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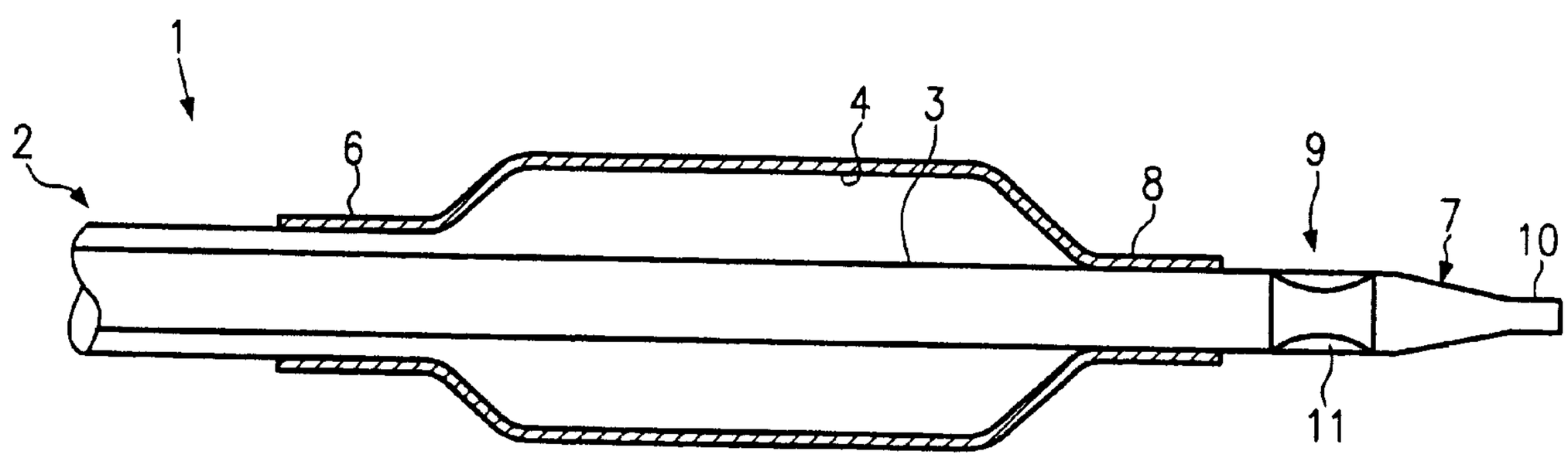
(54) Titre : CATHETER ET METHODE DE FABRICATION DE CELUI-CI
(54) Title: CATHETER AND METHOD OF MANUFACTURING SAME



(57) Abrégé/Abstract:
The invention relates to a catheter 1 comprising a catheter shaft 2, the catheter tip 7 of which is provided with a joint 9 made of a material 11 which is more flexible than the material of the catheter shaft 2. The joint 9 is disposed between the distal end 8 of the catheter shaft 2 and the distal end 10 of the catheter tip 7. The front end 10 consists of a material being the same or more rigid than that of the catheter shaft 2.

Abstract

The invention relates to a catheter 1 comprising a catheter shaft 2, the catheter tip 7 of which is provided with a joint 9 made of a material 11 which is more flexible than the material of the catheter shaft 2. The joint 9 is disposed between the distal end 8 of the catheter shaft 2 and the distal end 10 of the catheter tip 7. The front end 10 consists of a material being the same or more rigid than that of the catheter shaft 2.

Description

The invention relates to a catheter as well as a method for producing same.

For an expansion of a stenosis in body vessels or body hollows, catheter arrangements are used nowadays which comprise an expandable balloon at their distal ends. A stent may additionally be crimped on said expandable balloon, which can be placed in the stenosis for stabilizing the vascular wall. The catheter arrangement is guided to the constricted position in the patient's body with the help of a guiding wire. The stenosis is then expanded by expanding the balloon or the crimped stent is placed in the stenosis, respectively.

It is an object of the present invention to provide a catheter according to the preamble portion of claim 1, said catheter having an especially high flexibility at its distal end portion, but also a sufficient stability for achieving a good pushability.

This object is solved by the features of claim 1.

From US patent 4,782,834, a catheter having a soft tip is known, however, the soft tip of this catheter is achieved by a material transition to a material of lesser stability. This means that the complete tip is made of the soft material, resulting in the problem that this portion tends to bend. A possible result thereof is a deformation of the tip, which may lead to a constriction of the inner lumen or a permanent deformation.

The quality of a balloon catheter stands out due to the fact that the catheter can follow winding vessels easily and that the catheter can be pushed as far as possible into a stenosis,

guided by the guide wire ("tracking"). Said tracking is supported by the fact that the tip is flexible enough to guide the balloon. In case when in particular the distal end, also referred to as tip, is made from an especially suitable flexible material, the complete system follows the windings of the vessel. At the same time, it has to be guaranteed that the catheter can be securely pushed into the constricted portions of the vessel. This property is referred to as "pushability". In case the complete catheter tip, as that of the US patent 4,782,834, is formed of a soft material, in particular this required property is negatively affected. When pushing the catheter tip, same can be deformed reversibly or irreversibly and therefore also an entangling at the guide wire can occur (friction). With decreasing size of the profile of the tip, i. e. the smaller the so-called leasion entry profile, the more the mechanical sensitiveness of the tip increases and the more are the properties of the tip negatively affected by the soft material.

However, as it is desired to have an entry profile of the catheter as small as possible in order to penetrate narrow stenoses, it would be ideal to be able to form a tip having a minimum entry profile but being mechanically stable, featuring a continuously increasing diameter, but being flexible and having a homogenous transition into the balloon cone. The present invention discloses a catheter and a method for manufacturing same, which provides these mechanical properties of the tip.

According to the invention, a catheter is provided, the tip of which comprises a joint made of a material which is more flexible than the material of the catheter shaft. Said joint is arranged in balloon catheters between the distal end of the balloon and the distal end of the catheter tip. In an advantageous embodiment, the distal end of the catheter tip is

made of the same material as the catheter shaft. In a further advantageous embodiment, the distal end of the catheter tip is made of a stiffer material than the catheter shaft. The catheter tip may e. g. be a metal tip, a metal ring or be made of PTFE, it may be coated, galvanized or X-ray visible or radioopaque.

The above arrangement guarantees a nearly optimum combination of flexible tip and high pushability.

The subclaims include advantageous developments of the invention.

In claim 9, a method for manufacturing the inventive catheter as explained above is disclosed. According to an embodiment of this method, a material, e. g. in the form of a metal ring, is at first applied on a portion between the distal end of the balloon and the front end of the catheter shaft, said material being more flexible than that of the catheter shaft. For pre-fixing, this material ring can be fixed on the catheter shaft by means of a shrinkdown tubing. Subsequently, a welding is carried out by heating with a suitable radiation energy, e. g. monochrome or polycrome light, laser light, electromagnetic radiation, hot air or heat, which integrates the softer material at the desired position into the catheter shaft by the occurring material flux or material crowding. The welding is preferably executed rotationally symmetrically by a fast and aggressive energy influence. After this integration, the shrinkdown tubing is removed and the joint being movable in all directions is fixed at the desired position in the catheter shaft in its distal tip portion.

Further details, features and advantages of the invention result from the following description of the embodiments when taken in combination with the drawings.

Fig. 1 is a schematically simplified illustration of the inventive catheter,

Fig. 2 is an illustration corresponding to Fig. 1 of the distal end portion of the catheter of Fig. 1 for explaining the inventive method, and

Fig. 3 is an illustration corresponding to Fig. 1 of a second embodiment of the inventive catheter.

In Fig. 1, the inventive catheter 1 comprises a customarily formed catheter shaft 2, at the distal end 3 of which a balloon 4 having a proximal end 6 and a distal end 8 is arranged.

The catheter shaft 2 has a catheter tip 7 being part of the catheter shaft 2 and protruding beyond the distal end 8 of the balloon 3.

The catheter tip 7 of the inventive catheter 1 comprises a joint 9 composed of a material which is more flexible that the material of the catheter shaft 2. Said joint 9 is disposed between the distal end 8 of the balloon 4 and the front end 10 of the catheter tip 7 or the catheter shaft 2, respectively. As a consequence, a flexible property of the catheter tip 7 is achieved on the one hand, whereas on the other hand a high pushability is guaranteed, as the front end 10 of the catheter tip 7 is made of the same rigid material as the catheter shaft 2 or a more rigid material.

In Fig. 2, the distal end portion of the catheter 1 is shown to explain the inventive method. In this method, a material is at first applied on the portion between the distal end 8 of the balloon and the front end 10 of the catheter shaft 2, said

material being more flexible than the material of the catheter shaft 2. This material may e. g. be applied at the desired position in the form of a ring 11. In the especially advantageous embodiment shown in Fig. 2, a pre-fixing of said ring 11 is carried out by applying a shrinking foil 12. Subsequently, radiation energy, indicated in Fig. 2 by the two waved arrows L, is applied to the material 11, such that the integration of said material 11 into the material of the catheter shaft as shown in Fig. 1 and thus the formation of the flexible joint 9 is achieved.

In Fig. 3, a second embodiment of an inventive catheter 1 is disclosed, said catheter again comprising a catheter shaft 2 having a catheter tip 7 with a distal front end 10.

However, the catheter 1 shown in Fig. 3 does not comprise a balloon. Accordingly, the joint 9, which corresponds in principle to those of Figs. 1 and 2, is arranged proximal to the catheter tip 7.

The catheter tip 7 may again be made of the same material as the catheter shaft 2 or of a more rigid material.

In a further alternative embodiment, an ultrasonic head (not shown in the figures) can be provided at the distal end of the catheter shaft 2. In such an embodiment, the joint 9 is disposed between said ultrasonic head and the distal end 10 of the catheter tip 7.

Claims

1. A catheter comprising
   - a catheter shaft being made of a first material, and
   - a catheter tip
   - the catheter shaft including a joint made of a second material which is more flexible than the first material of the catheter shaft and which is arranged proximal to the catheter tip.

2. The catheter according to claim 1, characterized in that the distal end of the catheter tip is made of the same material as the catheter shaft.

3. The catheter according to claim 1, characterized in that the distal end of the catheter tip is made of a material more rigid than that of the catheter shaft.

4. The catheter according to any of claims 1 to 3, characterized in that the joint is integrated into the catheter tip.

5. The catheter according to any of claims 1 to 4, characterized in that the joint is formed as a ring.

6. The catheter according to any of claims 1 to 5, characterized in that the material of the joint is plastics.

7. The catheter according to any of claims 1 to 6, characterized in that a balloon having a proximal end and a distal end is arranged at the distal end of the catheter shaft, and that the joint is disposed between the distal end of the balloon and the distal end of the catheter tip.

8. The catheter according to any of claims 1 to 6, characterized in that an ultrasonic head is arranged at the distal end of the catheter shaft, and that the joint is disposed between said ultrasonic head and the distal end of the catheter tip.

9. Method for manufacturing a catheter comprising a catheter made of a first material and a catheter tip being part of the catheter shaft, comprising the following method steps:

- applying a second material to the catheter tip, said second material being more flexible than the first material of the catheter shaft;
- treating the second material with a radiation energy;
- welding the second material with the first material of the catheter shaft to form the joint.

10. The method according to claim 9, characterized in that the material is pre-fixed prior to the welding step.

11. The method according to claim 9 or 10, characterized in that a shrinkdown tubing is used for the pre-fixation.

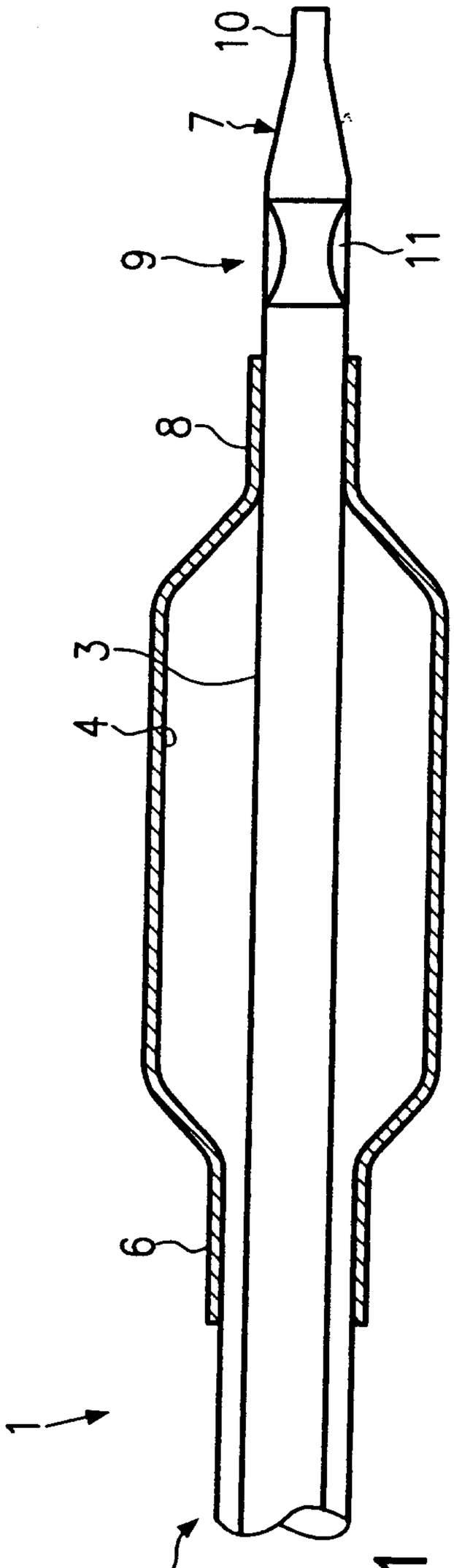


Fig.1

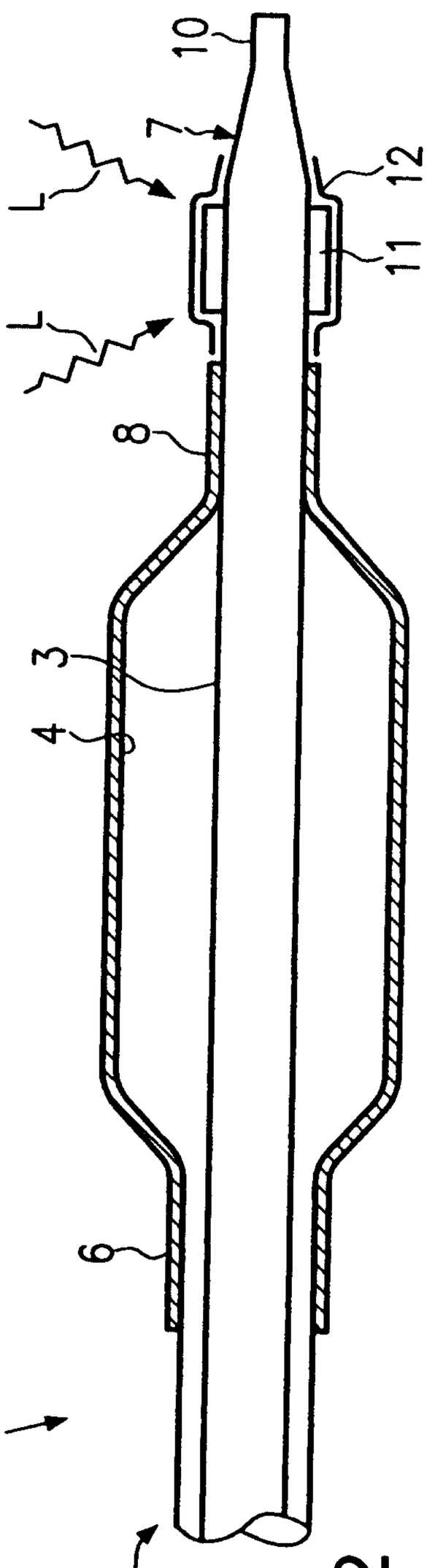


Fig.2

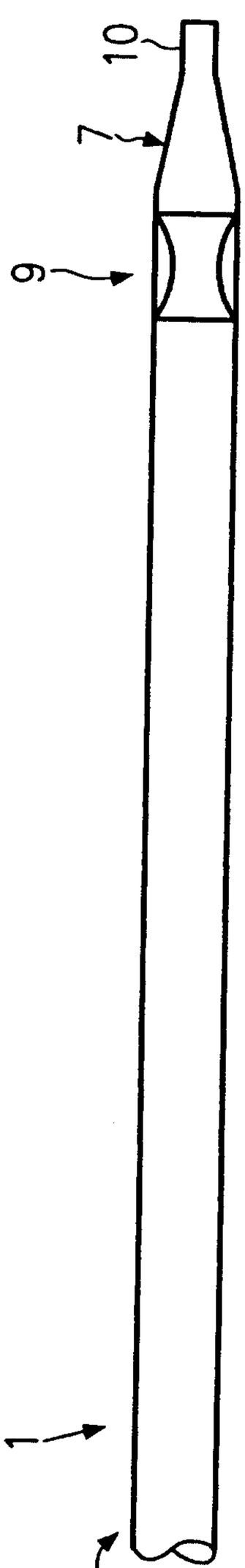
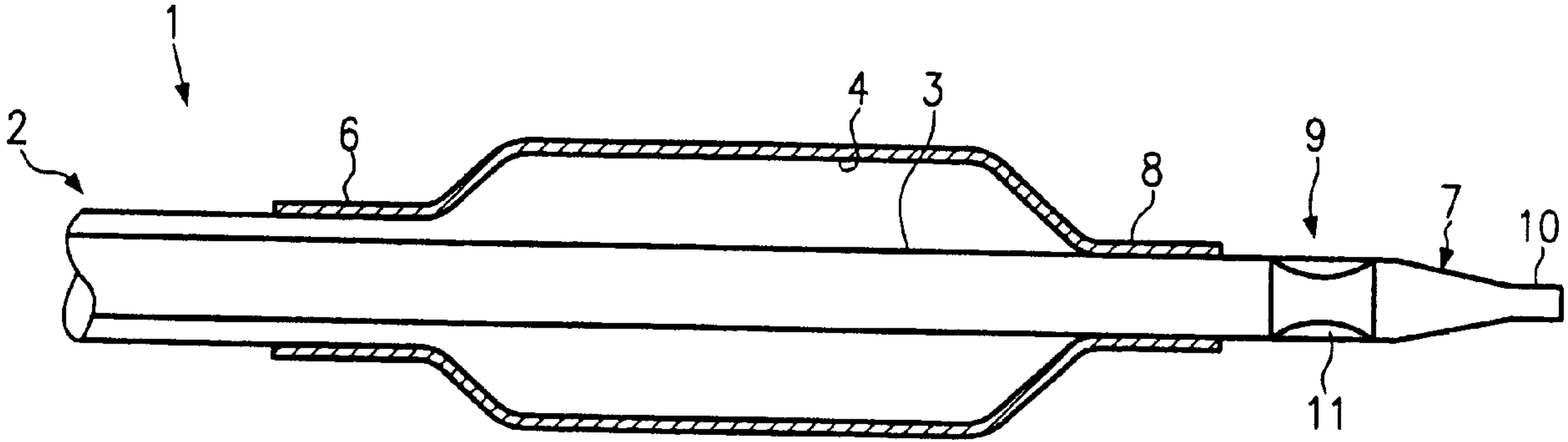


Fig.3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