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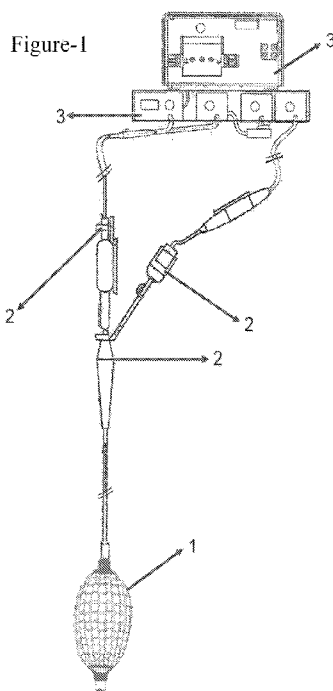
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(54) Title: COPD PEELING BALLOON CATHETER SYSTEM AND APPLICATION METHOD



(57) Abstract: Subject of the Invention is a COPD peeling balloon catheter system and application method by which endoluminal and/or endobronchial benign, premalignant and/or malignant tissue and/or hypertrophic cellular growths and/or hyperplastic cellular formations and/or unwanted biological material such as solidified lung fluids and/or lesions, secretions, body fluids and/or biologic formations in hollow tubular organs such as tracheobronchial, vascular, esophageal, urethral, vaginal, gastrointestinal ones are removed from the mucosa surfaces by peeling and/or stripping, without damaging the mucosa, using the operation channels of Bronchoscopes or Endoscopes and/or Rigid and/or Flexible endoscopes.

COPD PEELING BALLOON CATHETER SYSTEM AND APPLICATION METHOD

5 The technical field in which the invention is incorporated;

Subject of the Invention is a COPD peeling balloon catheter system and application method by which endoluminal and/or endobronchial benign, premalignant and/or malignant tissue and/or hypertrophic cellular growths and/or hyperplastic cellular structures and/or unwanted biological material such as solidified lung fluids and/or lesions, secretions, body fluids and/or
10 biologic formations in hollow tubular organs such as tracheobronchial, vascular, esophageal, urethral, vaginal, gastrointestinal ones are removed from the mucosa surfaces without damaging the mucosa by peeling and/or stripping, using the operation channels of Bronchoscopes or Endoscopes and/or Rigid and/or Flexible endoscopes.

State of art:

15 The disorder due to the Chronic Obstructive Lung Disease (COPD) emerges with the impairment of the elastic recoil feature, muscle strength metabolism and functions regarding the respiration. The main characteristic of COPD is an irreversible, progressive airway obstruction (The symptoms are being reduced and the life expectancy is being prolonged by using bronchodilators). However, in many cases the progress of the disease dyspnea, to the
20 extend, that it causes disability, and deterioration of the lung functions lead to increased hospital applications. The prognosis of such cases with progressive dysfunction is bad. The 3-year survival of cases with Cor pulmonale and undergoing long-term oxygen therapy at home has been found out to be 42%. In the study of Gore et al. it has been shown that the daily life activities, physical, social and emotional functions of patients with serious COPD is worse than
25 those with inoperable non-small-cell lung cancer. Further, it has been shown that 90% of COPD patients suffer from depression and anxiety, while the incidence is 52% among patients with a malignant tumor. It has been reported that patients with COPD are less well informed about their disease compared to cancer patients, that they enjoy less social support and that their life expectancy is restricted more.

30 It has been emphasized that for this reason palliative approaches are being applied immediately in cases with cancer, while cases with COPD are deprived of such services. It is of vital importance that secretions and/or benign, premalignant and/or malignant tissue and/or hypertrophic cellular growths and/or hyperplastic structures are removed by peeling and/or

stripping without damaging the inner surface of the bronchi, and without causing any bleeding and/or perforation.

The human body contains many tubular channels through which body fluids flow. Among these tubular organs containing bronchi, vessels and channels are the pulmonary system, the vascular system, the urinary system, the neurologic system, the ear nose and throat system, the gastrointestinal system and other body channels. Fluids passing through these channels can be occluded by an obstacle or any other obstructive process. For instance, the accumulation and solidification of secretions in the airways and/or the obstruction through benign, premalignant and malignant tissue and/or cellular growth (hypertrophia) or hyperplastic structures may restrict or prevent the airflow to a certain portion of the lung. As a second example, an obstruction in the vascular system can reduce or stop the blood perfusion at a certain region of a certain organ. And as a third example, an obstruction of the ureter due to a prostatic hyperplasia may restrict the passage of the urine through the ureter.

The removal of unwanted and/or life threatening benign, premalignant and malignant tissues and/or hypertrophic cellular growths and/or unwanted biological materials such as solidified lung secretions, secretions, body fluids and/or biological formations from the inside of different tubular body cavities is widespread procedure used in different medical disciplines such as pulmonology, cardiology, urology, gynecology, gastroenterology, neurology, otorhinolaryngology, orthopedics and general surgery.

Such procedures have significant complications.

The perforation and/or bleeding and the resulting morbidity experienced with most of known surgical procedures or resection applications are a result of abrasive, traumatic and invasive excision and resection techniques. Many of these techniques increase the risk of perforation of the lumen subject to the intervention and this leads to serious complications regarding patient and surgeon. Further, such special equipment and the methods for using them bear some disadvantages. The most common complication of such applications is perforation, deformation and/or massive bleeding. These therapy methods can be traumatic. Further, complications such as massive bleeding and structural perforation and/or deformation of the effected anatomic structure can occur. Additionally, many disorders can not be simply treated with these procedures, because they have no interventional, minimal invasive modalities, the methods are not effective, reliable and reproducible and/or the used equipment is not able to provide suitable visualization, physiologic measurements and/or the reliability of the procedure.

Therefore, more effective treatment methods focused on the results are needed. Existing conventional endobronchial and/or endoluminal balloon dilatation catheters usually have smooth surfaces. However, it is usually desired to contact the inner walls of the bronchi and/or bronchioles or tubular channels and that they have an effective stripping and sensitive abrasive surface. The abrasive surface must provide easier removal of the obstructive material, but at the same time should not lead to the development of stenosis or bleeding and/or perforation due to the contact of the balloon to the mucosa and its friction.

Additionally, there is need to a balloon catheter with a more abrasive surface in order to be used in other applications such as removing other obstacles from artificial grafts. Therefore, there is need for a balloon catheter with a stripping surface, which at the same time does not inflict damage on the mucosa and/or inner surface of the endobronchial and/or endoluminal channel. Such a abrasive surface which keeps a coherent abrasiveness independent from the inflation or dilatation of the balloon is needed.

Further, a catheter with a suitable abrasive surface to remove a thrombus or other obstructive material from an artificial graft.

An obstruction in relevant tubular organs, lungs, bronchi, vascular system, and other organs providing vital functions with blood and other body fluids can have serious consequences. Therefore, such obstructions have to be removed immediately while reducing trauma and other adverse effects to a minimum. There are some different treatments to remove obstructive formations from a bronchus, bronchiole or vessel or another tubular organ. Especially cryotherapy system, argon plasma laser system and resector balloon catheter are some therapies and systems used to resect tumoral obstructions in the lungs, trachea and bronchi. Especially thanks to the possibility to adjust the energy level (joule) through wavelengths and fiber energy transmission catheters they are used effectively in many surgical applications including bleeding control and tissue vaporization. The laser ray is transmitted to tumorous area by a fiber carrier cable for tumor ablation and/or vaporization and also in low Watt mode for bleeding control. Ultrasound and/or pneumatic shock waves are used as vasorelaxant and for the dilatation of obstructive formations with low pressure as well as to break up stones obstructing the urethra using shock waves and pneumatic vibrations effectively.

As seen in the European patent Application EP 1 913 882 A1 by Prof. Dr. Yalçın Karakoca, a new balloon class has been suggested for tumor resections. This appliance uses a balloon/catheter which can be inserted in body cavities, with a Weft Knit (Knit Stitch) (Figure-2, Detail A, Figure Explanation No. 4) surface form called Hardening Surface, made of twisted/wrapped filaments and having sharp shaving features. After placing the appliance, the

balloon is inflated and moved forwards and backwards in the cavity in order to realize a dilatation and/or resection movement over the unwanted biological material. Thus, the target material is dilatated and/or resected. This may be suitable for tumor resections with resector balloons made of metal mesh. Because tumors have to be removed by resection and bleeding and severe bleeding is a natural result of tumors. However, in the treatment of COPD a resection or with other words the removal by cutting or stripping is not possible. Because in COPD there is an extensive cellular hyperplasia and/or hypertrophy and also intensive accumulation of secretions. Cellular hyperplasia and/or hypertrophy do exist in all segments of the mucosa of the bronchial segments having a diameter of 3-5 mm in a generalized obstructive manner, so that the intensive accumulation of secretions covers all the lung mucosa in an obstructive way. Whereas tumors are local and therefore a resection may be effective even if some severe bleeding occurs. However, COPD is not a local disease, but a generalized obstructive disease. Therefore, resector balloons do not have the suitable structure and features for the treatment of COPD.

Patent applications for various Balloon Meshs have been made in the past, like in the case of the Balloon Catheter Mesh of Erhan H. Gunday with the reference number US 2012/0289982. However, as seen in FIG-4 in this application, knitting or weaving of Weft Knit (Knit Stitch) Mesh Balloons has been mentioned. This knitting or weaving form has no effective abrasive feature. Maybe it can be used to prevent the slipping of the balloon from the tissue during dilatation, but it is very insufficient in abrasion and/or stripping of the tissue without damaging the mucosa. Operations can most of the time not be made because they take too long. Again, in this patent application there is mention of a resector balloon where the Balloon Mesh (net) is knitted or woven with a metallic filament. This resector balloons made of metallic mesh may be suitable for tumor resections. Because tumors have to be removed by resection. Bleeding and even severe bleeding is a natural result of tumor resection. However, in the treatment of COPD a resection, which is the removal by cutting or stripping is not possible. Because in COPD there is a generalized cellular hyperplasia and/or hypertrophy accompanied by intensive obstructive accumulation of secretion. Cellular hyperplasia and/or hypertrophy do exist in all segments of the mucosa of all bronchial segments having a diameter of 3-8 mm in a generalized manner, so that the intensive obstructive accumulation of secretions covers all the lung mucosa. Whereas tumors are local and therefore a resection may be effective even if some severe bleeding occurs. However, COPD is not a local disease, but a generalized obstructive disease. Therefore, resector balloons do not have the suitable structure and features for the treatment of COPD.

The balloon dilatation technique includes a procedure including the inserting a deflated balloon to an obstructed area in the traches, brochus, vessel or other body tube. Later the balloon is inflated in order to open the passage of the lumen or channel. The inflation of the balloon is a method used to press the obstructive material against the wall of the channel and to provide a dilatation of the channel. While tracheal and/or bronchial dilatation balloons, balloon angioplasty are quite successful in opening the lumen of certain channels and vessels, they do not remove the obstructive material. While the obstructive material is not removed, it is quite likely that the tube will be obstructed in a relatively short period of time at the location where the application has been carried out.

The most common cause of death among patients with lung cancer is the obstruction of airways. Among lung cancer patients, one third of the cases show main airway obstructions early on, and two thirds in later phases, which may lead to asphyxia, hemorrhages and infections. These complications are the most common cause of death among patients with lung cancer. One of the commonly used appliances for various medical procedures is the “Balloon Dilatation Catheter” containing an inflatable balloon. Such catheters have many application fields including the lungs. However, the obstructions can be opened with the dilatation balloon catheters provisionally. It is also not possible to collect a sufficient amount of fluid for the pathologic examination. It is not possible to remove obstructive secretions covering all the lung and the cellular hyperplastic and/or hypertrophic structures from bronchioles with a diameter of 3-8 mm. The interventional bronchoscopy used for the treatment of lung cancer and the consequent removal of the airway obstruction increases the life quality and life expectancy among patients suffering from obstructive comorbidities in association with the cancer. Accordingly, balloon catheters are used routinely together with various endoscopes and for the dilatation with flexible and rigid bronchoscopes, as a tamponade to stop bleeding and for the fixation of appliances and as interference fixation tools to prevent the retropulsion of these appliances under backflow pressure.

In the light of an aforementioned new treatment method to remove unwanted biologic material and/or tumors from body cavities, it has been understood that inflatable balloon catheters can be used as interventional appliances to dilatate and/or resect such material – e.g. endoluminal obstructions and tumors and endovascular occlusions – in the aforementioned various interventional medical fields like cardiology, urology, gynecology, gastroenterology, neurology, otorhinolaryngology, and general surgery.

Thus, the use of dilatation and/or resector balloon catheters have provided a relatively easy, reliable, quite effective and cheap treatment method compared to other methods using mechanical laser, electrocautery, cryotherapy etc.

Resection, cutting and shaving fittings of the resector balloon catheter with a sharp shaving surface, made of filaments twisted/wrapped with metal, tend to perforate the channel wall and/or cause bleeding. Such features bring up some serious concern especially regarding incurred sections of vessels or channels. Taking this into consideration, it is clear that a surgical appliance is needed to remove obstructive structures effectively from bronchi and/or bronchioles, vessels or channels without causing perforation or any other damage in the channel.

A surgical appliance is needed to be used for the removal of various obstructive structures from various body channels, having different calibers, flexion or other configuration. An appliance is needed which is easy to use and cheap. Existing traditional resector balloons and/or dilatation balloons do not show sufficient performance regarding effective abrasion and/or stripping of the tissue without leading to bleeding. Further, existing traditional resector balloons and/or dilatation balloons do not provide sufficient performance regarding invivo or real-time effective abrasion and/or stripping and removal of unwanted biological material such as solidified obstructive lung secretions and/or benign, premalignant and/or malignant tissue and/or hypertrophic cellular growth and/or hyperplastic cellular growth in tubular organs and or tissue or secretions. Another deficiency is that known balloons are not able to collect samples for laboratory analysis or biopsy in a suitable way. Typically, such conventional balloons used for dilatation or resection have lengths of 5, 10, 15, 20, 30 or 50 mm and calibers of 2.5, 5, 10, 15, 20 30 or 50 mm. There are various smaller and larger bronchial branches with various lengths and calibers.

However, the goblet cell hyperplasia and/or goblet hypertrophy is seen in bronchioles with up to 3-5 mm diameter.

Abrasive and/or stripping balloons with 1 mm and 1.3 mm and 1.5 mm diameter in deflated state are needed to reach lobular and terminal bronchioles having a diameter up to 3-5 mm and to be able to peel and/or strip the solidified mucous obstructive material covering the epithelial surface and reaching to the terminal bronchioles together with the occurring goblet cell hyperplasia and/or goblet hypertrophy.

Aim of the invention:

In order to find a solution to the encountered problems with the aforementioned methods an endoluminal and/or endobronchial COPD peeling balloon system has been developed to remove endoluminal and/or endobronchial benign, premalignant and/or malignant tissue and/or hypertrophic cellular growth and/or hyperplastic cellular growth and/or unwanted biological material like solidified obstructive mucous secretions of the lung and/or lesions, secretions, body fluids and/or biological formations occurring in tubular organs by peeling and/or stripping from the mucosal surface, without causing unnecessary trauma and/or perforation and/or bleeding.

An endoluminal and/or endobronchial COPD peeling balloon system is provided which is used to remove unwanted and/or life-threatening benign, premalignant and/or malignant tissue and/or hypertrophic cellular growth and/or hyperplastic formations and/or unwanted biological material like solidified obstructive mucous secretions of the lung and/or secretions, body fluids and/or biological formations by peeling and/or stripping from hollow tubular organs effectively without damaging the mucosa and does not need any scrapping and/or cutting mechanism and/or metalized resector balloon sheet (mesh), woven from elastical mono and/or multifilament or elastic fiber (Knit stitch) and later turned inside out (Purl Stitch) so that it wins peeling and/or stripping features, as well as the procedure of forming, dressing and/or coating such with an elastic net structured knitting and/or coating material.

Figures explaining the invention:

Figure- 1 COPD Peeling Balloon Catheter (CPBC) system

Figure - 2 COPD Peeling Balloon and multi-path catheter and knitting texture and/or weaving thread of the net (mesh) on the balloon, knitted and/or woven and/or dressed with polymer and/or copolymer and/or silicone and/or natural rubber and/or synthetic rubber and/or metal powder and/or derivates and/or combinations thereof.

Figure -3 Interior and Section-view of the COPD Peeling Balloon and catheter

Figure -4 Exterior surface of the COPD Peeling Balloon with which it has been dressed and/or overspread and/or coated, which is mobile and/or fixed and/or pressed by molding and/or coated, knitted with mono and/or multi elastic filaments and/or filament bundles (Knit Stitch) and/or given peeling and/or reverse stripping features by turning inside out (Purl Stitch) and/or knitted as Reverse Stockinette.

Figure -5 Balloon net knitting stitch.

Figure -6 Knitting and weaving model of the Mesh Texture with Knit Stitch or Weft Knit.

Figure -7 Purl Stitch or weaving model developed to give sensitive peeling and/or stripping features to the COPD Peeling Balloon.

Figure -8 Stockinette Stitch-right side of the mesh

Figure -9 Reverse Stockinette-wrong side model developed to give sensitive peeling and/or stripping features to the COPD Peeling Balloon.

5

Accessories mentioned in the figures:

- 10 1- COPD Peeling Balloon Catheter
- 2- Connectors
- 3- Air and / or liquid pump and electric, electronic, ultrasonic and / or hydraulic shock waves and / or laser beam and / or combination thereof; an electromechanical generator and / or source,
- 15 4- Holes for electrical, electronic, ultrasonic and / or hydraulic shock waves,
- 5- Holes for laser beam,
- 6- Reverse mesh knit (Purl Stitch and / or Reverse Stockinette) and / or Mesh on the COPD Peeling Balloon
- 7- Reverse mesh knit of the COPD Peeling Balloon – Stitch head
- 20 8- Reverse mesh knit of the COPD Peeling Balloon – Stitch legs
- 9- Reverse mesh knit of the COPD Peeling Balloon – Stitch feet
- 10- Escape channel for inflation and deflation of the balloon,
- 11- Ultrasonic shock wave catheter and / or laser fiber catheter and / or inspiration and / or aspiration channel
- 25 12- Injection channel for medication and/or stopping bleeding
- 13- Balloon
- 14- Reverse mesh knit (Mesh)
- 15- Ultrasonic Shock waves
- 16- Inflatable surface of the balloon

30 Explanation of the figures:

The invention – COPD Peeling Balloon Catheter (CPBC) system - as seen in Figure 1, is a combined system which can be connected to control and energy sources (3) through connector(2).

Said system comprises an electromechanical source (3) in the form of one or more air and / or liquid and / or electric, electronic, ultrasonic and / or hydraulic shock waves and / or laser beams and / or combinations thereof. The system has an interface that can be controlled via the console or remotely via the remote control.

- 5 The COPD Peeling Balloon Catheter (1) has channels to move, inflate, deflate and/or to carry out the inflation-deflation function at high frequencies and/or to keep inflated with the aim of compression for bleeding control and/or to support with matter and/or energies (11) like air and/or fluid and/or electric, electronic, ultrasonic (15) and/or hydraulic shock waves (4) and/or laser beam (5) and/or a combination thereof.
- 10 Figure-2: The COPD Peeling Balloon (1) has structural features, produced from polymer and/or copolymer and/or silicone and/or natural rubber and/or synthetic rubber and/or metal powder and/or derivatives and/or combinations thereof.

Figure-3: A knitting and/or weaving stitch is seen. The Stitch is divided into three sections, being the head (7), legs (8) and feet (9).

- 15 Figure-4: The cover and / or Envelope and / or Enclosure and / or Sheath (Mesh) (14) with net structure with which the COPD Peeling Balloon has been dressed and/or overspread and/or coated, which is mobile and/or fixed and/or pressed by molding and/or coated, knitted with mono and/or multi elastic filaments and/or filament bundles (Knit Stitch) (6) and/or given peeling and/or reverse stripping features by turning inside out (Purl Stitch)(7) and/or knitted as
- 20 Reverse Stockinette-wrong side (9), so that it shows peeling and/or stripping features can be seen.

- The system also includes three usable calibers, being 1 mm and 1.3 mm and 1.5 mm in deflated state, in order to provide sending the COPD Peeling Balloon Catheter (1) dressed with Reverse Stockinette (9) and / or Reversed (Purl Stitch) (7) net woven and / or mesh to the bronchi
- 25 through working channels with a diameter up to 2 mm and also making it possible to aspirate material from the same channels.

The length of the inflatable (16) surface of the balloon is 10 mm, 15 mm and 20 mm, while the length of the catheters is about 100 cm or 120 cm.

- As a result, the COPD Peeling Balloon catheter (1) carries the structure and features providing
- 30 that it can be inserted into the bronchus and / or the tubular organs of the body by inserting them through the working channel of flexible bronchoscopes which have been inserted into the current body opening.

Consequently, the COPD Peeling The balloon catheter (1) carries the structure and features providing that it can be inserted into the bronchus and / or the tubular organs of the body by

inserting through the working channel of flexible bronchoscopes introduced into the current body opening, which is up to 2 mm in diameter.

Figure-5 COPD Peeling Balloon showing a cross-section of the balloon catheter (1): The COPD Peeling Balloon is covered with a woven sleeve (4) placed on the surface of the balloon catheter (1). The woven sleeve (4) can be made from elastic, polyurethane, metallic dyes, elastic-containing threads.

It is positioned so as to cover the entirety (4) of the peeling balloon (1).

Detailed explanation of the invention:

Subject of the Invention is a COPD peeling balloon catheter system and application method by which endoluminal and/or endobronchial benign, premalignant and/or malignant tissue and/or hypertrophic cellular growths and/or hyperplastic cellular structures and/or unwanted biological material such as solidified lung fluids and/or lesions, secretions, body fluids and/or biologic formations in hollow tubular organs such as tracheobronchial, vascular, esophageal, urethral, vaginal, gastrointestinal ones are removed from the mucosa surfaces without damaging the mucosa by peeling and/or stripping, using the operation channels of Bronchoscopes or Endoscopes and/or Rigid and/or Flexible endoscopes.

It has been developed for the sensitive peeling and/or stripping of dismembered cells and/or tissues whose connective tissues have been weakened and/or disconnected by using a balloon or high frequency pressure applications and/or hypertrophic cellular growth and/or hyperplastic formations and unwanted biological material like solidified lung secretions and/or lesions, secretions, body fluids which lead to COPD, from the mucosal surfaces where they are located, without damaging the mucosa.

Another subject of the invention is to provide a peeling and/or stripping surface and/or providing a peeling and/or stripping surface combined with a fluid and/or air pump for destruction by pressure. There is a catheter connected to the balloon and a controlled pump source which supplying fluid and/or air through the catheter inflates the COPD peeling balloon, deflates it, works in high frequency mode and permanent inflation mode.

It can be inflated by a fluid and/or air pump whose speed, pressure and frequency can be adjusted electronically.

Further, the efficiency can be enhanced by supporting with radial fiber laser and ultrasonic shock wave technologies.

Available is a laser production source or generator which works simultaneously with the COPD peeling balloon, a laser fiber catheter to transmit the produced laser beams to the balloon

segment and a channel to make the laser fiber catheter reach to the balloon segment along the COPD Peeling Balloon Catheter.

More specifically:

The procedure of forming, dressing and/or coating of a balloon catheter (1) with a mesh having elastic net structure and/or coating material, which has been knitted in tubular form (Knit Stitch and/or Stockinette Stitch), and then been given peeling and/or stripping features by inverting (Purl Stitch ve/veya Reverse Stockinette) to make it have peeling and/or stripping features. Further, by supporting the COPD Peeling Balloon Catheter by available laser and/or high and/or low frequency ultrasonic and/or pneumatic shock waves, its efficiency can be enhanced.

In our invention, in which,

The distal and proximal terminals of the elastic mesh is being attached on and to the distal terminal of a multi-path, multi-channel and multi-connector catheter,

It is fixated by thermal curing with silicone and/or photocuring and/or ultrasonic welding and/or binding with an elastic and/or non-elastic thread and/or a very thin wire,

There are beam windows in the interior of the balloon of the multi-path or multi-channel catheter which provide the transmission of the laser beams to the bronchial mucosa when the balloon is inflated,

There is an open-ended channel providing the simultaneous pressure application of the ultrasonic and/or pneumatic shock waves on the bronchial mucosa and transmission of ultrasonic shock waves to the mucosa through the elastic ultrasonic shock wave transmission wire available inside the balloon, from the terminal and windows when the balloon is inflated,

An endoluminal peeling balloon system has been developed which:

- Can work combined with an air and/or fluid pump and/or electromechanic energy sources, having inflation and/or deflation rates with adjustable frequency, vibration, speed and pressure.

Also,

- Having compatible balloon geometries which can be controlled independently
- Having the structure and functions to harmonize with the inner diameters of the lumen in which the obstructive and/or biological formations are located

- Making it possible to collect tissues in a suitable way for sampling/analysis.

Industrial application

Our COPD peeling balloon catheter system and application method by which endoluminal
5 and/or endobronchial benign, premalignant and/or malignant tissue and/or hypertrophic
cellular growths and/or hyperplastic cellular structures and/or unwanted biological material
such as solidified lung fluids and/or lesions, secretions, body fluids and/or biologic formations
in hollow tubular organs such as tracheobronchial, vascular, esophageal, urethral, vaginal,
gastrointestinal ones are removed from the mucosa surfaces without damaging the mucosa by
10 peeling and/or stripping, using the operation channels of Bronchoscopes or Endoscopes and/or
Rigid and/or Flexible endoscopes also provide,

- support of the developed woven and/or knitted elastic mesh sheet of the balloon with laser
beams and high and/or low frequency ultrasonic and/or pneumatic shock waves, to effectively
remove obstructive biological material and/or cellular formations from bronchi and/or
15 bronchioles without damaging the mucosa surface and without causing stenosis or bleeding
and/or perforation.

- a control unit with compact structure, touch screen, equipped with remote control, practical
multi-connector and a pneumatic system which can be operated in connection with the central
medical pressure air system and/or a portable bottle, which can be connected to the local grid
20 circuit, to support and/or control the COPD Peeling Balloon System

- a flexible balloon system where the endobronchial COPD Peeling Balloon can be connected
with a catheter and the proximal and distal terminals of the woven sleeve can be attached to the
catheter, and be fixated by the shrink balloon method, be fixated by ultrasonic welding and
thus, moving simultaneously to the inflation and deflation of the balloon.

25 These features will be a reason for preference in the health sector.

CLAIMS

1. A COPD peeling balloon catheter system (1) and application method by which endoluminal and/or endobronchial benign, premalignant and/or malignant tissue and/or hypertrophic cellular growths and/or hyperplastic cellular structures and/or unwanted biological material such as solidified lung fluids and/or lesions, secretions, body fluids and/or biologic formations in hollow tubular organs such as tracheobronchial, vascular, esophageal, urethral, vaginal, gastrointestinal ones are removed from the mucosa surfaces without damaging the mucosa by peeling and/or stripping, using the operation channels of Bronchoscopes or Endoscopes and/or Rigid and/or Flexible endoscopes, wherein the balloon catheter (1) has been given peeling and/or stripping features by dressing, fixating, attaching, welding (3) and/or forming, dressing and/or coating with a coating agent of the elastic mesh, which has been given peeling and/or stripping features by weaving and/or knitting as a round tube (Knit Stitch (6) and/or Stockinette Stitch), so that the head (7) and the feet (9) of the stitch is on the upside and the legs (8) are on the underside, and then inverting the tube (Purl Stitch (7) and/or Reverse Stockinette (9)), on the balloon (13).
- 2-The developed COPD peeling balloon catheter system (1) and application method of claim 1, wherein laser (5) and high and/or low frequency ultrasonic and/or pneumatic shock waves (15) can be used.
- 3- The developed COPD peeling balloon catheter system (1) and application method of claim 1, wherein it comprises a mesh, woven and/or knitted from mono and/or multi-filament threads or thread bundles (Purl Stitch (7) and/or Reverse Stockinette Mesh (14)) and dressed, overspread, coated, attached on the balloon (13).
- 4- The mesh overspread on the balloon (13) of claim 3, wherein it has been produced with polymer and/or copolymer and/or silicone and/or natural rubber and/or synthetic rubber and/or metal powder and/or derivatives and/or combinations thereof.
- 5- The developed COPD peeling balloon catheter system (1) and application method of claim 1, wherein
- the distal and proximal terminals of the mesh are attached on and to the distal terminal of a multi-path, multi-channel and multi-connector (2) catheter, and

- it is fixated by thermal curing with silicone and/or photocuring and/or ultrasonic welding (3) and/or binding with an elastic and/or non-elastic thread and/or a very thin wire.

6- The developed COPD peeling balloon catheter system (1) and application method of claim 1, wherein it comprises beam windows in the interior of the balloon of the multi-path or multi-channel catheter which provide the transmission of the laser beams (5) to the bronchial mucosa when the balloon is inflated.

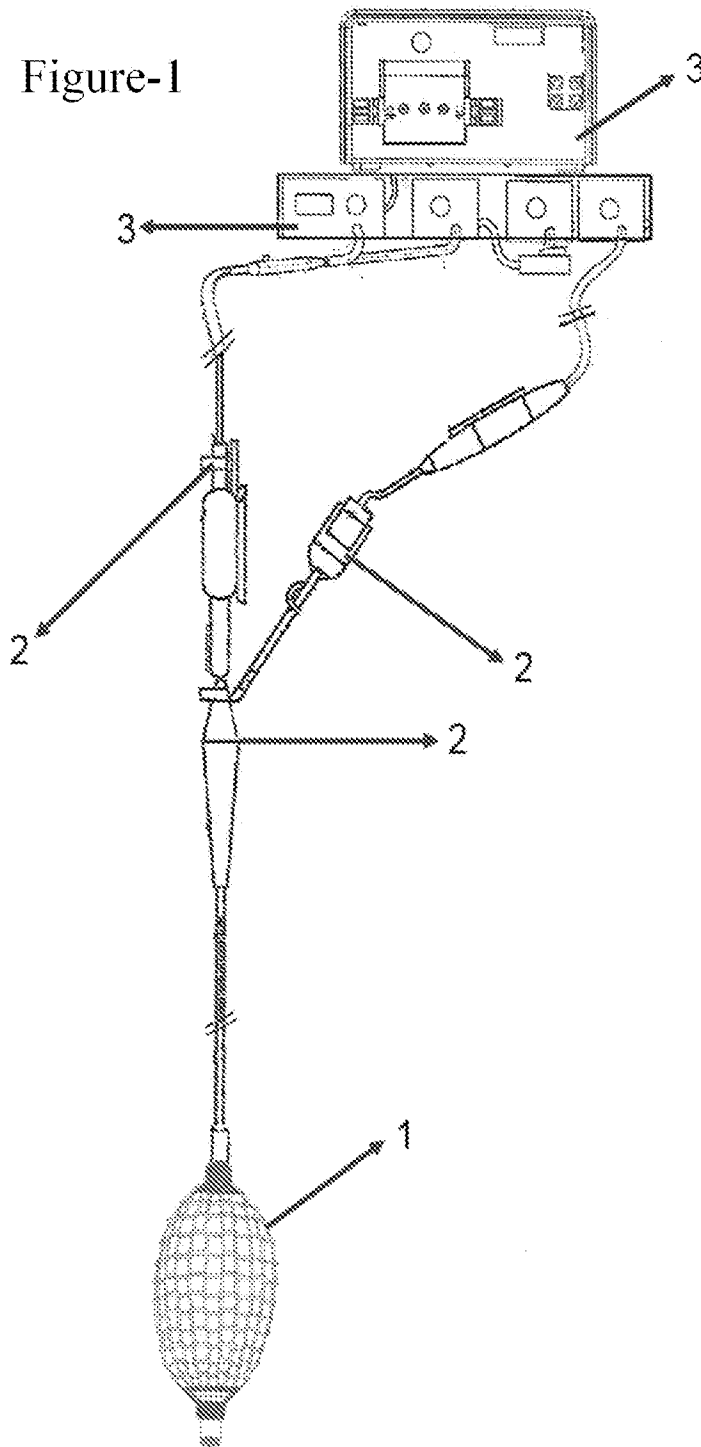
7. The developed COPD peeling balloon catheter system (1) and application method of claim 1, wherein it comprises an open-ended channel (11) providing the simultaneous pressure application of the ultrasonic and/or pneumatic shock waves (15) on the mucosa and transmission of ultrasonic shock waves (15) to the mucosa through the elastic ultrasonic shock wave transmission wire (15) available inside the balloon, from the terminal and windows when the balloon is inflated.

8- The developed COPD peeling balloon catheter system (1) and application method of claim 1, wherein it comprises a catheter connected to the balloon (1) and a controlled pump source which by supplying fluid and/or air through the catheter inflates the COPD peeling balloon, deflates it, works in high frequency mode, intermittent inflation mode, deflation mode and permanent inflation mode.

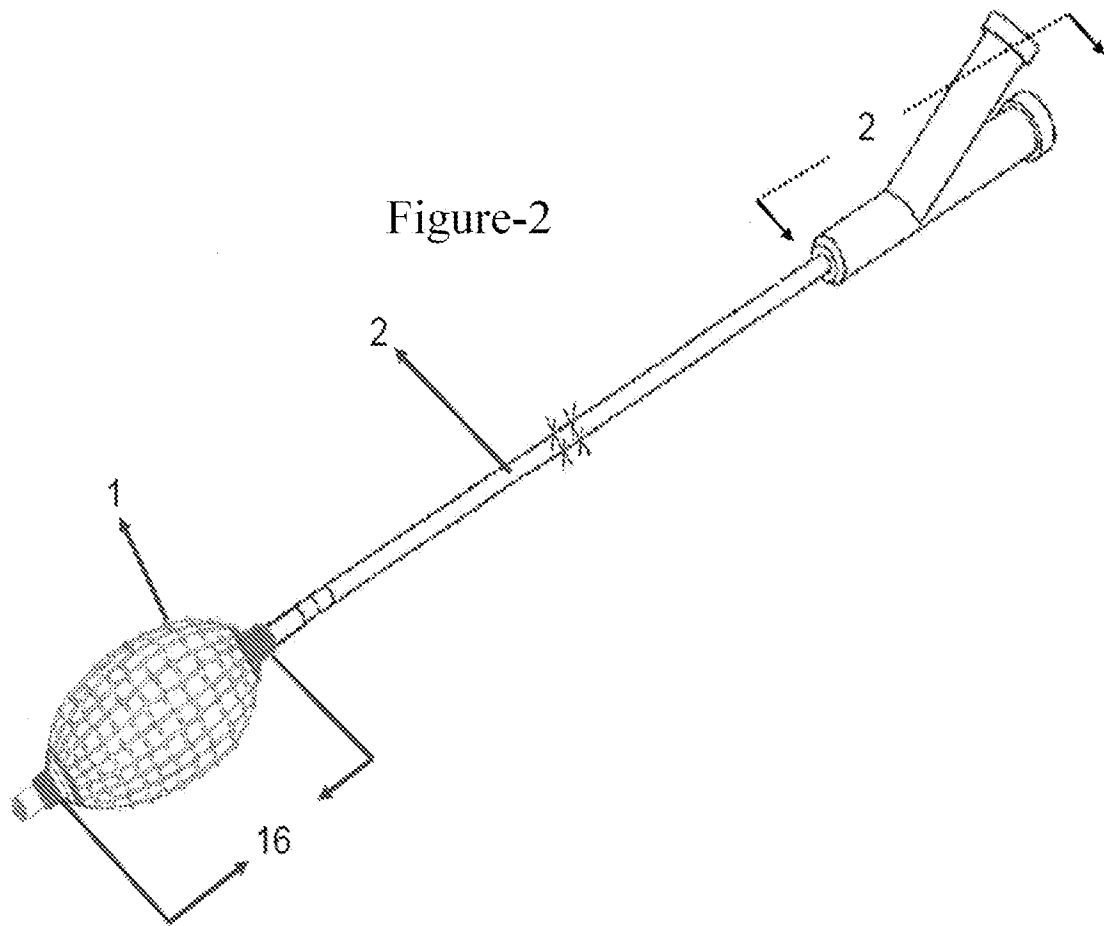
9- The developed COPD peeling balloon catheter system (1) and application method of claim 1, wherein it comprises a laser (5) production source or generator (3) which works simultaneously with the COPD peeling balloon, a laser fiber catheter to transmit the produced laser beams (5) to the balloon segment and a channel (11) to make the laser fiber catheter reach to the balloon segment along the COPD Peeling Balloon Catheter.

10- The developed COPD peeling balloon catheter system (1) and application method of claim 1, wherein it comprises a production source or generator (3) for high and/or low frequency ultrasonic and/or pneumatic shock waves (15), which works simultaneously with the COPD peeling balloon, an elastic shock wave transmission wire to transmit the shock waves produced by the source (3) to the balloon segment and a channel (11) to make the elastic shock wave transmission wire reach to the balloon segment along the COPD Peeling Balloon Catheter.

Figure-1

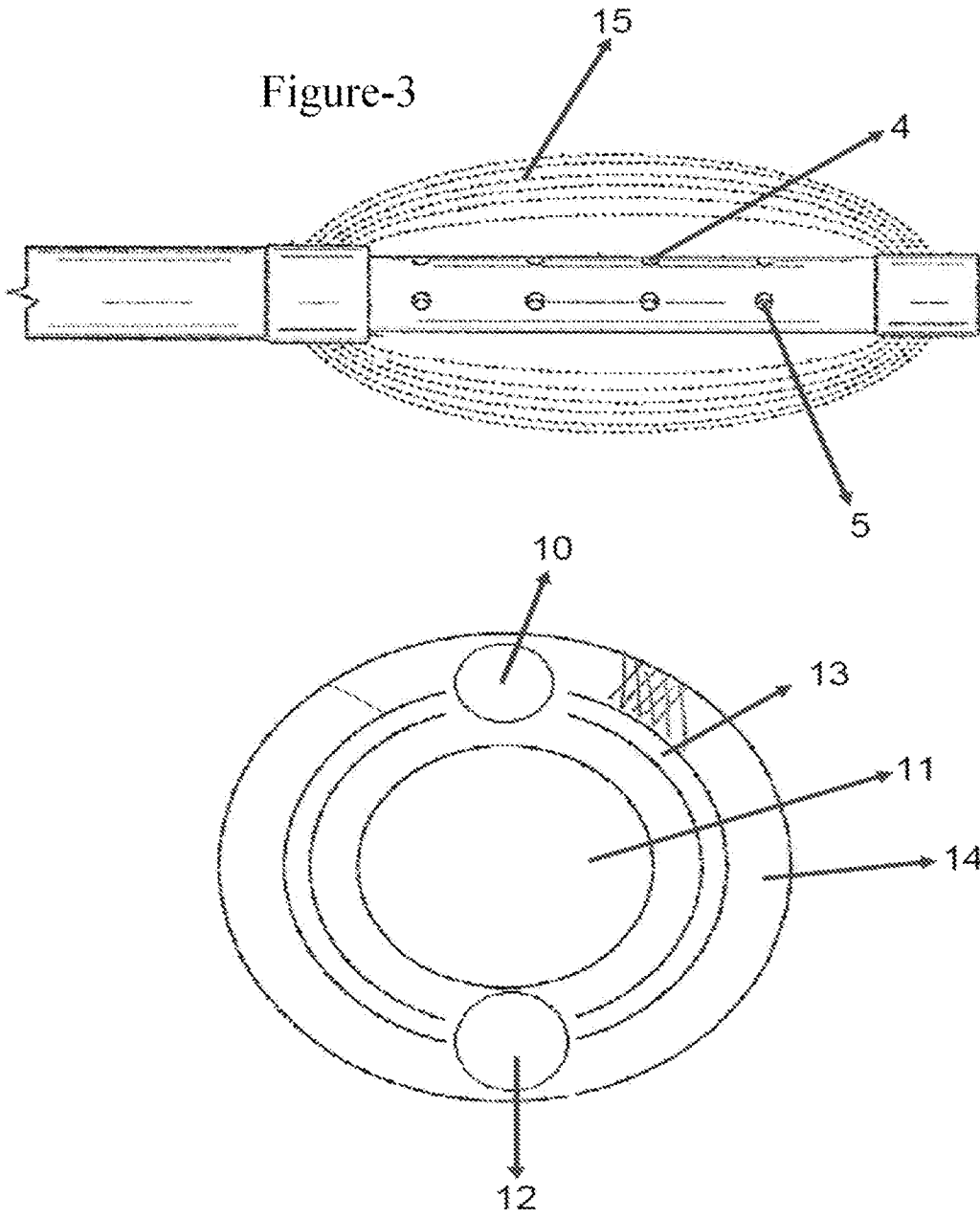


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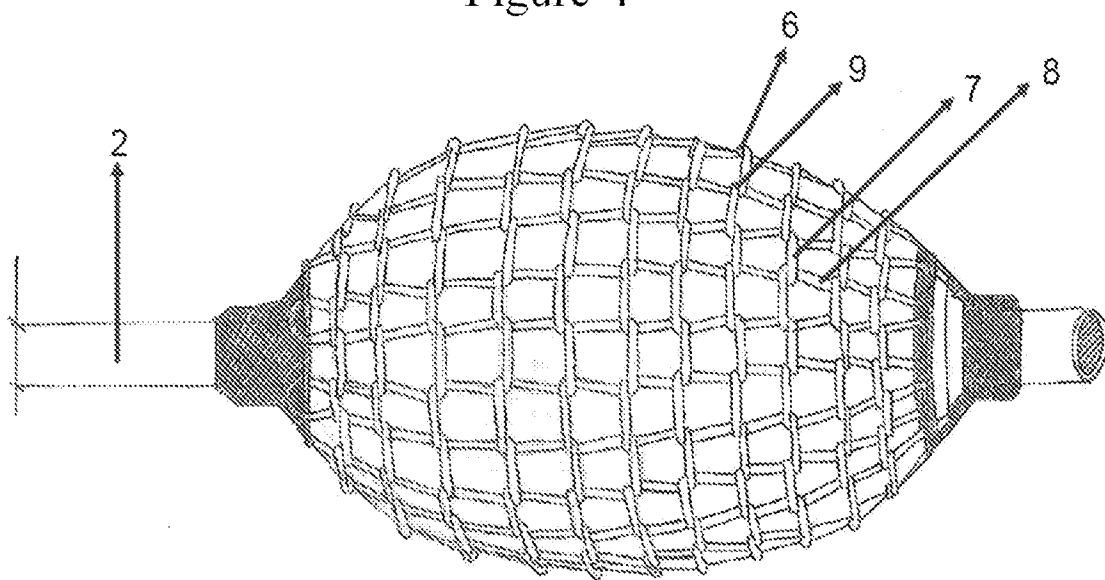
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Figure-3



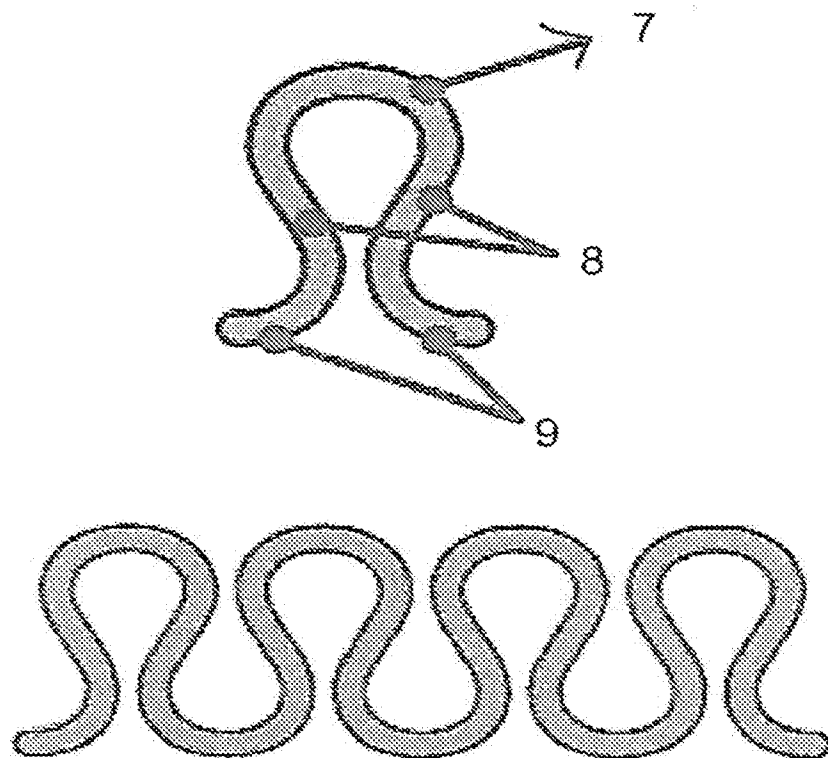
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Figure-4



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Figure-5



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Figure-6

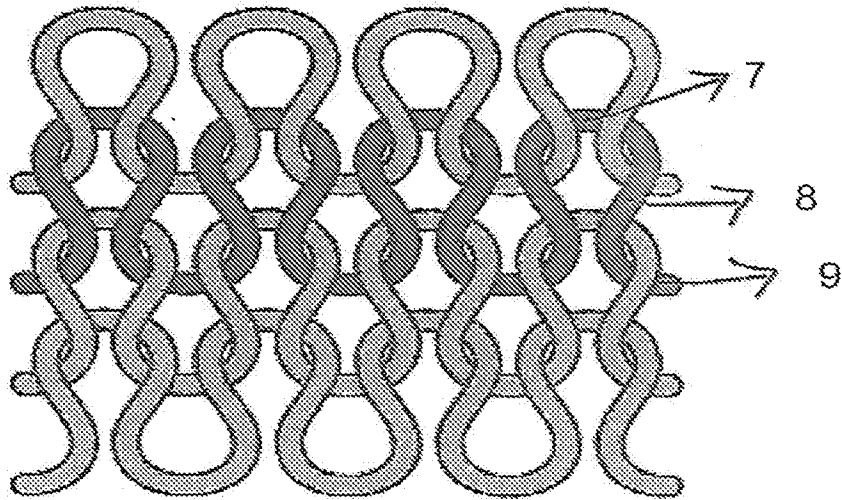
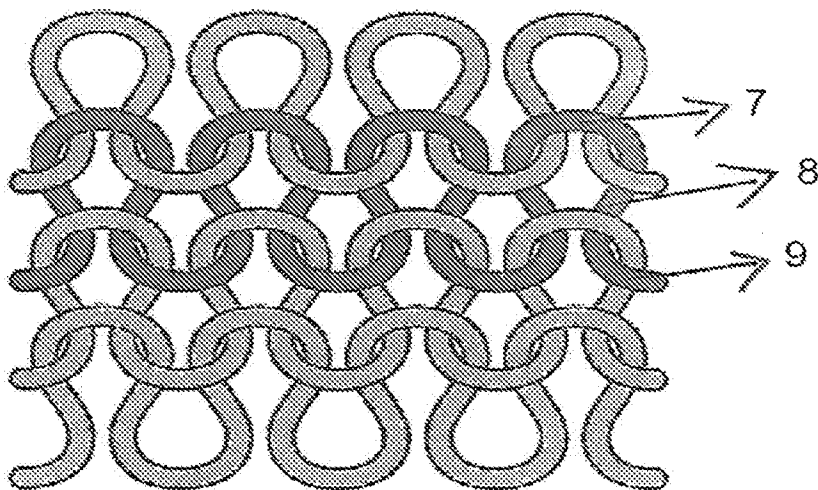


Figure-7



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Figure-8

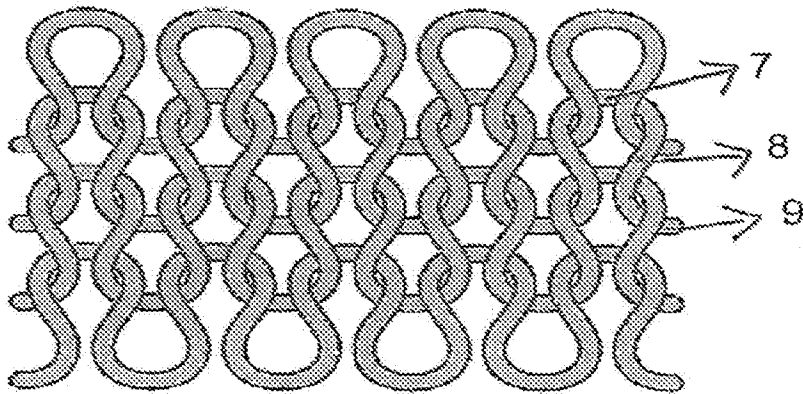


Figure-9

