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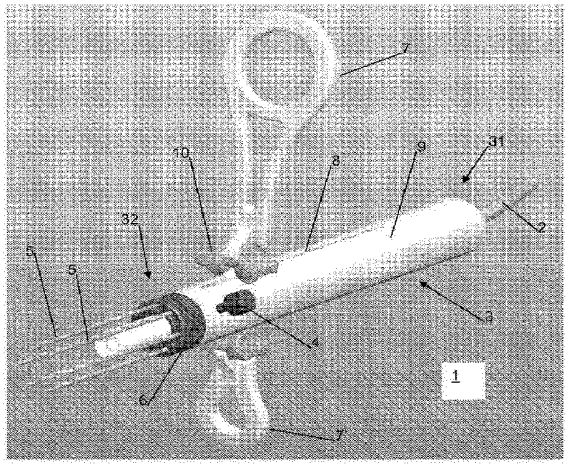
(54) **Brachytherapy applicator device for insertion in a body cavity.**

(57) The invention relates to a brachytherapy applicator device for insertion in a body cavity. The applicator device comprises an applicator shaped for insertion in the body cavity; the applicator comprising connectable segments; at least one connectable part having a form following wall surface shaped to follow the body cavity, the wall surface having a multichannel groove structure, so as to guide a plurality of catheters along the grooves in the groove structure along the wall surface.



NL C 2005005

P91408NL00

Title: Brachytherapy applicator device for insertion in a body cavity

FIELD

The invention relates to a brachytherapy applicator device for insertion in a body cavity. In particular, the invention relates to a brachytherapy applicator device for irradiating tumours.

BACKGROUND

DE4413490 shows such an instrument of the cylindrical vaginal applicator type, where irradiation positions are realized by a central catheter which is introduced into the applicator. The applicator can be connected to a so-called remote afterloading machine which via tubes moves a radioactive source to an irradiation position in the central catheter. In this device some radiation shielding is provided by a central filler element which is inserted in the applicator and can be made from different materials to provide differential radiation shielding with a relatively limited control over the dose distribution.

Such an applicator may comprise multiple catheters provided along a wall part of the cylinder, which thereby generally follows the form of the body cavity wherein the applicator is inserted. The guidance of the catheters along the wall part enables the irradiation doses to be shaped and so optimised, whilst keeping the dose at the surface of the organ at or below the desired limit. The irradiation is done by bringing a radiation source provided at the end of a guide cable via a transfer tube and the catheter to a predetermined correct position and allowing it to deliver radiation there for a predetermined length of time to combat the tumour.

It is noted that conventional applicators are instruments assembled from complex parts and frequently comprise long guide through bores that are difficult to clean when sterilizing the instruments for repeated use.

It is an object of the invention to provide an instrument which can be assembled quickly and introduced easily into the body cavity and whose positioning is accurate and reliable. In addition, it is an object to provide an instrument that is easily dis-assembled and so can easily be cleaned and sterilized.

SUMMARY

According to an aspect, a brachytherapy applicator device is provided for insertion in a body cavity, comprising an applicator shaped for insertion in the body cavity; the applicator comprising connectable parts;

at least one connectable part having a form following wall surface shaped to follow the body cavity, the wall surface having a multichannel groove structure, so as to guide a plurality of catheters along the grooves in the groove structure along the wall surface.

The groove structure provides efficient and reliable guiding of irradiation catheters at a predetermined distance from the cavity wall while at the same time being easy to clean. In addition, the segments allow for quick assembly and disassembly of the applicator, so that the constituting segments are exposed for cleaning.

EXEMPLARY EMBODIMENTS

The invention will be elucidated in more detail in and by a description of the drawings, in which:

Figure 1 shows a complete assembly of an applicator device;

Figure 2 shows a perspective view of a two-piece applicator of the applicator device in disassembled condition;

Figure 3 shows a perspective view of the applicator of Figure 2 in assembled condition;

Figure 4 shows a view of proximal part of the applicator of Figure 3 in disassembled condition;

Figure 5 shows a detailed view of the proximal part of Figure 2;

Figure 6 shows a schematic perspective view of the keyhole structure in the proximal part in particular;

Figure 7 shows an alternative cap structure;

Figure 8 shows a connectable part of an alternative applicator device

Figure 8a and 8b shows a detailed view of the distal and proximal parts respectively; and

Figure 9 shows the applicator device having a sleeve structure slided on the connectable part.

In the drawings, the same or corresponding parts are designated by the same reference numerals.

Figure 1 shows a complete assembly of an applicator device 1. In assembled condition, a brachytherapy applicator device 1 is provided for insertion in a body cavity. The assemblies and components described herein would be suitable for administration of all types of brachytherapy treatment. This applicator can be used for treatment of gynaecological tumours of the vagina and cervix and can also be used for the treatment of colo-rectal tumours or those affecting the endo-metrium. During brachytherapy treatment energy emitting (radioactive) sources are inserted near or into the tumourous tissue of the human or animal body to be treated. For this purpose, an active energy emitting source is used to administer what is generally known as High Dose Rate (HDR) treatment. In HDR treatment the radiation source is guided into the tissue or body cavity for one or more periods by means of a needle or a catheter and is always contained within a closed capsule so it never comes into direct contact with the tissue. Brachytherapy can also be performed with PDR (pulse dose rate) or LDR (low dose rate) treatments. In addition, as long as the applicator is shaped in a corresponding effective form the applicator device may be used for any intracavitary or interstitial treatment.

In this embodiment the version of the applicator, which comprises a plurality of connectable parts, could be used for treatment of gynecological tumours of the vagina and cervix will be described. In more detail, the embodiment shows further an optional central intrauterine tube 2 that can be fixed relative to the applicator 3 and which is guided through a central opening in the dome-shaped distal end 31 of the applicator 3. The intra-uterine tube 2 is provided with a positioning means 4 for fixation relative to the applicator. This means comprises in the exemplary embodiment a fixation screw. In this embodiment, the intra-uterine tube is of fixed length, but an adjustable length tube could be used. In a further alternative, different angles can be used to provide suit different patient anatomies. The intra-uterine tube 2 accordingly serves for insertion into the cervix and can be used for intrauterine irradiation. Exemplary for an applicator form shaped for insertion into the body cavity, is a multi-channel cylindrical type of the present embodiment, which has a form following wall surface shaped to follow the body cavity. In this embodiment, the applicator comprises a plurality of guiding grooves in the wall for guiding catheters 5 along their respective longitudinal axes and restrain the catheters 5 against any motion in a direction away from their longitudinal axes. In addition the device 1 further comprises a catheter locking structure, in this example in the form of a cap 6 on the proximal part 32 further detailed in Figure 4 and Figure 6 that locks the catheters 5 against axial movement relative to the applicator 3. After placement, during the irradiation, a high dose can be delivered to the base of the uterus without the surrounding organs such as large intestine and bladder needing to be irradiated unduly heavily. Preventing this excessive irradiation is of major importance since otherwise serious complications may be expected. A connectable handle 7 known as a perineal bar is slidingly engageable in a corresponding slot 8. The slot 8 is arranged along an outer surface 9 of the applicator 3. For fixation, a knob or lever 10 is provided which fixes the perineal bar 7 relative to the groove 8. The knob

10 has a cam structure which fixes the bar 7 when rotated. The perineal bar can be selectively provided in various sizes 7, 7' and fixed on one or either side of the applicator 3.

Figure 2 shows the applicator 3 in more detail. The applicator is formed by two connectable parts 33 and 34 having connectors 35 for ready connection. The connectors 35 are provided by mating wedges 351, 352, each arranged on opposite end sides of the connectable segments 33, 34 each forming a partly tubular shaped segment. Alternatively a fastener 35 can be provided by, for example, in the form of a locking groove and a locking knob to be locked in sliding engagement in a corresponding locking slot.

The wall surface comprising the groove structure 36 is advantageously distanced from the body surface, but this is not essential; it may be formed as an outer surface that is in direct contact with the body cavity or by a surface distanced from the outer surface such as in the present example. In this example, inner wall surface 90 has a multichannel groove structure 36 that is provided to guide the catheters 5 along grooves 361 in the groove structure 36 along the wall surface. Alternatively, the groove structure 36 may be provided on the outer surface 9, in addition to the locking slot 8 for the perineal bar 7 (see Fig. 1).

The grooves 361 may be formed as open trench structures that can be the continuations of through holes 372 of a relatively short depth that may be provided on the segment edges, in particular, the proximal part 32 thereof. Alternatively, the grooves may be continued without through holes 372, as shown in Fig 2a. While Figure 2 shows an applicator comprised of two segments 33, 34, the tubular applicator could be formed of more segments which may be connected together. Each segment may be provided with one or more grooves 361 on inner wall 90.

An important aspect of the grooves, in addition to their favourable cleaning properties, is that they facilitate in guiding the catheter along curved surface 91, particularly for instance, in the dome shaped distal end

31 where the segment 34 is shaped to have a rounded inner wall part 91 comprising a groove 362 curved in the axial direction along a center axis of the applicator. Accordingly, in this embodiment, the catheters follow the groove structure 36 radially around the dome shape 31.

With this curved guidance of the catheters, the cervix area can be reached better so helping to improve dose distribution with the aim of optimizing the radiation treatment.

Figure 3 shows the segments 33 and 34 in assembled condition. A filler tube 11 may be provided. Advantageously the filler piece 11 may comprise a plurality of interlocking segments (not shown) made from different materials having different radiation shielding properties, which can differentially reduce the dose of the radiation emitted from the catheters and passing through the applicator. This is advantageous for calculation purposes. Optionally the filler tube could be formed from a plurality of interlocking segments arranged in such a manner to tune the radiation profile. The filler tube 11 may form a close fit inside the cylindrical segments 33 and 34 for ensuring the catheters remain inside the grooves 361. Alternatively, as shown in the present embodiment, the groove structure comprises a groove 361 that locks the catheter along a more than semicircular circumference.

The present embodiment thus forms a brachytherapy applicator device for insertion in a body cavity, comprising an applicator 3 shaped for insertion in the body cavity; the applicator 3 comprising a plurality of connectable parts 33, 34 at least one of the connectable parts 33, 34 having a first wall surface 9 shaped to follow the body cavity, a second wall surface 90 having a plurality of catheter guide grooves 36 therein capable of guiding a catheter 5 along a groove 361, a third wall surface 11 cooperating with the second wall surface 90 to maintain the catheter in the groove when the applicator is assembled.

Figure 4 shows in more detail the applicator's proximal end 32 and cap 6. The cap 6 may be optionally provided and has advantageous locking features. Not shown are connectors of cap 6 connectable to the cylinders' proximal end 32. For locking the catheters, the cap 6 comprises a catheter locking structure 61 aligned with the groove structure 361. In the example, the catheter locking structure 61 is formed by keyholes provided in the cap 6 and aligned with a corresponding groove 361 in the cylinder segments 33, 34. The cap 6 can be rotated to lock the catheter 5 in the keyhole 61. Accordingly, cap 6 is to guide catheters 5 through keyholes 61 and has a central opening for passing of the intrauterine tube 2. Depressions 62 are provided for providing grip.

As an example of a cap connector structure, Figure 5 shows a detail of a proximal end 32 of the applicator, in particular, L-shaped recess 321. The cap connectors are formed by resilient locking knobs (not shown). The recess 321 accordingly receives a knob provided on cap 6 (not shown) and can be clicked in the recess 321 from an unlock to a lock position (322, 323) via a local thickening 324 provided in the recess 321.

Figure 6 shows the cap 6 in mounted position, wherein it can be seen that a catheter 5 is provided that is guided through keyhole 61 and is shown in locking position.

Figure 7 shows an alternative locking mechanism, wherein the locking structure is formed by catheter locking insert 51 to be inserted in a corresponding recess 63 arranged in the cap. By way of example, such inserts 51 can fixate the catheter 5 by twisting it in a corresponding threaded part or by a bayonet click conventionally known.

Figure 8 shows a connectable part comprising a core piece 330 of an alternative applicator device. In this embodiments, the core piece 330 is not segmented but tubular shaped and forms a core piece of the applicator device 30 illustrated in more detail in the following figures. The core piece 330 has an elongated rounded form shaped for insertion into a cylinder 340

which has a substantially smooth inner wall surface. The cylinder 340 forms an outer sleeve of an applicator device which can be inserted into a body cavity such as the vagina or rectum. The core piece 330 has a multichannel groove structure 36 on the outer surface of the wall 900, to guide a plurality of catheters along the grooves 345 in the groove structure along the outer wall surface 900.

Figure 8a shows a detailed view of the distal part of the core piece 330, where it can be shown that the applicator has a dome-shaped distal end portion 31, the groove 345 extending into the distal dome shaped end portion and curved towards a central region of the dome 31. In addition, tongue structures 363 are used to enclose more than a semicircular circumference in order to retain the catheter (not shown) in the groove. In use, brachytherapy catheters can be easily inserted in and removed from the groove structure 345, prior to assembly or disassembly.

Figure 8b shows a proximal view of the core piece 330. A cap 60 is connectable to a proximal end of the applicator core piece 330 via a slot 64 that engages a knob 331 on the core piece 330. The cap may include a catheter locking structure similar in operation as the previous embodiment which can lock or unlock by rotating the cap 60.

Figure 9 shows the applicator device having a sleeve 340 connected over the core piece 330 in assembled form. The sleeve 340 is located in the correct orientation over the core piece 330 by knob 331 engaging a cooperating slot on the outer sleeve 340 and maintained in position by a latching tooth which engages in a cooperating latching recess in the outer sleeve 340. The pressbar 332 arranged on the core piece 330 can be pressed inwards towards the centre of the core piece to release the parts. The sleeve 340 discloses marks 341 for accurately locating a sliding a bar similar to the perineal bar 7 disclosed in Figure 1. Alternatively, the marks can be used as an indication of the depth of insertion of the applicator into the body cavity.

The present embodiment thus forms a brachytherapy applicator device for insertion in a body cavity, comprising an applicator 30 shaped for insertion in the body cavity; the applicator 30 comprising a plurality of connectable parts 330, 340 at least one of the connectable parts 330, 340 having a first wall surface 99 shaped to follow the body cavity, a second wall surface 900 having a plurality of catheter guide grooves 345 therein capable of guiding a catheter 5 along a groove 361, a third wall surface 342 cooperating with the second wall surface 900 to maintain the catheter in the groove 345 when the applicator is assembled.

The insert piece and catheters are preferably made from a plastics material. Preferably, the catheters are sufficiently flexible to allow bending in the groove structure. Although the invention has been elucidated with reference to the examples shown in the drawings, the invention is not limited thereto but may also comprise variations or modifications without deviating from the spirit of the invention. The groove structure may be formed in an applicator outer surface directly in contact with the body cavity. In addition, where the text refers to a tubular shape, these shapes are understood to encompass any suitable round or elliptical forms and which may be of cylindrical, sleeve form and even slightly curved along the length axis. The scope of the invention is determined by the following claims.

Conclusies

1. Een brachytherapie applicator inrichting voor insertie in een lichaamsholte, omvattende:

- een applicator gevormd voor insertie in de lichaamsholte welke applicator connecteerbare delen omvat;
- ten minste één connecteerbaar deel voorzien van een vormvolgend wandoppervlak, gevormd om de lichaamsholte te volgen, waarbij het wandoppervlak is voorzien van een meerkanaals groefstructuur, om meerdere katheters langs de groeven in de groefstructuur langs het wandoppervlak te geleiden.
-

2. Brachytherapie applicator inrichting volgens conclusie 1, waarin het verbindbare deel een buisvorm heeft langs ten minste een deel van zijn lengte.

3. Brachytherapie applicator inrichting volgens conclusie 1, waarin het connecteerbare deel een gedeeltelijk buisvormig segment vormt.

4. Brachytherapie applicator inrichting volgens conclusie 1, waarin het instrument een koepelvormig distaal eindgedeelte heeft en de groef zich uitstrekt in het koepelvormig distaal eindgedeelte en is gekromd naar een centraal gebied van de koepel.

5. Brachytherapie applicator inrichting volgens conclusie 1, waarin de groefstructuur een groef omvat die langs ten minste een deel van zijn lengte geconstrueerd is om meer dan een halve cirkelomtrek in te sluiten om de katheter in de groef te houden.

6. Brachytherapie applicator inrichting volgens conclusie 1, waarin het instrument een vulstuk omvat dat een middel verschaft om te helpen de katheter in de groefstructuur te houden.

7. Brachytherapie applicator inrichting volgens conclusie 6, waarin het vulstuk een aantal in elkaar grijpende segmenten omvat die zijn gemaakt van verschillende materialen met verschillende stralingsafscherming eigenschappen.

8. Brachytherapie applicator inrichting volgens conclusie 1, waarin de connecteerbare delen voorzien zijn van bij elkaar passende oppervlakken ingericht aan tegenoverliggende eindkanten van de delen.

9. Brachytherapie applicator inrichting volgens conclusie 1, waarin het instrument buisvormig is en de connecteerbare delen gevormd worden door gedeeltelijk buisvormige segmenten die een koepelvormig distaal einde definiëren, waarin katheters, ingebracht in het instrument, de groefstructuur radiaal rond de koepelvorm zullen volgen.

10. Brachytherapie applicator inrichting volgens conclusie 9, verder omvat met een centrale buis voor in de baarmoeder die vastgezet kan worden ten opzichte van het instrument en welke zich uitstrekt vanaf een centrale opening in het koepelvormige distale einde.

11. Brachytherapie applicator inrichting volgens conclusie 1, waarin het instrument verder een kap omvat welke kapconnectors heeft die geconnecteerd kunnen worden met een proximaal einde van het instrument, welke kap verder een katheter opsluitstructuur omvat die is uitgelijnd met de groefstructuur.

12. Brachytherapie applicator inrichting volgens conclusie 11, waarin de kapverbindingen worden gevormd door veerkrachtige sluitknoppen.

13. Brachytherapie applicator inrichting volgens conclusie 11, waarin de katheter opsluitstructuur wordt gevormd door een sleutelgat dat is verschaft in de kap en die is uitgelijnd met een corresponderende groef, en waarin de kap gedraaid kan worden om de katheter in het sleutelgat op te sluiten.

14. Brachytherapie applicator inrichting volgens conclusie 11, waarin de opsluitstructuur gevormd wordt door een katheter opsluitend inbrengstuk dat in een corresponderende inham voorzien in de kap geïnserteerd kan worden.

15. Brachytherapie applicator inrichting volgens conclusie 1, dat verder een connecteerbare hendel omvat welke al schuivend gekoppeld kan worden met een corresponderende opening van het connecteerbare deel.

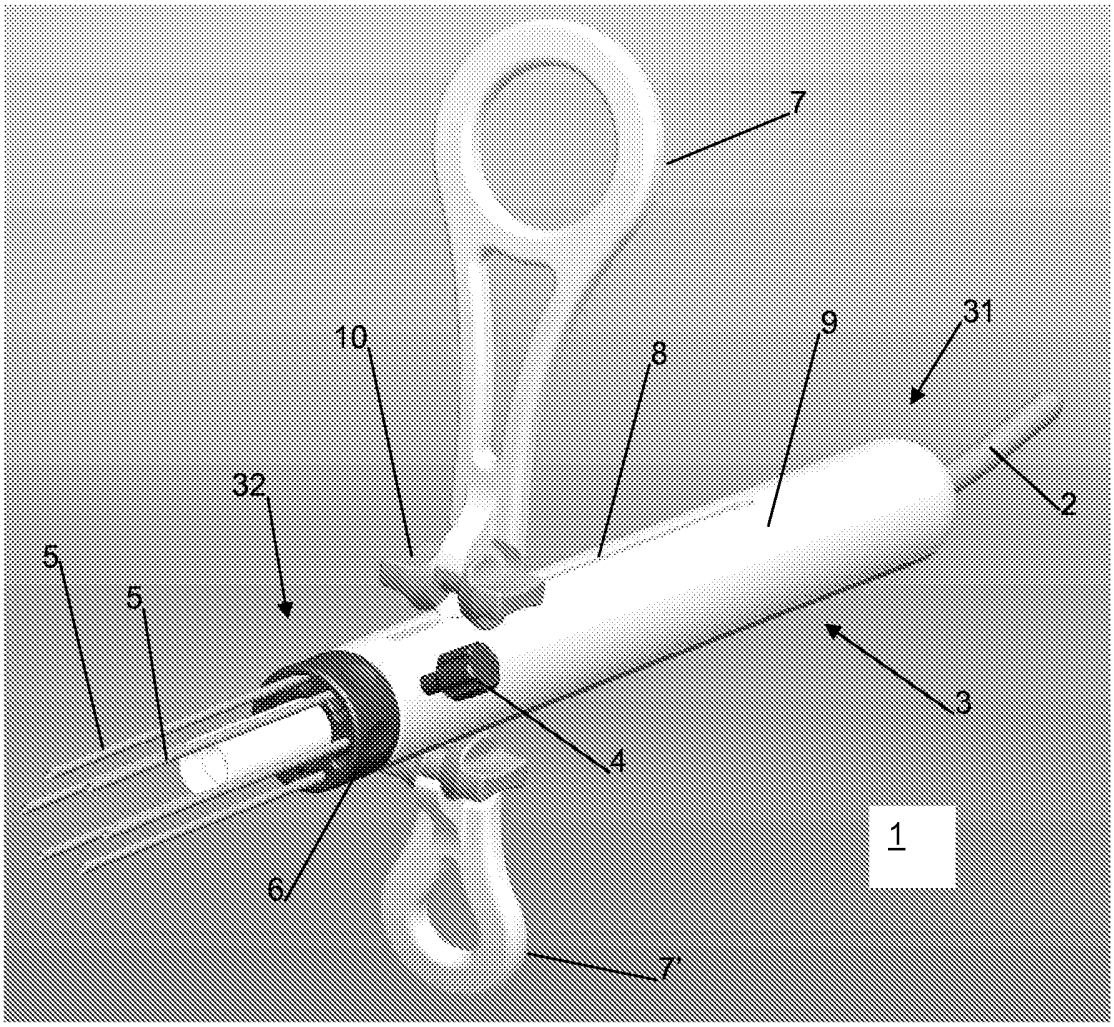


Fig. 1

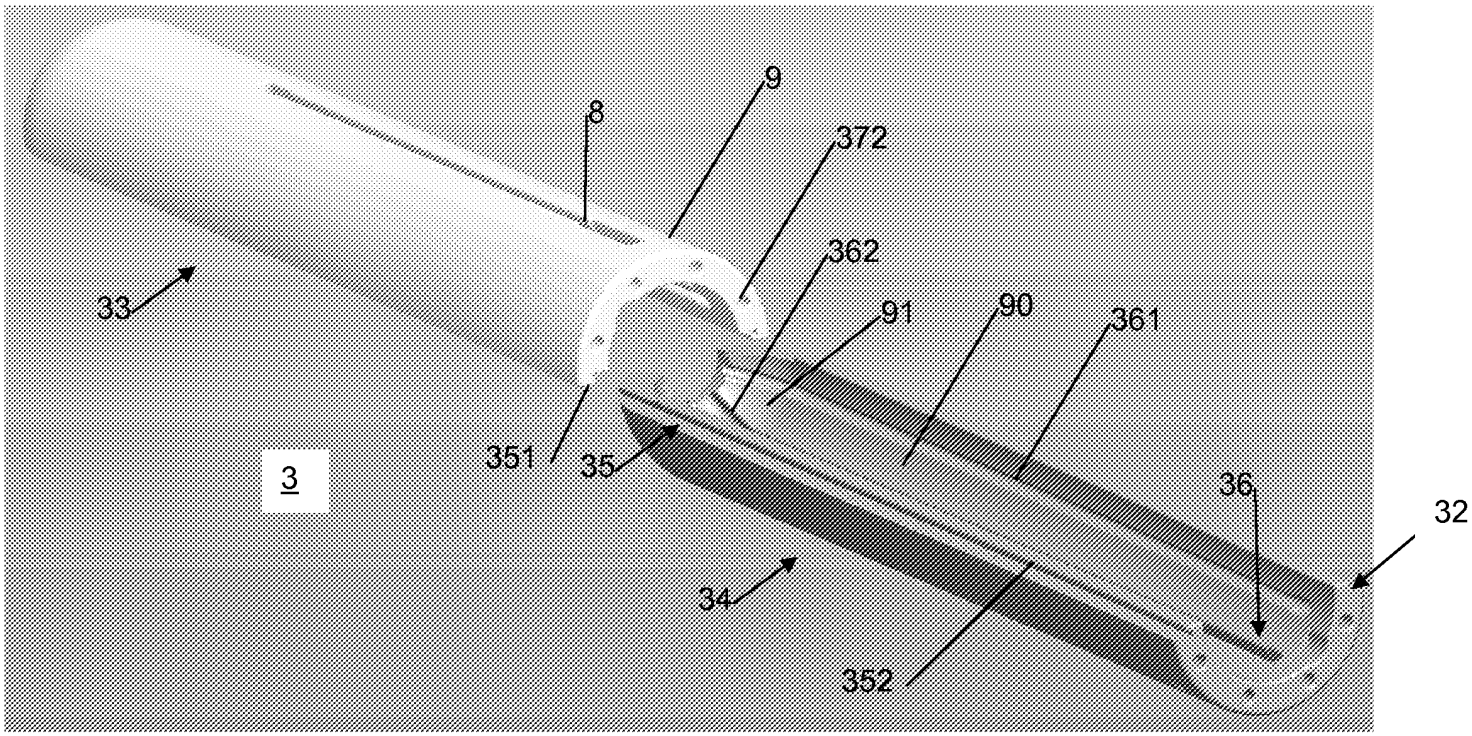


Fig. 2

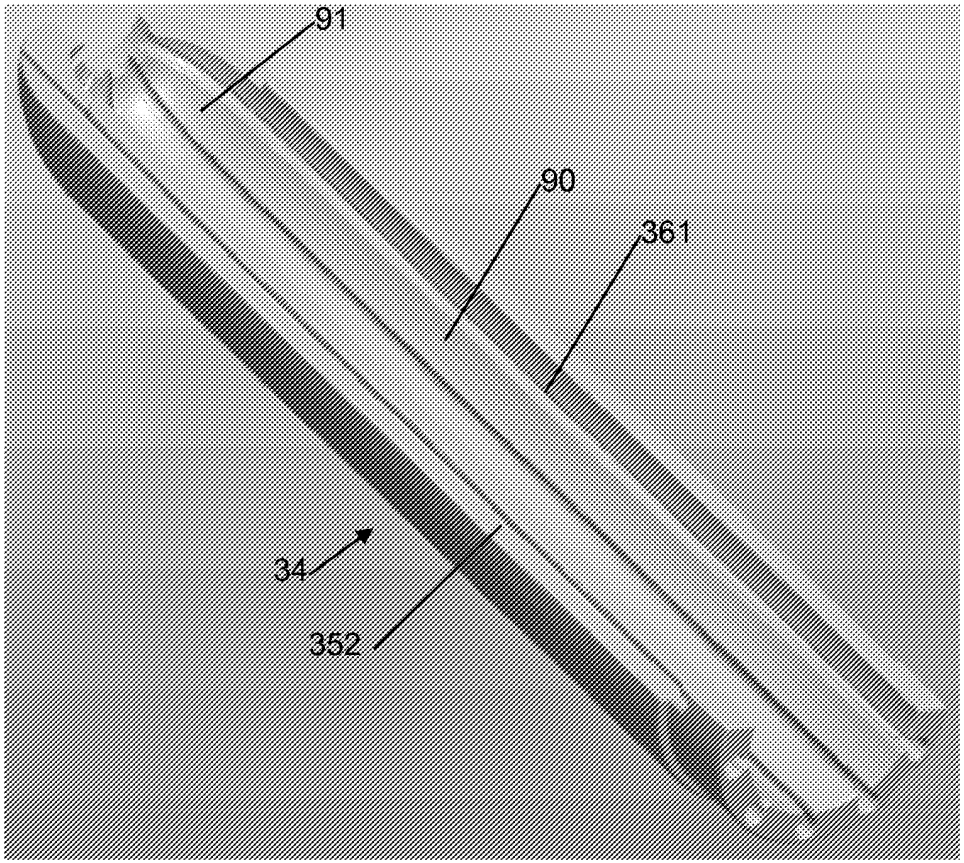


Fig. 2a

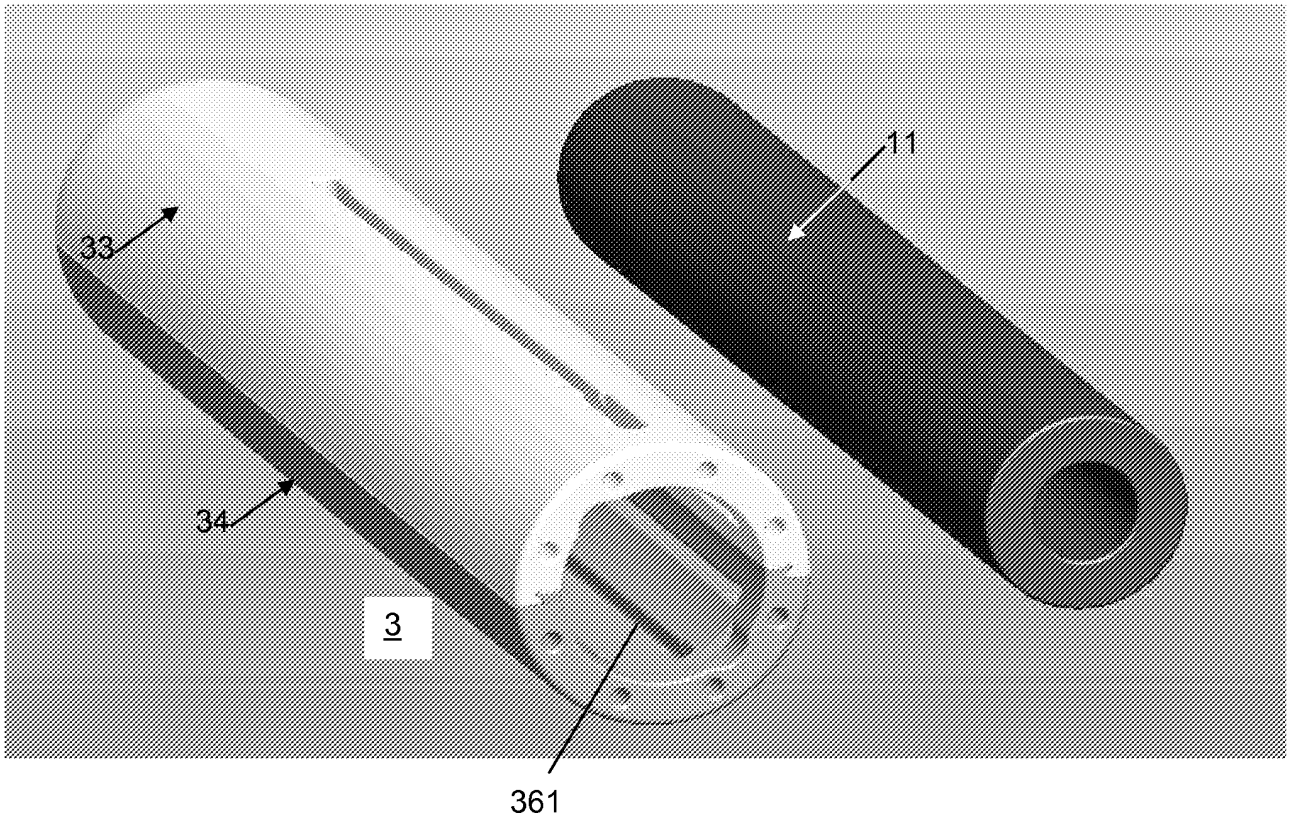


Fig. 3

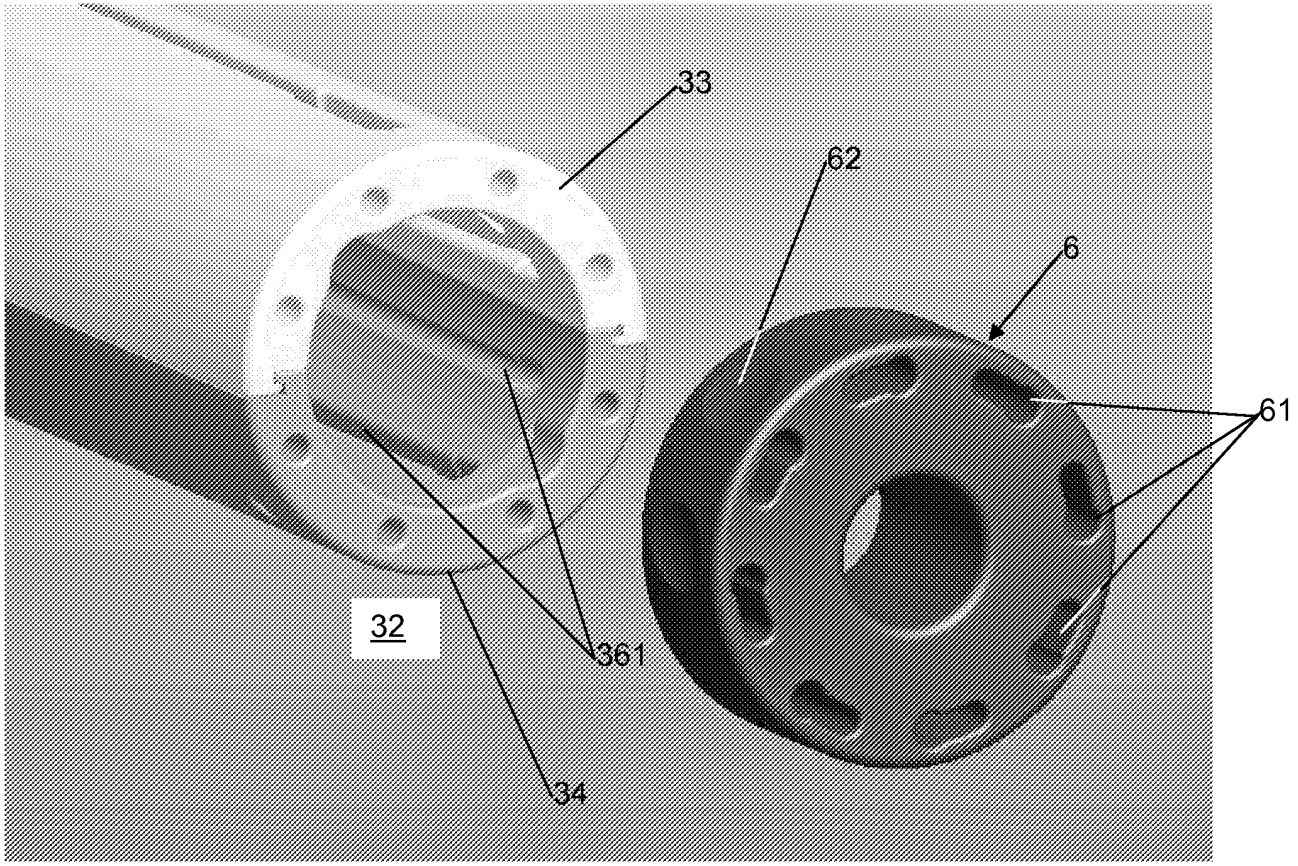


Fig. 4

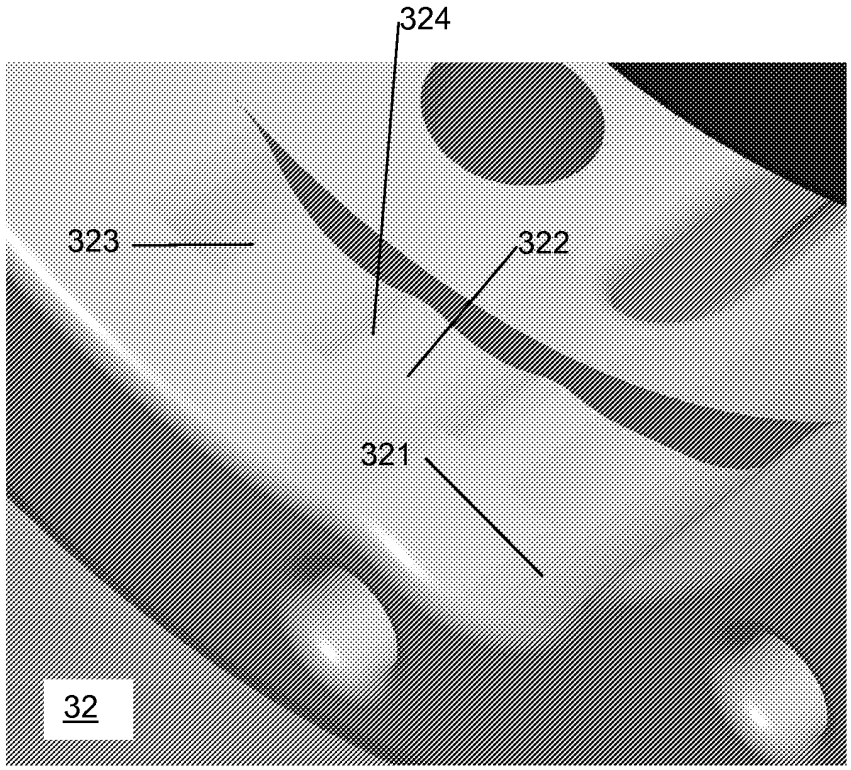


Fig. 5

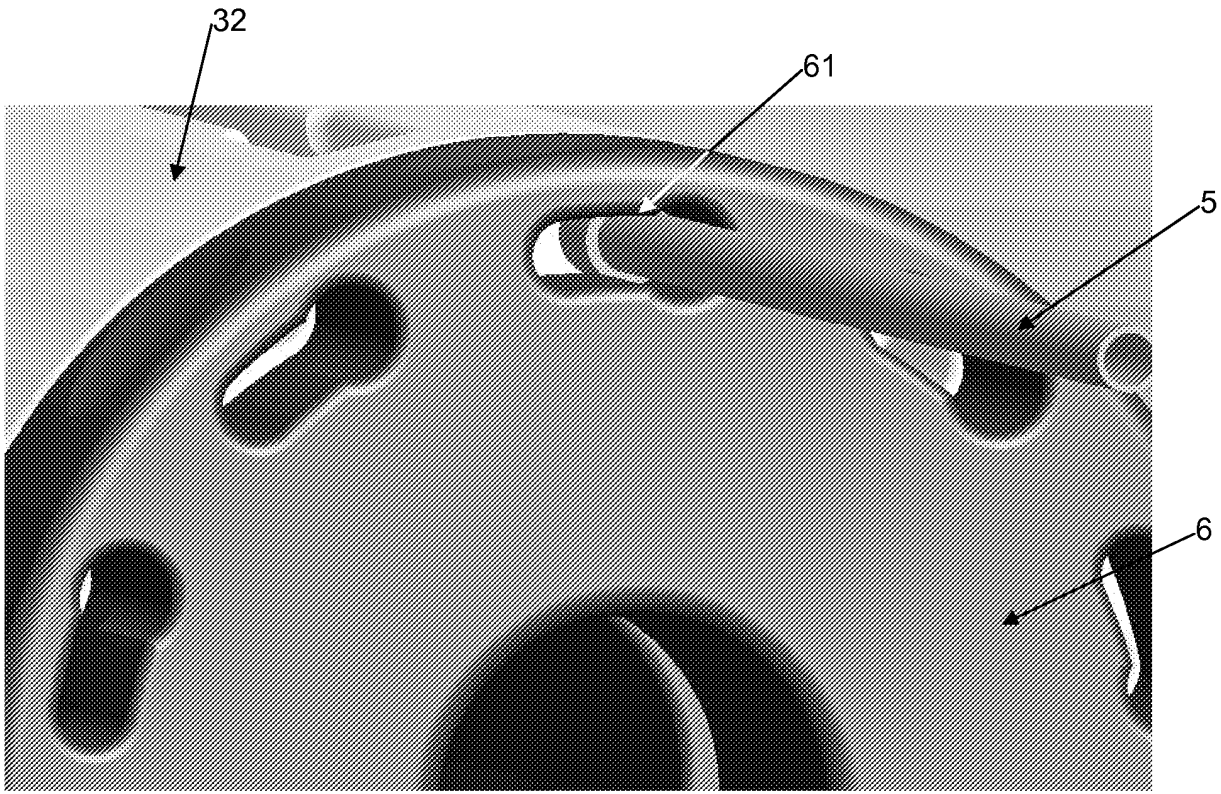


Fig. 6

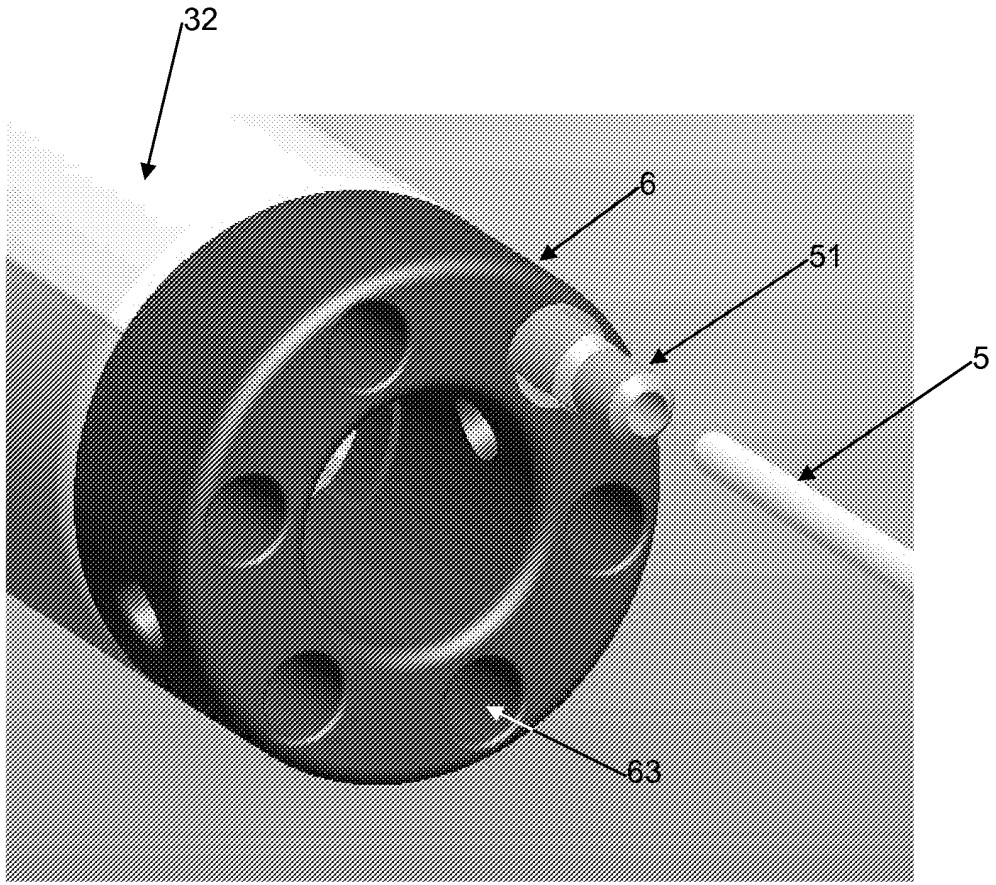


Fig. 7

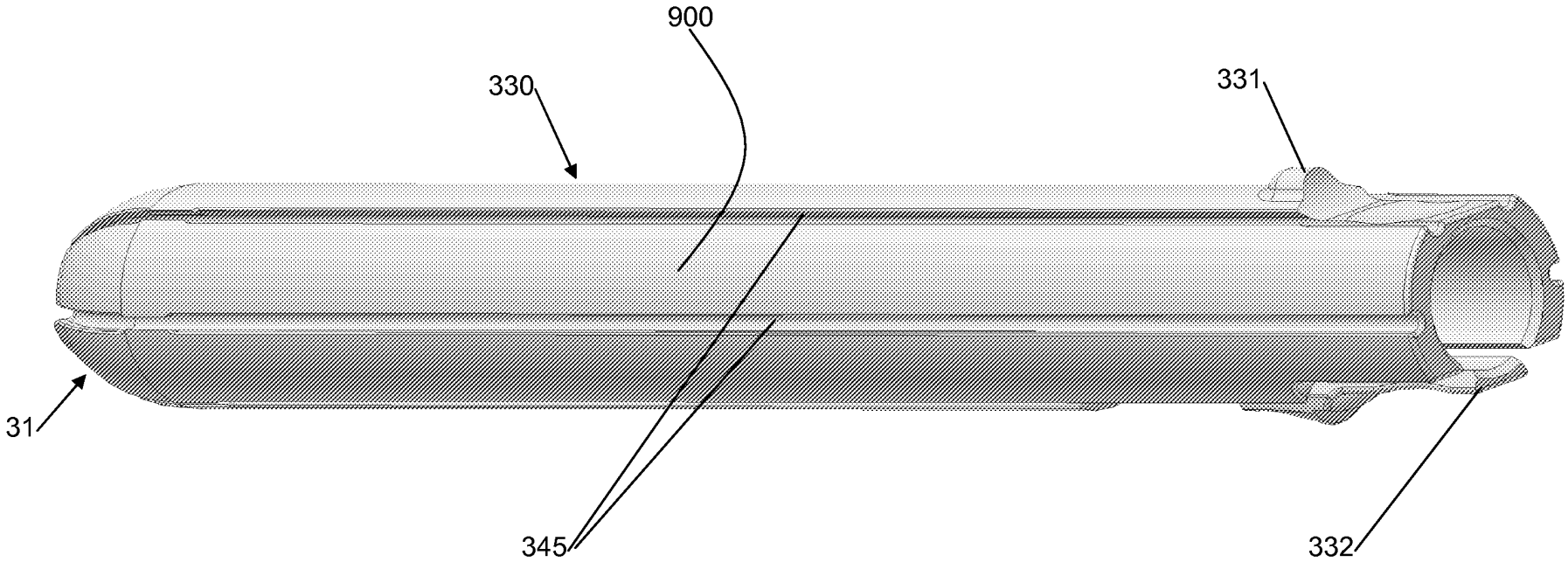


Fig. 8

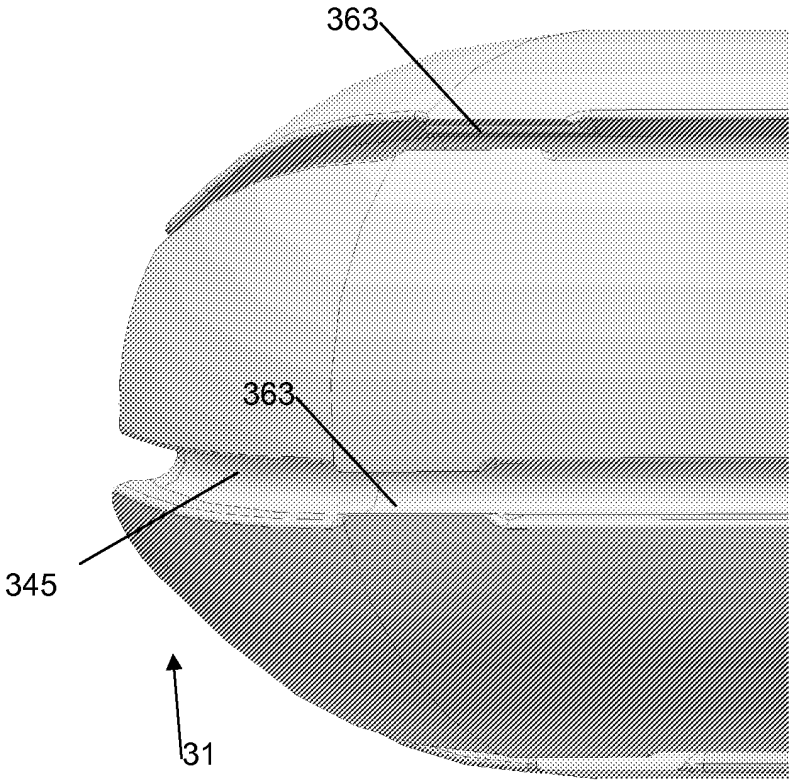


Fig. 8a

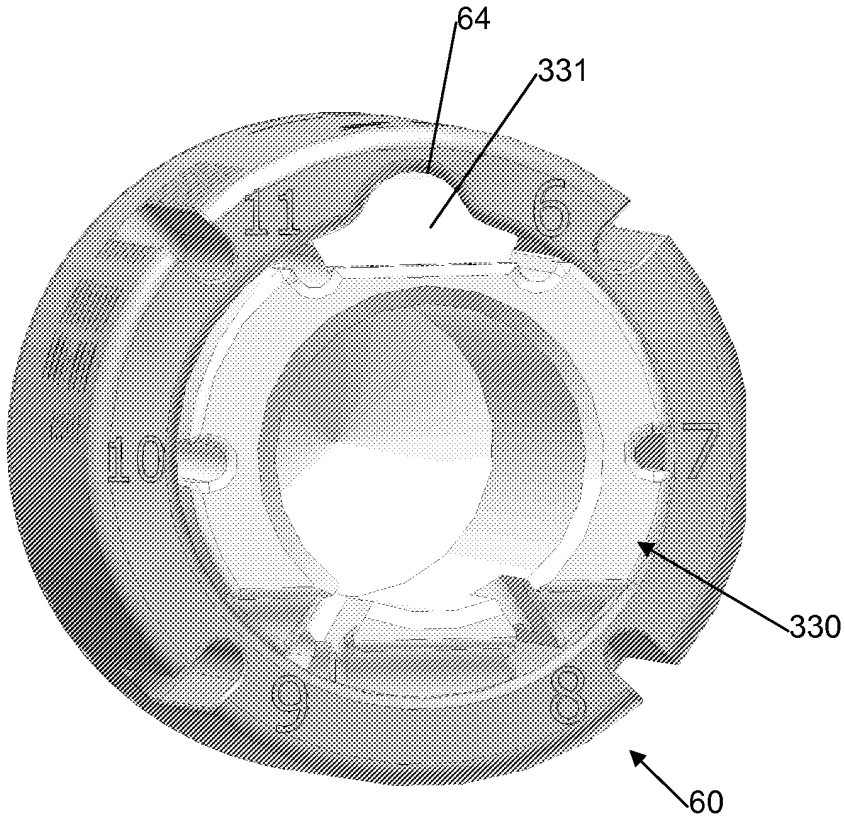


Fig. 8b

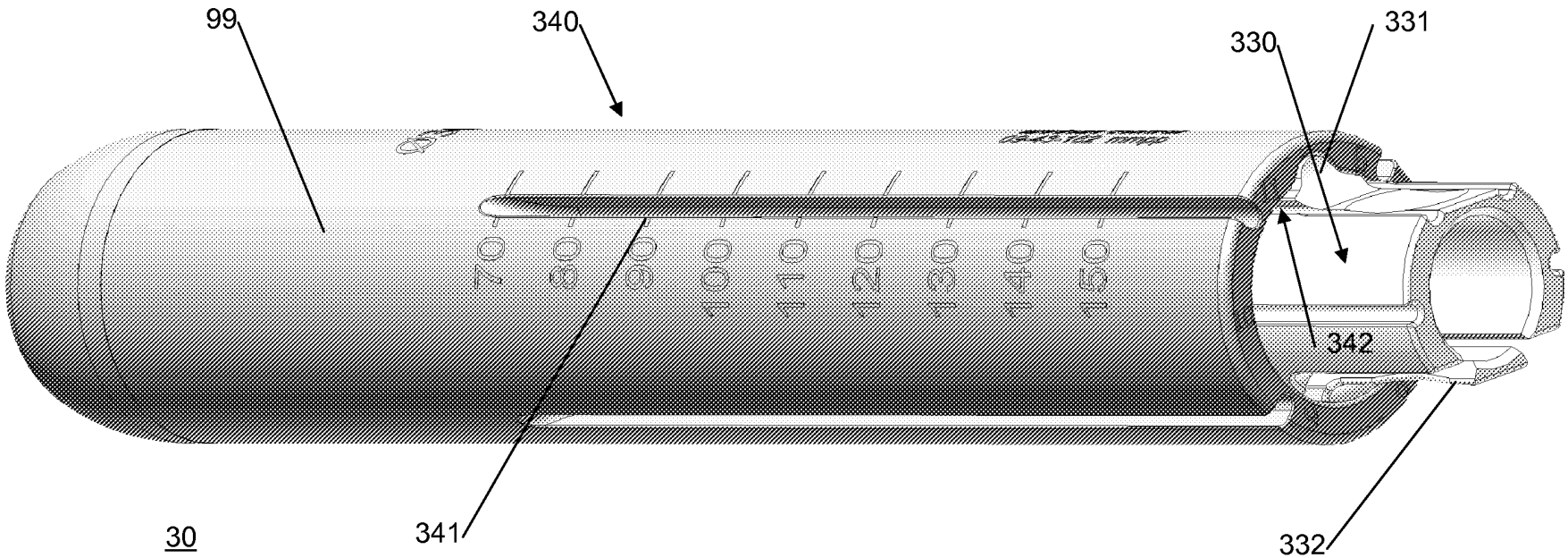


Fig. 9

OCTROOICENTRUM NEDERLAND

OCTROOIAANVRAAG NR.:
NO 137450
NL 2005005

ONDERZOEKSRAPPORT

BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK

RELEVANTE LITERATUUR

Categorie[1]	Literatuur met, voor zover nodig, aanduiding van speciaal van belang zijnde tekstgedeelten of figuren.	Van belang voor conclusie(s) nr:	Classificatie (IPC)
X Y A	WO 2010/036103 A2 (NUCLETRON BV [NL]; HANNOUN-LEVI M D JEAN-MICHEL [FR]; WARDT COR V D [N) 1 april 2010 (2010-04-01) * figuren 1, 3, 7b, 10a * * bladzijde 7, regel 1 - bladzijde 8, regel 34 *	1-3,5,6, 8,10,15 4,9 7,11-14	INV. A61N5/10
Y	US 2009/234178 A1 (LEBOVIC GAIL S [US] ET AL) 17 september 2009 (2009-09-17) * alinea [0044]; figuur 2 *	4,9	
A	DE 44 13 490 C1 (UNIV SCHILLER JENA [DE]) 10 augustus 1995 (1995-08-10) * samenvatting *	7	
A	EP 1 374 951 A1 (NUCLETRON BV [NL]) 2 januari 2004 (2004-01-02) * alinea [0059] - alinea [0062]; figuur 7 *	11-14	

Onderzochte gebieden van de techniek
A61N

Indien gewijzigde conclusies zijn ingediend, heeft dit rapport betrekking op de conclusies ingediend op:

Plaats van onderzoek:	Datum waarop het onderzoek werd voltooid:	Bevoegd ambtenaar:
's-Gravenhage	9 maart 2011	Petter, Erwin

[1] CATEGORIE VAN DE VERMELDE LITERATUUR

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
A: niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft
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
E: eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven
D: in de octrooiaanvrage vermeld
L: om andere redenen vermelde literatuur
&: lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

EOB FORM 02.83 (P0414B)

AANHANGSEL BEHORENDE BIJ HET RAPPORT BETREFFENDE HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK, UITGEVOERD IN DE OCTROOIAANVRAGE NR.

NO 137450
NL 2005005

Het aanhangsel bevat een opgave van elders gepubliceerde octrooiaanvragen of octrooien (zogenaamde leden van dezelfde octrooifamilie), die overeenkomen met octrooischriften genoemd in het rapport.
De opgave is samengesteld aan de hand van gegevens uit het computerbestand van het Europees Octrooibureau per
De juistheid en volledigheid van deze opgave wordt noch door het Europees Octrooibureau, noch door het Bureau voor de Industriële eigendom gegarandeerd; de gegevens worden verstrekt voor informatiedoeleinden.

09-03-2011

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
WO 2010036103 A2	01-04-2010	GEEN	
US 2009234178 A1	17-09-2009	EP 2274052 A1	19-01-2011
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OCTROOICENTRUM NEDERLAND

SCHRIFTELIJKE OPINIE

DOSSIER NUMMER	INDIENINGSDATUM	VOORRANGSDATUM	AANVRAAGNUMMER
NO137450	30.06.2010		NL2005005
CLASSIFICATIE INV. A61N5/10			
AANVRAGER Nucletron B.V.			

Deze schriftelijke opinie bevat een toelichting op de volgende onderdelen:

- ☒ Onderdeel I Basis van de schriftelijke opinie
- ☐ Onderdeel II Voorrang
- ☐ Onderdeel III Vaststelling nieuwheid, inventiviteit en industriële toepasbaarheid niet mogelijk
- ☐ Onderdeel IV De aanvraag heeft betrekking op meer dan één uitvinding
- ☒ Onderdeel V Gemotiveerde verklaring ten aanzien van nieuwheid, inventiviteit en industriële toepasbaarheid
- ☐ Onderdeel VI Andere geciteerde documenten
- ☐ Onderdeel VII Overige gebreken
- ☐ Onderdeel VIII Overige opmerkingen

	DE BEVOEGDE AMBTENAAR
	Petter, Erwin

Aanvraag nr.:

SCHRIFTELIJKE OPINIE

NL2005005

Onderdeel I Basis van de Schriftelijke Opinie

1. Deze schriftelijke opinie is opgesteld op basis van de meest recente conclusies ingediend voor aanvang van het onderzoek.

2. Met betrekking tot **nucleotide en/of aminozuur sequenties** die genoemd worden in de aanvraag en relevant zijn voor de uitvinding zoals beschreven in de conclusies, is dit onderzoek gedaan op basis van:

   a. type materiaal:

   ☐ sequentie opsomming

   ☐ tabel met betrekking tot de sequentie lijst

   b. vorm van het materiaal:

   ☐ op papier

   ☐ in elektronische vorm

   c. moment van indiening/aanlevering:

   ☐ opgenomen in de aanvraag zoals ingediend

   ☐ samen met de aanvraag elektronisch ingediend

   ☐ later aangeleverd voor het onderzoek

3. ☐ In geval er meer dan één versie of kopie van een sequentie opsomming of tabel met betrekking op een sequentie is ingediend of aangeleverd, zijn de benodigde verklaringen ingediend dat de informatie in de latere of additionele kopieën identiek is aan de aanvraag zoals ingediend of niet meer informatie bevatten dan de aanvraag zoals oorspronkelijk werd ingediend.

4. Overige opmerkingen:

Aanvraag nr.:

SCHRIFTELIJKE OPINIE

NL2005005

Onderdeel V Gemotiveerde verklaring ten aanzien van nieuwheid, inventiviteit en industriële toepasbaarheid

1. Verklaring

Nieuwheid	Ja:	Conclusies	4, 7, 9, 11-14
	Nee:	Conclusies	1-3, 5, 6, 8, 10, 15
Inventiviteit	Ja:	Conclusies	7, 11-14
	Nee:	Conclusies	1-6, 8-10, 15
Industriële toepasbaarheid	Ja:	Conclusies	1-15
	Nee:	Conclusies	

2. Citaties en toelichting:

Zie aparte bladzijde

Re Item V

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

1 The following documents are referred to:

D1 WO 2010/036103 A2 (NUCLETRON BV [NL]; HANNOUN-LEVI M D JEAN-MICHEL [FR]; WARDT COR V D [N) 1 april 2010

D2 US 2009/234178 A1 (LEBOVIC GAIL S [US] ET AL) 17 september 2009

D3 DE 44 13 490 C1 (UNIV SCHILLER JENA [DE]) 10 augustus 1995

D4 EP 1 374 951 A1 (NUCLETRON BV [NL]) 2 januari 2004

2 The document D1 discloses all features of claim 1 as follows (the references in parentheses applying to D1):

A brachytherapy applicator (*figure 1*) device for insertion in a body cavity (*see abstract: "intracavitary"*), comprising:

- an applicator shaped for insertion in the body cavity; the applicator comprising connectable parts (*this follows already from the fact that the applicator is referred to as an "assembly", see in particular page 7, lines 3-4: "the guiding unit is connectable to the intracavitary component"*);

- at least one connectable part (*guiding unit 7*) having a form following wall surface shaped to follow the body cavity (*the guiding unit 7 is tubular thereby following the shape of a body organ like the vagina*), the wall surface having a multichannel groove structure (*see figures 3, 7b with grooves 33*), so as to guide a plurality of catheters (*needles 5*) along the grooves (*33*) in the groove structure along the wall surface.

Accordingly, the subject matter of claim 1 lacks novelty in view of D1.

3 The further features defined in claims 2, 3, 5, 6, 8, 10, 15 are also known from D1 so that the subject matter of those claims also lacks novelty:

3.1 Claims 2, 3: the guiding unit (7) has indeed a tubular shape, see figure 3;

3.2 Claim 5: see figures 3 and 7b: the needles 5 are retained in the grooves 33;

3.3 Claim 6: D1 also provides a means for retaining a catheter (needle) in the groove, see figure 10a;

3.4 Claim 8: any connectable parts evidently have "mating surfaces";

3.5 Claim 10: the assembly of D1 comprises a central intrauterine tube (18), see page 7, line 16;

3.6 Claim 15: the template (15) of D10 slides on the guiding unit (7), see figures 4, 5 and may be considered as a "handle".

4 The additional features of claims 4, 9 are known from related prior art, so that the subject matter of claims 4, 9 is not considered to involve an inventive step.

Claims 4, 9: the document D2 discloses channels (lumens) in a vaginal applicator which curve towards a dome shaped distal end, see D2: paragraph 44, first lines: "conform to the distal end" and figure 2. A skilled person would consider such a "dome shaped end" also in the applicator of D1.

5 The additional features defined in claims 7, 11-14 have not been found in the related prior art and therefore the subject matter of claims 7, 11-14 seem to meet the requirements of novelty and inventive step:

5.1 Claim 7: D3 discloses filler pieces ("Absorberelemente", see abstract), but they do not at the same time function as a means for retaining catheters in the groove.

It is noted that this feature requires that the channels are open at the inner wall of the applicator. This however is not clearly defined in the claims.

5.2 Claims 11-14: a cap with "keyholes" for locking multiple catheters was not found in the art. A similar locking structure is known from document D4, but this document appears to be "too far away" from the subject matter of D1.