

## Trial Decision

Invalidation 2015-800133

|                 |                          |
|-----------------|--------------------------|
| Demandant       | Asahi Intecc Co., Ltd.   |
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The case for patent invalidation trial against the invention "Medical Guidewire" in JP 4354525B between the above parties is decided as follows.

### Conclusion

The patent for the invention according to Claims 1 to 9 of JP 4354525B is declared invalid.

Trial costs should be borne by the demandee.

### Reason

#### No. 1 History of the procedures

|                    |  |
|--------------------|--|
| May 20, 2009       | : Filing of this application   |
| August 7, 2009     | : Registration of establishment (JP 4354525B)  |
| June 27, 2012      | : Request for invalidation trial in separate case<br>(Invalidation 2012-800111)                    |
| March 11, 2013     | : Decision for invalidation trial in separate case (patent valid)                                  |
| June 3, 2015       | : Request for invalidation trial in this case<br>(Invalidation 2015-800133)                        |
| August 21, 2015    | : Submission of reply to trial case by demandee<br>(hereinafter simply referred to as the "reply") |
| September 16, 2015 | : Notification of matters to be examined   |

October 15, 2015 : Submission of rebuttal by demandant  
October 30, 2015 : Submission of oral proceedings statement brief by demandee  
November 10, 2015 : Submission of oral proceedings statement brief by demandant  
November 16, 2015 : 1st oral proceedings  
November 30, 2015 : Submission of statement (hereinafter simply referred to as the "statement 1") by demandee  
December 10, 2015 : Submission of statement (hereinafter simply referred to as the "statement 2") by demandee  
December 14, 2015 : Submission of statement by demandant  
February 29, 2016 : Advanced notice of trial decision

The demandee did not respond to the advanced notice of the trial decision.

In addition, in this trial decision, when specifying the description part by line, the number of lines does not include blank lines. Also, when pointing out the provisions of the Patent Law, the phrase "Patent Law" is sometimes omitted.

## No. 2 The present invention

The inventions according to Claims 1 to 9 of the present patent (hereinafter referred to as "the present invention 1", etc., and collectively referred to as "the present invention".) are as follows, which are recited in Claims 1 to 9 of the scope of claims of the patent description.

"[Claim 1]

A medical guidewire, comprising:

a core wire having a distal end-side small-diameter portion and a proximal end-side large-diameter portion with a larger outer diameter than the distal end-side small-diameter portion;

and a coil spring attached along the axial direction to the outer circumference of the distal end-side small-diameter portion of the core wire and having a tip-side small-diameter portion, a rear end-side large-diameter portion with a larger coil outer diameter than the tip-side small-diameter portion, and a tapered portion located between the tip-side small-diameter portion and the rear end-side large-diameter portion, which is adhered to the core wire at least at the tip and the rear end portions,

characterized in that the length of the tip-side small-diameter portion of the coil spring is 5 to 100 mm, the outer diameter of the coil is 0.012 inch or less, and the tip of the coil spring is adhered to the core wire by Au-Sn based solder, and the length of the hardened

tip portion by Au-Sn based solder is 0.1 to 0.5 mm.

[Claim 2]

The medical guidewire according to Claim 1, wherein the coil outer diameter of the tip-side small-diameter portion of the coil spring is 0.010 inch or less.

[Claim 3]

The medical guidewire according to Claim 2, wherein the outer diameter of the proximal end-side large-diameter portion of the core wire and the coil outer diameter of the rear end-side large-diameter portion of the coil spring are both 0.014 inch or more.

[Claim 4]

The medical guidewire according to any of Claims 1 to 3, wherein the coil pitch at the tip-side small-diameter portion of the coil spring is 1.0 to 1.8 times the coil wire diameter, and the Au-Sn based solder penetrates into the coil in the range corresponding to 1 to 3 pitches of the coil spring.

[Claim 5]

The medical guidewire according to any of Claims 1 to 4, wherein the inside of the coil spring is filled with resin, a resin layer is formed on the outer circumference of the coil spring by the resin, a hydrophilic resin layer is laminated and formed on the surface of the resin layer, and a hydrophobic resin layer is formed on the surface of the core wire.

[Claim 6]

The medical guidewire according to Claim 5, wherein the outer circumference including the tapered portion of the coil spring is coated with the resin layer and the hydrophilic resin layer to form a taper as the shape of the guidewire, and the taper angle is smaller than the taper angle of the tapered portion of the coil spring.

[Claim 7]

The medical guidewire according to any of Claims 1 to 6, wherein the coil spring comprises a tip-side tightly wound portion with a coil pitch of 1.0 to 1.8 times the coil wire diameter and a rear end-side loosely wound portion with a coil pitch exceeding 1.8 times the coil wire diameter.

[Claim 8]

The medical guidewire according to Claim 7, wherein the tip-side small-diameter portion and tapered portion are formed by the tip-side tightly wound portion of the coil spring, and the rear end-side large-diameter portion is formed by the rear end-side loosely wound portion of the coil spring.

[Claim 9]

The medical guidewire according to any of Claims 1 to 8, wherein the core wire

is made of stainless steel."

### No. 3 Demandant's assertions

#### 1 Main points

The purpose of the claim asserted by the demandant is to request a trial decision that the patents for the present inventions 1 to 9 are invalidated and that the trial costs should be borne by the demandee.

And, the main points of the reasons for invalidation are as follows, in view of the contents of the request for a trial (hereinafter simply referred to as the "request"), the rebuttal, the oral proceedings statement brief, and the statement.

The present inventions 1 to 9 are not described in the detailed description of the invention in the description, and the scope of claims attached to the application for the present patent does not satisfy the requirements as provided in Patent Act Article 36(6)(i), and the patents for the inventions according to the present inventions 1 to 9 fall under Patent Act Article 123(1)(iv) and should be invalidated.

#### 2 Method of evidence

The method of evidence submitted by the demandant are as follows.

Evidence A1: Hajime Sudo, Imao Tamura, Taiji Nishizawa Joint authors, Metallography, Maruzen Co., Ltd., October 10, 2006, p. 27-28, cover and colophon

Evidence A2: Wikipedia "solder" section

Evidence A3: New Edition Joining Technology Overview (Edited by New Joining Technology Overview Editing Committee), Industrial Technology Service Center Co., Ltd., November 28, 1994, p. 432-435, cover and colophon

Evidence A4: Katsuaki Suganuma, Soldering Technique for Beginners, Industrial Research Institute, December 15, 2002, p. 44-46, cover and colophon

Evidence A5: Nao Osawa, Soldering Technique: Why-Why 100 Questions, Industrial Research Institute, September 20, 1997, p. 84-87, 126-129, cover and colophon

Evidence A6: Tokyo District Court 2014 (Wa) No. 25577 Plaintiff Second Briefing

Evidence A7: Katsuaki Suganuma, Revised and Enlarged Edition of Lead-free Soldering Technology, Industrial Research Institute, January 25, 2006, p. 122-133, 148-149, 206-207, 216-217, cover and colophon

Evidence A8: Standard Micro Soldering Technology First Edition (edited by the Japan Welding Association Micro Soldering Technology Certification and Examination

Committee), Nikkan Kogyo Shimbun, November 30, 1992, p. 299-303, cover and colophon

Evidence A9: Solder Material Evaluation Report 1 AMD-D15069

Evidence A10: Solder Material Evaluation Report 2 AMD-D15070

Evidence A11: Judgment of Tokyo District Court 2014 (Wa) No. 25577

Evidence A12: Judgment of Intellectual Property High Court 2012 (Gyo-Ke) No. 10151

Evidence A13: Report (Experimental report ADD-K15-001 Evaluation of tensile strength of Au-Sn based solder materials with different Au contents)

Evidence A14: Akimitsu Nakagami and Nobuyuki Kawakami, "Mechanical Characteristic Evaluation of Thin Films by Nanoindentation Method", Kobe Steel Technical Report, Vol. 52, No. 2, September 2002

Evidence A15: Wikipedia "bulk" section

### 3 Summary of assertions

A summary of the demandant's assertions is as follows.

(1) "Claims 1 to 9 of the scope of claims of the present patent comprehensively recite "Au (gold [hereinafter referred to as "Au"])-Sn (tin [hereinafter referred to as "Sn"]) solder" as a means to solve the problem of the invention, and the recitation does not specify the types of the constituent elements or the composition ratio of the elements, and furthermore, according to the demandee's assertion, it is a broad concept description of "a broad concept of solder that includes elements other than Au and Sn and intermetallic compounds with a heterogeneous structure, etc." , while they are not supported in their entirety in the description of the present patent description and exceed the description of the detailed description of the invention, and therefore, the scope of claims attached to the application for the present patent does not satisfy the requirements as provided in Patent Act Article 36(6)(i), and the present patents fall under Patent Act Article 123(1)(iv) and should be invalidated."

(Request, page 2, lines 16-26)

(2) "(e) Summary

(...omitted...)

e-1. Among the matters specifying the invention recited in Claim 1 of the present patent invention, if the wording of "Au-Sn based solder" is understood as "a solder containing Au and Sn, including a solder to which elements other than Au and Sn have been added, regarding the composition of the "Au-Sn based solder", the detailed description of the

invention of the present patent states that "the Au-Sn based solder used in the present invention, for example, consists of an alloy of Au 75 to 80% by mass and Sn 25 to 80% by mass ([0057]), and merely states that "by adhering stainless steel and platinum (alloy) using Au-Sn based solder, about 2.5 times higher adhesion strength (tensile strength) can be obtained than when adhering with Au-Sn based solder" ([0058]), even by the ordinary meaning of the wording or the technical understanding of a person skilled in the art, it must be said that the detailed description of the invention of the present patent does not clearly state that "Au-Sn based solder" in the scope of claims has the effect described in the present description in terms of its definition, specific composition and its properties (adhesion strength), i.e., the length of the hardened tip portion can be shortened to 0.1-0.5 mm (narrower adhesion area by solder), and the adhesion strength of the coil spring to the core wire can be sufficiently high (higher than the breaking strength of the distal end-side small-diameter portion of the core wire).

e-2. Furthermore, among the matters specifying the invention recited in Claim 1 of the present patent invention, If the wording of "Au-Sn based solder" is understood as "a broad concept of solder that includes elements other than Au and Sn and intermetallic compounds with a heterogeneous structure, etc." as asserted by the demandee, not only is it mentioned in the publicly known literature that intermetallic compounds are generally hard and brittle, which may weaken the solder joint, but according to the above comparative experiments, "AuSn4", a type of intermetallic compound, has the same or lower adhesion strength (tensile strength) than "Sn96.5-Ag3.5", a type of "Ag-Sn solder", and therefore, since it has been demonstrated that the effects described in the present description cannot be exerted, it is clear that the present scope of claims is not wholly supported by the description of the present description.

e-3. Therefore, since the present scope of claims includes a broad technical scope that goes beyond the technical matters, the invention according to Claim 1 among the present patent inventions violates the support requirements as provided in Patent Act Article 36(6)(i)." (Request, page 14, lines 1-34)

(3) "It is also not recognized that at the time of filing of the present patent application, there was a common technical knowledge of a person skilled in the art, such as, 'a solder containing Au and Sn (including solder containing other elements, intermetallic compounds, and heterogeneous structures) does not impair the effect of the present patent invention'." (Rebuttal, page 7, lines 19-22)

(4) "The embodiments only describe "Au-Sn based" and "Ag-Sn based" as the type of

solder used for adhering the tip and the middle parts, and do not describe their composition ratio (specific content), and therefore, it is not possible to generalize from the comparative results of the embodiments that "the adhesion strength with 'Au-Sn based solder' in the ordinary sense is higher than that with 'Ag-Sn based solder' in the ordinary sense." (Rebuttal, page 8, lines 12-16)

(5) "Concerning the matters requested by the body for clarification to "assert and prove what a person skilled in the art can recognize from the description of the detailed description of the invention and the common technical knowledge at the time of filing", the demandee states the following and asserts that these are recognizable by those skilled in the art:

○1 (Note of the body: A number in ○, such as "○1" means a number written in ○. The same shall apply hereinafter.) The specific contents of "Au" and "Sn", which are "within the range that does not impair the effect of the present patent invention" is "the amount in which they are contained as the main components".

○2 The specific names of "other elements", which are "within the range that does not impair the effect of the present patent invention" are "Ag and Pb" (A3), "Cu, In, Bi, Ag" (A4 and A7), "Sb, Bi, Cu, In, Al, As, Cd, Fe, Ni and Zn" (B5).

○3 The specific contents of "other elements" (○2 above), which are "within the range that does not impair the effect of the present patent invention" is "an amount that does not prevent Au and Sn from being contained as the main components" (the meaning is not clear, but it is understood to mean "an amount that does not exceed the amount of Au and Sn components").

However, the present description does not describe any of the above ○1, ○2 and ○3.

In addition, as for ○2 above, A3, A4, A7, and B5 do not describe at all that "solder containing Au, Sn, and the above 'other elements'" is "within the range that does not impair the effect of the present patent invention".

Also, as for ○3 above, A3, A4, A7 and B5 do not disclose or suggest anything.

Since A4, A7 and B5 do not describe the relation between the other elements "Cu, In, Bi, Ag" and "Sb, Bi, Cu, In, Al, As, Cd, Fe, Ni and Zn" and "Au-Sn based solder", the former elements are not "other elements" contained in "Au-Sn based solders".

The demandee asserts that the matters in ○1, ○2, and ○3 above are "recognizable by those skilled in the art," but no concrete evidence as to the basis of "recognizable by those skilled in the art" has been submitted, and nothing has been proven in the first place.

On the other hand, Evidence A No. 5 and Evidence A No. 8 state that when Au-based solder (Including the above "Au-Sn based solder other than solder made of an alloy of Au 75 to 80% by mass and Sn 25 to 20% by mass".) is used, intermetallic compounds, which are generally hard and brittle in nature, tend to form, which in turn may weaken the soldered part.

(···omitted···) It is common technical knowledge of those skilled in the art that "in the first place, it is usually difficult to predict what characteristic an alloy will have from its composition (components, composition range, etc.), and that increasing or decreasing the content of a certain component or adding other components will significantly change its characteristic".

Therefore, the specific content of "within the range that does not impair the effect of the present patent invention" has not been asserted or proved at all based on objective basis." (Oral proceedings statement brief by demandant, page 7, line 24 - page 8, line 2 from the bottom)

(6) The demandee's assertion that "therefore, the alloy solder (Au 75 to 80% by mass and Sn 25 to 20% by mass) described in the detailed description of the invention of the present patent can be extended or generalized to a (binary alloy) solder composed of Au and Sn, which is not limited to such a composition ratio." Based on only two examples of "eutectic solders", Au<sub>80</sub>Sn<sub>20</sub> and Au<sub>10</sub>Sn<sub>90</sub> is a leap in logic and cannot be said to be a reasonable assertion." (Statement, page 5, lines 11-16)

(7) With regard to the ternary alloy solder composed of Au, Sn, and Ag, neither Evidence A No. 3 nor Evidence B No. 10 describes or suggests any specific contents of "Au" and "Sn", which are "within the range that does not impair the effect of the present patent invention, any specific names of "other elements", which are "within the range that does not impair the effect of the present patent invention, or any specific contents of "other elements", which are "within the range that does not impair the effect of the present patent invention", and therefore, the demandee's assertion that "therefore, the alloy solder (Au 75 to 80% by mass and Sn 25 to 20% by mass) described in the detailed description of the invention of the present patent can be extended or generalized to a (ternary or higher) solder composed of Au, Sn and other elements" is a leap in logic and cannot be said to be a reasonable assertion." (Statement, page 8, lines 1-9)

No. 4 Demandee's assertions



## 1 Main Points and methods of evidence

In response, the demandee requests a trial decision that the request for this trial is not approved and that the trial costs should be borne by the demandant, based on the following method of evidence.

Evidence B1: McGraw-Hill Encyclopedia of Science and Technology Terms, Third Edition, Nikkan Kogyo Shimbun, September 30, 1996, p. 544, cover and colophon

Evidence B2: Judgment of Tokyo District Court 2014 (Wa) No. 25577

Evidence B3: Katsuaki Suganuma, Edited, Handbook of Lead-Free Soldering Technology and Materials, Industrial Research Institute, July 10, 2007, p. 197-199, cover and colophon

Evidence B4: Welding Techniques, Sanpo Publishing Co., Ltd., Vol. 60, No. 1, p. 86-90, cover and colophon

Evidence B5: JIS Z3282 (2006)

Evidence B6: INDIUM CORPORATION product data sheet

Evidence B7: Physical properties and parallel state diagram of gold-tin (AuSn) alloys of Mitsubishi Materials Corporation

(<http://www.mmc.co.jp/adv/ele/ja/products/assembly/ausn-special03.html>)

Evidence B8: JP 2008-161913A

Evidence B9: Demandant's statement in Invalidation 2012-800110

Evidence B10: JP 4305511B

Evidence B11: Journal of MATERIALS RESEARCH, Volume 20, Number 8, August 2005

Evidence B11-2: Partial translation of Evidence B No. 11

Evidence B12: JP 2000-52083A

Evidence B13: JP 4617902B

Evidence B14: JP 4811661B

Evidence B15: JP 4872764B

Evidence B16: JP 5633812B

Evidence B17: JP 5633815B

Evidence B18: JP 5633816B

Evidence B19: United States Patent No.4682607

Evidence B19-2: Translation of Evidence B No.19

Evidence B20: Intellectual Property High Court 2015 (Ne) No. 10114 Demandee's First Briefing

Evidence B21: Views Report by Prof. Masanori Kajiwara, Interdisciplinary Graduate

## 2 Summary of the assertions

The summary of the demandee's assertions is as follows.

(1)"The "Au-Sn based solder" in the scope of claims comprises Au and Sn, and may comprise other elements within a scope that does not impair the effects of the present patent invention, may comprise intermetallic compounds of the constituent elements, and it is a solder (alloy) that may comprise heterogeneous organizational structure.

In addition, the "Ag-Sn based solder" to be compared comprises Ag and Sn, and may comprise other elements, may comprise intermetallic compounds of the constituent elements, and it is a solder (alloy) that may comprise heterogeneous organizational structure." (Reply, page 5, lines 11 to 17)

(2)"The same term "Au-Sn based solder" is used in the scope of claims of the present patent and in the detailed description of the invention, particularly in the embodiments of paragraphs [0075] to [0079].

Further, there is no description that the "Au-Sn based solder" recited in the scope of claims in the detailed description of the invention is a generic concept of the "Au-Sn based solder" described in the detailed description (embodiments) of the invention.

Therefore, it is considerable to think that the "Au-Sn based solder" recited in the scope of the claims of the present patent and the "Au-Sn based solder" described in the detailed description of the invention have the same concept (scope). Thus, it is not reasonable that the term "Au-Sn based solder" is interpreted broadly in the scope of the claims (e.g., interpreted to comprise other elements) and narrowly interpreted in the detailed description of the invention (examples) (e.g., be construed as consisting only of Au and Sn)." (Oral proceedings statement brief by demandee, page 1, lines 10 to line 1 from bottom)

(3) "The present 'Au-Sn based solder' and the 'Au-Sn based solder' that is the only specific embodiment described in the detailed description of the invention have the same concept, and both are solders mainly composed of Au and Sn, and thus, it may be a structure comprising a metallic element such as Ag or an intermetallic compound such as AuSn<sub>4</sub>, or may comprise a heterogeneous alloy organizational structure. There are no grounds that the "Au-Sn based solder" used in the specific examples (embodiments) is

limited to binary based solder consisting only of Au and Sn.” (Oral proceedings statement brief by demandee, page 3, line 6 to line 1 from bottom)

(4) ”○1

(... omitted ...) The "Au-Sn based solder" of the present patent is,

- comprising Au and Sn (as the main components),
- may be comprising other elements within the "scope that does not impair the effect of the present patent invention",
- may be comprising an intermetallic compound by the constituent elements,
- may be comprising heterogeneous organizational structure.

○2 A person skilled in the art can recognize that the specific contents of "Au" and "Sn", which are "a scope that does not impair the effect of the present patent invention", are the amounts that comprised the main components.

○3 Regarding the specific names of "other elements" that are "a scope that does not impair the effect of the present patent invention", Ag and Pb described in Table 3.7 on page 434 of Evidence A3; Cu, In, Bi, Ag described in Table 3.1 on page 44 of Evidence A4 and Table 5.3 on page 123 of Evidence A7; and Sb, Bi, Cu, In, Al, As, Cd, Fe, Ni and Zn described in Table 2 (types, symbols and chemical components of lead-free solder) of Evidence B5 (JIS Z 3282 2006), can be recognized by a person skilled in the art.

Furthermore, each of the above metals described in Evidence A4, Evidence A7, and Evidence B5 do not relate to other elements in Au-Sn solder, but are represented by "M1-M2 based" and are shown as metal elements other than M1 and M2 in lead-free solders.

○4 Regarding the specific content of "other elements", which is "a scope that does not impair the effect of the present patent invention", a person skilled in the art can recognize that the amount other elements do not prevent comprising "Au" and "Sn" as the main components.

○5 Regarding the intermetallic compound of the constituent elements, there is no limitation of "a scope that does not impair the effects of the present patent invention". (... omitted ...) This is because the Au80-Sn20 solder itself is composed of an intermetallic compound, and there is no need to discuss a specific scope for the amount of the intermetallic compound.

○6 Regarding heterogeneous organizational structure, there is no limitation of "a scope that does not impair the effect of the present patent invention". (... omitted ...) This is because the Au-Sn alloy forms various phases due to changes in composition, and is considered to comprise a heterogeneous organizational structure.” (Oral proceedings statement brief by demandee, line 9 from bottom on page 5 to line 22 on page 6)

(5) "As a (binary based alloy) solder composed of Au and Sn having a bonding strength higher than that of Ag<sub>3.5</sub>Sn<sub>96.5</sub>, solder made of an alloy with an Au-rich composition (Au 75 to 80% by mass and Sn 25 to 20% by mass) close to Au<sub>80</sub>Sn<sub>20</sub>, also, solder made of an alloy with a composition close to Au<sub>10</sub>Sn<sub>90</sub> (for example, the Au content is 5 to 15% by mass as recited in Claim 1 of Evidence B8) is used, a person skilled in the art can also recognize that.

Therefore, the alloy solder (Au 75 to 80% by mass and Sn 25 to 20% by mass) described in the detailed description of the invention of the present patent can be extended or generalized to (binary based alloy) solder composed of Au and Sn, which is not limited to such a composition ratio." (Statement 1, page 3, lines 12 to 19)

(6) " From Table 1 of the above patent publication (Note of the body: Evidence B10 (Table 1 in paragraph [0025] of JP 430551B)), the mechanical strength of the "Au-Sn based solder" (Examples 1 to 12 and Comparative Example 1) having an Ag content of 20wt% or less (a specific content of Au and Sn is 80wt% or more) is as good as or better than the mechanical strength (59MPa) of "Au-Sn solder" (Comparative Example 2) having an Au 80wt% and Sn 20wt%, and it is understood that addition of 20wt% or less of Ag does not greatly change the mechanical strength of the Ag-Sn based.

(... omitted ...)

○4 As mentioned above, "Au-Sn based solder" in which the specific content (total content) of "Au" and "Sn" is 80wt% or more, the specific name of "other elements" other than Au and Sn is "Ag", and the specific content of "Ag" as "other elements" is 20wt% or less, is equivalent to or higher than "Au-Sn based solder" having Au 80wt% and Sn 20wt% of tensile strength (Considering Evidence B6 and Evidence B7 together, the tensile strength is at least remarkably higher than Ag<sub>3.5</sub>Sn<sub>96.5</sub>).

In addition, according to the demandant, who is a person skilled in the art, the higher the tensile strength of the solder, the higher the bonding strength of the solder (the tensile strength is an index of the bonding strength), and thus a person skilled in the art will recognize that "Au-Sn based solder" containing "Ag" at a rate of 20wt% or less has a bonding strength (at least higher than Ag<sub>3.5</sub>Sn<sub>96.5</sub>) that is equivalent to or greater than "Au-Sn based solder" having Au 80wt% and Sn 20wt%, therefore "Au-Sn based solder" containing "Ag" at a rate of 20wt% or less is "Au-Sn based solder" within the "scope that does not impair the effects of the present patent invention."

○5

(... omitted...)

- A person skilled in the art can recognize that the specific content of "Au" and "Sn" (the content recognized as the main component), which is "a scope that does not impair the effects of the present patent invention", is 80wt% or more, from the common technical knowledge described in Evidence A3 and Evidence B10 (further Evidence B13 to be described later).

- A person skilled in the art can recognizes that "Ag" is comprised as "another element" within the "scope that does not impair the effect of the present patent invention" from the common technical knowledge described in Evidence A3 and Evidence B10.

- A person skilled in the art can recognize that the specific content of "Ag", which is "another element" that is "a scope that does not impair the effects of the present patent invention", is 20wt% or less, from the common technical knowledge described in Evidence A3 and Evidence B10, etc.

○6 Therefore, the alloy solder (Au 75 to 80wt% and Sn 25 to 20% by mass) described in the detailed description of the invention of the present patent can be extended or generalized to (ternary based or higher) solder composed of Au, Sn and other elements.” (Statement 1, line 4 from bottom on page 4 to line 7 from bottom on page 5)

(7) "As specific names (and specific contents) of "other elements", Ge (0.03-1.5% by mass), Bi (0.1-5% by mass), Sb (0.01-1% by mass), In (0.1-5% by mass), W (0.02-0.5 % by mass), Mo (0.02-4.3 % by mass), Co (0.01-2.0% by mass), P (0.001-0.5% by mass), Zn, Te and Si can be recognized by a person skilled in the art.

In addition, according to the description of Evidence B13, a person skilled in the art can recognize that the total content of Au and Sn, which are the main components, is 80% by mass or more (the content of other elements is 20% by mass or less).” (Statement 1, page 14, lines 9 to 16)

## No. 5 Judgment by the body

### 1 Support requirement for description

The Patent Act Article 36(6)(i) provides that a claimed invention shall be disclosed in the description (hereinafter referred to as "support requirement for description"), and whether or not the description of the scope of claims satisfies the support requirement for description should be judged by considering that comparing the description of the scope of claims with the description of the detailed description of the invention, the invention described in the scope of claims is the invention described in the detailed description of the invention, and whether or not it is within the range that a person skilled in the art can

recognize that the problem of the present invention can be solved by the description of the detailed description of the invention or in light of the common technical knowledge at the time of filing even without the description or suggestion.

Therefore, in the following, the description of the scope of claims and the description of the detailed description of the invention will be confirmed for this case, and from the description of the detailed description of the invention, the problem to be solved by the present invention and means for solving the problem will be considered.

## 2 Regarding the description of the scope of claims in the present description

Claim 1 of the scope of claims according to the present Invention 1 recites that regarding a medical guidewire that "has a core wire having the distal end-side small-diameter portion and the proximal end-side large-diameter portion with an outer diameter larger than that of the distal end-side small-diameter portion, and a coil spring that is mounted along the axial direction on the outer circumference of the distal end-side small-diameter portion of the core wire, and has the tip-side small-diameter portion, the rear end-side large-diameter portion with a coil outer diameter larger than that of the tip-side small-diameter portion, and a tapered portion located between the tip-side small-diameter portion and the rear end-side large-diameter portion, and adhered to the core wire at least at the tip and rear end portions", and in which "the length of the tip-side small-diameter portion of the coil spring is 5 to 100 mm and the coil outer diameter is 0.012 inches or less", the tip portion of the coil spring is adhered to the core wire by Au-Sn based solder, and the length of the hardened tip portion by Au-Sn based solder is 0.1 to 0.5 mm.

In addition, Claims 2 to 9 in the scope of claims according to the present Inventions 2 to 9 all refer to Claim 1 of the present invention.

## 3 Regarding the description of the detailed description of the invention in the present description

The following matters are described in the present description.

### (1) "[0001]"

The present invention relates to a medical guidewire having a coil spring mounted on the outer circumference of the distal end-side small-diameter portion of the core wire, and more specifically, to a medical guidewire having high adhesion strength of the coil spring to the core wire, capable of shortening the shaping length in the shaping operation of the tip portion as compared with the conventional one, and having high bending rigidity and excellent torque transmission."

(2) "[0004]

Here, Ag-Sn based solder is used as the solder to adhere the tip portion and the rear end portion of the coil spring to the core wire because it has a low melting point and is easy to handle."

(3) "[0016]

The present invention has been made based on the above circumstances.

The first object of the present invention is to provide a medical guidewire having high adhesion strength of the coil spring to the core wire and capable of shortening the shaping length as compared with the conventional one.

The second object of the present invention is to provide a medical guidewire having excellent operability in the microchannel of CTO lesions.

The third object of the present invention is to provide a medical guidewire that is minimally invasive, has good operability when accessing microchannels, yet has sufficient bending rigidity and excellent torque transmission."

(4) "[0027]

According to the medical guidewire according to Claims 1 to 4, since Au-Sn based solder is used as the solder to adhere the tip portion of the coil spring to the core wire, despite the short length of the hardened tip portion of 0.1 to 0.5 mm (the adhered area by solder is narrow), the adhesion strength of the coil spring to the core wire can be made sufficiently high (higher than the breaking strength of the distal end-side small-diameter portion of the core wire), and even if a tensile force is applied to the core wire inserted in the coil spring, the core wire will not be pulled out.

And, since the length of the hardened tip portion is as short as 0.1 to 0.5 mm, the shaping length (bending length of the tip) can be shortened (to 0.7 mm or less), and as a result, frictional resistance can be sufficiently reduced during operation in the microchannel.

In addition, it also enables treatment in narrow areas that could not be performed using a conventional guidewire.

[0028]

The medical guidewire of the present invention has excellent operability in the microchannel of CTO lesions due to the thin coil outer diameter of 0.012 inches or less at the tip-small-diameter portion, high adhesion strength by Au-Sn based solder, and the short hardened tip portion of 0.1 to 0.5 mm.

The coil spring that constitutes the medical guidewire of the present invention

ensures bending rigidity and has excellent torque transmission, by having the rear end-side large-diameter portion with a large coil outer diameter due to the tip-side small-diameter portion."

(5) "[0057]

The medical guidewire of the present invention is characterized in that Au-Sn based solder is used as the solder to adhere the tip-side small-diameter portion of the coil spring to the core wire.

The Au-Sn based solder used in the present invention, for example, consists of an alloy of Au 75 to 80% by mass and Sn 25 to 20% by mass.

[0058]

By adhering stainless steel and platinum (alloy) using Au-Sn based solder, the adhesion force (tensile strength) of about 2.5 times can be obtained as compared with the case of adhering by Ag-Sn based solder.

Therefore, even when the length of the hardened tip portion is as short as 0.1 to 0.5 mm (when the solder penetration range is 1 to 3 times the coil pitch), the adhesion strength of the coil spring 20 to the core wire 10 can be made sufficiently high, and specifically, it can be made higher than the tensile breaking strength of the distal end-side small-diameter portion 11 of the core wire 10. Therefore, even if a tensile force is applied between the coil spring 20 and the core wire 10, it is possible to prevent the core wire 10 from being pulled out.

In addition, Au-Sn based solder is superior to Ag-Sn based solder in contrast imaging properties.

Furthermore, Au-Sn based solder is also superior to Ag-Sn based solder in corrosion resistance to blood and body fluids."

(6) "[0060]

As shown in Fig. 1 and Fig. 3(C), the rear end portion of the rear end-side large-diameter portion 23, which is the rear end portion of the coil spring 20, is adhered to the core wire 10 by Ag-Sn based solder 33.

That is, the Ag-Sn based solder 33 permeates the inside of the rear end portion (the rear end portion of the rear end-side large-diameter portion 23) of the coil spring 20 and comes into contact with the outer circumference of the core wire 10 (the distal end-side small-diameter portion 11), thereby the rear end portion of the coil spring 20 is adhered to the core wire 10 (the distal end-side small-diameter portion 11).

[0061]



In the distal end-side small-diameter portion 11 of the core wire 10, since the outer diameter of the portion to which the rear end-side large-diameter portion 23 of the coil spring 20 is adhered is larger than the outer diameter of the portion (distal end) to which the tip-side small-diameter portion 21 of the coil spring 20 is adhered (the adhered area is relatively large), Ag-Sn based solder having lower adhesion force than Au-Sn based solder can be used."

According to the above description, the detailed description of the invention in the present description describes that Ag-Sn based solders have been used to adhere the tip and rear end portions of the coil springs to the core wire because it has a low melting point and is easy to handle ((1) and (2) above), in a conventional medical guidewire having a coil spring mounted to the outer circumference of the distal end-side small-diameter portion of the core wire, but, since by adhering stainless steel and platinum using Au-Sn based solder, higher adhesion force (tensile strength) can be obtained as compared with the case of adhering using Ag-Sn based solder ((4) and (5) above), despite the short length of the hardened tip portion, the adhesion strength of the coil spring to the core wire can be made sufficiently high and the length of the hardened tip portion can be shortened, so that frictional resistance can be reduced during operation within the microchannel, making it possible to treat in narrow areas that could not be treated using conventional guidewires ((3) and (4) above), and a guidewire with excellent operability is provided by the thin wire diameter of 0.012 inches or less, the high adhesion strength of the Au-Sn based solder, and the short hardened tip portion of 0.1 to 0.5 mm ((4) above).

Therefore, based on the description in the detailed description of the invention, it can be understood that the problem to be solved by the present invention is that conventional guidewires with a wire diameter of 0.012 inches or less use Ag-Sn based solder, and since the adhesion strength of the solder is low and the adhesion area cannot be reduced, the shaping length (the bending length of the tip of the guidewire), which depends on the size of the adhesion area, could not be shortened, and can be understood that the present invention uses as a means for solving the problem that the tip portion of the coil spring is adhered to the core wire using Au-Sn based solder and the length of the hardened tip portion by the Au-Sn based solder shall be 0.1 to 0.5 mm, and by adopting this means, a medical guidewire with a coil outer diameter of 0.012 inches or less exerts an effect that the desired adhesion strength and the shaping length can be satisfied.

Further, as a specific example of the Au-Sn based solder, an alloy of Au 75 to 80% by mass and Sn 25 to 20% by mass is exemplified (see (5) above).

4 Regarding the support requirement for the present description

It will be examined below whether or not the present invention, that is, the guidewire described in the scope of claims using Au-Sn based solder is within the range that can be recognized as being able to solve the above problem of the present invention based on the matters described for the guidewire using Au-Sn based solder in the detailed description of the invention, or in light of the common technical knowledge at the time of filing of the patent application, even without such a description or suggestion.

(1) Regarding "Au-Sn based solder" in the present invention

The scope of claims in the present invention describes as a specific matter that the tip of the coil spring is adhered to the core wire by Au-Sn based solder and the length of the hardened tip portion by Au-Sn based solder is 0.1 to 0.5 mm.

However, regarding "solder", it merely specifies the use of "Au-Sn based solder" and does not specify any specific content of Au and Sn, the presence or absence of other elements or intermetallic compounds, or specific examples and content of other elements or intermetallic compounds when other elements or intermetallic compounds are included.

Further, there is no particular definition of the term "Au-Sn based solder" in the detailed description of the invention.

Then, since the "Au-Sn based solder" described in the scope of claims can only be interpreted as a general technical term, in the following, it is considered what "Au-Sn based solder" as a general technical term is.

A From the description that "A thing in which two or more kinds of metals or metals and non-metals are melted is called an alloy, and is distinguished from binary alloys, ternary alloys, etc., according to the number of constituent elements" in Evidence A1, page 27, lines 4 to 6, and that "Solder is an alloy containing lead and tin as the main components used for soldering (... omitted ...) Lead-free solder that does not contain lead is often used" in Evidence A2, page 1, lines 2 to 10, since solder is a type of alloy and it is recognized that the expression "-based" is used to describe its components (constituent elements), it is clear from the wording that "Au-Sn based solder" as a general technical term contains Au and Sn as the main components.

B From the description in the column of Au-based solder on page 433 (5) and Table 3.7 on page 434 in Evidence A No. 3, it is understood that "Au-Sn based solder" as a general technical term includes both solder composed of only Au and Sn and solder as an alloy composed of Au, Sn and other elements such as Ag.

C From the product data sheet column in Evidence B6, the table of “Physical Properties” in Evidence B7, and the description in paragraphs [0002] to [0003] in Evidence B8, It is understood that “Au-Sn based solder” as a general technical term includes not only the component ratios of Au 75 to 80% by mass and Sn 25 to 20% by mass, but also various ratios as the component ratios of both when composed of only Au and Sn.

D From the description on page 45, line 7 to page 46, line 16 and Fig. 3.2 in Evidence A4, It is understood that “Au-Sn based solder” as a general technical term may include elements other than Au and Sn, intermetallic compounds having a non-uniform structure such as AuSn<sub>4</sub>, and the like.

Summarizing the above A to D, “Au-Sn based solder” as a general technical term needs to be a solder containing Au and Sn as the main components, and may or may not contain other elements other than Au and Sn or intermetallic compounds, and if it does not, it is recognized as a "solder" without any limitation on the component ratio of Au and Sn.

In addition, this interpretation is also consistent with the demandee's assertion regarding the interpretation of "Au-Sn based solder" in view of No.4-2(1) and (3).

## (2) Judgment for support requirement for the present description

As described above, "Au-Sn based solder" described in the scope of claims should be understood to mean "Au-Sn based solder" as a general technical term, and it will be examined whether or not the guidewire described in the scope of claims using "Au-Sn based solder" as a general technical term is within the range that a person skilled in the art can recognize that the above problem of the present invention can be solved from the matters described for the guidewire using Au-Sn based solder in the detailed description of the invention, or in light of the common technical knowledge at the time of filing without the description or suggestion.

Looking at the detailed description of the invention in the present description, as a means for solving the above problem to be solved by the present invention, examples and effects thereof are merely described for guidewires using Au 75 to 80% by mass and Sn 25 to 20% by mass, as discussed in 3 above, and in the case of a guidewire using a solder consisting of two components of Au and Sn, there is no disclosure in the detailed description of the invention as to what component ratio of solder other than Au 75 to 80% by mass and Sn 25 to 20% by mass should be used to solve the above problem.

In addition, in the case of a guidewire using solder containing Au and Sn and other elements other than Au and Sn, or intermetallic compounds, there is no disclosure in the detailed description of the invention as to what other elements are used and how much content of solder is used to solve the above problem.

Therefore, considering the common technical knowledge at the time of filing, it cannot be recognized that it is common technical knowledge that the guidewire described in the scope of claims using "Au-Sn based solder" as a general technical term has higher adhesion strength than using Ag-Sn based solder, even if solder of any component ratio is used, and when the tip of the coil spring is adhered to the core wire using Au-Sn based solder, the shaping length can be shortened as compared with using Ag-Sn based solder, and there is no evidence sufficient to recognize that it can be recognized as such.

Rather, it is usually difficult to predict what properties an alloy will have from its composition (components and composition range, etc.), and in light of the fact that it is common technical knowledge of a person skilled in the art that if the content of a certain component is slightly increased or decreased, or if another component is added even slightly, its property will change significantly, it is almost impossible for a person skilled in the art to predict that a guidewire using "Au-Sn based solder" as a general technical term can always solve the above problem regardless of the specific components of the solder.

In view of this, it cannot be said for a person skilled in the art that the guidewire described in the scope of claims using "Au-Sn based solder" as a general technical term is within the range that a person skilled in the art can recognize that the guidewire can solve the above problem of the present invention even in light of the common technical knowledge at the time of filing.

### (3) Regarding the demandee's assertion

It is recognized that the demandee asserts that regarding Au-Sn based solder as a general technical term, specific numerical values of the contents of each element and the like are mentioned in the assertion of No. 4-2 (5) to (7) above, and Au-Sn based solder as a general technical term can solve the above problem.

These assertions are organized into the three assertions; the assertion about the contents of Au and Sn in Au-Sn based solder composed of Au and Sn, (No.4-2 (5) above), the assertion about the contents of each element in Au-Sn based solders containing other elements or intermetallic compounds (No. 4-2 (6) and (7) above), and the assertion about the lower limit of the total content of Au and Sn in Au-Sn based solder (No. 4-2 (6) and

(7) above), but they are not adoptable as described in A to C below.

A The demandee asserts that in view of the above assertion of No. 4-2(5), a person skilled in the art can recognize solders made of alloys having an Au-rich composition (Au 75-80% by mass and Sn 25-20% by mass) close to Au<sub>80</sub>Sn<sub>20</sub> as a (binary alloy) solder composed of Au and Sn, which has higher bonding strength than Ag<sub>3.5</sub>Sn<sub>96.5</sub>, according to Evidence B6 to 8, as well as eutectic solders made of alloys having a composition close to Au<sub>10</sub>Sn<sub>90</sub> (for example, the content of Au is 5 to 15% by mass as recited in Claim 1 of Evidence B8), and therefore, the alloy solder (of Au 75 to 80% by mass and Sn 25 to 20% by mass) described in the detailed description of the invention in the present description can be extended or generalized to a (binary alloy) solder composed of Au and Sn, which is not limited to such a composition ratio.

However, from Evidence B6 to 8, It can only be recognized that Au<sub>80</sub>Sn<sub>20</sub> and Au<sub>10</sub>Sn<sub>90</sub>, which are examples of "Au-Sn based solder" as a general technical term, have higher bonding strength than Ag<sub>3.5</sub>Sn<sub>96.5</sub>, which is one of Ag-Sn based solders, and cannot be determined that "Au-Sn based solder" as a general technical term other than these has higher bonding strength than Ag-Sn based solder.

In addition, the demandee has not submitted any other method of evidence that any content of Au and Sn, other than eutectic solder, has higher adhesion strength than general Ag-Sn based solder other than solder consisting of Ag<sub>3.5</sub>Sn<sub>96.5</sub>, and as to whether or not a person skilled in the art can recognize that the problem identified in 3 above can be solved.

Then, from Evidence B6 to 8 submitted by the demandee, it is not recognized the demandee's assertion that the alloy solder (of Au 75 to 80% by mass and Sn 25 to 20% by mass) described in the detailed description of the invention of the present description can be extended or generalized to solders having any content other than the component ratios of Au 75 to 80% by mass and Sn 25 to 20% by mass, when it is composed only of Au and Sn.

B The demandee asserts that in view of the above assertion of No. 4-2 (6), according to Evidence A3 and Evidence B6, 7, 10 and 13, since a person skilled in the art can recognize that a (ternary alloy) solder composed of Au and Sn, which has a higher bonding strength than Ag<sub>3.5</sub>Sn<sub>96.5</sub>, is shown and the "Au-Sn based solder" containing "Ag" in a proportion of 20 wt% or less has a bonding strength equal to or higher than that of the "Au-Sn based solder" composed of Au 80 wt% and Sn 20 wt% (at least higher bonding strength than Ag<sub>3.5</sub>Sn<sub>96.5</sub>), the "Au-Sn based solder" containing "Ag" in a proportion of

20 wt% or less is an "Au-Sn based solder" within the "range that does not impair the effects of the present patent invention", and the specific content of "Au" and "Sn" (content recognized as the main component), which is "a range that does not impair the effect of the present patent invention", is 80% by weight or more, and "Ag" is included as "other elements" which is "a range that does not impair the effect of the present patent invention", and the specific content of "Ag", which is a "other element" that is "a range that does not impair the effects of the present patent invention", is 20% by weight or less, and further, the alloy solder (of Au 75 to 80% by weight and Sn 25 to 20% by mass) described in the detailed description of the invention in the present patent can be extended or generalized to solders (more than ternary) composed of Au, Sn and other elements.

In addition, in view of the assertion in No. 4-2 (7) above, the demandee asserts that a person skilled in the art can recognize Ge (0.03 to 1.5% by mass), Bi (0.1 to 5% by mass), Sb (0.01 to 1% by mass), In (0.1 to 5% by mass), W (0.02 to 0.5% by mass), Mo (0.02 to 4.3% by mass), Co (0.01 to 2.0% by mass), P (0.001 to 0.5% by mass), Zn, Te and Si as specific names (and specific contents) of "other elements".

However, from Evidence A3 and Evidence B6, 7 and 10, some solders, which are examples of "Au-Sn based solders" as a general technical term, only show higher bonding strength than Ag<sub>3.5</sub>Sn<sub>96.5</sub>, which is one of the Ag-Sn based solders, and then, it cannot be determined that "Au-Sn based solder" as a general technical term other than these has higher bonding strength than Ag-Sn based solder.

In addition, from Evidence B13, it cannot be determined that "Au-Sn based solder" as a general technical term containing Ge (0.03 to 1.5% by mass), Bi (0.1 to 5% by mass), Sb (0.01 to 1% by mass), In (0.1 to 5% by mass), W (0.02 to 0.5% by mass), Mo (0.02 to 4.3% by mass), Co (0.01 to 2.0% by mass), P (0.001 to 0.5% by mass), Zn, Te and Si as "other elements", has higher bonding strength than Ag-Sn based solder.

In the first place, "Ag-Au-Sn based solder" is described in Evidence B10, paragraph [0023], and regarding Examples 1 to 12 in Table 1, the demandee asserts on the premise that it is not "Ag-Sn based solder" but "Au-Sn based solder", but regarding the "Ag-Au-Sn based solder" shown in Examples 1 to 12 in Table 1, it does not provide an objective basis that it can be recognized for a person skilled in the art that "Au-Sn based solder" that is compared to "Ag-Sn based solder" is understood.

In addition, the demandee has not submitted any other method of evidence as to whether or not a person skilled in the art can recognize that the problem identified in 3 above can be solved, regardless of the content of Au and Sn, the specific element of the other elements, and the specific content of the other elements, if Au and Sn are the main

components, when "Au-Sn based solder" as a general technical term contains other elements.

Then, from Evidence A3 and Evidence B6, 7, 10 and 13 submitted by the demandee, it is not recognized that alloy solders (of Au 75 to 80% by mass and Sn 25 to 20% by mass) described in the detailed description of the invention of the present description, can be extended or generalized to solders of the form containing other elements other than Au and Sn or intermetallic compounds, which is not limited to such a composition ratio.

C The demandee asserts that in view of the assertions of No. 4-2 (6) and (7) above, if the total content of Au and Sn is 80 wt% or more, it is within the range that does not impair the effect of the present invention.

However, this assertion cannot be adopted because it is not based on the description of the scope of claims.

Further, there is no evidence that specifies a lower limit for the total content of Au and Sn in "Au-Sn based solder" as a general technical term, and needless to say, no mention is made of how much of the above total content is required to solve the above problem.

#### (4) Summary

As discussed in (2) above, since it cannot be said for a person skilled in the art in contact with the present description that all forms of the guidewire described in the scope of claims using "Au-Sn based solder" as a general technical term, are described in the detailed description of the invention, and moreover, as it is not recognized that the detailed description of the invention suggests it, it cannot be said that the guidewire described in the scope of claims using "Au-Sn based solder" as a general technical term is within the range that a person skilled in the art can recognize that the above problem can be solved by the detailed description of the invention.

In addition, it cannot be said for a person skilled in the art that the guidewire described in the scope of claims using "Au-Sn based solder" as a general technical term is within the range that a person skilled in the art can recognize that the above problem of the present invention can be solved in light of the common technical knowledge at the time of filing.

In addition, as discussed in (3) above, even if the demandee's assertions are taken into consideration, it cannot be said that it is enough to overturn the above judgment.

Therefore, it cannot be said that the recitation of Claim 1 in the scope of claims in

the present description satisfies the support requirement for the description.

Further, it also cannot be said that the recitations of Claims 2 to 9 that cite Claim 1 satisfy the support requirement for the same reason.

As described above, it cannot be said that the guidewire using the "Au-Sn based solder" of the present invention is supported by the description of the detailed description of the invention in the present description and the common technical knowledge at the time of filing.

#### No. 6 Closing

As described above, since the present invention cannot be said to have been described in the detailed description of the invention, the description of the scope of claims in the present description does not satisfy the requirement of provision of the Patent Act Article 36(6)(i).

Therefore, since the patent for the present invention has been granted for a patent application that does not satisfy the requirement of provision of the Patent Act Article 36(6)(i), it falls under the Patent Act Article 123(1)(iv) and should be invalidated.

The trial costs shall be borne by the demandee pursuant to the provisions of Article 61 of the Code of Civil Procedure, which is applied mutatis mutandis pursuant to the provisions of the Patent Act Article 169(2).

Therefore, the trial decision shall be made as described in the conclusion.

June 7, 2016

Chief administrative judge: TAKAGI, Akira

Administrative judge: MIYASHITA, Koji

Administrative judge: SEKIYA, Kazuo