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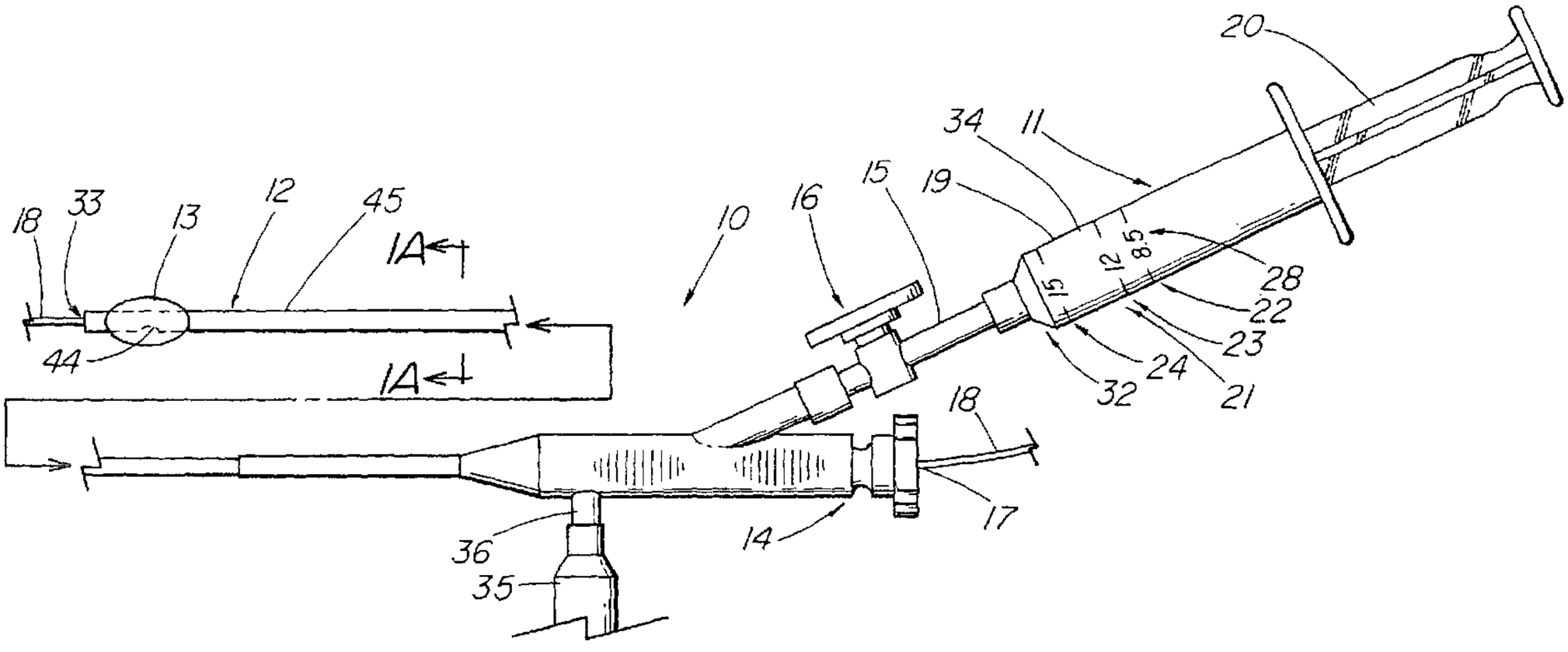
(54) Title: PRECALIBRATED INFLATION DEVICE FOR BALLOON CATHETER



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A medical device including an inflation element, such as a syringe, and a balloon catheter in which the inflation element includes a series of indicia to which an operative portion of the inflation device can be aligned. The indicia directly correspond to a particular balloon diameter. A method of inflating a balloon to at least two desired diameters in a body lumen and determining the inflation diameter of the balloon within the body lumen. A method of calibrating the inflation device to allow a user to inflate a balloon to a desired diameter.

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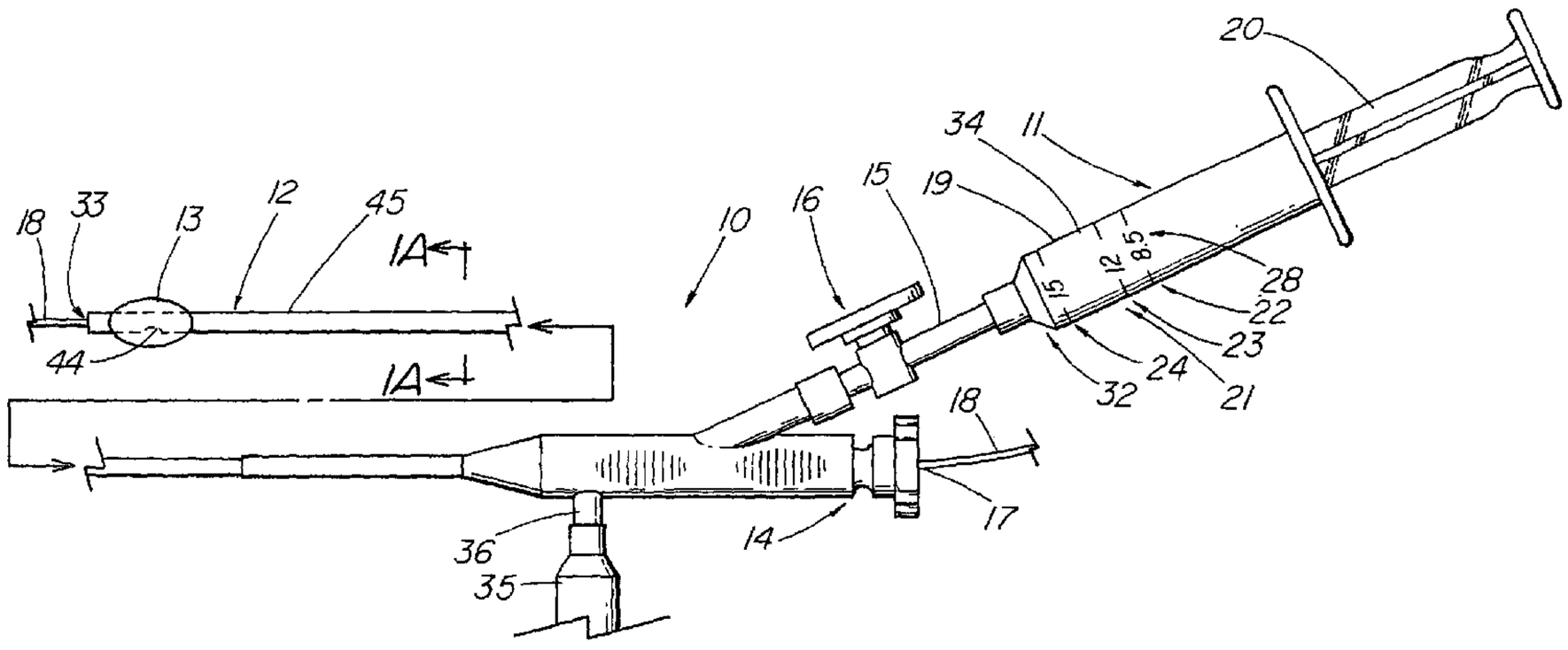
(54) Title: PRECALIBRATED INFLATION DEVICE FOR BALLOON CATHETER



(57) Abstract: A medical device including an inflation element, such as a syringe, and a balloon catheter in which the inflation element includes a series of indicia to which an operative portion of the inflation device can be aligned. The indicia directly correspond to a particular balloon diameter. A method of inflating a balloon to at least two desired diameters in a body lumen and determining the inflation diameter of the balloon within the body lumen. A method of calibrating the inflation device to allow a user to inflate a balloon to a desired diameter.

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PRECALIBRATED INFLATION DEVICE FOR BALLOON CATHETER

TECHNICAL FIELD

[0002] This invention relates to medical devices, more particularly to inflation devices used in combination with a balloon catheter.

BACKGROUND OF THE INVENTION

[0003] Balloon catheters are commonly used in endoscopic procedures in the biliary tree, such as to extract stones and calculi obstructing the bile duct or pancreatic duct. In such a procedure, the endoscopist typically performs a sphincterotomy at the opening to the common bile duct then replaces the sphincterotome with a balloon catheter and advances it over the indwelling wire guide past the stone. Contrast media is usually injected prior to introduction of the balloon cathcter so that the obstruction can be located fluoroscopically and also, to help determine what size of extraction balloon would be most appropriate. The balloon, which is made of latex or some other compliant material, is then fully inflated in the duct to assess the optimum balloon diameter for sweeping the stone from the duct. Generally there is a predetermined amount of infuscate delivered to achieve the nominal volume and diameter of the balloon. Often the endoscopist will elect to deflate the balloon slightly in order to perform the procedure, especially if the nominal or fully inflated diameter of the balloon is too large for the duct. Another reason is that a fully inflated balloon is more taut and thus, more subject to rupture when contacting a sharp edge of a stone within the duct. A partially deflated balloon is more forgiving and less likely to puncture. One problem with partially deflating the balloon to sweep the stone is that the operator cannot readily determine the diameter of the balloon following deflation and thus, must make an educated guess as to whether it is appropriate for that particular patient's anatomy. The problem is that the calibrations on an inflation device typically refer only to the

actual volume being delivered and thus, require that the operator be able to calculate the syringe volume that corresponds to a given balloon size. If a mark is provided that corresponds to the nominal size of that particular balloon, it is of limited use if trying to extrapolate to inflate or deflate to another size. For example, U.S. Patent No. 6,234,996 describes a device for inflating various specified balloons to their nominal size. Since the balloon diameter cannot be easily adjusted downward to a known value using a conventional inflation device, a smaller balloon must be used and inflated to the nominal size to achieve certainty of size. This means that the fully inflated smaller balloon may be less forgiving in case of contact with a sharp edge. Because compliant balloons can assume a range of diameters to address a specific need, what is needed is a system that allows the operator to be able to use a single balloon and be able to determine and control the diameter as needed.

SUMMARY OF THE INVENTION

[0004] The foregoing problems are solved and a technical advance is achieved in an illustrative inflation device and a balloon catheter apparatus in which the inflation device includes a series of indicia to which an operative portion of the inflation device (e.g., a plunger head) can be aligned. Each indicia marking corresponds to a particular volume of air or liquid that produces a balloon diameter indicated at the mark when the inflation device is deployed. In an exemplary embodiment, the balloon catheter comprises a biliary stone extraction balloon in which the balloon portion comprises latex or another compliant elastomeric material. In a first embodiment used for the extraction of stones within the biliary or pancreatic ducts, the inflation device comprises a standard 5 ml plastic syringe with a luer fitting that is connectable to a port communicating with the inflation lumen of the balloon catheter. The inflation device includes a stop to hold the plunger at a first position and three indicator markings that correspond to the position to where the plunger head of the syringe should be advanced to result in the balloon being filled to a diameter of 8.5, 12, and 15mm, respectively. The numerical value of the resultant balloon diameter is indicated next to the mark. In

the exemplary embodiment, the leading edge of the first seal of the plunger head is advanced to the mark to achieve the corresponding balloon size. This allows the operator to readily adjust the balloon diameter by inflating or deflating the balloon accordingly without having to calculate or calibrate the volume of air necessary to produce the desired results.

[0004a] In summary, an aspect of the invention provides for a medical device having a balloon inflatable to a first inflated diameter having a first dimension, the first dimension measurable in a first unit of length, and a second inflated diameter having a second dimension, the second dimension measurable in a second unit of length, and an inflation device adapted to inflate the balloon, wherein the inflation device is characterized by:

a first marking and a second marking, the first marking comprising a numeric indicia expressing the first unit of length that substantially equals the first dimension, the second marking comprising a numeric indicia expressing the second unit of length that substantially equals the second dimension; wherein the first inflated diameter is directly ascertainable when an indicator is substantially adjacent to the first marking and the second inflated diameter is directly ascertainable when the indicator is substantially adjacent to the second marking.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] Embodiments of the present invention will now be described by way of example with reference to the accompanying drawings, in which:

[0006] FIG. 1 depicts a side view of the illustrative embodiment of the present invention;

[0007] FIG. 1A depicts a cross-sectional view taken along Line 1A–1A of FIG. 1;

[0008] FIG. 2 depicts a partially sectioned side view of the inflation device of the embodiment of FIG. 1; and

[0009] FIG. 3 depicts an enlarged side view of the balloon portion of the embodiment of FIG. 1.

DETAILED DESCRIPTION

[0010] FIGS. 1-3 depict the illustrative balloon apparatus 10 of the present invention which comprises a balloon catheter 12 that includes a shaft portion 44 and balloon portion 13 affixed thereto just proximal to the distal tip 33 of the shaft. The balloon portion 13 is made of a compliant material such as latex, silicone or another suitable elastomeric material that can allow the balloon to assume a range of diameters, unlike a non-compliant balloon which is inflatable to a single, maximum diameter. The present balloon apparatus 10 further comprises an inflation device 11, such as the illustrative syringe, which includes a plurality of unique indicia 21 that indicate the predetermined position where the operative portion 20 (e.g., the illustrative plunger) of the inflation device 11 must be advanced or withdrawn to deliver the proper amount of fluid 31, such as air, to achieve the desired balloon diameter 37, 38, 39, respectively (see FIG. 3). The

corresponding diameter is indicated in some manner at that particular mark 22, 23, 24 located on the surface 34 of the syringe barrel 19, typically by the appropriate corresponding numerical value 28. Because the internal volume of each model of balloon catheter can vary, the syringe 11 must be pre-calibrated for that particular balloon catheter 12 design so that the indicia 21 accurately indicate the positions to which the inflation device 11 should be advanced. Alternatively, the inflation device 11 may comprise any appropriate manually operated or electro-mechanical device that is intended for delivering a measurable amount of gas or liquid for inflating a balloon in a medical application. For example, it is contemplated that the series of unique indicia 21 comprise separate buttons or switches that activate the operative portion 20 of the inflation device 11 to deliver a different pre-measured amount of infuscate 31 to the balloon 13.

[0011] As depicted in FIG. 1 and 1A, the illustrative balloon apparatus 10, which is used for sweeping gall stones, calculi, or other obstructions from the biliary tree, comprises a triple-lumen balloon catheter 12, such as a Howell DASH™ Extraction Balloon (Wilson-Cook Medical, Inc.), having a first pair of small lumens 41 dedicated for inflation of the balloon, and a third, larger lumen 42 for both accommodating a standard wire guide 18 and providing a pathway for infusion of contrast media or other agents around the wire guide 18. Each lumen extends through the shaft portion of the catheter proximally from the distal end 33 or balloon portion 13, where they communicate with a port 15, 17, 36 located on the proximal hub assembly 14 of the device. The first pair of lumens 41 provide communication between the a balloon inflation port 44, (a scive in the catheter tubing located within the balloon 13) and the proximal inflation port 15, which is a luer fitting located at the proximal end of an optional stopcock 16 used to help prevent loss of air pressure once the balloon has been inflated. The distal end 32 of the inflation syringe 11 is configured to couple with the luer fitting (inflation port 15). The third lumen 42, which is generally larger because of its dual function, communicates with both the infusion port 36, which is configured to receive a second syringe 35 for injection of contrast media or other agents (such as saline

for flushing) and a wire guide port 17, such as a Tuohy-Borst fitting. The two ports 17, 36 merge to form a common pathway that comprises the second lumen 42. The inflation device 11 of the present invention includes a plurality of unique indicia 21 comprising a first, second and third indicium or marking 22, 23, 24 disposed along the length thereof which includes the corresponding numerical value 28 alongside. The indicia are printed in ink on the outer surface 34 of the syringe barrel, although they can be etched, embossed, or otherwise applied thereto or incorporated thereinto. Alternatively, other types of unique indicia (i.e., other alphanumeric characters, symbols, colors, etc.) may be utilized to correspond with any calibrated balloon diameters 37, 38, 39 that one wants to identify.

[0012] Referring now to FIGS. 2 and 3, the illustrative inflation syringe 11 includes a stop 30 which comprises a pair of protuberances on the inside of the syringe barrel 19 that temporarily lock the plunger 20 at the designated pre-deployment 43 position. The rear edge 29 or flange of the plunger head 25 is configured to rest against the stop 30 until additional force is applied during deployment to overcome resistance provided by the stop 30. The plunger 20 is then advanced to the marking 21 corresponding to the desired balloon size. The first marking 22 corresponds to the position to which the plunger 20 of the inflation syringe 11 is advanced to achieve a first balloon diameter 37 of 8.5 mm. To inflate the balloon to the first diameter, the plunger head 25, which includes a distal and a proximal seal 26, 27, is positioned such that the leading edge of the distal seal 26 is aligned at the mark 22. Typically, the plunger head must be advanced beyond the first mark 22 (e.g., to the second mark 23) and subsequently withdrawn back to the first mark 22 when inflating the balloon 13 to the smaller diameters, such as 8.5 mm. This is generally not necessary for the larger balloon diameters. The plunger head is aligned with the second mark 23 to inflate (or deflate) the balloon to the second diameter 38 (12 mm) or aligned with the third mark 24 (essentially the full deployment of the syringe contents 31) to inflate the balloon 13 to the third diameter 39, which is about 15 mm. While these diameters represent the most commonly available biliary extraction balloon sizes, any precalibrated balloon diameters may be indicated depending on the application or

the physician preference. In addition, the present invention may be adapted for vascular, pulmonary, genitourinary, or other gastrointestinal uses which might require a different range and set of balloon diameters.

[0013] Any other undisclosed or incidental details of the construction or composition of the various elements of the disclosed embodiment of the present invention are not believed to be critical to the achievement of the advantages of the present invention, so long as the elements possess the attributes needed for them to perform as disclosed. The selection of these and other details of construction are believed to be well within the ability of one of even rudimentary skills in this area, in view of the present disclosure. Illustrative embodiments of the present invention have been described in considerable detail for the purpose of disclosing a practical, operative structure whereby the invention may be practiced advantageously. The designs described herein are intended to be exemplary only. The novel characteristics of the invention as defined by the claims may be incorporated in other structural forms without departing from the spirit and scope of the invention.

Unless otherwise indicated, all ordinary words and terms used herein shall take their customary meaning as defined in *The New Shorter Oxford English Dictionary, 1993 edition.* All technical terms shall take on their customary meaning as established by the appropriate technical discipline utilized by those normally skilled in that particular art area. All medical terms shall take their meaning as defined by *Stedman's Medical Dictionary, 27th edition.*

WHAT IS CLAIMED IS:

1. A medical device having a balloon inflatable to a first inflated diameter having a first dimension, the first dimension measurable in a first unit of length, and a second inflated diameter having a second dimension, the second dimension measurable in a second unit of length, and an inflation device adapted to inflate the balloon, wherein the inflation device is characterized by:

a first marking and a second marking, the first marking comprising a numeric indicia expressing the first unit of length that substantially equals the first dimension, the second marking comprising a numeric indicia expressing the second unit of length that substantially equals the second dimension; wherein the first inflated diameter is directly ascertainable when an indicator is substantially adjacent to the first marking and the second inflated diameter is directly ascertainable when the indicator is substantially adjacent to the second marking.

2. The medical device of claim 1, wherein the inflation device is a syringe comprising a distal tip and a barrel, and the indicator is a plunger movable within the barrel.

3. The medical device of claim 1 or 2, wherein the distal tip is attachable to a luer fitting.

4. The medical device of claim 3, further comprising a stopcock operably connected to the luer fitting.

5. The medical device of claim 2 or 3, wherein the barrel comprises a protuberance adapted to selectively lock the plunger at a predetermined position within the barrel relative to one of the markings.

6. The medical device according to any one of claims 1-5, wherein the numeric indicia each comprise a predetermined metric length equal to an inflated diameter of the balloon.

7. The medical device according to any one of claims 1-6, wherein each of the plurality of metric lengths is expressed in millimeters.

8. The medical device according to any one of claims 1-7, wherein the inflation device includes at least three markings displayed thereon, and further wherein each adjacent pair of markings comprise a different spacing therebetween.

9. The medical device according to any one of claims 1-8, further comprising:

a catheter having a longitudinal shaft extending between a distal end and a proximal end, and a passageway extending along the longitudinal shaft from the proximal end to the distal end, wherein a proximal end of the passageway is operably connected to the inflation device and the distal end of the passageway is operably connected to the balloon .

10. The medical device of claim 9, further comprising: a dual function passageway extending along the longitudinal axis from the proximal end to the distal end, comprising a syringe port provided at the proximal end of the dual function passageway, and a wireguide port provided at the proximal end of the dual function passageway, wherein the syringe port is adapted to receive a second syringe and the wireguide port is adapted to receive a wireguide.

11. The medical device according to any one of claims 1-10, wherein the indicator is adapted to control the inflated diameter of the balloon.

12. The medical device according to any one of claims 1-11, wherein the markings are printed on the inflation device .

13. The medical device of claim 1, 8 or 10, wherein the markings are etched on the inflation device.

14. The medical device of claim 1, 8 or 10, wherein the markings are embossed on the inflation device.

15. The medical device according to any one of claims 1-14, wherein the balloon is formed of an elastomeric material.

16. The medical device of claim 15, wherein the elastomeric material is latex.

17. The medical device of claim 15, wherein the elastomeric material is silicone.

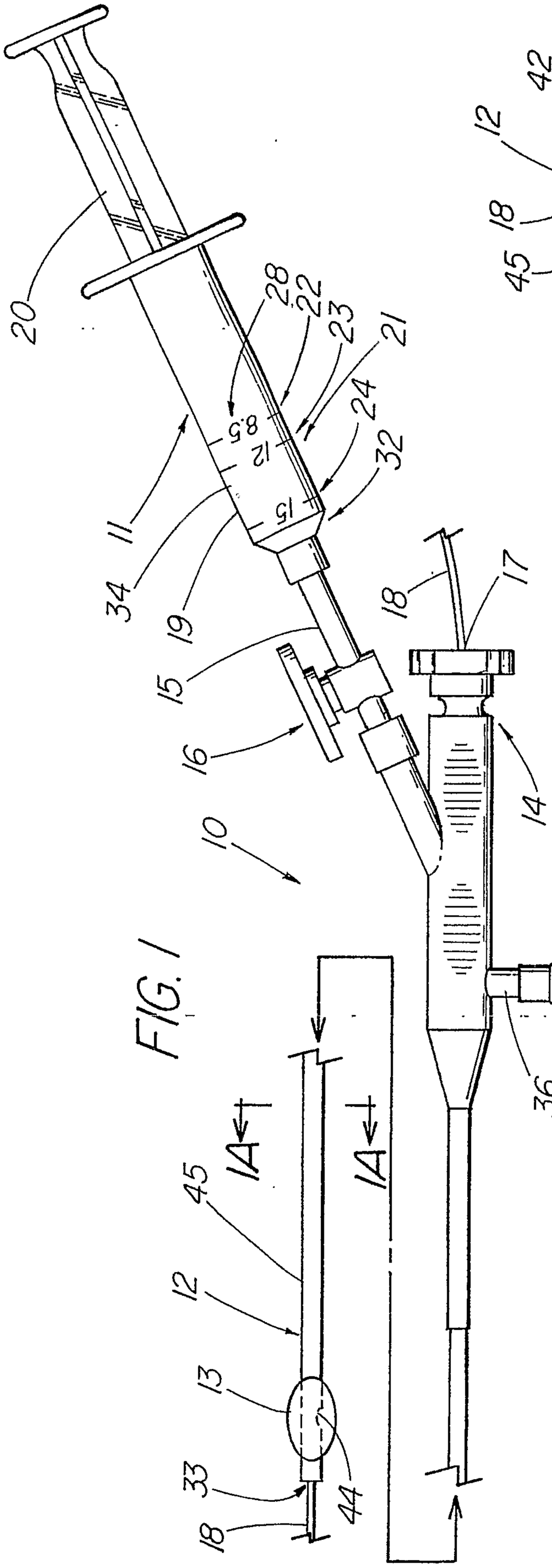


FIG. 1

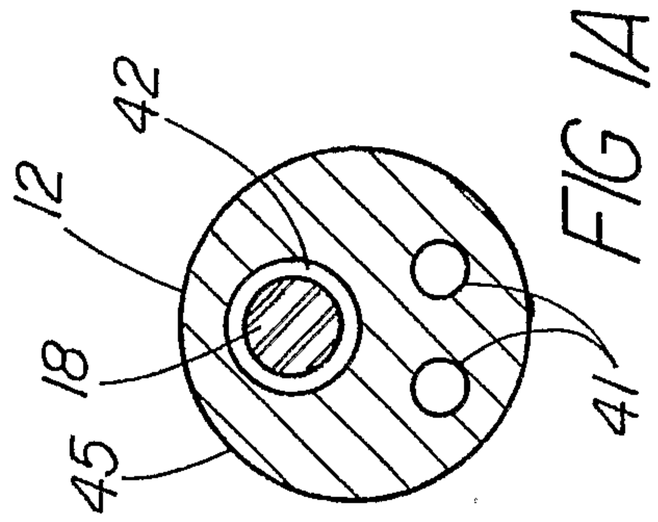


FIG 1A

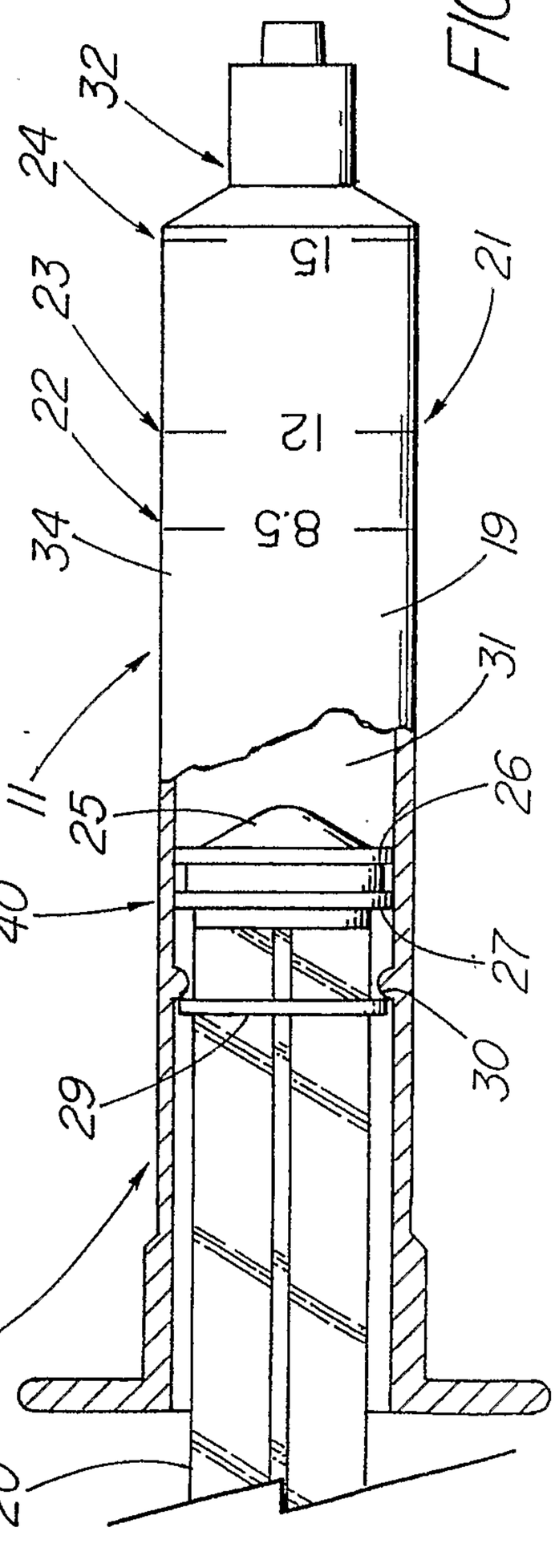


FIG. 2

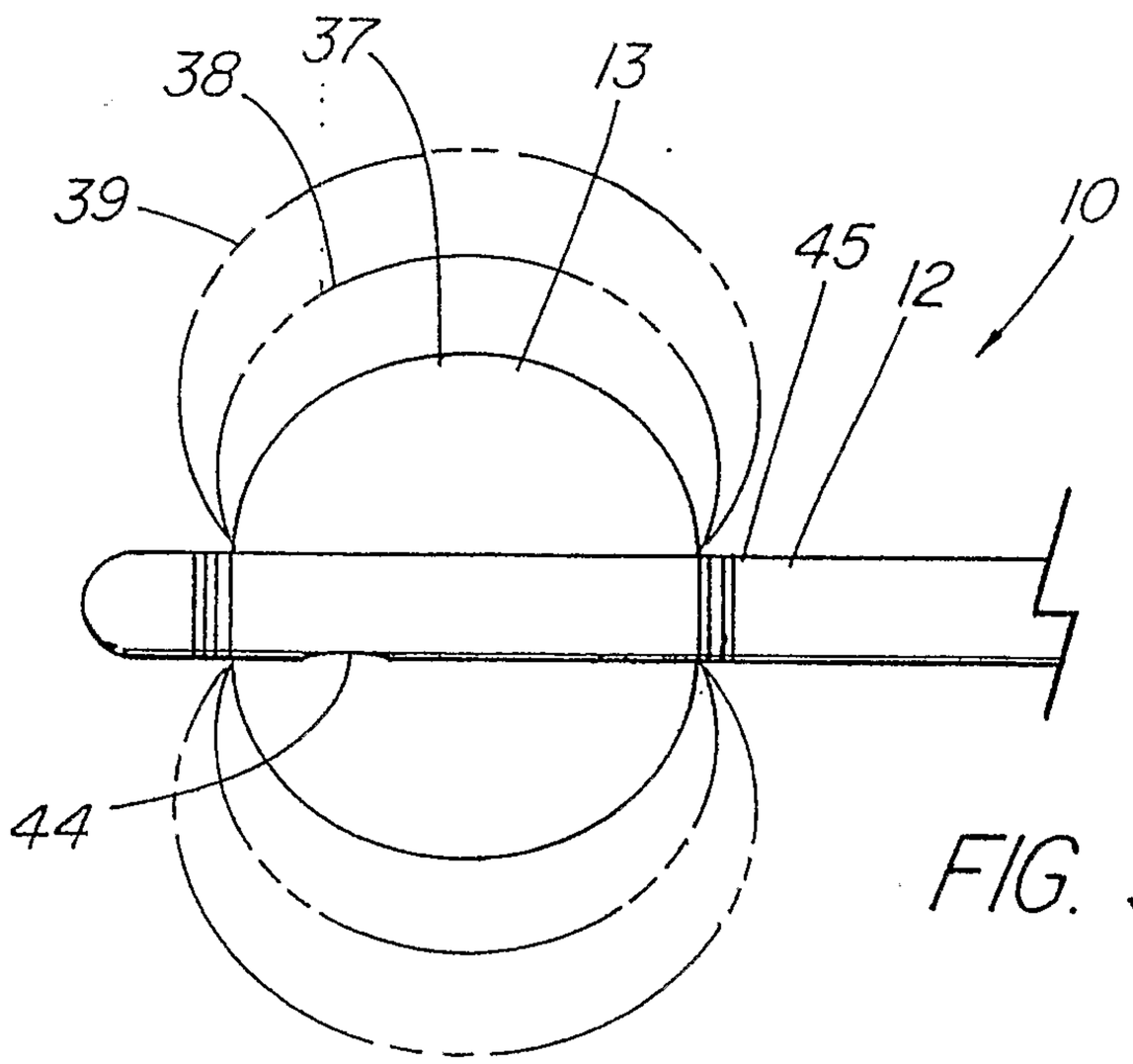
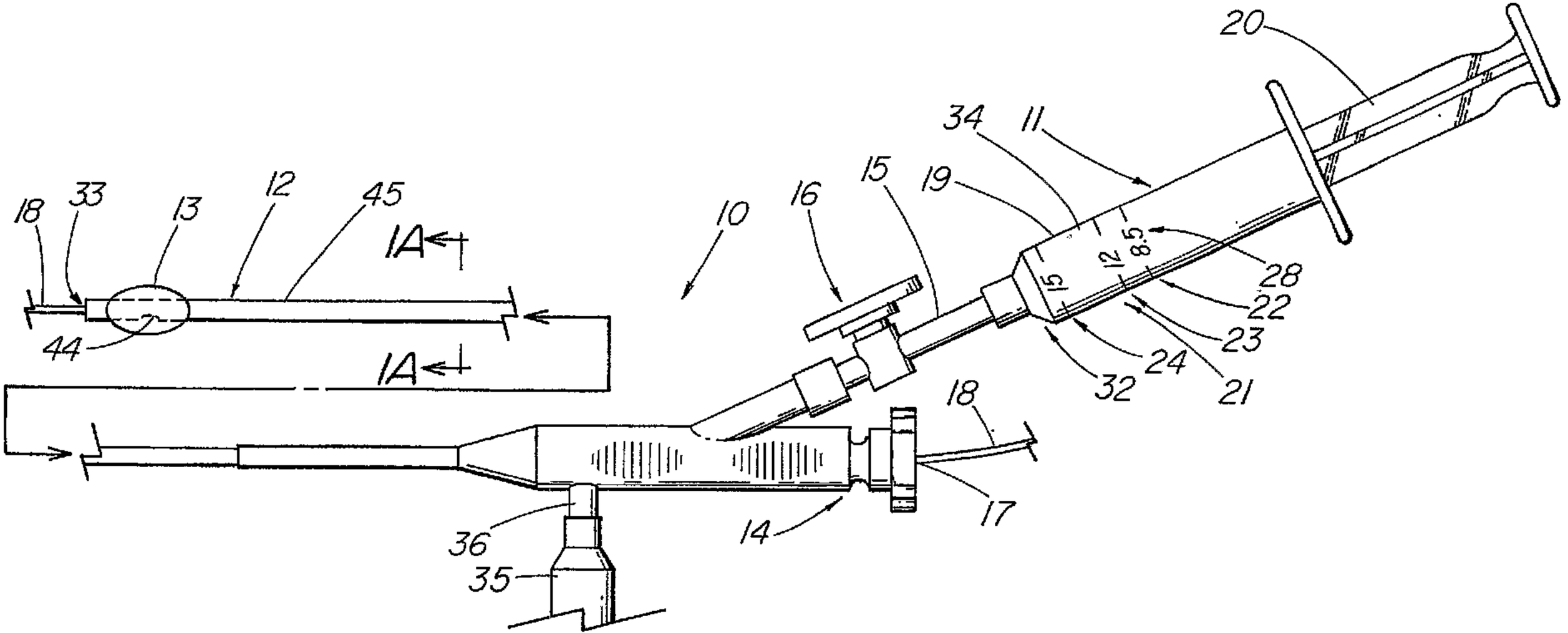


FIG. 3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