Abstract:
The invention of the present application is a balloon dilatation catheter providing illumination at the distal tip. Different from the known status of the art and via the novel system found in its structure, it provides the advantage of observing not only the proximal tip of the balloon, but also the distal tip. Said paranasal sinus balloon dilatation catheter, comprises a battery (14) performing the task of power source, a LED (16) performing the task of light source (16), and on-off button (15) in the hub (10) part. It comprises one or more optic fibers (23) extending within the tubular catheter shaft (20) towards distal direction from the proximal hub (10) body and providing illumination at the catheter tip part.

Figure 6

Title: A BALLOON DILATATION CATHETER FOR TREATMENT OF PARANASAL SINUS DISEASES
Description

Title of Invention: A BALLOON DILATATION CATHETER FOR TREATMENT OF PARANASAL SINUS DISEASES

Technical Field

[1] The present invention relates to a steerable sinus balloon catheter and it relates to use of this catheter in treatment of paranasal sinus diseases with some improved functions. Said improvements are based on providing illumination at the distal tip of the catheter without the need for an external source by means of adding light source and optic fibers into the structure of the catheter.

Disclosure of Invention

Technical Problem

[2] In order to provide thorough understanding of the present invention, sinus system anatomy has to be considered. Therefore, paranasal sinus system anatomy is shortly described below.

[3] Paranasal sinuses are four pairs of cavities found within the cranium or within the cranial bones surrounding the nose and they are normally filled with air. These are the frontal sinuses found at the brow region above the eyes, the maxillary sinuses found within each of the cheekbones, the ethmoid sinuses found just behind the nose bridge and between the eyes, and the sphenoid sinuses found behind the eyes and the ethmoid sinuses.

[4] Paranasal sinuses comprise ducts called ostium for drainage of mucus, air, and other substances and their movement within the sinus system. In case of occurrence of inflammation in the tissues forming this duct and the ostiums, it would cause swelling of these tissues and prevention of normal liquid flow. Said inflammation may occur due to allergy, toxic substances, nose polyps, and other factors. Pathological increase that occurs in the inflammatory tissue in time would cause permanent disruption of liquid flow within the sinus system.

[5] Sinusitis; is the situation wherein one or more of the four paired sinus couples are chronically or episodically blocked due to inflammation and swelling. The most significant symptom of chronic sinusitis is nasal blockage that becomes severe at night. The basic problem behind chronic sinusitis is arrival of inadequate air to sinuses as a result of blockage of the sinus ducts.

[6] Nowadays, sinusitis is a frequently encountered disease that affects large populations. Recently, especially as a result of the improvements made in medical technology, the technologies and devices, which both increase the chance of success in chronic sinusitis surgical treatment with less trauma and greatly reduces the risk of
complication, have been presented to use.

Considering above described sinus anatomy, the devices and visualization techniques used during surgical intervention in dark and narrow sinus structures are of great importance in terms of the success of treatment. In the known status of the art, sinus operations are generally endoscopically made. Thanks to the use of endoscope in sinus surgery and the improvements made, these surgeries can be made intranasally. In this way, external incision made in the classical sinus surgery is no more required.

This method used in the prior art is called Functional Endoscopic Sinus Surgery and it is based on cutting of the hypertrophic sinus tissue and bones of the patient by endoscopic surgery and thus broadening of the narrowed or blocked ostiums and providing normal drainage. Nose endoscopes are optic tools providing the facility to reach and illuminate the dark regions in the nasal cavity without making an externally visible incision.

Although endoscopic sinus surgery is among the methods that are frequently preferred, it is observed to cause some complications. Pain and haemorrhage of the patient following surgery can be given as examples to the disadvantages of this surgical treatment method. Moreover, it is also known that many patients continue to have the symptoms although they have gone through a series of endoscopic surgical operations.

Moreover, important organs and anatomic structures found around the sinuses may be damaged as a result of the non-rigid and non-flexible structures of the medical instruments used in this surgery. And this is the main reason of pain following surgery. In addition to these, it also has the disadvantage of having long recovery period.

Since a great deal of the problems encountered is caused by inadequate consideration of the anatomy during surgery due to various reasons, the need for surgical navigation has occurred and improvements are made in this field. As a result, computer-aided surgery used in various fields is improved to be used in endoscopic sinus surgery.

This method developed for computer-aided sinus surgery is based on real time monitoring of the functional parts of the instruments used during surgery with the help of a special device and software within the complex sinus anatomy with a margin of error that is less than 1 mm.

In spite of the improvements made in the field of visualization, with the purpose of eliminating the drawbacks mentioned above as the non-rigid and non-flexible structures of the medical instruments used giving harm to important organs and anatomic structures around the sinuses and correspondingly occurrence of post-operation pain in the patients and having long recovery period etc, some improvements are made in the tools and methods. In addition to these, balloon dilatation method can be given, which is frequently preferred, and minimizes the damage given to the tissue.
and bones.

[14] Treatment of diseases by means of inflating balloon etc. flexible structures within the nose is known from the patent Nos US 6027478 and US 5546964. However, these patents relate to use of the said inflatable flexible structures in treatment of nasal bleeding etc. diseases.

[15] The main principle of using balloon dilatation in sinuses is reaching the sinus duct with the help of sufficiently thin catheters without damaging tissues and broadening of the blocked area via balloon. In more detail, in this method, a flexible balloon catheter is inflated at the blocked region and then removed. In this way, blocked sinus ducts are broadened and normal flow is obtained. Balloon dilatation is known to be a method used alone or together with other endoscopic surgery techniques.

[16] In the prior art, during balloon dilatation method, visualization (imaging) is achieved by means of fluoroscopy or endoscopy and illumination is made by means of luminous guide wires. Balloon dilatation method is used in maxillary sinus, frontal sinus, and sphenoid sinus diseases, and cannot be used alone in ethmoid sinuses.

[17] Patent publication no US 201 1/00224652 can be given as an example to the documents using sinus treatment tools operating with the use of inflatable balloons. Said patent discloses; a balloon dilatation catheter comprising a rigid internal guide wire and a movable shaft in connection with a balloon adapted such that it would skid over this internal guide wire.

[18] The American patent no US 2008/00208243 A1 discloses a balloon catheter having a previously adjusted angle in order to be able to be pushed into the sinuses and comprising a hard hypotube. In order to be able to position the balloon catheter in the desired ostium during surgical operation, the balloon catheter has to be pushed forward within the complex sinus anatomy. The catheter, which is the subject of the said patent application, does not enable pushing forward easily and without giving damage to other tissues within the sinus anatomy due to its rigid structure and previously determined fixed angle. Moreover, the problem of not fitting of a fixed-angle catheter formed of hard hypotube into different sinus anatomies of different people is another disadvantage for doctors. And production of various catheter sets having different fixed angles for patients having different anatomic structures is not a practical solution, which is quite expensive.

[19] An application made for bringing solution to the above said problem is the application no US 2006/0004323 A1. The invention of this application is developed for providing easy navigation within the complex sinus anatomy. The purpose of the invention is to provide surgical instruments and methods about the use of these instruments, which have form and flexibility that would be adapted to sinus structures varying according to different patients.
The requirement for the surgeon to hold the endoscope with one hand and manipulate the surgical instruments with the other hand can be given as an example to the problems about visualization encountered during endoscopic surgery and balloon dilatation method. As a result of the need for integrating surgical instruments with the endoscope, sinus guide catheters, which can be used transnasally, and are connected to an endoscope are developed. The patent application with publication no US 2006/0063973 A1 can be given as an example to similar patents.

Briefly, if the prior art sinus balloon dilatation instruments and methods, various examples of which are given above, are to be assessed in general terms, it can be said that the main problem is the lack of instruments, which has a structure to be used easily within the sinus anatomy, and at the same time helps providing an effective visualization. Starting from the prior art products and methods, in the balloon dilatation method, two general systems are presently used for observing the position of the balloon within the sinus anatomy.

One of these is visualization by fluoroscopy technique, as described above. In this method, balloon catheter marker bands are used. As known, fluoroscopy is formation of the view of the patient on a fluorescent screen by means of an X-ray source. Although the level of X-rays used in this treatment method is low, the patients and the doctors are exposed to high level of radiation as a result of the long exposure time. In addition to this, a radiology laboratory is required, which brings limitation to the environments where the operation can be made.

In order to eliminate the problem of using fluoroscopy device for providing appropriate location of the balloon catheter in the sinus ducts, guide wires providing light at the tip part are developed, and thus operations can be made on the frontal and maxillary sinuses without using fluoroscopy. In this method, first of all, the guide wire enters into the sinuses with the help of shape-adjusted sinus guide. Following entrance of the wire into the sinus cavity, the light emitted from the tip of the guide wire can be observed outside the area of operation, on the face of the patient. In this way, entrance of the guide into the sinus cavity is observed. Afterwards, the balloon catheter is sent forward from the sinus entrance on this guide wire. Since the guide wire cannot support the balloon catheter, a sinus guide has to support the catheter for entrance into the sinus structures with the correct angle.

Since the illumination provided by the luminous guide wire would only show the position of the guide wire entering into the sinus, there would be still need for visualization of the balloon position. However, only the proximal tip of the balloon can be visualized by means of endoscopic camera.

The main purpose of the invention of the present application is to eliminate the above said problems. In the prior art instruments, illumination is provided by means of
separate devices or guide wires. The purpose is to provide a sinus balloon catheter, which is more advantageous than the prior art instruments, and which provides an illumination system at the tip part. In this way, it enables more effective observation of the sinus balloon catheter position in the sinus ducts.

**Brief Description of The Invention**

[26] The invention of the present application is a sinus balloon catheter providing illumination at its distal tip. It provides visualization by using a separate endoscopic camera as in the prior art. Here, the important part is, it not only enables observation of the proximal tip of the balloon (1), but also provides the advantage of observing the position of the distal tip, thanks to the system providing illumination at the distal tip of the catheter. In other words, the light spread from the catheter tip part can be observed at the outer part of the operation area, which is, on the face of the patient.

[27] In addition to this, since the said optic fibers (23) support the required pushing capability, the need for using a separate guide wire is eliminated. In this way, a flush lumen (22) found in the catheter structure can be used for sinus irrigation when required.

[28] Another advantage is having the illumination system (14, 15, 16) at the hub (10) of the catheter instead of having in a separate device. In this way, illumination can be made without the need for using a separate light source or a connection. This would naturally increase the ergonomics of the surgical instrument for the doctor.

[29] The catheter of the invention is basically formed of a hub (10) and a shaft (20). Catheter comprises a balloon inflation-deflation port (11) in the hub (10) part, a battery (14) performing the task of power source (14), a LED (Light Emitting Diode) (16) performing the task of light source (16), and on-off button (15). Moreover, it comprises a chamber for battery, accumulator etc. power source (14). It comprises one or more optic fibers (23) providing illumination at the catheter tip part in its body.

[30] In one embodiment of the invention, said catheter tip part is made of soft and flexible material. In another embodiment of the invention, the tip of the catheter is made of hard and transparent material performing the task of a lens. Said catheter can have previously shape-adjusted linear form, previously shape-adjusted curved form, or re-shapeable and steerable form in accordance with the embodiments/configurations to be preferred. Moreover, in any embodiment, the present invention catheter can comprise flush lumen (22).

**Solution to Problem**

**Detailed Description of The Invention**

[31] The sinus illumination system (14, 15, 16, 23) of the invention relates to having the optic fibers (23), which provide light transmission to the target region, in balloon
catheter structure. An embodiment of the novel sinus balloon catheter of the present invention developed for paranasal sinus surgery is shown in Figure-1. Novel balloon dilatation catheter, comprises a hub (10), which enables manipulation by means of being held by an operator from the proximal tip, and also forms the weld; a balloon inflation-deflation port (11) found on the said hub (10) body; and a light source (16) found on the said hub (10) body. Said light source (16) can be a high power led (16). Moreover, it comprises accumulator, battery (14) etc., and a chamber for these and an on-off button (15).

The invention comprises one or more optic fibers (23) laying along its inner body (25) and providing transmission of light to the distal tip of the sinus balloon dilatation catheter. As described above, different from the prior art sinus balloon dilatation catheters, said catheter comprises the light source (16) required for illuminating of the sinus cavities in its structure, and thus the operator using the said catheter can see the position of the balloon (1) without the need for using external sources and devices, X-ray etc. methods harmful for the health of both the patient and the operator. Usage of the catheter without the need of being connected to another light source (16) also provides advantage in terms of ergonomic purposes.

The sinus balloon dilatation catheter of the invention has elongated form and comprises a tubular catheter shaft (20) extending in distal direction from the said catheter hub (10) part. Said tubular catheter shaft (20) cross-section view is shown in Figure-1A and at the outermost, it comprises the outer jacket (26), and towards the inner part, balloon inflation-deflation lumen (24), inner body (25), and one or more fiber optics (23) are found, respectively.

In other embodiments, there is not an extra outer jacket (26) and elements structured in the inner body (25). In other words, said catheter shaft (20) comprises a lumen (24) which has optic fibers (23) laying along inside of it or a lumen (24) and optic fiber (23) which are laying along inside the inner body(25).

Catheter shaft (20) outer jacket (26) and inner body (25) material can be selected from thermoplastic elastomers, polymer, or polyester groups comprising polyamide, polyether block amides, thermoplastic urethane, polyurethane, and pet etc. materials. These materials can be used alone or in combination.

In the embodiments comprising outer jacket (26), the outer jacket (26) is formed in a way that it would cylindrically surround the inner body (25) and sized such that space/gap would be left between them. Outer jacket (26) outer diameter can be about 1.5 mm and inner diameter can be about 1.2 mm.

This space forms the lumen (24) which provides inflation-deflation of the balloon (1) by means of passing liquid or gases through it. And the balloon (1) is found at the distal tip of the catheter shaft (20) and its position and the balloon-shaft weld (2) are
seen in the figures. Also, marker bands (3) are found on the balloon (1).


In the said embodiments which are not comprising outer jacket (26), inflation-deflation is made via the tubular-form lumen (24) formed along the inner body (25) instead of the coaxial space found between the lumen (24), inner body (25), and outer jacket (26).

In more detail, in one of the two different embodiments, not comprising outer jacket (26), an inflation-deflation lumen (24) is found as extending within the inner body (25) and the optic fiber (23) or fibers (23) are also extended within the lumen (24) along the shaft (20). In the region of the balloon (1), one or more inflation-deflation holes (50) are configured on the inner body (25). Said inflation-deflation holes (50) are the spaces that provide the passage of the substances, which are sent from the lumen (24) with the purpose of inflating or deflating the balloon (1), through the lumen (24) towards the balloon (1).

In the other embodiment, a tubular inflation-deflation lumen (24) extending within the inner body (25) and optic fiber (23) or fibers (23) extending along the shaft (20) beside this tubular lumen (24) are found. When the tubular inflation-deflation lumen (24) reaches the region where the balloon (1) is found, it reaches the inner region of the balloon (1) by being bent outwards. Said region is an inflation-deflation hole (50) opened from the inner body (25) towards the balloon (1).

The sinus balloon dilatation catheter of the present invention can comprise a soft flexible tip (30) or a tip in the form of a hard transparent lens. This soft and flexible material used at the catheter tip part is selected from transparent polymer, polyurethane, and soft thermoplastic elastomers. And the hard and transparent material used at the catheter tip part can be selected from the group formed of high index plastic, polycarbonate, and conventional plastic materials.

Moreover, the sinus balloon dilatation catheter of the present invention can comprise a linear (30) or a previously shape-adjusted curved (31) or a steerable (33) and optionally a re-shapeable (33) tip in different embodiments. The angle of curvature of the previously shape-adjusted curved tip is formed such that, it would enter the sinus ducts in the most suitable manner and it is preferably 110° or 40° or any angle between these two values. Also, in different embodiments, the sinus balloon dilatation catheter can comprise one or more lumen, flush lumen (22). These embodiments will be described in detail in the following sections.

In the embodiment described above and shown in Figure-1, the tip part (30) of the catheter has linear form and is made of soft and flexible material.

Catheter tip part can have curved, or in other words, circular form (31) such that it would adapt the structure of sinus cavities. Alternatively, it can have an optionally re-shapeable (33) distal tip, which can be added later on. The angle of curvature is the
most suitable angle for entering into sinus ducts such that it is preferably 110° or 40° or any angle between these two values.

In Figure-2 and Figure-3, other embodiments of the sinus balloon dilatation catheter, which is the subject of the invention, are shown, and as also described above; the tip part of the catheter has previously shape-adjusted curved form (31) and is made of soft and flexible material. Figure-2 shows a catheter comprising an optic fiber (23), while Figure-3 shows a catheter comprising more than one optic fiber (23). While the optic fibers (23) can be made of fiber glass material, it can also be formed of polymers with appropriate optic light refraction index.

Figure-2A, is the cross-section view of the catheter shaft (20) having previously shape-adjusted (31) curved tip form shown in Figure-2 and it is the same with Figure-1A when looked starting from the outside towards the inner parts. In Figure-3A, the cross-section view of the catheter shaft (20) having previously shape-adjusted (31) circular tip form shown in Figure-3 is shown and starting from the outside, it is formed of the outer jacket (26), balloon inflation-deflation lumen (24), inner body (25), and more than one optic fibers (23) in this inner body (25).

In Figure-4 and Figure-5, again different embodiments of the invention are shown and the B cross-sections of the catheter shaft (20) distal tip are given. Since this part is found after the balloon (1), the balloon inflation-deflation lumen (24) does not continue here and it is clearly seen in the cross-section. Figure-4A cross-section is the same with the previously described ones and figure-4B is formed of the inner body (25) and the optic fiber (23) starting from the outside. In Figure-5, catheter comprising more than one optic fiber (23) is shown. In the cross-section views of this catheter shaft (20), the number of optic fibers (23) within the inner body (25) is more than one.

As described above, in different embodiments of the invention, the sinus balloon dilatation catheter can comprise a flush lumen (22) and a port (12) in connection with this. An embodiment of this invention comprising flush lumen (22) is shown in figure-6 and figure-7, and figure-7 is the view of the catheter comprising more than one optic fiber (23).

As it is seen in these figures, the balloon dilatation catheter comprises one flush port (12) formed on the hub (10) of the proximal tip and one flush lumen (22) extending towards distal direction from this flush port (12) in the inner body (25) found in the catheter shaft (20). This flush port (12) can be configured by means of a conventional interface such as Luer connector.

The cross-sections of the catheter shaft (20) distal tip shown in Figure-6, before and after the balloon (1) are given as the cross-section A and cross-section B in Figure-6A and Figure-6B, respectively. In Figure-6A, outer jacket (26), balloon inflation-deflation lumen (24), inner body (25), and flush lumen (22) found in the inner body...
(25) are present starting from outside towards the inner parts. In Figure-7A, it is seen that more than one optic fiber (23) are found within the inner body (25).

The cross-sections of the distal tip of the catheter embodiments shown in Figure-7, before and after the balloon (1) are given as the cross-section A and cross-section B in Figure-7A and Figure-7B, respectively. The outer jacket (26) and the balloon (1) inflation-deflation lumen (24) shown in the cross-section A of the catheter is not included in the cross-section B, which is the distal tip cross-section found after the balloon (1).

In another embodiment of the present invention sinus balloon catheter, an alternative steerable or re-shapeable (33) distal tip can be found as described above. In the embodiments comprising a steerable distal tip (33), shape adjustment wire (21) is found in the inner body (25) within the catheter shaft (20) providing adjustment of the curvature required for the said steerability and form adaptation and a shape adjustment wheel (13) is found for controlling it.

Said shape adjustment wheel (13) is found at the catheter hub (10) part and the shape adjustment wire (21) connected to it extends towards the distal direction and continues up to the catheter tip part. In this way, adjustments about the balloon dilatation catheter orientation and position can be made.

In Figure-8 and Figure-9, different views of the said embodiment of the invention is given and in Figure-8, a catheter not comprising flush lumen (22) and port (12) is shown, whereas the catheter shown in Figure-9 comprises a flush lumen (22) and port (12).

In the most comprehensive embodiment of the invention shown in Figure-9, it comprises a balloon inflation-deflation port (11), a flush port (12), a shape adjustment wheel (13), and a light source (14, 15, 16) at the catheter hub (10) part; the catheter shaft (20) part extending towards distal direction in elongated form comprises outer jacket (26) at the outermost part and towards the inner parts it comprises balloon inflation-deflation lumen (24), inner body (25), shape adjustment wire (21) and one or more optic fibers (23) and flush lumen (22) in the inner body (25). The cross-section of the distal tip of this catheter shaft (20) described is given in Figure-9A. And balloon (1) is present at the distal tip of the said catheter and marker bands (3) are found on the balloon (1).

In the above said embodiment of the invention, catheter tip can have soft, flexible form or hard, transparent (lens) form.

The first one of the above said embodiments that is based on not having outer jacket (26) in the catheter shaft (20) structure and having inner body (25) as the outermost layer, and having the components in extended form within the said inner body (25) is given in Figure 11. As also can be seen there, the coaxial space found within the inner
body (25) forms the inflation-deflation lumen (24). Passage of the gases or liquids to
the balloon (1) is ensured by means of the inflation-deflation holes (50) opened from
the lumen (24) towards the balloon (1). As it would also be understood from AA’
section of the catheter shaft (20) in Figure 11A, the layers from outside-in are inner
body (25), inflation-deflation lumen (24), and optic fiber (23). The number of optic
fibers (23) extending within the lumen (24) can be more than one in different em-
bdiments. Section BB’ of the tip part (31) is given in Figure 11B.

The other embodiment without outer jacket (26) is shown in figure 12. Here, a
tubular inflation-deflation lumen (24) is found within the shaft (20) formed by the
inner body (25). This lumen (24) extends up to the region where balloon (1) is found
and makes an outward curve, which is towards the balloon (1) and ends at the space
of the balloon (1). In this way, the inflation-deflation hole (50) through which the liquids
or gases would be transferred to the balloon (1) is formed. As it would also be seen
from section AA’ of the catheter shaft (20) of this embodiment shown in Figure 12A,
the inner body (25) is found at the outermost part and an inflation-deflation lumen (24)
is found within this inner body (25) and the optic fiber (23) extend just nearby. Optic
fiber (23) extends towards the end. Section BB’ of the shaft (20) can be seen in Figure
12B. Since the lumen (24) ends at the balloon (1), only the inner body (25) and the
optic fiber (23) extending within the inner body (25) are seen in section BB’.

In all of the above said embodiments of the present invention catheter, the power
source (14), on-off button (15), and light source (16) are found in the hub (10) body. In
addition to these parts described, they can be optionally included in the mechanism as
a separate apparatus (40) comprising the power source (14), on-off button (15) and
light source (16) components. In order to include the said apparatus (40) into the
catheter structure, a separate apparatus integration port (41) is found on the hub (10).
In this way, an apparatus (40) comprising high power light source (16), power source
(14), and on-off button (15) can be optionally integrated into the hub (10) structure and
provide light transmission to the optic fiber (23). This apparatus integration port (41)
found on the hub (10) can be applied to all of the above said embodiments of the
invention. Said apparatus (4) and the integration port (41) are given in detail in figure-
10. Moreover, the cross-section views of the said catheter are given in Figures- 10A
and 10B.

In order to summarize the advantages of the novel catheter embodiment, which is
developed for solving the problems related to the use of medical devices found in the
prior art, and described above according to the figures, a comparison is made below
with the prior art.

In the prior art, while balloon dilatation surgery is performed, the doctor places a
sinus guide catheter through the nostril via endoscopic view in order to reach the sinus
ostium. Endoscope provides the doctor with the facility to see the sinus cavities through the nasal passage in order to be sure that the catheter is inserted in the correct and suitable position. Afterwards, a sinus guide wire or another sinus illumination system is inserted into the target sinus by means of sinus guide catheter. Following confirmation of the desired location via light (or fluoroscopy), the balloon catheter is inserted into the sinus cavity through the sinus guide wire or sinus illumination system and positioned to be inflated in the blocked ostium and the position of the catheter is confirmed by endoscopic view. Then, it is inflated to broaden and open the said blockage. When the said operation is complete, the balloon is deflated and removed. Afterwards, an irrigation catheter can be used to clean the inflammation and mucus found in the sinus by means of being pushed forward on the sinus guide wire or the illumination system. Integrated irrigation system is present in some of the balloon catheter structures and these catheters make the procedure easier.

While balloon dilatation surgery is made with the novel device, the doctor inserts a sinus guide catheter through the nostril for the balloon catheter embodiments that are not steerable. Use of endoscope camera can be preferred in order to make sure that the doctor inserts the catheter to the correct and appropriate position. Afterwards, the sinus catheter of the present invention emitting light from the distal tip is pushed towards the sinus duct with the help of guide catheter or alone if it is a steerable catheter. After the light found at the tip of the catheter entering the sinus duct illuminates the sinus cavity and is seen from the outside and confirmed, the balloon (1) is inflated to broaden and open the blockage. The balloon (1) is deflated when this operation is complete. If the catheter embodiment comprises the flush lumen (22), then flush and irrigation can be made.

As a result; with the novel sinus balloon dilatation catheter, the need for a separate guide wire is eliminated and the need for endoscopic visualization is reduced by providing better confirmation of the balloon position. By means of the fibreglass inner part (23) found within the catheter body, the need for a guide wire that would help supporting of the catheter and pushing of the catheter into the ostia would be eliminated.

With the illumination system (14, 15, 16) found in the catheter hub (10) part, the need for using a separate source is eliminated.

Illumination is provided at the tip part of the catheter in order to enable safer confirmation of the balloon (1) position.

Briefly; the invention is a balloon dilatation catheter developed for solving the said problems and providing the said advantages in treatment of paranasal sinus diseases, and it comprises:

a flexible and elongated-form tubular shaft (20), which has a proximal and a distal
tip, and through which a primary lumen (24) and an inner body (25) passes; a hub (10) fixed at the proximal tip of the said tubular shaft (20); a primary port (11) that is connected to the primary lumen (24) passing through the said tubular shaft (20) in the said hub (10) body; an inflatable member (1) found at the distal tip of the flexible elongated shaft (20) and having internal part that is connected to the said primary lumen (24); an illumination system (14, 15, 16) permanently adapted to the hub (10) body and providing illumination at the distal part of the said inflatable member (1) and the distal tip of the tubular shaft (20) for safer correction of the said inflatable member (1) position, and comprising at least one power source (14), on-off button (15) and at least one light source (16); and one or more fiber optics (23), which extend longitudinally towards distal direction within the inner body (25) found in the tubular shaft (20) from the said light source (16) up to the distal tip of the tubular shaft (20), and which thus transmits light towards the distal part of the inflatable member (1) and the distal tip of the catheter.

[68] Briefly, in another embodiment:

[69] The invention comprises a shape adjustment wire (21), which provides orientability to catheter and gives optional shape adjustment capability to its tip part, and extends longitudinally from the proximal hub (10) body up to the distal tip within the inner body (25) found in the tubular shaft (20); and a shape adjustment wheel (13) found on the hub (10) body and connected to the shape adjustment wire (21) and providing control of the shape adjustment wire (21).

[70] Briefly, in another embodiment:

[71] It comprises a secondary lumen (22) extending longitudinally up to the distal tip within the inner body (25) found in the tubular shaft (20); and a secondary port (12) connected to the said secondary lumen (22) in the hub (10) body.

[72] Briefly, in different embodiments:

[73] One or more marker bands (3) are found on the inflatable member (1) found in its structure. The primary lumen (24) connected to the inflatable member (1) is an inflation-deflation lumen (24) used for inflating and deflating the inflatable member (I) when required by means of passing liquids or gases through it; and the primary port (II) that is found on the hub (10) body and connected to the said primary lumen (24) is an inflation-deflation port (11). The inflatable member (1) found at the distal tip of the tubular shaft (20) is balloon (1). The secondary lumen (22) that extends longitudinally up to the distal tip within the inner body (25) found in the tubular shaft (20) is a flush lumen (22) that is used for irrigation when required; and the secondary port (12) that is connected with the said secondary lumen (22) in the hub (10) body is a flush port (12). In different embodiments, the invention has a soft and flexible tip (30) or a hard and transparent tip (30). It may have a linear-shaped or a previously shape-adjusted curved
shaped or a re-shapeable and steerable tip (33). Any part of the tubular shaft (20) and the catheter tip has a structure that can be bendable to adapt the sinus cavities. Catheter can have conical tip.

As a result; said paranasal sinus operations can be made in much safer manner than the past and in more ergonomic and easier way for the doctors thanks to the above said advantages. Operation steps would be reduced by means of elimination of the need for separate illumination systems and use of guide wire, and thus the operation time would be reduced.

**Brief Description of Drawings**

**Figure-1:** is the view of a linear and soft tip embodiment of the sinus balloon dilatation catheter.

**Figure-1A:** is the cross-section view of the catheter shaft of a linear and soft tip embodiment of the sinus balloon dilatation catheter.

**Figure-2:** is the view of an embodiment of the sinus balloon dilatation catheter, which is previously shape-adjusted as curved and has soft tip.

**Figure-2A:** is the cross-section view of the catheter shaft of an embodiment of the sinus balloon dilatation catheter, which is previously shape-adjusted as curved and has soft tip.

**Figure-3:** is the view of an embodiment of the sinus balloon dilatation catheter, which has previously curved shape-adjusted and soft tip and comprises more than one optic fiber.

**Figure-3A:** is the cross-section view of the catheter shaft of an embodiment of the sinus balloon dilatation catheter, which has previously curved shape-adjusted and soft tip and comprises more than one optic fiber.

**Figure-4:** is the view of a previously curved shape-adjusted tip embodiment of the sinus balloon dilatation catheter.

**Figure-4A:** is the cross-section view of a previously curved shape-adjusted tip embodiment of the sinus balloon dilatation catheter.

**Figure-4B:** is the cross section view of the distal tip a previously curved shape-adjusted tip embodiment of the sinus balloon dilatation catheter.

**Figure-5:** is the view of an embodiment of the sinus balloon dilatation catheter, which has previously curved shape-adjusted tip and comprises more than one optic fibers.

**Figure-5A:** is the cross-section view of an embodiment of the sinus balloon dilatation catheter, which has previously curved shape-adjusted tip and comprises more than one fiber optics.

**Figure-5B:** is the cross-section view the distal tip of an embodiment of the sinus
balloon dilatation catheter, which has previously curved shape-adjusted tip and comprises more than one fiber optics.

[87] **Figure-6:** is the view of an embodiment of the previously curved shape-adjusted tip sinus balloon dilatation catheter comprising flush lumen.

[88] **Figure-6A:** is the cross-section view of an embodiment of the previously curved shape-adjusted tip sinus balloon dilatation catheter comprising flush lumen.

[89] **Figure-6B:** is the cross-section view of the distal tip of an embodiment of the previously curved shape-adjusted tip sinus balloon dilatation catheter comprising flush lumen.

[90] **Figure-7:** is the view of an embodiment of the previously curved shape-adjusted tip sinus balloon dilatation catheter comprising flush lumen and more than one optic fiber.

[91] **Figure-7A:** is the cross-section view of an embodiment of the previously curved shape-adjusted tip sinus balloon dilatation catheter comprising flush lumen and more than one optic fiber.

[92] **Figure-7B:** is the cross-section view of the distal tip of an embodiment of the previously curved shape-adjusted tip sinus balloon dilatation catheter comprising flush lumen and more than one optic fiber.

[93] **Figure-8:** is the view of the steerable and re-shapeable tip embodiment of the sinus balloon dilatation catheter.

[94] **Figure-8A:** is the cross-section view of the steerable and re-shapeable tip embodiment of the sinus balloon dilatation catheter.

[95] **Figure-9:** is the view of the steerable and re-shapeable tip embodiment of the sinus balloon dilatation catheter comprising flush lumen.

[96] **Figure-9A:** is the cross-section view of the steerable and re-shapeable tip embodiment of the sinus balloon dilatation catheter comprising flush lumen.

[97] **Figure-10:** is the view of the external apparatus integrated at the hub part of the sinus balloon dilatation catheter and the embodiment comprising port for this apparatus.

[98] **Figure-10A:** is the cross-section view of the sinus balloon dilatation catheter embodiment comprising integration port for the apparatus.

[99] **Figure-10B:** is the cross-section view of the distal part of the sinus balloon dilatation catheter embodiment comprising integration port for the apparatus.

[100] **Figure-11:** is a view of an embodiment of the sinus balloon dilatation catheter not comprising outer jacket and comprising primary lumen through which optic fiber passes.

[101] **Figure-11A:** is a cross-sectional view of an embodiment of the sinus balloon dilatation catheter not comprising outer jacket and comprising primary lumen through which optic fiber passes.

[102] **Figure-11B:** is a cross-sectional view of a distal tip of an embodiment of the sinus
balloon dilatation catheter not comprising outer jacket and comprising primary lumen through which optic fiber passes.

Figure-12: is a view of an embodiment of the sinus balloon dilatation catheter not comprising outer jacket and comprising optic fiber and tubular primary lumen.

Figure-12A: is a cross sectional view of an embodiment of the sinus balloon dilatation catheter not comprising outer jacket and comprising optic fiber and tubular primary lumen.

Figure-12B: is a cross sectional view of a distal tip of an embodiment of the sinus balloon dilatation catheter not comprising outer jacket and comprising optic fiber and tubular primary lumen.

References

1. inflatable member (balloon)
2. inflatable member (balloon) weld
3. inflatable member (balloon) marker bands
10. hub (catheter weld)
11. inflatable member (balloon) inflation-deflation port (primary port)
12. flush port (secondary port)
13. shape adjustment wheel
14. power source (battery, accumulator etc.) and chamber
15. on-off button
16. light source (LED etc.)
20. tubular shaft
21. shape adjustment wire
22. flush lumen (secondary lumen)
23. optic fiber
24. inflation-deflation lumen (primary lumen)
25. inner body
26. outer jacket
30. soft flexible tip
31. curved soft flexible tip
33. steerable tip
40. integrated illumination apparatus
41. apparatus integration port
50. inflation-deflation hole
Claims

[Claim 1] A balloon dilatation catheter developed for treatment of paranasal sinus diseases, and it is characterized in that; it comprises:
- a flexible and elongated- form tubular shaft (20), which has a proximal and a distal tip, and through which a primary lumen (24), an inner body (25), and at least one optic fiber (23) passes;
- a hub (10) fixed at the proximal tip of the said tubular shaft (20);
- a primary port (11) that is connected to the primary lumen (24) passing through the said tubular shaft (20) in the said hub (10) body;
- an inflatable member (1) found at the distal tip of the flexible elongated shaft (20) and having internal part that is connected to the said primary lumen (24);
- at least one illumination system (14, 15, 16) providing illumination at the distal side of the inflatable member (1) and the distal tip of the tubular shaft (20), and permanently adapted at the hub (10) body; or; an illumination apparatus (40) that can be optionally integrated at the hub (10) body later on.

[Claim 2] A balloon dilatation catheter according to claim 1, and it is characterized in that; it comprises an outer jacket (26), which forms the outermost layer of said shaft (20) and at the same time the outer wall of said primary lumen (24), and which peripherally wraps the inner body (25) such that a space that forms the said primary lumen (24) would be left between them.

[Claim 3] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; when it comprises an illumination system (14, 15, 16) adapted to hub (10) body; it comprises one or more fiber optics (23), which extend longitudinally within the tubular shaft (20) from the illumination system (14, 15, 16) towards the distal tip of the tubular shaft (20), and which thus transmit light up to the distal part of the inflatable member (1) and the distal tip of the catheter.

[Claim 4] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; in order to provide integration of the illumination apparatus (40) that can be optionally integrated to the hub (10) body later on, it comprises at least one apparatus integration port (41) on the said hub (10) body.

[Claim 5] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it comprises one or more fiber optics
(23), which extend longitudinally within the tubular shaft (20) in distal direction from the apparatus integration port (41) towards the distal tip of the tubular shaft (20), and which thus transmit light up to the distal part of the inflatable member (1) and the distal tip of the catheter.

[Claim 6] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it comprises a coaxial primary lumen (24) longitudinally extending within the inner body (25); and one or more inflation-deflation holes (50) opened to the inflatable member (1) from the primary lumen (24) in order to provide the liquid or gas substances in to the inflatable member (1), which are transmitted from this primary lumen (24) to the inflatable member (1).

[Claim 7] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it comprises one or more optic fibers (23) longitudinally extending from the hub (10) part up to the distal tip within the primary lumen (24).

[Claim 8] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it comprises a tubular primary lumen (24), which extends within the inner body (25) from the hub (10) part up to the inflatable member (1), and opens to the inner region of the inflatable member (1) with at least one inflation-deflation hole (50).

[Claim 9] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it comprises one or more optic fibers (23), which extend longitudinally within the inner body (25) from the hub (10) part up to the distal tip by passing near the tubular primary lumen (24).

[Claim 10] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; the illumination system (14, 15, 16) comprises at least one power source (14), at least one on-off button (15), and at least one light source (16).

[Claim 11] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; the illumination apparatus (40) to be integrated later on comprises at least one power source (14), at least one on-off button (15), and at least one light source (16).

[Claim 12] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it comprises:
- a shape adjustment wire (21), which provides orientability to catheter and gives optional shape adjustment capability to its tip part, and extends longitudinally from the proximal hub (10) body up to the distal
tip within the inner body (25) found in the tubular shaft (20); and
- a shape adjustment wheel (13) found on the hub (10) body and
  connected to the shape adjustment wire (21) and providing control of
  the shape adjustment wire (21).

[Claim 13] A balloon dilatation catheter according to any one of the above claims,
and it is characterized in that; it comprises:
  - a secondary lumen (22) extending longitudinally up to the distal tip
    within the inner body (25) found in the tubular shaft (20); and
  - a secondary port (12) connected to the said secondary lumen (22) on
    the hub (10) body.

[Claim 14] A balloon dilatation catheter according to any one of the above claims,
and it is characterized in that; it comprises one or more marker bands
(3) on the inflatable member (1) found in its structure.

[Claim 15] A balloon dilatation catheter according to any one of the above claims,
and it is characterized in that;
  - the primary lumen (24) connected to the inflatable member (1) is
    inflation-deflation lumen (24) used for inflating and deflating the in-
    flatable member (1) when required by means of passing liquids or gases
    through it, and
  - the primary port (11) that is found on the hub (10) body and
    connected to the said primary lumen (24) is inflation-deflation port
    (11).

[Claim 16] A balloon dilatation catheter according to any one of the above claims,
and it is characterized in that; said inflatable member (1) found at the
distal tip of the shaft (20) is balloon (1).

[Claim 17] A balloon dilatation catheter according to any one of the above claims,
and it is characterized in that;
  - the secondary lumen(22) that extends longitudinally up to the distal
    tip within the inner body (25) found in the shaft (20) is a flush lumen
    (22) that is used for irrigation when required, and
  - the secondary port (12) that is connected with the said secondary
    lumen (22) in the hub body (10) is a flush port (12).

[Claim 18] A balloon dilatation catheter according to any one of the above claims,
and it is characterized in that; it has a soft and flexible tip (30).

[Claim 19] A balloon dilatation catheter according to any one of the above claims,
and it is characterized in that; the soft and flexible tip (30) material is
selected from the group consisting of transparent polymer,
polyurethane, and thermoplastic elastomers.
[Claim 20] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it has a hard and transparent tip (30).

[Claim 21] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; hard and transparent tip material is selected from the group consisting of high index plastic, polycarbonate, and conventional plastic.

[Claim 22] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it has a linear-shaped tip (30).

[Claim 23] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it has a previously shape-adjusted curved-form tip (31).

[Claim 24] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it comprises a tubular shaft (20) having a structure that can be bendable at any portion.

[Claim 25] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it has a tip (33) having a structure that can be bendable at any portion.

[Claim 26] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it has a re-shapeable and steerable tip (33).

[Claim 27] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it has conical tip.

[Claim 28] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; the outer jacket (26) is formed of one or more materials selected from thermoplastic elastomer, polymer, or polyester groups.

[Claim 29] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; the inner jacket (25) is formed of one or more materials selected from thermoplastic elastomer, polymer, or polyester groups.

[Claim 30] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; the angle of curvature of the previously shape-adjusted curved tip (31) is 70° or 140° or any value between these two values.

[Claim 31] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it has a tip (33) that is steerable and can be shape-adjusted by being bent with an angle of curvature that is 70° or 140° or any value between these two values.
[Claim 32] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; said power source (14) is a kind of battery or accumulator.

[Claim 33] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; it comprises a chamber wherein the said power source (14) is placed.

[Claim 34] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; said light source (16) is Light Emitting Diode (LED).

[Claim 35] A balloon dilatation catheter according to any one of the above claims, and it is characterized in that; the secondary port (12) having flush port (12) has the structure of a Luer connector.

[Claim 36] A steerable paranasal sinus balloon dilatation catheter, and it is characterized in that; it comprises:

- a flexible tubular shaft (20) having a proximal and a distal tip, a hub (10) at the proximal tip of the said tubular shaft (20);
- at least one inflation-deflation port (11) at the said hub (10) body, at least one inflation-deflation lumen (24) connected to this inflation-deflation port (11) and found in the tubular shaft (20) extending in distal direction from the catheter hub (10) body, a balloon (1) connected to the said inflation-deflation lumen (24) at the distal tip of the tubular shaft (20), one or more marker bands (3) on the balloon (1);
- an outer jacket (26) forming the outer layer of the tubular shaft (20) and cylindrical inner body (25) peripherally covered by this outer jacket (26) in a way that a space would be left between them to form the inflation-deflation lumen (24);
- at least one flush port (12) on the said hub (10) body, at least one flush lumen (22) connected to this flush port (12) and extending in distal direction in the inner body (25), an illumination system (14, 15, 16) providing illumination at the distal side of the balloon (1) and at the distal tip of the tubular shaft (20) in order to correct the place of balloon (1) in the said hub (10) body in a safer manner, eliminating the need for using a separate guide wire, and comprising at least one power source (14), on-off button (15), and at least one light source (16);
- one or more fiber optics (23), which extend longitudinally towards distal direction within the inner body (25) found in the tubular shaft (20) from the said light source (16) up to the distal tip of the tubular shaft (20) and having a marker band (3) on the balloon (1).
shaft (20), and which thus transmits light towards the distal part of the inflatable member (1) and the distal tip of the catheter; a shape adjustment wire (21), which provides orientability to catheter and gives optional shape adjustment capability to its tip part, and extends longitudinally from the proximal hub (10) body up to the distal tip within the inner body (25) found in the tubular shaft (20); and a shape adjustment wheel (13) found on the hub (10) body and connected to the shape adjustment wire (21) and providing control of the shape adjustment wire (21).
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

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According to International Patent Classification (IPC) and/or both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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Further documents are listed in the continuation of Box C.

See patent family annex.

**Date of the actual completion of the international search**

3 September 2013

**Date of mailing of the international search report**

12/09/2013

**Name and mailing address of the ISA/IB**

European Patent Office, P.B. 5818, Patenlaan 2
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Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

**Authorized officer**

Segerberg, Tomas
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