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(54) **Method for shaping a position stabilizing body and waterjet surgery system**

(57) A waterjet surgery system (1) comprising a water pump (3), a fluid line (4) and a nozzle (5), wherein the fluid line (4) connects the water pump (3) to the nozzle (5), wherein the nozzle (5) is embodied within a position stabilizing body (8), and a method for shaping such a position stabilizing body (8) comprising the steps of:

- imaging hard tissue (16), particularly bones (10), of a patient (15) on which surgery is to be carried out; and
- forming a nozzle within a position stabilizing body (8) by rapid prototyping, wherein the position stabilizing body (8) is shaped to match the shape of the bones (10) of the patient (15) at a position which has to be subjected to surgery.

The position stabilizing body (8) is provided with fixation means (9) to fix the position of the body (8) in relation to an external object (10). The fixation means can be embodied with pins. Alternatively the fixation means (9) can comprise inflation means (11) mounted on the position stabilizing body (8). The inflation means (11) can comprise an inflatable cushion (12). The fixation means (9) can further comprise a friction coating (13) provided on the position stabilizing body (8) and/or on inflation means (11) provided on the position stabilizing body (8). It is also possible that the position stabilizing body (8) is shaped to match the shape of an external object (10) on which it is to be applied.

NL B1 2024233

Method for shaping a position stabilizing body and waterjet surgery system

The invention relates to a waterjet surgery system comprising a water pump, a fluid line and a nozzle, wherein the fluid line connects the water pump to the nozzle.

EP 1 589 884 teaches an example of such a waterjet surgery system.

In waterjet surgery of hard tissue, particularly bone, a relatively high water pressure is required to drill or bore into the tissue. This poses a challenge on the positioning of the nozzle because of the thrust force that results from the waterjet being expelled from the nozzle, which may undesirably move the nozzle from its intended position. It is however a requirement in waterjet surgery to keep the nozzle stationary so as not to compromise the patient's safety and to maintain a high level of accuracy during execution of the waterjet surgery.

The invention is aimed at providing a solution for the above pictured problem. According to the invention the solution is promoted by applying one or more of the appended claims.

Essentially the invention provides that the nozzle is embodied within a position stabilizing body, such as a disc.

There are different embodiments for the position stabilizing body of the invention, which each can be applied independently from the other, or in combination.

The position stabilizing body of the invention can in one embodiment be provided with fixation means to fix the position of the body in relation to an external object.

In another embodiment the position stabilizing body of the invention can have fixation means which are embodied as pins.

In still another embodiment the fixation means comprise inflation means mounted on the position stabilizing body.

Suitably the inflation means are embodied as an inflatable cushion.

In still another embodiment the fixation means comprise a friction coating provided on the position stabilizing body. The friction coating can also be provided on the inflation means, notably on the cushion. With such a friction coating it is possible to either increase or to lower the friction, depending on the circumstances.

In still a further embodiment the position stabilizing body is shaped to match the shape of an external object on which the body with the nozzle is to be applied.

In connection with the embodiment of the body as used according to the previous paragraph, the invention is also embodied in a method for shaping a position stabilizing body for use in a waterjet surgery system according to the invention, comprising the steps of:

- imaging hard tissue, particularly bones, of a patient on which surgery is to be carried out; and
- forming a nozzle within a position stabilizing body by rapid prototyping, wherein the position stabilizing body is shaped to match the shape of the bones of the patient at a position which has to be subjected to surgery. With the term 'rapid prototyping' as used herein, reference is made for instance to additive manufacturing.

The invention will hereinafter be further elucidated with reference to the drawing of an exemplary embodiment of a waterjet surgery system according to the invention that is not limiting as to the appended claims.

In the drawing:

-figure 1 shows a waterjet surgery system wherein the position stabilizing body with the nozzle according to the invention can be applied;

-figures 2A/2B show one embodiment of the position stabilizing body which can be used in the waterjet surgery system of the invention;

-figure 3 shows an example of using the position stabilizing body with the nozzle of the invention;

-figure 4 pictures the method for shaping a position stabilizing body with a nozzle according to the invention; and

-figure 5 shows an example of using the position stabilizing body manufactured according to the method depicted in figure 4.

Whenever in the figures the same reference numerals are applied, these numerals refer to the same parts.

Making first reference to figure 1 a waterjet surgery system 1 is shown which comprises a source of water 2, a cylinder piston pump 3, and a fluid line 4 with a jet nozzle 5 which can be directed to an object which is to be cut or drilled. It is remarked that whenever in this application water is mentioned, it is not intended to refer to pure water, but to water which is suitable for medical applications and which accordingly comprises a saline solution derived from a storage 2.

The cylinder piston pump 3 with a piston 6 and a spring 7 that loads the piston 6 is only shown as an example of a possible embodiment of a pump. Other arrangements are also feasible.

The invention comes into play where it concerns the implementation of the nozzle 5.

Figures 2A and 2B show an embodiment of a position stabilizing body 8, which features the nozzle (not shown), usually located at the underside 8' of the body 8. The position stabilizing body 8, in this example a disc, is provided with fixation means 9 to fix the position of the body 8 in relation to an external object such as is shown in figure 3 with reference to a bone structure 10. In the shown embodiment the fixation means 9 are inflation means 11, preferably an inflatable cushion 12, mounted on the position stabilizing body 8. This is however not the only option. It is for instance also possible to provide the position stabilizing body 8 with outwardly projecting pins. This is not shown in the drawing of the figures, but how this can be implemented is entirely clear for the skilled person and it is therefore superfluous to show same in the drawing of the figures.

Figure 2A shows the position stabilizing body 8 wherein the inflatable cushion 12 is not yet inflated, whereas figure 2B shows the position stabilizing body 8 wherein inflation of the inflatable cushion 12 is completed. Accordingly

when arrived at a partly or fully inflated situation as show in figure 2B it is possible to fix the position of the position stabilizing body 8 when in use as is depicted in figure 3.

It is further possible to apply a friction coating 13 on the position stabilizing body 8. Such a friction coating can also be applied on the inflatable cushion 12, or in general on the inflation means 11, as depicted with reference 14.

In figure 4 a method is depicted for manufacturing and shaping a position stabilizing body 8 for use in a waterjet surgery system 1 as shown in figure 1. In this method first hard tissue 16 representing a bone structure 10 of a patient 15 is being imaged, as is shown in figure 4A and 4B. Thereafter a position stabilizing body 8 with a nozzle is formed by rapid prototyping as depicted in figure 4C, wherein the position stabilizing body 8 is shaped to match the shape of the bones 10 of the patient 15 at a position which has to be subjected to surgery. The eventual position stabilizing body 8 to be used is shown in figure 4D and in figure 5 same is shown in actual use. Figure 4D further images a waterjet stream 17, indicating the position of the nozzle (not shown) at the underside 8' of the position stabilizing body 8.

Although the invention has been discussed in the foregoing with reference to an exemplary embodiment of the position stabilizing body and an exemplary method for manufacturing such a position stabilizing body, the invention is not restricted to these particular embodiments which can be varied in many ways without departing from the invention. The body used exemplary embodiments shall therefore not be used to construe the appended claims strictly in accordance therewith. On the contrary the embodiments are merely intended to explain the wording of the appended claims without intent to limit the claims to these exemplary embodiments. The scope of protection of the invention shall therefore be construed in accordance with the appended claims only, wherein a possible ambiguity in the wording of the claims shall be resolved using these exemplary embodiments.

Aspects of the invention are itemized in the following section.

1. A waterjet surgery system (1) comprising a water pump (3), a fluid line (4) and a nozzle (5), wherein the fluid line (4) connects the water pump (3) to the nozzle (5), characterized in that the nozzle (5) is embodied within a position stabilizing body (8).
2. Waterjet surgery system according to claim 1, characterized in that the position stabilizing body (8) is provided with fixation means (9) to fix the position of the body (8) in relation to an external object (10).
3. Waterjet surgery system according to claim 1 or 2, characterized in that the fixation means are embodied with pins.
4. Waterjet surgery system according to any one of claims 1 - 3, characterized in that the fixation means (9) comprise inflation means (11) mounted on the position stabilizing body (8).
5. Waterjet surgery system according to claim 4, characterized in that the inflation means (11) comprise an inflatable cushion (12).
6. Waterjet surgery system according to any one of claims 1 - 5, characterized in that the fixation means (9) comprise a friction coating (13) provided on the position stabilizing body (8) and/or on inflation means (11) provided on the position stabilizing body (8).
7. Waterjet surgery system according to any one of claims 1 - 6, characterized in that the position stabilizing body (8) is shaped to match the shape of an external object (10) on which it is to be applied.
8. Method for shaping a position stabilizing body (8) for use in a waterjet surgery system (1) according to any one other claims 1 - 7, characterized by the steps of:
   - imaging hard tissue (16), particularly bones (10), of a patient (15) on which surgery is to be carried out; and
   - forming a nozzle within a position stabilizing body (8) by rapid prototyping, wherein the position stabilizing body (8) is shaped to match the shape of the bones (10) of the patient (15) at a position which has to be subjected to surgery.

CONCLUSIES

1. Waterstraalchirurgiesysteem (1) omvattende een waterpomp (3), een vloeistofleiding (4) en een mondstuk (5), waarbij de vloeistofleiding (4) de waterpomp (3) verbindt met het mondstuk (5), **met het kenmerk, dat** het mondstuk (5) is opgenomen in een positie-stabiliserend lichaam (8).

2. Waterstraalchirurgiesysteem volgens conclusie 1, **met het kenmerk, dat** het positie-stabiliserende lichaam (8) is voorzien van fixatiemiddelen (9) om de positie van het lichaam (8) ten opzichte van een extern object (10) te fixeren.

3. Waterstraalchirurgiesysteem volgens conclusie 1 of 2, **met het kenmerk, dat** de fixatiemiddelen zijn uitgerust met pennen.

4. Waterstraalchirurgiesysteem volgens één van de conclusies 1 - 3, **met het kenmerk, dat** de fixatiemiddelen (9) opblaasmiddelen (11) omvatten die zijn gemonteerd op het positie-stabiliserende lichaam (8).

5. Waterstraalchirurgiesysteem volgens conclusie 4, **met het kenmerk, dat** de opblaasmiddelen (11) een opblaasbaar kussen (12) omvatten.

6. Waterstraalchirurgiesysteem volgens één van de conclusies 1-5, **met het kenmerk, dat** de fixatiemiddelen (9) een wrijvingscoating (13) omvatten die is aangebracht op het positie-stabiliserende lichaam (8) en / of opblaasmiddelen (11) aangebracht op het positie-stabiliserende lichaam (8).

7. Waterstraalchirurgiesysteem volgens één van de conclusies 1 - 6, **met het kenmerk, dat** het positie-stabiliserende lichaam (8) in vorm is afgestemd op de vorm van een extern object (10) waarop het moet worden aangebracht.

8. Werkwijze voor het vormen van een positie-stabiliserend lichaam (8) voor gebruik in een waterstraalchirurgiesysteem (1) volgens een van de andere conclusies 1-7, **gekenmerkt door** de stappen:

- beeldvorming van hard weefsel (16), in het bijzonder botten (10), van een patiënt (15) waarop een operatie moet worden uitgevoerd; en
- het vormen van een mondstuk in een positie-stabiliserend lichaam (8) door snelle prototyping, waarbij het positie-stabiliserende lichaam (8) een vorm wordt gegeven die afge-

stemd is op de vorm van de botten (10) van de patiënt (15) op een positie die moet worden onderworpen aan een operatie.

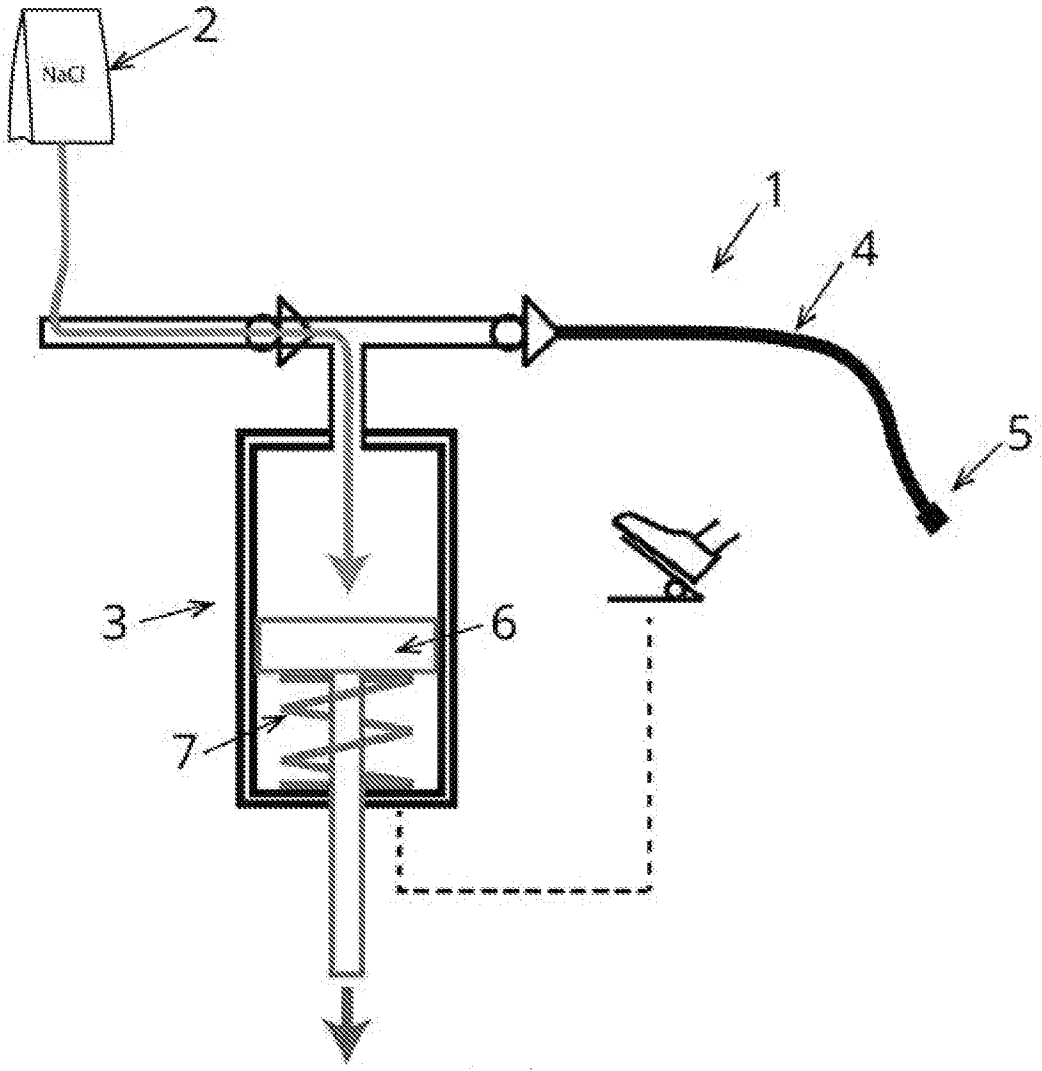

Fig. 1

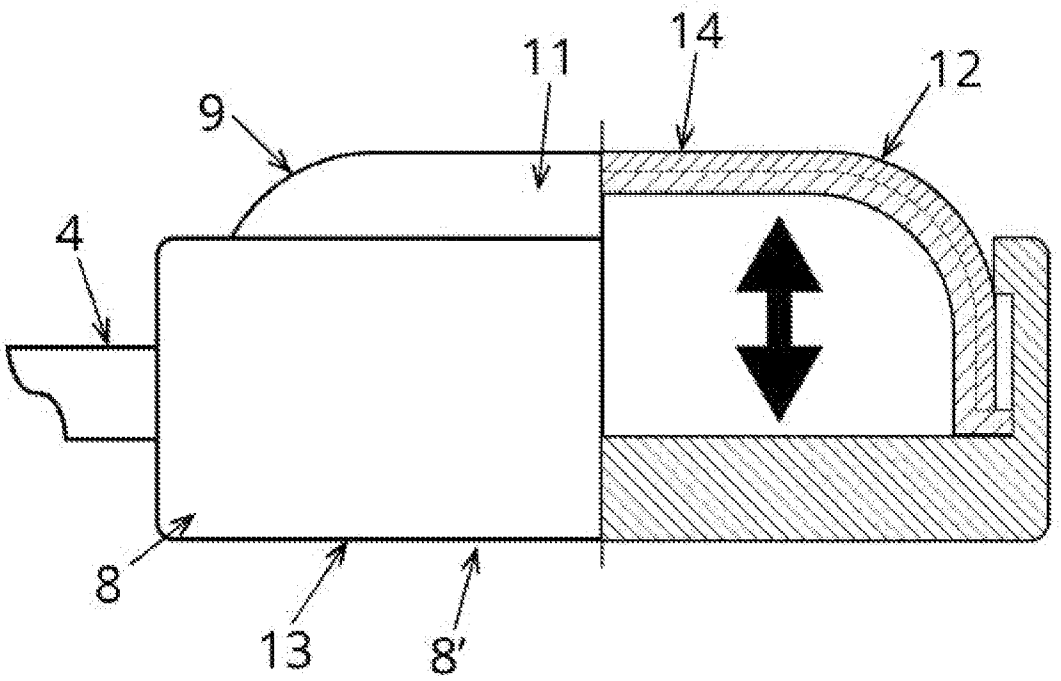

Fig. 2A

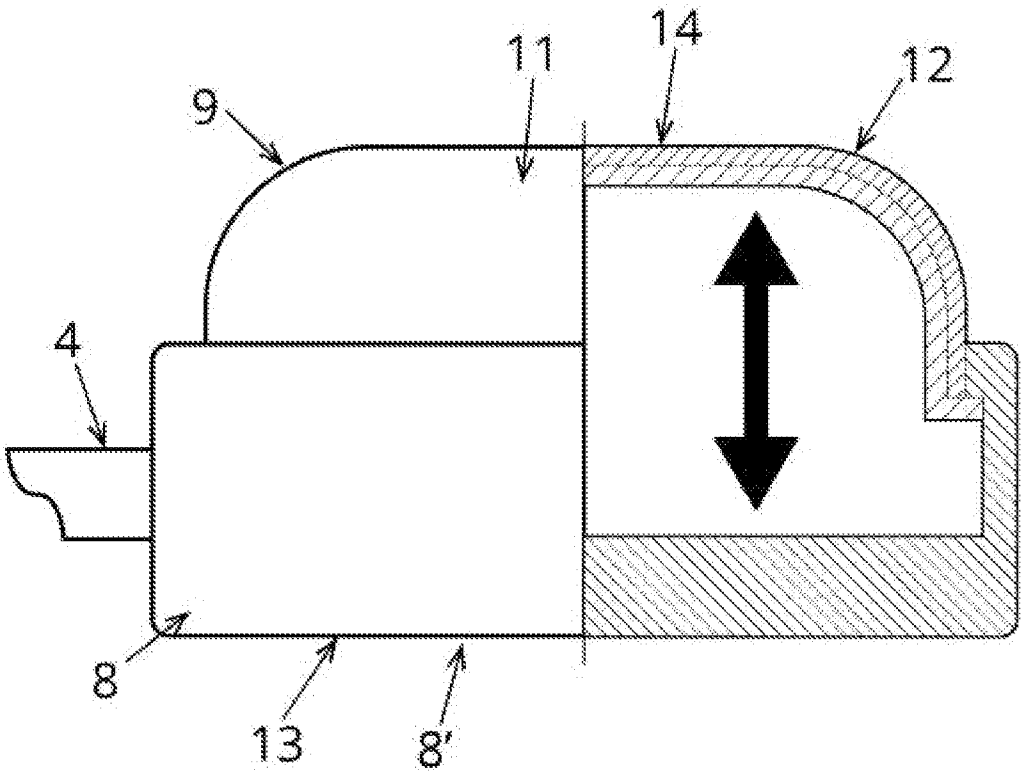

Fig. 2B

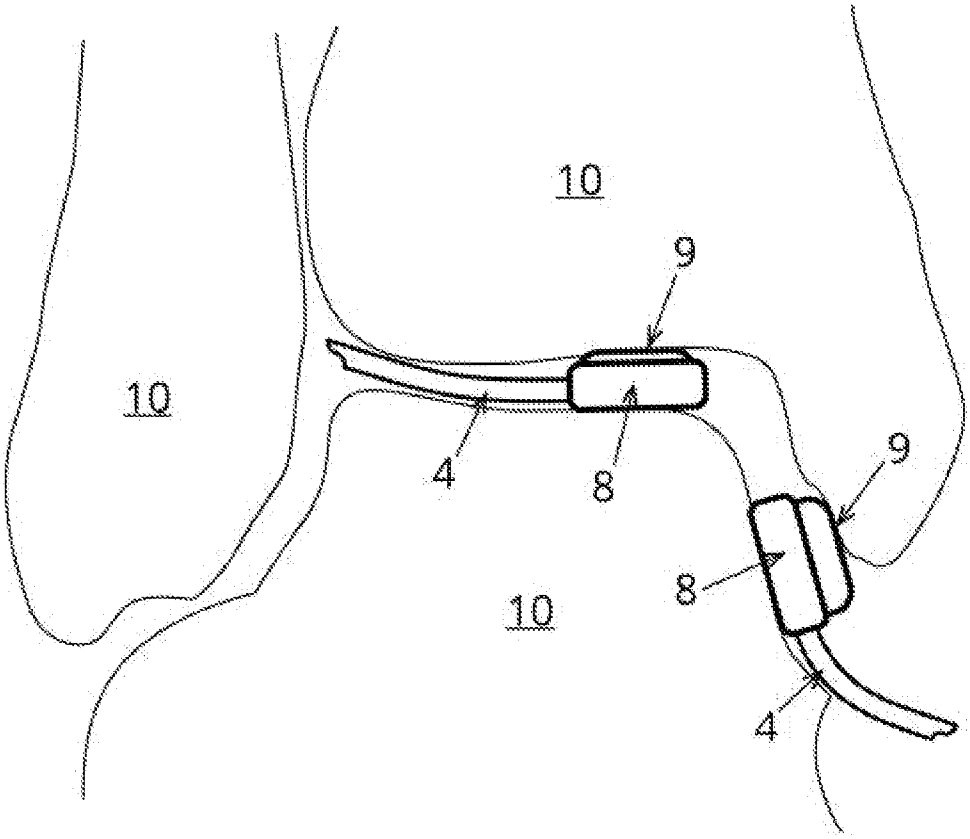

Fig. 3

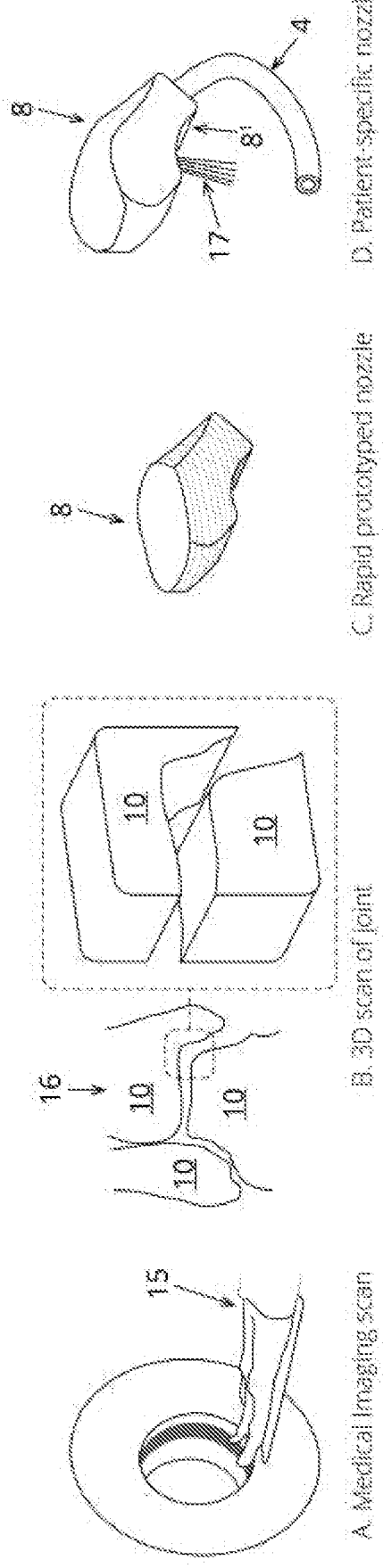
15
16
10
10
10
10
8
8
8'
17
4
A. Medical Imaging scan
B. 3D scan of joint
C. Rapid prototyped nozzle
D. Patient-specific nozzle

Fig. 4

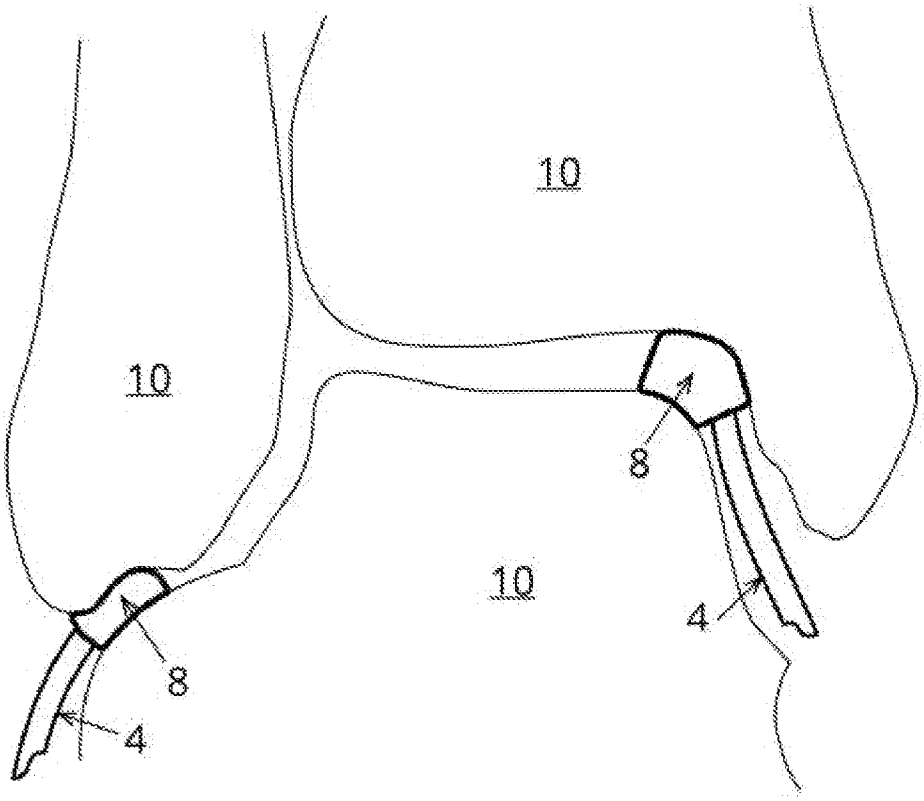

Fig. 5

SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE
	018980NL-PD
Nederlands aanvraag nr. **2024233**	Indieningsdatum **14-11-2019**
	Ingeroepen voorrangsdatum
Aanvrager (Naam) **Technische Universiteit Delft, et al**	
Datum van het verzoek voor een onderzoek van internationaal type **01-02-2020**	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. **SN75366**

I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)

Volgens de internationale classificatie (IPC)

Zie onderzoeksrapport

II. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimumdocumentatie

Classificatiesysteem	Classificatiesymbolen
IPC	**Zie onderzoeksrapport**

Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

III.	☐	**GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES**	(opmerkingen op aanvullingsblad)
IV.	☐	**GEBREK AAN EENHEID VAN UITVINDING**	(opmerkingen op aanvullingsblad)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2024233

A. CLASSIFICATIE VAN HET ONDERWERP
INV. A61B17/3203
ADD.

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte miminum documentatie (classificatie gevolgd door classificatiesymbolen)
A61B B33Y

Onderzochte andere documentatie dan de mimimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)
EPO-Internal, WPI Data

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
X	WO 2019/056248 A1 (ZIMMER INC [US]; XU ZION [US]; LI LEON [US]; WANG HERBERT [US]) 28 maart 2019 (2019-03-28) * alinea [0014] - alinea [0016] * * alinea [0021] - alinea [0023]; figuren 1-4,7 *	1-3,6-8
X	US 5 135 482 A (NERACHER ARNOLD [CH]) 4 augustus 1992 (1992-08-04) * kolom 2; figuren 1-4 *	1,2,4,5, 7
A	WO 2018/231983 A1 (UNIV NEBRASKA [US]) 20 december 2018 (2018-12-20) * bladzijde 1, regel 11 - regel 14; figuren 1,7-8 * * bladzijde 14, regel 15 - regel 19 *	1-8

-/--

[X] Verdere documenten worden vermeld in het vervolg van vak C.

[X] Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

"D" in de octrooiaanvrage vermeld

"E" eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

"L" om andere redenen vermelde literatuur

"O" niet-schriftelijke stand van de techniek

"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvrage, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

"&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid	Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type
18 juni 2020	

Naam en adres van de instantie	De bevoegde ambtenaar
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Martinez Ramos, A

2

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2024233

C.(Vervolg). VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
A	NL 1 016 653 C2 (GLASTRA HENDRIK [NL]; GIESSEN WILLEM JOHAN VAN DER D [NL]) 22 mei 2002 (2002-05-22) * bladzijde 5; figuur 4 * -----	1-7

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2024233

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
WO 2019056248 A1	28-03-2019	CN 111263616 A	09-06-2020
		WO 2019056248 A1	28-03-2019
US 5135482 A	04-08-1992	GEEN	
WO 2018231983 A1	20-12-2018	US 2020129201 A1	30-04-2020
		WO 2018231983 A1	20-12-2018
NL 1016653 C2	22-05-2002	GEEN	

WRITTEN OPINION

File No.	Filing date *(day/month/year)*	Priority date *(day/month/year)*	Application No.
SN75366	14.11.2019		NL2024233

International Patent Classification (IPC)
INV. A61B17/3203

Applicant
Technische Universiteit Delft, et al

This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the application
- ☐ Box No. VIII Certain observations on the application

	Examiner
	Martinez Ramos, A

Application number

WRITTEN OPINION

NL2024233

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the application as filed.

   ☐ filed together with the application in electronic form.

   ☐ furnished subsequently for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	6, 8
	No:	Claims	1-5, 7
Inventive step	Yes:	Claims	
	No:	Claims	1-8
Industrial applicability	Yes:	Claims	1-8
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 WO 2019/056248 A1 (ZIMMER INC [US]; XU ZION [US]; LI LEON [US]; WANG HERBERT [US]) 28 maart 2019 (2019-03-28)

D2 US 5 135 482 A (NERACHER ARNOLD [CH]) 4 augustus 1992 (1992-08-04)

2 The present application does not meet the criteria of patentability, because the subject-matter of **claim 1 is not new**.

2.1 **D1** discloses (the references apply to this document):

Waterstraalchirurgiesysteem (waterjet cutting system 100) omvattende een waterpomp (§16: implicitly disclosed to supply pressurized water), een vloeistofleiding (§16: "tubular portion to convey water to a nozzle portion") en een mondstuk (nozzle 108), waarbij de vloeistofleiding de waterpomp verbindt met het mondstuk (§16), met het kenmerk, dat het mondstuk is op-genomen in een positie-stabiliserend lichaam (§21: "The cut guide 104 may include one or more slots (e.g., slot 106A-106B) , which may be configured to receive a nozzle 108 of a waterjet cutting device").

2.2 **D2** also discloses all technical features of claim 1, and the novelty objection is also valid in view of this document.

3 The present application does not meet the criteria of patentability, because the subject-matter of **claim 8** does not involve an **inventive step**.

3.1 **D1** may be regarded as being the **prior art closest** to the subject-matter of claim 8, and discloses (the references apply to this document):

Werkwijze voor het vormen van een positie-stabiliserend lichaam (cut guide 104) voor gebruik in een waterstraalchirurgiesysteem (waterjet cutting system 100) volgens een van de andere conclusies 1-7, gekenmerkt doorde stappen:

- beeldvorming van hard weefsel, in het bijzonder botten, van een patiënt waarop een operatie moet worden uitgevoerd (§22: " The cut guide 104 may be custom to a patient", "The model may be creating using data from the patient,

such as an X-Ray, a CT scan or an MRI of the patient. The model may use measurements, such as of the patient's size, the angle of limb alignment (e.g., femur to tibia limb alignment) , soft tissue tension, etc."; en

- het vormen van ~~een mondstuk in~~ een positie-stabiliserend lichaam door snelle prototyping, waarbij het positie-stabiliserende lichaam een vorm wordt gegeven die afgestemd is op de vorm van de botten van de patiënt op een positie die moet worden onderworpen aan een operatie (§22: "The cut guide 104 may be custom to a patient. For example, the cut guide 104 may be printed using a 3D printer based on a model").

3.2 The subject-matter of claim 8 therefore differs from this known method in that **D1 is silent** about **forming** a nozzle within a position stabilizing body. D1 discloses a method of inserting a nozzle into a slot a position stabilizing body.

3.3 The problem to be solved by the present invention may therefore be regarded as how to provide an alternative method to engage the nozzle with the stabilizing body.

3.4 It would just imply a slight constructional change, which comes within the scope of the customary practice followed by persons skilled in the art, to **form** a nozzle within a position stabilizing body as claimed in claim 8, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claim 8 lacks an inventive step.

3.5 For these reasons the solution proposed in claim 8 of the present application cannot be considered as involving an inventive step.

4 **Dependent claims 2-7** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of novelty or inventive step:

4.1 **Re claim 2:** see D1, §21; D2, col.2, figs.2,4 (balloon 14).

4.2 **Re claim 3:** see D1, §21, figs.2A-2C.

4.3 **Re claims 4-5:** see D2, col.2, figs.2,4 (balloon 14).

4.4 **Re claim 6:** see D1, §23. It would be obvious for the skilled person to add a friction coating in order to achieve the effect disclosed in §23.

4.5 **Re claim 7:** see D1, §22; D2, col.2, figs.2,4 (balloon 14).