross-section designed to break when a predetermined tension is applied by the tang of the tool." Ex. 1009 at 3:27-29; Ex. 1002, ¶188. Indeed, Kirsch claims this feature by describing the neck has a "breaking strength ("predetermined tensile force")." Ex. 1009 at 3:29-31; Ex. 1002, ¶188.



1. <u>Claims 1, 14, and 15</u>

It would have been obvious to a POSITA to implement the breakable link of Kirsch with the device of Matsuno. Ex. 1002, ¶189. To do so, a POSITA could

merely design the j-hook of Matsuno such that it would be designed to fracture as opposed to deform and release the clip. *Id.* As taught by Kirsch, a POSITA would simply need to design the hook of Matsuno "such that its breaking strength (predetermined tensile force)" is such that the hook would break as opposed to bending and deforming. Ex. 1009 at 3:29-33; Ex. 1002, ¶189. Such a design would look like the annotated Figure 15B of Matsuno below.

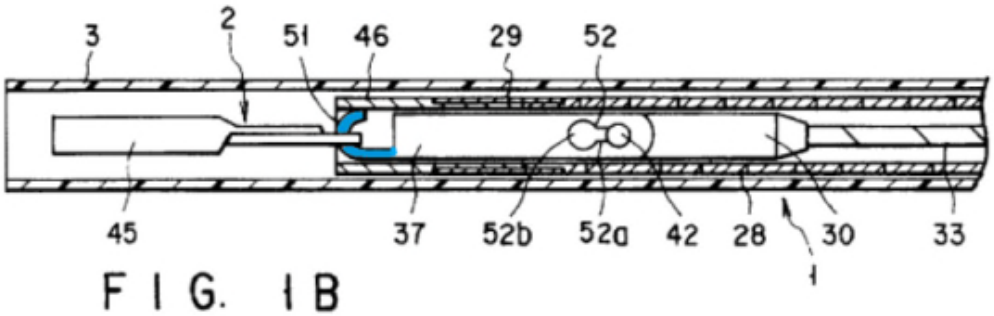


FIG. 1B

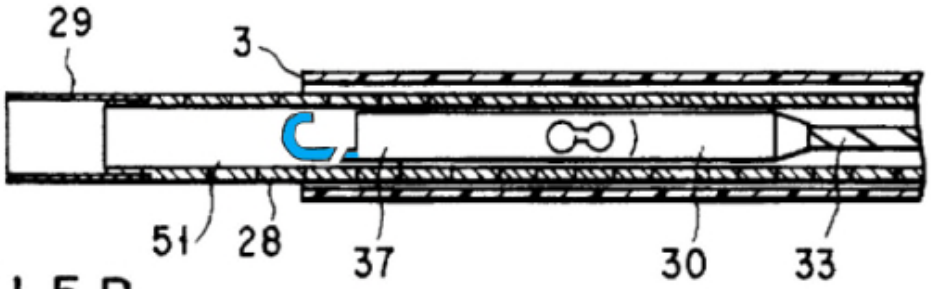


FIG. 15B

A POSITA would have understood that there were many different known ways of detaching a clip from the rest of the endoscopic device. Ex. 1002, ¶190. The Matsuno j-hook and the Kirsch breakable link were two examples. *Id.* This is an example of a simple substitution of one known element for another, to obtain predictable results (as described above), and thus the combination of the two would

have been obvious. *See* MPEP Section 2143.I.B. Further, a POSITA would have been motivated to substitute the breakable link for the j-hook because a POSITA would have known that a breakable link would have certain benefits over a j-hook in certain circumstances, such as a quicker release if designed for a brittle fracture, a more definitive feedback to the user with a fracture compared to a deformation, and the ability to use less material with a brittle fracture as compared to a deformation, thus saving material cost in a highly competitive commodity industry such as endoscopic clips. Ex. 1002, ¶191.

To the extent Patent Owner argues that a POSITA would not desire a tiny fragment of the hook to potentially remain in a patient's body, that is beside the point. Ex. 1002, ¶192. The '245 patent itself includes an embodiment (Figs. 18A-18F) in which the breakable link is an elastic band 1804 that when pulled "has the effect of breaking second elastic band 1804." Ex. 1001 at 13:3-4; Ex. 1002, ¶192. Once elastic band 1804 breaks, it could remain in the body just as the modified hook of Matsuno. Ex. 1002, ¶192. Given that the size of the hook in Matsuno and the elastic band in the '245 patent are much smaller than the clip left in the patient's body, there would be no issue with the patient passing the fragments. *Id.*

Accordingly, claims 1, 14, and 15 are obvious over Matsuno in view of the knowledge of a POSITA or Kirsch. The remainder of the claims (3-7 and 9-13)

are obvious for at least the same reasons discussed above in Section H in that Matsuno expressly discloses each of them.

J. Ground 7: Claims 1, 3-13, and 15 Are Rendered Obvious by Matsuno in View of the Knowledge of a POSITA and/or Rapacki

Matsuno anticipates claims 1, 3-7 and 9-15 as described above. To the extent Patent Owner argues that Matsuno does not expressly disclose certain elements of independent claims 1 or 15, it would have been obvious to combine Matsuno with the well-known knowledge of a POSITA as evidenced by, for example, U.S. Patent No. 5,569,274 ("Rapacki"). *Graham*, 383 U.S. 1; Ex. 1002, ¶193. Rapacki is in the same field of art as Matsuno (endoscopic devices) and a POSITA would have a high-level of working knowledge of the devices in Rapacki and Matsuno. Ex. 1002, ¶194. Moreover, both Matsuno and Rapacki are directed to solving the same alleged problems as the '245 patent – namely providing a device that allows an operator to accurately and easily apply a clip during an endoscopic procedure. *Id.* Both Matsuno and Rapacki, in fact, solved the same problem many years earlier. *Id.*

Rapacki is directed to an endoscopic device for applying clips during a minimally invasive procedure. Ex. 1008 at Abstract; Ex. 1002, ¶194. In particular, Rapacki is directed to the concept of repositioning the clip arms during a procedure to make it easier for a doctor to accurately apply the clip. Ex. 1008 at 2:54-3:2; Ex. 1002, ¶195. Thus, Rapacki points out what is obvious to a POSITA that

leaving the clip connected to the device allows the operator to open and close the clip before completely engaging it. Ex. 1008 at 9:20-26; Ex. 1002, ¶196. Rapacki further discusses how its repositional clip device was an improvement over the Gourlay reference relied upon by the examiner during prosecution of the '245 patent. Ex. 1008 at 2:49-3:12; Ex. 1002, ¶196.

1. Claims 1 and 15

With respect to the "reversibly operable" limitation of claims 1 and 15, no modification to Matsuno is needed to render the claims obvious. Instead, a POSITA need only take what is already implicit in Matsuno – that so long as the j-hook remains intact and attached to the clip that is not fully engaged in the lock tube, it is possible to move the clip open and closed based on retracting or protracting the control wire. Ex. 1002, ¶195. A POSITA also would be well-aware of the Rapacki patent's method of operation that describes opening and closing the clip to reposition the clip before deploying it. *Id.* The motivation to combine Rapacki and Matsuno comes from the express statements in Rapacki directed to the ability to reposition the clip before deployment. Ex. 1002, ¶¶196-98. Thus, what was implicit in Matsuno already was made explicit by Rapacki. *Id.* A POSITA needed to merely take what was already present in the prior art and operate the Matsuno device in that particular manner. *Id.*

Accordingly, claims 1 and 15 are obvious over Matsuno in view of Rapacki. The remainder of the claims (3-7 and 9-13) are obvious for at least the same reasons discussed above in Section H in that Matsuno expressly discloses each of them.

2. Claim 8 – "The medical device of claim 7, wherein the lock arrangement comprises: at least two lock holes, the number of lock holes corresponding to the number of clip legs, each of the at least two lock holes situated on a corresponding clip leg; a lock sleeve; and at least two lock pawls, the number of lock pawls corresponding to the number of clip legs, each of the at least two lock pawls situated on the lock sleeve; wherein the at least two lock holes are engageable by the at least two lock pawls."

Claim 8 is rendered obvious over Matsuno in view of the knowledge of a POSITA. Matsuno does not expressly disclose the use of lock holes on its clip legs that engage with a lock pawl on a lock sleeve. However, as discussed above for claim 7, Matsuno does disclose a lock sleeve that accomplishes the same function. In addition, elsewhere in its specification, Matsuno teaches the use of "engaging grooves" (i.e., holes or indentations) that engage with a pair of "protrusions" to lock in position members of the sliding assembly. Ex. 1007 at 6:1-54; Ex. 1002, ¶199. A POSITA could apply the same teachings of the engaging holes and protrusions used in the sliding assembly and apply them to the lock sleeve and clip in Matsuno. Ex. 1002, ¶200.

The resulting modification of Matsuno would appear as below. Ex. 1002, ¶201. This modification would not affect the function and result of the device in Matsuno, and an operator of the device would not even notice or be aware of the modification during use. Ex. 1002, ¶202. It is essentially nothing more than a minor alteration to the method of locking the clip arms in a closed position. *Id.*

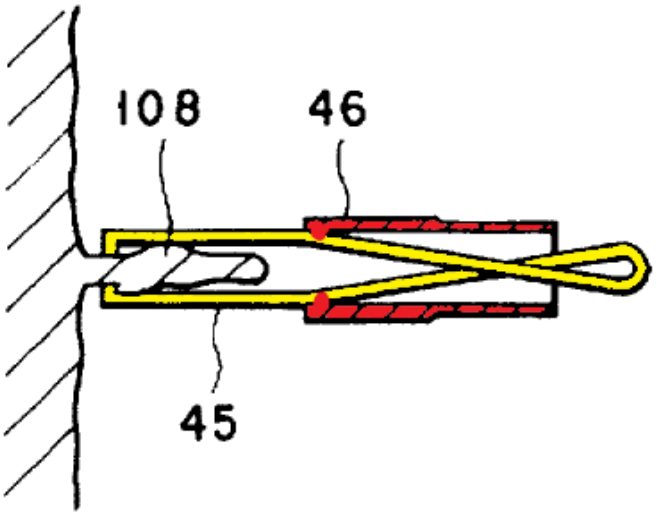
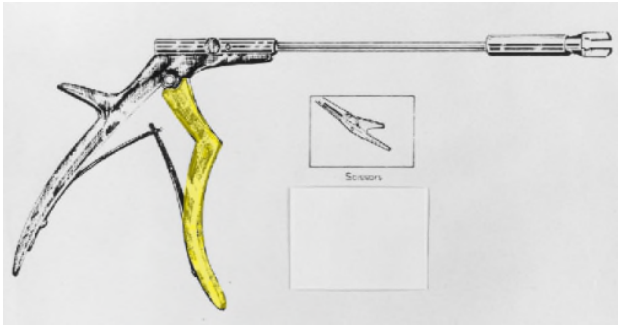


FIG. 15A

K. Ground 8: Claim 2 is Obvious Over Kortenbach I in View of Kirsch

Kortenbach I does not expressly disclose an actuator that comprises a lever as required by claim 2. Kirsch, however, discloses a common surgical clip applier in which a surgeon operates the device by "squeezing" the lever in his or her hand to retract the control wire. Ex. 1009 at 2:43-53, 4:24-38; Ex. 1002, ¶203. Indeed, handles on these types of devices were well-known and common in the industry at least as early as 1972. Ex. 1013 at 1-2; Ex. 1002, ¶203.



Such a lever would transmit only a fraction of the movement of the lever to the control wire as the size of the clip being closed is inherently smaller than the range of movement of the lever (shown in yellow). Ex. 1002, ¶204.

A POSITA would have at least two express motivations to combine the lever of Kirsch with the device of Kortenbach I. First it would require replacing the commonly used spool system of Kortenbach I, *see* Ex. 1004 at 4:54-58, with the other commonly used lever-handle system described in Kirsch. Ex. 1002, ¶205. Thus, this would simply involve substituting one known element for applying a tensile/compressive force with another to obtain predictable results. *See* MPEP Section 2143.I.B, Example 3 (citing *Ruiz v. AB Chance Co.*, 357 F.3d 1270 (Fed. Cir. 2004)); Ex. 1002, ¶205. Second, a POSITA would realize the added benefit of being able to distribute only a portion of an applied force by the operator to the clip mechanism given the disparity in the size of the clip, and thus the amount of force needed to operate the clip, and the amount of force the operator can apply using the actuator mechanism. Ex. 1002, ¶206. This was a commonly understood problem and solution in the art for many decades. *Id.*

Accordingly, the combination of Kortenbach I and Kirsch renders claim 2 obvious.

VI. CONCLUSION

Petitioners respectfully request that the Board institute *inter partes* review of and cancel claims 1-15 of the ’245 patent.

Dated: November 26, 2019

Respectfully submitted,

By: /Christopher J. Higgins/
Christopher J. Higgins

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Attorney for Petitioner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 7,094,245 contains, as measured by the word-processing system used to prepare this paper, 13,852 words. This does not include a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing.

/Christopher J. Higgins/
Christopher J. Higgins

CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a & b) on the Patent Owner via FedEx of a copy of this Petition for *Inter Partes* Review and supporting materials at the correspondence address of record for the '245 Patent:

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A courtesy copy is also being served by electronic mail to Boston Scientific Scimed, Inc.'s litigation counsel at:

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