Title: ELECTROACTIVE POLYMER ACTUATOR DEVICES AND SYSTEMS COMPRISING SUCH DEVICES
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Technical Field

The present disclosure mainly relates to devices comprising an electroactive polymer material actuator. More particularly, the present disclosure relates to devices wherein first and second parts are separated by a gap and the actuator is operable in the gap. Such devices may form part of body insertable devices for use in connection with surgical procedures. Other applications include microfluidic devices and "lab on a chip" type devices.

The present disclosure also relates to a method for measuring a dimension or change in dimension of an object.

The present disclosure also relates to a liquid electrolyte for use with a body-insertable electroactive polymer actuator.

Background

Electroactive polymers (EAP) are a comparatively novel class of materials that have electrically controlled properties. An overview on electroactive polymers can be found in "Electroactive Polymers (EAP) Actuators as Artificial Muscles – Reality, Potential, and Challenges" 2nd ed. Y. Bar-Cohen (ed.) ISBN 0-8194-5297-1.

One class of EAPs is conducting polymers. These are polymers with a backbone of alternating single and double bond. These materials are semiconductors and their conductivity can be altered from isolating to conducting
with conductivities approaching those of metals. Polypyrrole (PPy) is one conducting polymer and will throughout the present disclosure be taken as a non-limiting example of such materials.

Polypyrrole can be electrochemically or chemically synthesised from a solution of pyrrole monomer and a salt as is known to those skilled in the art. After synthesis PPy is in its oxidised, or also called doped, state. The polymer is doped with an anion A⁻.

PPy can be electrochemically oxidised and reduced by applying the appropriate potential to the material. This oxidation and reduction is accompanied with the transport of ions and solvents into and out of the conductive polymer. This redox reaction changes the properties of polypyrrole, such as the conductivity, colour, and volume.

Two different schemes of redox are possible. If PPy is doped with a large, immobile anion A⁻ scheme 1 occurs, which schematically can be written as:

\[
\text{PPy}^+ (A^-) + M^+(aq) + e^- \leftrightarrow \text{PPy}_0 (A^-M^+) \quad (1)
\]

0V, Oxidised
-1V, reduced

When PPy is reduced to its neutral state cations M⁺ including their hydration shell and solvent are inserted into the material and the material swells. When PPy is oxidised again the opposite reaction occurs, M⁺ cations (including hydration shell and solvent) leave the material and it decreases its volume.

If on the other hand PPy is doped with small, mobile anions a⁻, scheme 2 occurs:

\[
\text{PPy}^+ (a^-) + e^- \leftrightarrow \text{PPy}_0() + a^- (aq) \quad (2)
\]
0V, Oxidised -1V, reduced

In this case the opposite behaviour of scheme 1 occurs. In the reduced state the anions leave the material and it shrinks. The oxidised state is now the expanded state and the reduced state the contracted. Non limiting example of ions A- is dodecylbenzene sulfonate (DBS-), of a- perchlorate (ClO4-), and of M+ sodium (Na+) or lithium (Li+)


This redox reaction needs to be driven in an electrochemical cell that comprises a working electrode (i.e. the conducting polymer) and a counter electrode, preferably a reference electrode, and an electrolyte.

The electrolyte is preferably an aqueous salt solution, but can be a solid polymer electrolyte, gels, non-aqueous solvents, ionic liquids as is know to those skilled in the art, but even biologically relevant environments such as blood (plasma), cell culture media, or other physiological media, etc. can be used.

Furthermore, ability to function or fit into a small and narrow environment is essential for many medical applications. Also, adding additional materials is not desired due to possible negative side effects, e.g. biocompatibility issues. Actuating EAP requires at least a counter electrode (CE). Adding such an electrode will
typically both add to the overall size of the device, but also introduce additional materials.

For devices that include electroactive polymers, it is important that the amount of deposited electroactive polymer, e.g. thickness, is well defined and controlled. This is especially important, since for medical devices, quality control during fabrication is important and strictly regulated.

A general scheme for the electrosynthesis of conducting polymers, such as PPy is polycondensation of radical cations as is described by Diaz et al. (A.F. Diaz and J. Bargon, "Electrochemical synthesis of conducting polymers", in Handbook of conducting polymers, T.A. Skotheim, Editor, 1986, Marcel Dekker, Inc., New York, p. 81-115.) This can be schematically summarized as

$$H-M-H + H-(M)n-H -> H-(M)n+1-H + 2 \text{ H}^+ + 2 \text{ e}^- \quad (3)$$

with M being the monomer.

Normally, the amount of (conducting) polymer deposited during electrochemical synthesis is determined by collecting the amount of charge consumed during the synthesis. Taking PPy as a non-limiting example, the formulations are based on the principle that 2.25 electrons are consumed per monomer. The method assumes that 2 electrons are used for the pyrrole monomer to monomer coupling (1 electron at the 2 position and one at the 5 position) as schematically described in equation 3 and 0.25 electron is used to account for the doping with the dopant A- or a- (equations 1 or 2), assuming a doping density of 1 dopant per 4 monomers (thus 1 electron/4 monomers is 0.25 electron/monomer).
However, this method does have a few disadvantages. It is based on an assumed doping level of 1 dopant ion per 4 pyrrole monomers. This number is not set. Doping levels are known to vary, levels of 1 per 3 to 4 monomers have been presented. Also, in addition to the 2-5 coupling even 3,4 coupling exist. This would add an extra electron to the consumed charge and it is not known how many 3-4 couplings occur per monomer. Third, side reactions occur during synthesis. These reactions also consume charge, thus making the charge calculation method quite difficult in practice. Moreover, the method requires knowledge of the density of the EAP to derive e.g. the thickness. This density might vary for different electroactive polymers e.g. with the use of different dopants or different polymerization rates.

Other methods used to measure electroactive polymer layers are scanning probe measurements, but that can only be done after the synthesis and requires a step in the material. If the step is not present a scratch has to be made to provide such a step. Another method is using a standard micrometer, but that cannot be used in situ either and the material might be damaged from the contact with the micrometer.

Therefore, it would be desirable to have an alternative method to determine the amount of electroactive polymer e.g. the thickness.

In particular, little is known about how to design and position an EAP actuator for optimal operation, and on how to design and position counter electrodes and reference electrodes for interaction with the EAP actuator.

Furthermore, little is known about how to design and position an EAP actuator-based bushing or valve to
achieve sufficient and reliable clamping and/or sealing effect. Little is also known about how to verify that such effect has been achieved.

There is also a need for new solutions on how to provide access to electrolyte for EAP actuator-based systems, and on how to feed current to working electrodes, counter electrodes and reference electrodes in an EAP actuator-based system.

There is also a need for solutions on how to increase visibility of EAP actuator-based systems in connection with their use, in particular in connection with use of EAP actuator-based systems used in surgical instruments.

Fig. 1 schematically illustrates an electrochemical system 10, which comprises a control device 11, a container 12 containing electrolyte 13, a working electrode (WE) 14, a counter electrode (CE) 15 and a reference electrode (RE) 16.

Fig. 2a-2b schematically illustrates a balloon catheter 210, such as the one disclosed in US 2005/0187602A1 and US 2005/0187603A1, which may be rotatable, that is arranged at an outermost portion of a catheter comprising an outer tube 214 and an inner tube 212. The inner tube 212 presents a channel 211, wherein a guide wire 213 may be removably received. Between the outer tube 214 and the inner tube 212, there is formed a channel 242, which may be used to provide a fluid to inflate a balloon 216. The balloon 216 comprises an inflatable portion 216 providing an interior lumen 240 and connecting/sealing portions 220, 222 protruding axially therefrom. The connecting/sealing 220, 222 portions are arranged to selectively form a tight seal relative to the inner and outer tubes 212, 214,
respectively, such that the balloon 240 can be inflated. To control the sealing, annular EAP actuators 230, 232 are provided between on the one hand the inner tube 212 and the distal connecting/sealing portion 220 of the balloon 216, and on the other hand between the outer tube 214 and the proximal connecting/sealing portion 222 of the balloon 240.

The balloon catheter is provided with marker bands 256, which are used to render the balloon catheter visible on x-ray, on one of which the counter electrode 257 is arranged.

Fig. 2b illustrates a detail of the proximal and distal portions of the balloon 216, with an annular EAP actuator 114 arranged on the outer tube 214 (or inner tube 212), forming a first part 101, and acting against a connecting/sealing portion 222 (or 220) of the balloon, forming a second part 102. Reference numeral 103 designates the proximal side of the EAP actuator 114 and reference numeral 104 designates the distal side of the EAP actuator 114.

Fig. 2c illustrates a micro fluidic channel, with an EAP actuator 114 arranged on a first part 101, and acting against a second part 102. Reference numeral 103 designates the proximal side of the EAP actuator 114 and reference numeral 104 designates the distal side of the EAP actuator 114. An example of a microfluidic valve is disclosed in Y. Berdichevsky and Y.-H. Lo, "Polymer Microvalve Based on Anisotropic Expansion of Polypyrrole", in Mat. Res. Soc. Symp. Proc., 2004, Materials Research Society, p. A4.4.1-7.

In view of the fact that electroactive polymer materials are a comparatively new class of materials, little is known about how to arrange these materials and
the system which they form part of, in order to provide better operation, reliability, actuation speed and system integration.

Hence, there is a general need for improvements in this area.

Summary

It is thus a general object of the present disclosure to provide conceptual solutions on how to arrange electroactive polymer material actuators and systems of which they form part, in order to provide better operation, reliability, actuation speed and/or system integration.

Hence, there is provided a device comprising a first part a second part; and an actuator, comprising an electroactive polymer material, wherein the first and second parts are separated by a gap and the actuator is operable in the gap.

According to different embodiments or combinations:

the actuator may present a substantially annular shape; the first part may be substantially encircled by the second part. The first and second parts may be substantially concentrically arranged; the gap may be substantially annular; the first and second parts may be arranged as inner and outer parts, respectively; the first and second parts may be axially displaceable relative each other; one of the first and second parts may form a shaft, relative to which the other one of the first and second parts may be rotatably and/or slidably arranged; one of the first and second parts may comprise, or may form part of, an inflatable body; the electroactive polymer material may change volume upon activation, e.g. when subjected to an electrical
potential; the electroactive polymer material may be arranged such that its major expansion is to occur in a direction from the first part towards the second part; the first part and/or the second part may be substantially electrochemically passive; the actuator may be arranged to control a size of the gap; the actuator may be arranged to counteract relative movement between the first and second parts; the actuator may be arranged to lock the first and second part relative to each other; an edge portion of the electroactive polymer material may be passivated.

According to another group of embodiments, which may be combined with any other group or groups of embodiments mentioned herein, the actuator may comprise a substrate base, on which the electroactive polymer material is arranged. The substrate base may be arranged on one of the first and second parts. The substrate base may comprise a carrier layer and optionally an adhesion layer, which may be arranged between the carrier layer and the electroactive polymer material. The substrate base may have a thickness, in a direction perpendicular to a surface of the one of the first and second parts, on which surface the actuator is arranged, which is less than one half the thickness of the electroactive polymer material. The substrate base may have a thickness, in a direction perpendicular to a surface of the one of the first and second parts, on which surface the actuator is arranged, which is larger than the thickness of the electroactive polymer material. The substrate base, as seen in a longitudinal section of the device, may present a width, which is larger than a thickness thereof. The substrate base may be integrated with the one of the first and second parts. The substrate base may be formed
in one piece with the one of the first and second parts. The substrate base may be arranged in a recess in the one of the first and second parts. The substrate base may be exposed in at least one direction parallel with a surface of the one of the first and second parts, on which surface the actuator is arranged. The substrate base may present a varying thickness. The substrate base may, in a direction perpendicular to a surface of the one of the first and second parts, on which surface the actuator is arranged, present a curved section. The substrate base may have at least one tapering edge portion. The substrate base may extend in a direction perpendicular to a surface of the one of the first and second parts, on which surface the actuator is arranged, and the electroactive polymer material may be arranged such that its major expansion is to occur in a direction substantially parallel with the surface. The actuator may be at least partially arranged in a recess in the one of the first and second parts. The substrate base may have a thickness which is less than 0.1 μm, less than 1.0 μm, less than 20 μm, less than 50 μm, or less than 100 μm, or less than 500 μm.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the device may comprise a counter electrode. The counter electrode may be positioned on a proximal or distal side of the actuator. The proximal and distal sides may be e.g. the upstream and downstream sides of the actuator when it is arranged as a valve. The counter electrode may be positioned in the gap. The counter electrode may be positioned on one of the first and second parts. In particular, the counter electrode may be formed or attached directly to the first or second
part, or on an intermediate part, which in turn is arranged on the first or second part. The counter electrode may, as a complement, or in the alternative, be positioned on a third part. Such third part may be substantially electrochemically passive. The counter electrode may be positioned on a proximal side of the actuator. In the alternative, the counter electrode may be positioned on a distal side of the actuator. The counter electrode may be positioned across the gap from the actuator. The device may comprise at least two counter electrodes. The counter electrodes may be positioned on a respective proximal and distal side of the actuator. The counter electrodes may be positioned on one of the first and second parts, and at least one further counter electrode may be positioned on the other one of the first and second parts. The counter electrode may be positioned on a respective one of the first and second parts. The device may comprise at least two actuators and at least one counter electrode may be positioned between the actuators. The counter electrode may be positioned not more than 60 mm, preferably not more than 30 mm, 10 mm, 5 mm, 2 mm, 1 mm, 0.5 mm, or 0.1 mm from the electroactive polymer material. The actuator may be arranged on one of the first and second parts, and the counter electrode, or at least one of the counter electrodes, may be arranged on the other one of the first and second parts. The counter electrode may be integrated with a catheter, a guide wire, a sheath, a lead, an outer tubing, an inner tubing, a trocar, a stylet, an embolic coil, a part of a filter device, a part of an endoscope, or a part of a gastroscope. The counter electrode may be arranged on an inflatable body, or on a part protruding therefrom. The counter electrode may be at least
partially integrated with the inflatable body, or on the part protruding therefrom. The counter electrode may at least partially extend along the inflatable body into the gap. The counter electrode may be arranged across the gap, on a part protruding from the inflatable body. The actuator may be arranged on the one of the first and second parts, which is associated with the inflatable body. The actuator may be arranged on the one of the first and second parts, which is not associated with the inflatable body. The counter electrode may be substantially annular. The counter electrode may form at least one segment of an annulus. The counter electrode may be at least partially formed from an organic material. Hence, a normally non-conducting part of the device may be used to form a counter electrode. This may be achieved by providing electrically conducting organic material on the normally non-conducting part of the device. Such a part may be the balloon part of a balloon catheter. Non-limiting examples of electrically conductive polymer materials include polymer-metal composites, conducting polymers, conducting spheres, redox-polymers, etc. The device may further be arranged on the surgical tool. The surgical tool may be selected from a group consisting of a dilation balloon, a knife, a needle, a scissors, a pliers, a tweezers, a clamp, a guide wire and a catheter, a sheath, a lead, an outer tubing, an inner tubing, a trocar, a stylet, an embolic coil, a part of a filter device a part of an endoscopes, and a part of a gastroscope.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the device may further comprise a reference electrode. The reference electrode may be
positioned in the gap. The reference electrode may be positioned across the gap from the actuator. The device may comprise at least two actuators and the reference electrode may be positioned between the actuators. A reference electrode may be positioned between the actuator and a counter electrode. The counter electrode may be positioned between a reference electrode and the actuator. The actuator may be positioned between a reference electrode and the counter electrode. The reference electrode may be positioned not more than 30 mm, preferably not more than 10 mm, 5 mm, 2 mm, 1 mm, 0.5 mm, or 0.1 mm from the electroactive polymer material. The reference electrode may be substantially annular. The reference electrode may form at least one segment of an annulus. The counter electrode and the reference electrode may be angularly spaced apart. The actuator may be arranged on one of the first and second parts and the reference electrode may be arranged on the other one of the first and second parts.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the actuator may present a fast expanding portion and a slow expanding portion, which, upon actuation, expands slower than the fast expanding portion. Portions expanding at different rates may arise as a consequence of a difference in ion concentration in the electrolyte or electrolytes at different portions of the EAP actuator. This may be the case where the actuator operates in a limited space or in a space where ion access is limited. Portions expanding at different rates may also arise where an actuator portion (typically the fast expanding portion) is close a tube ending, or is close to a counter electrode. A distance between an
actuator surface and a surface of the one of the first and second parts against which the actuator operates diminishes in a direction away from the fast expanding portion. Such diminishing may be linear, non-linear or stepwise. The actuator may taper in thickness in a direction towards the fast expanding portion. A distance between the first and second parts may taper in a direction away from the fast expanding portion. The actuator may present first and second fast expanding portions, and a slow expanding portion may be arranged between the fast expanding portions. The actuator may taper in thickness from the slow expanding portion towards the respective fast expanding portion. The actuator may present an actuator portion, wherein the distance between the actuator surface and the one of the first and second parts against which the actuator operates diminishes in a direction from the slow expanding portion towards the respective fast expanding portion. The fast and slow expanding portions may be longitudinally juxtaposed.

The actuator may comprise at least two juxtaposed actuator portions, wherein an actuator portion that is further away from the fast expanding portion is more expanded than an actuator portion that is closer to the fast expanding portion, such that the gap tapers in depth in a direction away from the fast expanding portion only upon activation of the actuator. The actuator may comprise at least two juxtaposed actuator portions, which are individually actutable. The device may further comprise means for actuating a second one of the actuator portions, such that a finally applied potential applied thereto occurs before a finally applied potential of a first one of the actuator portions occurs. The device may
further comprise means for actuating a second one of the actuator portions with a time delay relative to a first one of the actuator portions. The device may further comprise means for actuating a second one of the actuator portions with a lower increase rate in applied potential, relative to a first one of the actuator portions. The actuator may be positioned near a portion of the device, where a distance between the first and second parts begins to increase. In one embodiment, the actuator may be positioned less than 5 mm from that portion of the device. At least one of the first and second parts may form a channel, wherein the actuator is situated near an end of the channel. In one embodiment, the actuator may be positioned less than 5 mm from the end.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the device may present a first portion, wherein a distance between the first and second parts is substantially constant, and a second portion, wherein the distance between the first and second parts increases or decreases, wherein the actuator may be arranged where the first and second portions intersect.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the device may be arranged for sealing or locking the first part relative to the second part, and the actuator may comprise at least two separate actuator sections. The actuator sections may be spaced apart in a longitudinal direction of the device. The actuator sections may be arranged on a respective one of the first and second parts. The actuator sections may be aligned in an axial direction of the annular gap. The actuator portions may be angularly spaced apart.
According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the device may be arranged for sealing or locking the first part relative to the second part, and the actuator may be arranged on one of the first and second parts and may be expandable towards a protrusion on the other one of the first and second parts. The actuator and the protrusion may be contactable. The protrusion may be formed in one piece with the other one of the first and second parts. The protrusion may be formed as a separate part and attached to the other one of the first and second parts. At least two protrusions may be provided and separated in a longitudinal direction of the device.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the device may be arranged for sealing or locking the first part relative to the second part, and the actuator may have an extent in a longitudinal direction of the gap, which is more than twice its extent in a thickness direction of the gap. Thus, the longitudinal direction may be an axial direction and the thickness direction may be a radial direction.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the device may be arranged for sealing or locking the first part relative to the second part, and the device may comprise means for counteracting or limiting relative axial movement between the first and second parts. A protrusion of a first one of the first and second parts may be arranged to engage a recess in the other one of the first and second parts. The actuator
may be arranged on one of the first and second parts, and spaced from the protrusion in a longitudinal direction of the device. A first protrusion on one of the first and second parts may be arranged to engage a second protrusion on the other one of the first and second parts. The actuator may be arranged on one of the protrusions. The actuators may be arranged on both of the protrusions. The protrusions may be complimentarily shaped.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the device may be arranged for sealing or locking the first part relative to the second part, and the actuator may be arranged on one of the first and second parts and arranged for interaction with a recess in the other one of the first and second parts. The actuator may be expandable towards, or into, the recess. The recess may be formed by a pair of protrusions, extending from the other one of the first and second parts. The recess may be provided in a protrusion which may be aligned with the actuator. The recess and the actuator may be complimentarily shaped. The actuator may, in a direction perpendicular to a surface of the one of the first and second parts, on which surface the actuator is arranged, present a curved section. The protrusion presents a recess having a substantially V-shaped section. The actuator may present a substantially V-shaped section. At least two longitudinally spaced-apart actuator sections may be arranged for interaction with respective longitudinally spaced-apart recesses. The actuator may extend into the recess, and may be expandable in a substantially longitudinal direction, towards side edges of the recess.
According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the device may be arranged for sealing or locking the first part relative to the second part, and the actuator may be arranged on one of the first and second parts and arranged for interaction with a protrusion arranged on the other one of the first and second parts, and at least one of the actuator and the protrusion may present a substantially wedge-shaped cross-section. Both the actuator and the protrusion may present wedge-shaped cross-sections.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, a hydrophobic surface portion may be provided on at least one of the first and second parts, adjacent the actuator. For this aspect, it is not necessary that the actuator comprises an electroactive polymer material, but other types of actuators may also be used. Hydrophobic surface portions may be provided on both proximal and distal sides of the actuator. Hydrophobic surface portions may be provided on both first and second parts. The hydrophobic surface portion may be provided on at least one of the first and second parts, on a first side of the actuator, and a hydrophilic surface portion may be provided on at least one of the first and second parts, on a second side of the actuator. The hydrophobic surface portion may be provided across the gap from the actuator.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, a hydrophilic surface portion may be provided on at least one of the first and second parts, adjacent the actuator. Hydrophilic surface
portions may be provided on both proximal and distal sides of the actuator. Hydrophilic surface portions may be provided on both first and second parts. The hydrophilic surface portion may be provided across the gap from the actuator.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the actuator is arranged on one of the first and second members, and the device may further comprise means for detecting contact between the actuator and the other one of the first and second members. The detection means may comprise an electrically conducting portion arranged on the other one of the first and second members. The detection means may comprise a plurality of separate electrically conducting portions, arranged on the other one of the first and second members. The detection means may comprise a pressure sensor arranged to detect pressure between the actuator and the other one of the first and second members. The detection means may comprise a pressure sensing arrangement arranged to detect a pressure difference between proximal and distal sides of the actuator. The detection means may comprise a flow meter for detecting a flow in the gap.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the actuator may be arranged on one of the first and second parts, and the actuator may present first and second opposite surfaces, the first one of which faces the other one of the first and second parts, and means may be provided for supplying ions to the second surface of the actuator. The first surface may be provided with a covering layer. The covering layer may be arranged to protect the electroactive polymer material.
from an environment in the gap. The actuator may be arranged on an ion conducting material. The actuator may be arranged on a porous material. The second surface may be directly contactable by the ions. Substantially all of the second surface may be contactable by the ions. The first part may be substantially hollow. The first part may comprise an electrolyte supply channel.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the device may further comprise spacing means, arranged to control a relative position of the first and second parts. The spacing means may comprise at least one spacer part, which is arranged to position the first and second parts in a predetermined position relative to each other. The first and second parts may be substantially concentrically arranged.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the first part may constitute an inner member, the second part may constitute an outer member, which at least partially encircles the inner member, and the actuator may present a tapering radial thickness. A contact surface of one of the inner and outer members, which contact surface faces the actuator, may present a substantially conical surface portion. The actuator may present a substantially conical surface facing the outer member. The actuator may present a substantially conical surface facing the inner member. The actuator may present a substantially cylindrical surface facing the outer member. The actuator may comprise first and second actuator sections, which are positioned on a respective one of the inner and outer
members. The actuator sections may present interacting conical surfaces.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the actuator may be mechanically modified to reduce its bending stiffness. The actuator may comprise a substantially cylindrical body, comprising portions of removed material. The portions of removed material may comprise at least one substantially annular groove. Such a groove may have any cross section and it may extend through all or part of the material. The groove may form radially retracted portions or the groove may effectively form several actuator sections. The portions of removed material may comprise at least one slot, extending in an axial direction of the actuator. Such a slot may have any cross section, and it may extend through all or part of the material. Slots may alternating extend from a proximal side and a distal side of the actuator. The portions of removed material may comprise at least one substantially helical groove. Such a groove may have any cross section, and it may extend through all or part of the material. In fact, effectively, the actuator may be seen as spiraling about the member on which it is arranged, i.e. on about the outside of an inner member or an inside of the outer member. The portions of removed material may comprise at least one slot extending along a partial circumference of the actuator. The slot may have any cross section, and it may extend through all or part of the material. The portions of removed material may comprise a recess in the actuator. Such a recess may have any form and may extend through all or part of the actuator. The recess may be a perforation. The recess may be circular, elliptic,
square, elongate, rectangular, and/or regularly or irregularly distributed.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the actuator may be arranged on one of the first and second parts, and one of the first and second parts may be flexible, so as to compensate for thickness deviations of the electroactive polymer material or of the underlying substrate. The second part may comprises a portion made from a flexible material, which is softer than the electroactive polymer material. The first part may comprise a portion made from a flexible material, which is softer than the electroactive polymer material.

According to another group of embodiments, which may be combined with one or more of the previously mentioned groups of embodiments, the first part may constitute an inner member, and the second part may constitute an outer member, which at least partially encircles the inner member, and at least one of the inner member and outer member may present an attachment portion for attachment of at least one further tubular part. The inner member is substantially tubular. The outer member may be substantially tubular. The inner member may comprise an attachment portion for a tubular surgical device. The outer member may comprise a balloon attachment portion.

The device may further comprise means for retaining the inner and outer members in a substantially fixed axial position relative to each other.

According to another aspect, there is provided a tubular surgical device comprising a device as described above. In such a the tubular surgical device, a catheter
portion may be attached to the inner member. An inflatable member may be attached to the outer member.

According to another aspect, there is provided a bushing for connecting a pair of tubular devices to each other, so as to form a device as described above. The bushing may comprise a tubular body having an attachment portion for receiving at least one of the tubular devices, and an actuator, comprising an electroactive polymer material. The actuator may be arranged to interact in a sealing and/or locking manner with the other one of the tubular devices. The actuator may be arranged on an outside of the tubular body. The actuator may be arranged on the inside of the tubular body.

According to another aspect, there is provided a bushing arrangement for connecting a pair of tubular devices to each other, so as to form a device as described above. The bushing arrangement may comprise a tubular body having an attachment portion for receiving at one of the tubular devices, and an actuator, arranged on the other one of the tubular devices, and comprising an electroactive polymer material. The actuator may be arranged to interact in a sealing and/or locking manner with the other one of the tubular devices. The actuator may be arranged on an outside of the tubular body. The actuator may be arranged on the inside of the tubular body.

According to another aspect, there is provided a bushing comprising a device as described above.

According to another aspect, there is provided a valve comprising a device as described above.

According to another aspect, there is provided an elongate medical device for insertion into the body, comprising a conducting part which is covered by an
insulating material, wherein the insulating material is partially removed to expose the conducting part. Such a device may be a guide wire which is provided with the insulating material in at least a body-insertable portion thereof. The conducting part may be arranged as a layer encircling a central axis of the device. The layer may be a sheet layer. The layer may be formed from a plurality of filaments. The conducting part may be a solid core. The insulating material may be fixedly attached to the conducting core or layer. The conducting core may comprise at least two separate conducting cores, which are electrically insulated from each other, and wherein the insulating material is partially removed to expose both of the separate conducting cores. A transducer may be arranged on the device. Such a transducer may be an actuator (as described above), a sensor or a drug release portion. The transducer may comprise an electroactive polymer material. The transducer may form part of a device as described above. The device may be at least partially hollow, e.g. such that a lead or a wire is removably insertable in the device. Thus, the device may be a catheter. According to another aspect, there is provided use of an elongate medical device as described above, as a conductor as a conductor for providing electrical connection to a transducer or electrode. The electrical connection may be provided to an electrode in an electrochemical system comprising at least one electroactive polymer material.

According to another aspect, there is provided a hollow, elongate medical device for insertion into the body, comprising an insulating tubular body, in which a wire is insertable, wherein an opening is provided in the tubular body to expose the wire. Such a device may be a
catheter and the wire may be a guide wire. The wire may comprise a conducting core, covered by an insulating material. The conducting core may comprise at least two separate conducting cores, which are electrically insulated from each other, and at least one of the conducting cores may be exposed through at least one opening. Separate openings may be provided for exposing the respective conducting cores. The conducting wire core may be covered with an insulating material, and the insulating material may be partially removed to expose the conducting core. A transducer may be arranged on the device. The transducer may comprise an electroactive polymer material. The transducer form part of a device as described above.

According to another aspect, there is provided use of a hollow, elongate medical device as described above, for housing a conductor for providing electrical connection to a transducer or electrode. The electrical connection may be provided to an electrode in an electrochemical system comprising at least one electroactive polymer material. The conductor may be an elongate medical device as described in the previous aspect, or a conducting wire, such as a metal wire.

According to another aspect, there is provided a system comprising a device as described above and an electrolyte arranged to interact with the actuator. An ion concentration of the electrolyte on one of the proximal and distal sides of the actuator is higher than an ion concentration on the other one of the proximal and distal sides. The gap may increases in size in a direction towards the one of the proximal and distal sides of the actuator where the ion concentration is highest.
According to another aspect, there is provided an actuator system, comprising a substrate, an electrolyte-conducting polymer material, arranged on the substrate an electrode, in contact with the electrolyte-conducting polymer material, an aqueous electrolyte, contacting the electrolyte-conducting polymer material, drive means for providing a voltage sufficient to provide gas production in an interface between the electrolyte-conducting polymer material and the electrode, wherein the electrolyte conducting polymer material is attached, at perimeter portions thereof, to the substrate, and wherein a central portion of the electrolyte conducting polymer material is inflatable by the gas production. Such drive means may comprise a conductor and a power source. The substrate may form part of a first member, which may be separated by a gap from a second member, and wherein the electrolyte conducting polymer material is arranged to control a size of the gap. The electrolyte conducting polymer material may be gas impermeable. The electrolyte conducting polymer material may be enclosed in a protection layer. The protection layer may be a semi-permeable membrane, allowing electrolyte influx, but preventing gas outflux. The gap may be substantially annular. The first member is an inner part and the second member is an outer part, wherein the inner and outer parts are substantially concentrically arranged.

According to another aspect, there is provided a method for measuring a dimension or change in dimension of an object, comprising positioning, between a source of electromagnetic radiation and a sensor, a liquid container, which is at least partially transparent to the electromagnetic radiation, positioning the object in the liquid container, exposing the object to the
electromagnetic radiation, recording an amount of received electromagnetic radiation at the sensor, and determining the dimension or change in dimension of an object, based on a signal from the sensor.

The electromagnetic radiation source may comprise a laser source. The object may be elongate, and the electromagnetic radiation may be applied in a direction substantially perpendicular to a longitudinal axis of the substrate. The electromagnetic radiation may be applied along a direction substantially parallel with a cross section of the object. The object may be substantially planar, and the electromagnetic radiation may be applied in a direction which is substantially parallel with a main plane of the object. The object may comprise a conveyor-like structure, which is deflected by a pulley or the like, and the electromagnetic radiation may be applied in a direction perpendicular to an axis about which the object is deflected. The object may comprise at least one through hole, and the electromagnetic radiation may be applied through the through hole. The method may further comprise forming, based on a compound present in the liquid, a layer on the object. The recording is carried out while forming the layer. The forming may comprise synthesizing an electroactive polymer material.

The forming may comprise electroplating the object. The method may further comprise actuating an electroactive polymer material, which changes volume upon actuation, and which is arranged on the object.

According to another aspect, there is provided a liquid electrolyte for use with a body-insertable electroactive polymer actuator, which electrolyte comprises radiological contrast media. The liquid electrolyte may consist of an ion-containing radiological
contrast media. The radiological contrast media may comprise at least one radiological contrast media selected from a group consisting of Acetrizoate Sodium, Barium Sulfate, Diatrizoate Meglumine, Diatrizoate Meglumine and Diatrizoate Sodium, Diatrizoate Meglumine, Diatrizoate Sodium, Ethiodized Oil, Gadopentetate Dimeglumine, Iocetamic Acid, Iodamide Meglumine, Iodipamide Meglumine, Ioglicate, Iopanoic Acid, Iothalamate Meglumine and Iothalamate Sodium, Iothalamate Sodium, Ioxaglate Meglumine and Ioxaglate Sodium, Ioxithalamate, Ipodate Calcium, Ipodate Sodium, Isosulfan Blue, Metrizoate, Propyliodone, and Tyropanoate Sodium. In the alternative, or as a complement, the liquid electrolyte may consist of a radiological contrast media, which per se is substantially free from ions, and added ions of at least one type. Thus, the the radiological contrast media may comprise at least one radiological contrast media selected from a group consisting of Iodixanol, Iohexol, Iopamidol, Iopentol, Iopromide, Ioversol, Ioxilan and Metrizamide.

According to another aspect, there is provided a method for making an electrolyte for use with a body-insertable polymer actuator, the method comprising adding ions to a substantially non-ionic radiological contrast media.

According to another aspect, there is provided an ion-containing radiological contrast media for use as an electrolyte for a body-insertable electroactive polymer actuator.

According to another aspect, there is provided use of an ion-containing radiological contrast media as an electrolyte for a body-insertable electroactive polymer actuator.
According to another aspect, there is provided a method for operating an actuator in an electrochemical system, the method comprising providing an operating current to the actuator, a counter electrode or a reference electrode, wherein the current is provided through a conducting wire that is inserted into a tubular device. The conducting wire may be displaceably inserted into the tubular device. The actuator may be arranged on or in the tubular device. The tubular device and the conducting wire may form part of a device as described above. The tubular device may be at least partially electrically insulating. The tubular device may be adapted for insertion into a body lumen. The actuator may form part of a device or system as described above.

Brief Description of the Drawings

In all figures, the dimensions as sketched are for illustration only and do no reflect the true dimensions or ratios of the disclosure. All figures are schematic and not to scale, and in particular vertical dimensions are greatly exaggerated. In addition, electrical leads or wires to and from the actuators, electrodes, etc. have been omitted from the drawings for clarity.

Fig. 1 is a schematic overview of an electrochemical system.

Figs 2a-2c schematically illustrate, in longitudinal cross section, a prior art system with some portions enlarged for increased clarity.

Figs 3a-3i schematically illustrate, in longitudinal cross section, different embodiments of actuator arrangements.
Figs 4a-4b schematically illustrate, in longitudinal cross section, further embodiments of actuator arrangements.

Figs 5a-5f schematically illustrate, in longitudinal cross section, further embodiments of actuator arrangements.

Figs 6a-6f schematically illustrate, in longitudinal and transverse cross section, respectively, further embodiments of actuator arrangements.

Figs 7a-7f schematically illustrate, in longitudinal cross section, embodiments of actuator arrangements in connection with a balloon catheter.

Figs 8a-8f schematically illustrate, in perspective views, elongate body-insertable devices.

Figs 9a-9s schematically illustrate, in longitudinal cross section, further embodiments of actuator arrangements.

Figs 10a-10d schematically illustrate, in longitudinal cross section, embodiments of a bushing for use in balloon catheters.

Figs 11a-11d schematically illustrate, in longitudinal cross section or perspective views, further embodiments of actuator arrangements.

Fig. 12 schematically illustrates, in longitudinal cross section, further embodiments of actuator arrangements.

Figs 13a-13c schematically illustrate, in longitudinal cross section, further embodiments of actuator arrangements.

Figs 14a-14b schematically illustrate, in transverse cross section, a spacer arrangement for use with an actuator.
Figs 15a-15f schematically illustrate, in transverse cross section, a compensation arrangement for use with an actuator.

Fig. 16 schematically illustrate, in longitudinal cross section, an arrangement for verifying actuation status for use with an actuator.

Figs 17a-17e schematically illustrate, in longitudinal cross section, another type of actuator configuration.

Figs 18a-18h schematically illustrate a measurement set up according to another aspect of the present disclosure.

Figs 19a-19g schematically illustrate, in longitudinal cross section, actuator arrangements having modified bending resistance.

Fig. 20 schematically illustrates expansion of a PPY ring in ionic contrast media and NaCl(ag), respectively.

Figs. 21a-21b are diagrams illustrating expansion of a PPY ring inside and outside a narrow channel system with and without a reference electrode, respectively.

Fig. 22 illustrates expansion of a PPY ring in a 2-electrode system with a carbon fibre CE and Ti/Pt CE respectively.

Description of Embodiments

It is noted that in the following figures although there is illustrated a rotational axis R, indicating that the actuator may be rotationally symmetric, each of the designs may also be applicable to other circumstances, e.g. where the actuator is planar, or forms a section of an annulus, etc.

Referring to Figs 3a-3i, there are illustrated a plurality of different EAP actuator 114 designs.
Fig. 3a illustrates a first embodiment of an EAP actuator, arranged on a first part 101, and comprising a substrate base 105a and an active portion 106a formed substantially of EAP material. The dashed line indicates the activated, in the illustrated embodiments, expanded, state of the actuator. It is noted that, depending on which scheme (see above) is used, activation may lead to volume increase or volume decrease.

Hence, in all of the described embodiments, while the EAP actuator is illustrated as being in its contracted (deactivated) state (illustrated by solid lines) and arranged to expand (illustrated by dashed lines) upon actuation (scheme 1), the drawings may also be interpreted as if the EAP is in its expanded (deactivated) state (illustrated by dashed lines) and arranged to contract (illustrated by solid lines) upon actuation (scheme 2).

Fig. 3b illustrates a second embodiment of an EAP actuator, wherein the substrate base 105b is very thin relative to the thickness of the EAP material 106b. In one embodiment, the substrate base 105b may have a thickness that is less than half that of the EAP material, in other embodiments, the thickness of the substrate base 105b may be less than one fourth, less than one tenth or less than one hundredth of the thickness of the EAP material 106b.

Fig. 3c illustrates a third embodiment of an EAP actuator, wherein the substrate base 105c is very thick relative to the thickness of the EAP material. In different embodiments, the substrate base 105c may be thicker than the EAP material 106c, more than 25% thicker, more than 50% thicker, more than 75% thicker or more than 100% thicker.
The substrate base may have a thickness which is less than 0.1 μm, less than 1.0 μm, less than 20 μm, less than 50 μm, less than 100 μm, or less than 500 μm.

Fig. 3d illustrates a fourth embodiment of an EAP actuator, wherein the substrate base 105d is exposed at the side portions thereof, i.e. wherein the EAP material 106d is arranged only on top of the substrate base 105, but does not cover its sides.

Fig. 3e illustrates a fifth embodiment of an EAP actuator, wherein the EAP actuator 114 presents a curved cross section. In such an embodiment, the substrate base 105e may present a varying thickness. The EAP material 106e may present a substantially constant thickness.

Fig. 3f illustrates a sixth embodiment of an EAP actuator, wherein the EAP material 106f is arranged such that its main expansion direction is parallel with the first part 101. This may be achieved by providing the substrate base 105f with a substantial extent in a direction perpendicular to the first part 101, and arranging the EAP material 106f on one or both sides thereof.

Fig. 3g, 3h illustrates a seventh embodiment of an EAP actuator, wherein the substrate base 105g, 105hh is arranged in a recess in the first part 101. Optionally, the EAP material 106g, 106h may also be arranged in the recess (Fig. 3g).

Fig. 3i illustrates an eighth embodiment of an EAP actuator, wherein the substrate base 105i is integrated or formed in one piece with the first part 101.

The actuator may have a length in the longitudinal direction R, which is less than about 10 mm, less than about 5 mm or less than about 1 mm.
The EAP material 106i may have a thickness of more than about 1 μm, more than about 10 μm, more than about 25 μm, more than about 50 μm, more than about 100 μm or more than about 250 μm. In specific embodiments, the thickness may be about 10-100 μm, about 40-80 μm or about 50-70 μm.

Referring to Figs 4a-4b, there is illustrated an approach to solving the problem of the polymer deposition rate being higher at edges of the substrate 105, due to the higher field strength and ion access. To seal off a gap it is critical that the EAP contacts the entire opposite surface, otherwise there can be insufficient sealing.

The edge defect problem can be solved by using a WE substrate base 105 that is thicker in the central areas than close to its edge, thus having a varying thickness. Typically, such a varying thickness may be provided by having tapering or rounded edges. Even if the actual EAP material 106 thickness is larger close to the edges, it may still be smaller than the total actuator thickness in the central areas. Yet another way of solving the problem is by passivating the edges so that they become inactive and thus the EAP does not expand there.

Referring to Figs 5a-5f, there is provided a solution to the problem relating to actuation of PPy in a confined volume with limited amount of electrolyte, where the PPy expands laterally uneven. The PPy expands faster at one end 195 than at the other 196. This may occur close to the CE, close to areas with higher ion concentration or close to the end of the gap.

In Figs 5a, 5b, the dashed lines illustrate the EAP material shape at different points of time during the activation. Hence, initially, the EAP material will have
the shape indicated at 114-T0, a first time period after activation, the EAP material will have the shape indicated at 114-T1, and after some further time, the shape indicated at 114-T2.

The PPy area closest to the CE may expand faster than areas further away. When using the volume expansion of PPy to seal off a gap, a typical behavior is that the PPy will seal a portion close to the CE, while areas further away are less contributing to the sealing ability initially. In expanded/sealed state, the areas close to the CE are also sealing off access to electrolyte for areas further away.

In some applications, it may occur, or it may be possible to provide, different ion concentrations on the proximal 103 and distal 104 sides of the actuator 114. In such applications, the PPy area near the high ion concentration part will expand faster than areas near the lower ion concentration.

Likewise, the actuator may be positioned near the end of the gap, for instance at the end or opening of a channel, and due to a higher availability of ions outside the channel and reduced effect of ion depletion. In such applications, the electroactive material area near the end/opening will expand faster than areas further away from the cap. Such effects have been observed in an annular channel gap of about 70 μm between a pair of concentrically arranged parts, wherein the electroactive polymer material was about 60 μm thick and was positioned between about 1 and about 5 mm from the channel opening.

Enabling electrolyte access for a longer time period for areas further away will contribute to sealing speed and ability. Therefore it may be advantageous to provide a gap which increases in size, or an actuator 114 that decreases in size, in a direction towards the one of the
proximal and distal sides wherein the actuation is fastest. That is, the total gap increases in size in a direction towards the CE or in a direction towards where the ion concentration is higher or in a direction towards the end of the gap.

Now, taking the CE position as an example.

The solution to the problem may be to use a wedge-shaped EAP structure, as illustrated in Figs 5b and 5c, wherein the thickness of the PPy of the actuator 114 tapers towards the CE 115. Thus, the PPy will still expand faster closer to the CE, but this part will not prevent electrolyte access to areas further away until a late stage. This enables a larger portion of the PPy to expand early on, hence increasing sealing speed. As a larger portion of the PPy is in its expanded state early on, sealing ability is also improved.

Alternatively, a gap of tapering thickness may be provided as described with respect to Fig. 5d. Here, the gap tapers in thickness away from the CE 115, thus allowing fluid contact between the CE and the distal portion of the actuator (as seen from the CE) for a longer time, to achieve the same effect as in Figs 5b and 5c. Where the actuator 114 is arranged on the first part 101, the tapering gap may thus be provided by arranging a wedge shaped groove 107 in the second part 102.

Another option is as illustrated in Fig. 5e, wherein the actuator 114 is arranged at an intersection between a portion 102-1 having a constant cross section and a portion 102-2 having a varying cross section, as would be the case in a balloon catheter, such as the one illustrated in Figs 2a-2b. Here, the CE 115 is positioned in the portion 102-2, whose cross section diminishes towards the first portion 102-1, such that the part of
the actuator 114 which is closest to the CE 115 will not prevent the parts furthest away from expanding. Another option is provided in Fig. 5f, wherein a plurality of actuator portions 114-1, 114-2, 114-3, 114-4 are provided.

In one embodiment, the actuator portions may be individually controllable, such that the one 114-1 furthest away from the CE 115 may be actuated first, then the next one 114-2 and the next etc, until all actuator portions have been actuated.

In another embodiment, the actuator portions may have different characteristic, e.g. expansion rate characteristic, such that the one 114-1 furthest away from the CE 115 expands faster than the next one 114-2 etc.

In yet another embodiment, the finally applied potential for each of the actuator sections 114-1, 114-2, 114-3 may be provided with a time delay. For example, the final potential of a first actuator section 114-1 may occur after the final potential has been applied to a second one of the actuator sections 114-2. Hence, different potential increase rates may be provided to different actuator sections.

If both ends of the PPY are fast expanding and the center is slow expanding, for instance as a consequence of having one or more of a high ion concentration, a tube ending and a counter electrode on one side, and one or more of a high ion concentration, a tube ending and a counter electrode on the other side, double wedge shaped tapering gap may be provided.

For example, each of the embodiments disclosed with respect to Figs 5c-5f may be provided in the form of two-way embodiments, e.g. with a EAP thickness tapering
towards both its proximal and distal edges, such that a central portion of the EAP is thicker than its edge portions; or with a gap size tapering towards its central portion, such that the gap is narrower at its central portion and wider near its proximal and distal edges.

Fig. 6a illustrates alternative or complimentary positioning of counter electrodes 115a, 115b, 115c, 115d.

In different embodiment, a single CE may be arranged in any of the positions illustrated in Fig. 6a.

In one embodiment, counter electrodes 115a, 115b may be positioned on both proximal and distal sides of the actuator 114, in another embodiment counter electrodes 115a, 115c; 115b, 115d may be positioned on both the first and second parts 101, 102, on proximal or down stream sides of the actuator 114. In yet another embodiment, counter electrodes 115a, 115b, 115c, 115d may be positioned on both first and second parts 101, 102 and on both proximal and distal sides of the actuator 114.

Fig. 6b illustrates yet another embodiment, wherein the counter electrode 115e is positioned on the second part 102, across the gap from the actuator 114, which is arranged on the first part 101.

Fig. 6c illustrates yet another embodiment, wherein a plurality of actuator sections 114a, 114b, 114c are spaced apart in a longitudinal direction (e.g. along the central axis R) of the gap, with counter electrodes 115f, 115g, 115h positioned between each adjacent pair of actuator sections 114a, 114b, 114c, or put differently, with counter electrodes positioned on both sides of each actuator section, or, put differently, a plurality of WE and CE are arranged in an alternating manner.

The CE should also be positioned close to the WE for good expansion. In general, at least one counter
electrode 115 may be positioned not more than 60 mm, preferably not more than 30 mm, 10 mm, 5 mm, 2 mm, 1 mm, 0.5 mm, 0.1 mm from the electroactive polymer material actuator 114.

The counter electrode may have a length in the longitudinal direction R, which is less than 10 mm, less than 5 mm or less than 1 mm.

Actuation of PPpy using only two electrodes (WE+CE) in a system with limited space, with limited amount of electrolyte, or with limited access to electrolyte (due to flow properties etc.) may be problematic. It is hard to control and achieve a high and fast expansion. Several aspects are influenced by the limited space or limited amount of electrolyte. The small space limits the amount of electrolyte, the size of the CE may be limited, which can negatively affect expansion and speed. If the limited space is elongate, it can generate a large distance between CE and WE, which will have negative effects on necessary voltages due to the large ohmic drop. These are factors that have a large impact on EAP performance, such as expansion and speed.

The problem may be solved by introducing a third electrode, a reference electrode (RE), in the system. An RE enables good control of the EAP actuation. The size of the RE is of minor importance. It is recommended that the CE is large and is placed close to the WE to get optimal performance from the 3-el system. In elongate embodiments, such as in catheters, it may be advantageous to position the RE between the CE and the WE, or to position the WE between an RE and a CE (see Fig. 6d).

In the embodiments illustrated with reference to Figs 5-6, a reference electrode may be positioned as illustrated with reference to the counter electrode 115.
The reference electrode may be positioned not more than 30 mm, preferably not more than 10 mm, 5 mm, 2 mm, 1 mm, 0.5 mm, or 0.1 mm from the electroactive polymer material (i.e. the WE). The reference electrode may have a length in the longitudinal direction R, which is less than 5 mm, less than 1 mm or less than 0.5 mm.

In a first group of specific embodiments, the counter electrode may be positioned less than 2 mm from the actuator, while the reference electrode may be positioned less than 1 mm, less than 0.5 mm or less than 0.1 mm from the actuator.

In a second group of specific embodiments, the counter electrode may be positioned less than 1 mm from the actuator, while the reference electrode may be positioned less than 1 mm, less than 0.5 mm or less than 0.1 mm from the actuator.

In a practical example, an EAP actuator was activated in a narrow channel volume (1.2 mm x 2 mm). Expansion and expansion speed were compared to results from actuation in a two electrode setup (Fig. 21a) and from actuation in a confined volume (inside a tubular channel) and bulk solution (Fig. 21b outside channel). As can be seen the three electrode set-up improves the performance compared to the two electrode set-up in a confined volume and is similar to actuation in the bulk.

Fig. 6d illustrates an embodiment, wherein a reference electrode 116 is positioned between the actuator 114 and a counter electrode 115k. Optionally, or as an alternative, additional counter electrodes may be positioned on the other, proximal or distal, side of the actuator 114, and optionally, or as an alternative, also with a counter electrode positioned across the gap from the actuator, i.e. on the second part 102.
Fig. 6e illustrates an embodiment wherein counter electrodes 115a, 115b, 115c, 115d may be positioned as illustrated in connection with Fig. 6a, and wherein a reference electrode 116 is positioned across the gap from the actuator, i.e. on the second part 102.

Fig. 6f illustrates another embodiment, wherein counter electrode 115 and reference electrode 116 are arranged as segments of annuli, and at different angular positions in an embodiment wherein the first and second parts 101, 102 are substantially concentrically arranged.

Integrating sufficiently large electrodes, such as a CE on medical devices, for instance as described in this disclosure, can sometimes be a problem since the size of the device is fixed. Considering most electrodes are made from metal, adding metal coatings or structures on the device may change the properties of the device, such as making it stiffer. Metals are generally hard to deposit on the inside of small irregular objects, typical features for medical device applications, which further complicates deposition of such a coating or structure.

This problem is solved by at least partially replacing existing polymer areas on the device with a polymer having similar mechanical properties but with a high conductivity. An example can be to partially replace a portion of a balloon used during PTCA with a high conductivity polymer and then to use this area as CE for activation of EAP. As an alternative, a compliant conducting layer may be added on these areas.

Figs 7a-7f illustrate different positioning of counter electrodes in a balloon catheter, such as the one illustrated in Figs 2a-2b in order to provide for further integration. It is noted that the CE/RE illustrated in Figs 3, 4, 5, 6 may be integrated in a manner similar to
that illustrated in e.g. Figs 7b, 7d, 7e, 7f. Such integration saves space, which is important in small medical devices.

In Fig. 7a, the counter electrode 115 is provided as a layer on the inside of the balloon part 109a of the balloon catheter.

In Fig. 7b, the counter electrode 115 is integrated with the balloon part 109b of the balloon catheter. The conducting area partially replaces the structural material of the balloon or conducting parts are integrated into the structural matrix.

In Fig. 7c, the counter electrode is provided as a layer on the inside of the balloon part 109a, and also extends on the inside of the connection/sealing part of the balloon catheter, such that it reaches into the gap where the actuator 114 is positioned. Thus, the counter electrode may also be across the gap from the actuator 114. Hence, this embodiment effectively constitutes a combination of Figs 7a and 6b.

Fig. 7d illustrates an embodiment similar to that of Fig. 7b, but where the counter electrode 115 extends into the gap like the one described with respect to Fig. 7c.

Fig. 7e illustrates an embodiment wherein the counter electrode is arranged on the portion 109c of the balloon (connecting/sealing part) across the gap from the actuator 114. In this embodiment, the counter electrode may be integrated with the second part 102.

Fig. 7f illustrates an embodiment wherein the counter electrode 115b is integrated with the first part 101, and positioned on an proximal side of the actuator 114. In the alternative, or as a complement, the counter electrode may be positioned on the distal side of the actuator 114.
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Thus, effectively, the embodiments of Figs 6a and 7b, 7d, 7e, 7f may be combined.

The counter electrode may be at least partially formed from an electrically conductive polymer material.

Such materials may be in the form of polymers comprising metal particles, conducting polymers, conducting spheres, conducting fibres, e.g. carbon fibres, and/or redox polymers. Non-limiting, examples of organic materials that may be used for providing a counter electrode includes glassy carbon, carbon fiber, PPy, Pedot/PEDT, Orgacon® (PEDT-PSS). Alternatively, the conducting area may be provided by laminating a conducting film, electroplate or electrolessly plate a conductor, evaporate or sputter a conductor (e.g. metals), chemically or electrochemically polymerise a conducting polymer, spin coat or dip coat a conducting layer, conducting inks, incorporate conducting particles (e.g. Ag, Pt) in the balloon material, use braided or coiled metal layers embedded in the balloon material, self-assembled nanocomposites (such as Metal Rubber™ from NanoSonic Inc.), assembling/affixing/mounting a balloon/tubing on a metal structure, such as crimping a tube on a marker band, such as those referred to above.

As an example, a PPy(DBS) ring was actuated in a 2-electrode system in 0.15 M NaCl. As seen in Fig. 22 expansion of PPy was comparable when actuated with a Ti/Pt or carbon fibre CE, respectively.

In addition using metals as CE material may sometimes be associated with problems, such as metal dissociation and migration (e.g. Au in NaCl), oxidation (e.g. Ag and Cu) or large voltage/energy requirements (e.g. Pt). Using an organic material as CE will solve these problems. Organic materials, such as carbon fibres and others mentioned previously, are generally stable, do
not obtain any passivating oxide layer, and have reasonable small voltage span. Metals are generally more stiff and brittle than organic materials, which is an additional advantage. Organic materials are also often more biocompatible.

Where the device on which the actuator is arranged is a surgical tool, the counter electrode may be positioned on another surgical tool, which may be e.g. catheter, a dilation balloon, a knife, a needle, a scissors, a pliers, a tweezers, a clamp, a guide wire and a catheter, a sheath, a lead, an outer tubing, an inner tubing, a trocar, a stylet, an embolic coil, a part of a filter device a part of an endoscopes, or a part of a gastroscope.

Referring to Figs 8a-8f, there is provided a solution to the problem of adding further materials or components to provide for electrode actuation in a body-insertable device, thereby saving space. According to Figs 8a-8f, use is made of the already existing conducting areas of the medical device as electrode. For instance, the core of a guide wire system can be used to actuate a PPy ring. This will not add any space or additional materials. In case the existing conducting area is coated or covered with, for instance a biocompatible polymer, which acts as insulation, this coating may need to be at least partially removed to expose the conducting area to the electrolyte. In order to maintain biocompatibility, the exposed area may be coated with a conducting polymer, such as PPy, or any other biocompatible conductive layer.

Fig. 8a illustrates a medical device, such as a guide wire having a conducting core 121, an isolating covering 120 with an opening 122 that exposes the conducting core,
which may be used as an electrode, for instance in an electrochemical system.

Fig. 8b illustrates a dual core guide wire, i.e. a guide wire having first and second core portions 121-1 and 121-2, which are electrically isolated from each other. The guide wire has an isolating covering 120 and a respective opening 122-1 and 122-2 for exposing the respective core. In such an arrangement, one of the cores may provide a reference electrode, while the other one provides a counter electrode. Likewise, one electrode may be used as the actuator/WE and the other as the counter electrode.

Fig. 8c illustrates a guide wire, similar to that of Fig. 8a, but with a schematically illustrated actuator device, which may be an annularly shaped electroactive polymer material actuator 114 as disclosed herein, arranged thereupon.

Fig. 8d illustrates a tubular medical device 123, such as a sheath, inner tubing, outer tubing, catheter, in which a medical device as described with reference to Figs 8a and 8b, is arranged. The catheter, which may be made from a non-conducting material, presents an opening 124 for exposing the opening 122 in the guide wire covering 120. Furthermore, as a schematic illustration, an actuator device, which may be an annularly shaped electroactive polymer material actuator 114 as disclosed herein, arranged thereupon is arranged on the catheter 123.

Fig. 8e illustrates a catheter 123, in which a dual core guide wire as described with respect to Fig. 8b is arranged. Openings 124-1, 124-2 are arranged to expose the openings 122-1, 122-2 in the guide wire coating 120.
Fig. 8f illustrates a tubular medical device 129, such as a catheter or tubing, comprising a conducting layer. An opening 122-3 is arranged to expose the conducting layer 121-3 and thus provide for an electrode area. The conducting core may be a wire, film, coiled or braided reinforcing layer, provided between an inner insulating layer and an outer insulating layer. Either one, or both, of the inner and outer insulating layers may have an opening for providing contact towards the interior or exterior, respectively, of the tubular device.

Examples of such tubings are "braided or coiled reinforced tubing" from MicroLumen, Inc. and "multi-layer reinforced tubing" from New England Catheter Cooperation. The construction of a typical reinforced tube may comprise a substrate layer, a braided or coiled reinforcement layer, and an exterior layer.

The conducting cores 121, 121-1, 121-2, and 121-3 may also be arranged to provide for electrical current to a part such as an electrode or actuator. This would eliminate the need for extra conducting wires and thus improve integration of the medical device. For instance, taking the expanding EAP ring actuator of Fig. 8c as an example, the actuator may be positioned outside the opening, and an electrical connection between the core 121 and actuator 114 may be provided by electrically contacting the actuator 114 with an opening 122. This may be achieved by electrical connection methods such as wire bonding and soldering or by integrated design such as positioning the actuator assembly 114 (i.e. conducting substrate base 105 and EAP material 106) at least partially on top of the opening 122 or the opening 122
may be utilized as the substrate base 105 resulting in an integration as illustrated in Figs. 3g and 3h.

The electroactive polymer actuator 114 as described with respect to Figs 8c-8e may be designed as the actuator device described with respect to any of Figs 3a-3i, 4a-4b, 5a-5f, 6a-6f, 7a-7f, 9a-9s, 11a-11d, 12, 13a-13c, 14a-14b, 15a-15f, 16, 17a-17e or 19a-19f.

The actuator may be produced separately and attached to the device near, in or partially in the opening, or it may be formed in situ near, in or partially in the opening.

In the alternative, or as a complement, the electroactive polymer material 114 may be arranged to release a biologically active substance.

Figs 9a-9s illustrate embodiments of actuator arrangements that are particularly suitable for providing secure valve functions, or in order to provide a bushing function (locking) of the first and second parts 101, 102 relative to each other.

In Fig. 9a, a plurality of actuator sections 114 are provided and spaced apart in a longitudinal direction (along line R). Each of the actuator sections may be individually controllable.

In Fig. 9b, there is illustrated a pair of actuator sections 114a, 114b, which are positioned on opposites of the gap, i.e. one on the first part 101 and one on the second part 102. The actuator sections may thus be arranged to contact each other when activated.

Figs 9c and 9d illustrate actuators engaging a protrusion 125 on the opposite side of the gap. The protrusion may be more rigid than the EAP material, such that the EAP material is slightly deformed in the area which contacts the protrusion, to thereby provide a tight
seal. In Fig. 9c, the protrusion 125 is formed in one piece with the second part 102, whereas in Fig. 9d, the protrusion 125 is arranged as a separate part, that is mounted on the second part 102. The protrusion may have any shape, such as rounded or sharp edges, as deemed suitable.

Figs 9e and 9f illustrate embodiments wherein an EAP actuator 114 has a relatively long extent in the longitudinal direction of the gap, e.g. more than twice its thickness, or more than ten times its thickness.

In Fig. 9e, a plurality of spaced apart protrusions are arranged across the gap from the actuator 114, similar to Figs 9c-9d.

In Fig. 9f, the actuator does not contact or only partially contacts the second part 102, thus forming a small play between the actuator and the second part 102. However such a small play may be sufficient to limit or even close a flow of liquid in the gap.

Figs 9g and 9h illustrate an embodiment, wherein the actuator 114 is positioned on the second part 102, rather than on the first part 101, such that it expands radially and inwardly, rather than outwardly.

Fig. 9i illustrates an embodiment, wherein a protrusion 127 on the first part 101 extends into a recess 128 in the second part 102, such as to limit relative axial movement between the first and second parts 101, 102, but still provide a gap. The actuator 114 may be positioned on one of the first and second parts 101, 102, on the proximal or distal side of the protrusion 127, and arranged to engage the other one of the first and second parts 101, 102. The protrusion may be annular or formed by a plurality of pins. Furthermore, the protrusion may be
provided on the second part 102, whereas the groove is on the first part 101.

Fig. 9j illustrates an embodiment, wherein the actuator 114 is arranged on the first part and arranged to extend, in its activated state, into a recess 128 in the second part 102.

Fig. 9k illustrates an embodiment which is similar to that of Fig. 3f, wherein the actuator has its main expansion in a direction parallel with the surface of the first part 101 upon which the actuator 114 is arranged. The actuator and its substrate base 105 extends into a recess 128 in the second part, and in its activated state, the actuator engages side walls of the recess 128.

Fig. 9l illustrates an embodiment, wherein the actuator is as described with respect to Fig. 3e, and wherein a recess 128 in the second part 102 presents a correspondingly curved section.

Fig. 9m illustrates an embodiment, wherein a plurality of actuator sections 114 engage a plurality of recesses 128, which may be formed as recesses or annular grooves in the second part, or which may be formed by adjacent protrusion 125 on the second part 102.

Fig. 9n illustrates an embodiment wherein an actuator 114 extends into a recess or an annular groove, between a pair of protrusions 125 arranged on the second part 102.

Fig. 9o illustrates an embodiment wherein the actuator 114 presents a V-shape, which is arranged to engage a protrusion on the second part having a correspondingly, inverted V-shape.

Fig. 9p illustrates an embodiment wherein the actuator 114 presents a wedge-shaped cross section, and is arranged to engage a protrusion 125 on the second part, which is complimentarily wedge-shaped.
Fig. 9q illustrates an embodiment, comprising a protrusion 125 on the first part 101 and a protrusion 125 on the second part 102, such as to limit relative axial movement between the first and second parts 101, 102, but still provide a gap. As an alternative to a protrusion on the first or second parts, there may be provided a step in the wall thickness of the first or second part, providing the same effect as a protrusion. The actuator 114 may be positioned on one of the first and second parts 101, 102, on the proximal or distal side of the protrusion 125, and arranged to engage the other one of the first and second parts 101, 102. The protrusions may be annular or formed by a plurality of pins. Furthermore, the device may comprise three protrusions, two on one of the parts 101, 102 and one on the other part 101, 102 positioned in between the two as to reduce or limit the axial movement between the first and second parts.

In Fig. 9r, there is illustrated an embodiment comprising a pair of actuator sections 114a, 114b, which are positioned on opposites of the gap, i.e. one on the first part 101 and one on the second part 102, and juxtaposed to each other. The actuator sections may thus be arranged to contact the opposing surface when activated as to provide for a double sealing and a bushing function simultaneously.

In Fig. 9s, there is illustrated an embodiment comprising a pair of protrusions 198 comprising hooked endings so that two opposing and complimentary parts catch into each other and to provide for a bushing function. The EAP material that provides for the sealing function may be provided on the surface opposing the part 101, 102 as illustrated. Likewise, any one of the surfaces of the hook part 198 may be provided with the EAP layer.
Fig. 10a-10d illustrate embodiments of a bushing, which may be used to connect a balloon portion 109 to a catheter portion 123, so as to provide a balloon catheter, which may be rotatable.

Fig. 10a schematically illustrates an embodiment of a bushing for forming a connection between a tubular part, such as a catheter 123, and an inflatable part 109, such as a balloon, which both form part of a balloon catheter.

The bushing may comprise an inner tubular member 131, having an attachment portion for attachment to an attachment portion 133 of the catheter. The interior of the tubular member connects to the channel 134 provided in the catheter 123. The bushing may further comprise an outer tubular member 130, having an attachment portion for attachment to a connecting portion 132 of the balloon 109. Between the tubular members 130, 131, an actuator 114, as described in the present disclosure, may be arranged.

The attachment portion 133 may be so thick as to prevent the outer tubular member 130 from disengaging the bushing.

Fig. 10b schematically illustrates another embodiment of a bushing for forming a connection between a tubular part, such as a catheter 123, and an inflatable part 109, such as a balloon, which both form part of a balloon catheter.

In the embodiment of Fig. 10b, the outer tubular part 123 and/or the inner tubular member 131 may be provided with a disengagement preventing part 135, 136, which may have the form of an annulus or a plurality of radial protrusions arranged on the inner or outer tubular member 130, 131, as illustrated in Fig. 10b. Likewise, part 133 may also function as a disengagement preventing means by
setting its thickness larger than the gap size as illustrated in Fig. 10a.

Fig. 10c illustrates a bushing that only comprises an outer tubular member 130 having an attachment portion for attachment to a connecting portion 132 of the balloon 109 and no separate inner tubular member. The actuator 114 may be provided on the catheter part 123 or on the inside of the outer tubular member 130. The bushing may comprise "locking" members to prevent axial movement, such as are presented in previous embodiments.

Fig. 10d illustrates a bushing that comprises only an inner tubular member 131, having an attachment portion for attachment to an attachment portion 133 of the catheter. The interior of the tubular member connects to the channel 134 provided in the catheter 123. There is no separate outer tubular member 130. The balloon connection portion 132 of the balloon 109 is provided directly over part 131. As an alternative to provide the "locking" function to prevent axial movement, a part of the portion 135 is folded inwards as indicated by 135b.

Such bushings (Figs. 10a-10d) may include CE and/or RE arrangements as illustrated in Figs 5-8. Having a separate bushing comprising the actuator part 114 part may have several advantages. The bushing-actuator assembly, catheter tubing 123 and balloon 109 may all be individually fabricated and thereafter assembled into a balloon catheter. Production methods that fit each part best may then be used, without having to compromise as might be the case in more integrated variants. In addition the separate bushing part may be made with different tolerances or materials then is needed for the other parts.
As illustrated in Fig. 10a, the attachment of the catheter and the balloon may be provided by crimping. In the alternative, or as a complement, a clamp may be used to secure the catheter and/or balloon to the bushing.

The electroactive polymer material actuator 114 as described with respect to Figs 10a-10d may be designed as the actuator device described with respect to any of Figs 3a-3h, 4a-4b, 5a-5j, 6a-6b, 7a-7f, 9a-9o, 11a-11d, 12, 13a-13c, 14a-14b, 15a-15f, 16, 17a-17e or 19a-19f.

Figs 11a-11b illustrate an actuator embodiment, which is useful when the first and second parts 101, 102 are displaceable relative each other. In this embodiment, actuators 114a, 114b are arranged on both first and second parts, 101, 102. The actuators 114a, 114b; 114a', 114b' are complementarily wedge-shaped, such that they may lock the first and second parts 101, 102 relatively to each other with a locking force that varies as a function of the relative position of the first and second parts 101, 102. Such an embodiment may be particularly useful, as it may provide improved sealing and/or locking as a function of the relative axial displacement of the first and second parts. The first and second parts may be concentrically arranged, such that the relative position may be a relative axial position. This embodiment is similar to Fig. 9p.

Figs 11c-11d illustrate an embodiment wherein the actuator 114 is positioned on an inner member 123, which may be a catheter (see Fig. 10), and wherein an outer member 109, which may be a balloon, is axially displaceable relative to the inner member 123. The outer member presents a first part having a constant section, a second part having tapering internal section, and a third
section with a smaller constant section. The actuator 114 is arranged to interact with at least one of said first, second and third sections. In the illustrated embodiment, the actuator 114 is arranged to interact with the first and second sections. Hence, the actuator presents a first cylindrical part, interacting with the first section of the outer member, and a second frustoconical part, interacting with the second section of the outer member.

Referring to Fig. 12, there is provided a solution to the problem of avoiding movement of a solution from one area to another in a defined structure, or to improve the sealing effect, the structure can partially be chemically or physico-chemically designed so that it does not allow for any solution to pass, due to large differences in surface tension between the surface/area to be avoided and the solution.

This can also be used to selectively allow some electrolytes (inflation liquid in balloon) to contact the EAP, while others (blood) are prevented. Only allowing an actuation electrolyte to reach the EAP will prevent unwanted reactions at the WE, hence maximizing performance.

Hence, proximal and distal surface areas 137-1, 137-2, respectively, which may be close to or adjacent the actuator 114, may be designed to have specific surface tension properties. For example, they may be made more or less hydrophilic or hydrophobic.

This selection of surface tensions in different areas can be used to help sealing off a gap between first and second parts 101, 102 in e.g. a tunnel design, where an EAP actuator 114 has been provided to function as a controllable valve to seal off a proximal, incoming water-based solution. The area 137-2 beyond the valve may
be designed to have large hydrophobicity to reduce or avoid any potential leakage of solution into the distal part of the actuator 114.

Simultaneously, the area 137-1 at the proximal side 103 of the actuator may be designed to have large hydrophilicity. The opposite relationship is also possible. In addition, the hydrophilic or hydrophobic parts may extend into the gap between the actuator 114 and second part 102. As an alternative, the hydrophyllic or hydrophobic part may only be positioned within the gap opposite to the actuator 114 on the substrate 102.

Figs. 13a-13c illustrate a method for supplying electrolyte to an EAP actuator. The method may be used as a complement to an electrolyte provided in the space where the EAP actuator operates, or it may be used as an exclusive electrolyte. An advantage is that more efficient electrolytes may be used, while reducing the risk of contacting the gap environment.

Ways of generating different surface tensions includes physical, chemical and biological methods. Examples are given below.

Methods that may be used for generating such hydrophobic and hydrophilic surface areas include surface-modification technologies such as plasma treatments, vacuum deposition techniques, ion assisted reactions, conventional coating processes such as spraying or dipping to apply a suitable coating layer, methods employing ionized-particle bombardment such as ion implantation and ion beam assisted deposition, chemical plating, grafting or bonding of specific molecules or layers (e.g. self-assembled monolayers, PEGylation) onto the surface, hydrogel application etc. Addition of or exposure to any reactive chemical may
alter the surface, making it more or less hydrophilic or hydrophobic.

Plasma treatments are a common approach for making hydrophilic or hydrophobic surfaces. The surface is placed in contact with the gas to be used in the treatment and imposing high-energy radiation, preferably radio frequency radiation, sufficient to ionize the gas to a plasma state. Examples of gases that are useful in activating the surface polymer chains are the noble gases, hydrogen gas, oxygen gas, organic fluorides and hydrocarbons. Preferred among these are argon, helium, hydrogen gas, oxygen gas, and tetrafluoromethane.

Examples of gases that are useful in converting the surface polymer chains to increase their hydrophilic character are oxygen gas, acetic acid, volatile siloxanes, ethylene oxide, and hydrocarbons with hydrophilic groups. Examples of gases that are useful in increasing the hydrophobic character of the surface polymer chains are organic fluorides, particularly trifluoromethane, tetrafluoromethane, tetrafluoroethane, hexafluoroethane, difluoroethylene, and hexafluoropropylene, as preferred organic fluorides, and tetrafluoroethane, hexafluoroethane, and hexafluoropropylene as the most preferred. These species can be used individually or as mixture.

Typical examples of hydrogel polymers that can be used are vinyl pyrrolidone and polyethylene glycol. An example of a method for bonding specific molecules to a surface is light-activated chemical immobilization where use of photoreactive reagents achieves covalent bonding of molecules to surfaces. Another example is grafting achieved by forming reactive groups at the surface e.g.
through isocyanate chemistry for subsequent grafting of suitable molecules to the surface.

Biological methods of surface treatment may include growth, spreading or other attachment of specific cells on a surface, or coating with biomolecules, e.g. proteins. These biomolecules may be directly or indirectly attached to the surface. Attachment to surface may include using a linker/spacer molecule such as PolyEthyleneOxide (PEO) or an antibody.

Another example of controlling surface energy and thus surface hydrophilicity or hydrophobicity, is by the electrowetting, a method where a potential is applied to the surface to control its surface energy.

The surface area of desired surface tension might also be formed from integrating a separate part of suitable material into the structure at the correct positions. Another example is laminating a suitable material on the surface at the desired positions.

In Fig. 13a, there is illustrated an actuator 114 arranged on a first part 101, and operable in a gap 141 between the first part 101 and a second part 102. The first and second parts 101, 102 may be concentrically arranged tubular parts. In a backside space 142 on the side of the first part 101 opposite to that where the actuator 114 is positioned, there is provided an electrolyte, and the first part 101 is arranged to allow ion/electrolyte transport from the backside space 142 to the actuator 114. For example, the first part 101 may, in the area 139 of the actuator 114, be provided with channels, pores or micropores, that allow ion/electrolyte transport.

Optionally, a further part 138, which is concentrically arranged inside the first part 101, may be
arranged to define the backside space 142, e.g. such that the backside space 142 has the form of an annular gap between the parts 101 and 138, and such that a further space may be provided inside the further part 138, e.g. in order to allow inclusion of a guide wire or in order to allow for injection of inflation liquid for a balloon catheter.

As illustrated in Fig. 13b, the actuator may be arranged in a recess in the first part 101, e.g. as illustrated in Fig. 3g.

As illustrated in Fig. 13c, a membrane 140 may be provided to isolate the actuator from the environment in the gap 140, whereby the only ion supply to the actuator is that of the backside space 142.

In a further embodiment, the actuator may be arranged in contact with both the gap space 141 and with the backside space 142. For example, the actuator may be arranged in a through hole in the first part 101.

Figs 14a-14b illustrate a method of improving actuator function by making sure that the first and second parts 101, 102 are optimally positioned relative each other. If the EAP material contacts another surface (as illustrated at 143 in Fig. 14a), this will limit or in some cases prevent the ions in the electrolyte from reaching the EAP material. By providing guide pins 144, which may be relatively soft, access to electrolyte is improved, which enables fast expansion of the PPy.

Figs 15a-15f illustrate a method of the improving sealing ability of an EAP actuator based valve, by providing a soft underlying substrate and/or soft opposing substrate to achieve a complete sealing.

An EAP material layer may be too inflexible to "fill up" a whole cavity if it is not perfectly shaped to fit
the cavity. Such imperfect shaping (such as a bulge or protrusion 145) may be difficult to avoid. A soft
underlying substrate 146 can be used to avoid incomplete sealing of an opening. The EAP material can then expand
completely, and the underlying substrate will be compressed and help to adjust the EAP evenly into the
cavity (Fig. 15e-15f).

The substrate 146 that is arranged opposite the EAP material and that will come in contact with the EAP
material surface when the EAP material is fully expanded, can be soft to achieve an even substrate, same principle
as for underlying substrate (Fig. 15c-15d). Such soft substrates may be provided by using compressible
elastomeric and/or foamed materials.

Referring to Fig. 16, in valve-like applications, where an EAP actuator is used to seal off a gap between
first and second parts 101, 102, it is important to have a way to verify that the EAP has expanded fully and
sealed the gap.

This may be solved by providing an electrically conducting contact area 147 opposite to the EAP actuator
114. When the EAP expands it will eventually come in contact with the contact area. Since the EAP is conducting, there will be a closed loop between the WE
114 and the contact area 147. The closed loop can be used to provide some kind of signal in a control device 148 to
indicate sealing e.g. sound or signal lamp. Since the EAP might expand irregularly it may be advisable to split the
contact area 147 in several parts/areas, each of which
being individually connected to the control device 148 to provide individual indication of its expansion.
A further advantage of this configuration is that the contact area can be used as counter or reference electrode during expansion.

In the alternative, a pressure sensor could be arranged in the gap, to detect the pressure provided by the interaction between the actuator and the part 101, 102 against which it is to seal. As yet an alternative the pressure difference between the proximal and distal part of the EAP actuator 114 may be measured to determine whether or how much the gap is closed. Or a flow sensor to measure the flow over the actuator and through the gap.

Referring to Figs 17a-17e, when a solution enters the EAP matrix, chemical reactions occur involving some or all chemical species present if a potential/current is applied to the material. A possible reaction that can occur if sufficient potential/current is supplied, is the formation of gas (e.g. from electrolysis of water). If the gas can be kept inside the matrix, optimally at an interface between the polymerized surface and the EAP, the EAP actuator 114 can be forced to swell like a balloon. This is due to gas formation, subsequent detachment of EAP from the surface (if not already detached from start) and then filling of the space in the interface. If the EAP is secured at end points the balloon-effect will be observed.

Fig. 17a illustrates a normal type of actuator 114, such as the ones previously described herein, which is arranged on a first part 101, on which a substrate base 105 is arranged. The substrate base 105 is covered by an EAP layer 106. When actuated, the device changes volume to assume the size as indicated by 106'.
Fig. 17b illustrates an alternative device, subsequent to the provision of a sufficiently high voltage to provide gas formation in an interface 182 between the EAP layer 106' and the substrate base 105. The required voltage may vary depending on the compounds present in the device and depending on environmental parameters, such as pressure and temperature. As the EAP layer 106, 106' is attached to the substrate base 105, at a perimeter portion 181 (see Fig. 17c) thereof, e.g. by differential adhesion methods, e.g. as disclosed in EP 0 870 319 A1, which are known to the skilled person, a gas bubble 180 may be formed and enclosed between the substrate base 105 and the EAP layer 106'.

Optionally, referring to Fig. 17d, the EAP layer 106, 106' may be attached to the substrate base by an a clamp or by an adhesive 183, defining the perimeter portion enclosing the gas bubble 180.

Optionally, referring to Fig. 17e, a membrane layer 184 may be provided, e.g. to prevent the gas in the gas bubble 180 from escaping. This membrane layer may e.g. be a semi-permeable membrane allowing water and ion influx but no or reduced gas out flux.

Referring to Figs 18a-18h, a measurement set-up, which is suitable for use with electroactive polymer materials and actuators will now be described.

In one embodiment a laser scan micrometer is used to in situ, in real-time and/or continuously, non-destructively, and without mechanical contact measure a layer thickness during synthesis or deposition thereof.

Fig. 18a illustrates a per se known measurement setup 160 comprising a laser scan micrometer (LSM). An example of such an LSM is Mitutoyo Laser Scan Micrometer LSM501H with a display unit LSM6100. The LSM works as
follows. A laser beam 161 is scanned over an area between the laser source 162 and a sensor part 163. An object 164 is inserted in this area. The scanning beam projects a shadow of the object on the sensor and this shadow is a measure of the thickness of the object.

Referring to Fig. 18b, the measurement set-up used with electroactive polymer materials further comprises an at least partially transparent container 165 that holds a liquid 166, which may comprise material to be synthesized or deposited on the object 164, e.g. monomer solution, and optionally supporting electrolyte, for a polymerization process, or an activation electrolyte for use in actuating an electroactive polymer material.

Thus, in a first embodiment, EAP, such as PPy may be electrochemically synthesised from a monomer solution, and optionally supporting electrolyte, onto a conducting object such as a gold wire, as is known to those skilled in the art. Or a metal layer may be electroplated onto a conducting substrate from a plating bath.

Fig. 18c shows a plot of the EAP PPy thickness over time for such a setup. This method gives an excellent reproduction of the thickness and the synthesis could be stopped easily at a predetermined thickness. Also, continuously measuring the thickness of the layer under fabrication of the PPy layer, gives the possibility to build a feedback loop. The synthesis parameters can thus be actively controlled so that a predetermined rate and thickness can be achieved and deviations of the programmed thickness or rate counteracted.

The method/set-up is not limited to annular circular objects as illustrated in Figs. 18a and 18b. Figs. 18d-18g schematically illustrate four non limiting examples of other shapes that may be used.
Fig 18d illustrates a layer of EAP 167 on an annular member 168, such as a rod or a tube.

Fig. 18e illustrates a layer of EAP 167 of a planar substrate 169 such as a sheet.

Fig. 18f illustrates a film 170 with an EAP layer 167. The film rotates on a rotating drum 171 or pulley as indicated by the arrows.

Fig. 18g illustrates a substrate 172 that comprises a hole or a slit 173. The substrate 172 is coated with a layer of EAP 167 covering all or parts of the substrate and the inside of hole. The substrate 172 may be a porous structure containing multiple holes or a mesh. As a laser micrometer can measure in several segments, depending on the machine specifications, multiple objects 164 can be measured simultaneously.

In another embodiment the laser micrometer may be used to study material properties of electroactive polymers, such as the volume change, during actuation. An Au wire is coated with PPy(DBS). As PPy is reduced, Na+ or other cations are intercalated into the PPy, and the material swells. As the material is oxidised again, the Na+ ions are expelled and the PPy coating shrinks. This volume changes can be followed using the LSM as is shown in Fig 18h.

Being able to precisely determine the volume change of a PPy coating is an important aspect of quality control during production. Proper function of the PPy coating for a device can then be ascertained quantitatively, and optionally automatically.

Referring to Figs 19a-19g, in medical devices, such as guide wires, leads, catheters etc. flexibility is a key requirement. In some applications an actuator ring is added on the surface of such a device. Such a ring can
for instance be used to seal a gap between first and second parts 101, 102, such as a catheter, a wire and/or a PTCA balloon, as disclosed in the previous embodiments. Adding a solid ring will, however, reduce the flexibility, which may be undesirable.

To solve this problem and still maintain the original functionality, such as sealing, the ring may be redesigned.

Fig. 19a illustrates a first approach to providing increased flexibility: the actuator 114 is divided into a plurality of actuator sections, which are spaced apart in an axial direction of the device.

Fig. 19b illustrates a second approach to providing increased flexibility: the actuator 114 is formed as a spiral or a helix, which winds around the first part 101. Equally, a double helix or mesh like structure may be provided.

Fig. 19c illustrates a third approach to providing increased flexibility: the actuator 114 is provided with longitudinal slots 190, extending over almost the entire axial extent of the actuator 114. The slots may extend alternately from opposing axial ends of the actuator 114.

Fig. 19d illustrates a fourth approach to providing increased flexibility: the actuator 114 is provided with partially circumferential slots 190, which may be grouped together. Several such slots or groups of slots may be provided over the circumferential and/or axial extent of the actuator. In the alternative, the slots may form a spiral pattern extending throughout a substantial part of the length of the actuator.

Fig 19e and 19f illustrate alternatives of a fifth approach to providing increased flexibility: the actuator 114 is provided with recesses, through holes, or
perforations 191a, 191b, which may have any desired shape, such as circular, elliptic, square, rectangular etc. The holes may be regularly or irregularly distributed.

Fig. 19g illustrates a sixth approach to providing increased flexibility: the actuator 114 is provided with one or more mutually spaced apart circumferential grooves 192 or furrows, which do not extend all the way through the actuator 114.

In the embodiments discussed with respect to Figs 19a-19g, the bending stiffness-modifying patterning of the actuator involves patterning the EAP material and/or any substrate base.

Referring to Fig. 20, for medical devices, such as balloon catheters, visibility of the device during the procedure is important. For this purpose contrast solutions may be used to successfully perform certain medical procedures. The contrast media gives the surgeon ability to visually map, e.g. through X-rays, blood vessels, the location of a balloon, etc.

An ionic electrolyte is required to actuate EAP actuators. For some applications it may be advantageous to have an electrolyte that can both function as the ion source/sink for the EAP actuator and as contrast media. This eliminates the need to separate the two solutions and thus reduce the complexity of the medical device.

Using ionic contrast media, such as Hypaque-76, or adding ionic substances containing for example Na+ or Cl- to an ionic or non-ionic contrast media, or adding contrast ions such as NaDiatrizoate to NaCl will solve the above described problem.

As an example, a standard PPy(DBS) ring was actuated in a water based mixture of diatrizoate sodium and sodium
chloride with equal concentrations. Diatrizoate is one of the active contrast species in Hypaque(TM). The expansion was compared to actuation in standard electrolyte containing only sodium chloride. Sodium ion concentration was 0.15M for both electrolytes. As is apparent from Fig. 20, expansion in the electrolyte containing diatrizoate sodium is comparable to expansion in pure sodium chloride, solving the above described problem. Examples of ionic radiological contrast solutions comprise at least one of Acetrizoate Sodium, Barium Sulfate, Diatrizoate Meglumine, Diatrizoate Meglumine and Diatrizoate Sodium, Diatrizoate Meglumine and Iodipamide Meglumine, Diatrizoate Sodium, Ethiodized Oil, Gadopentetate Dimeglumine, Iocetamic Acid, Iodamide Meglumine, Iodipamide Meglumine, Ioglicate, Iopanoic Acid, Iothalamate Meglumine and Iothalamate Sodium, Iothalamate Sodium, Ioxaglate Meglumine and Ioxaglate Sodium, Ioxithalamate, Ipodate Calcium, Ipodate Sodium, Isosulfan Blue, Metrizoate, Propyliodone, and Tyropanoate Sodium.

Furthermore, there are radiological contrast solutions comprising one or more of Iodixanol, Iohexol, Iopamidol, Iopentol, Iopromide, Ioversol, Ioxilan and Metrizamide, which may be complemented by addition of ions, so as to be rendered useful as electrolytes.

Combinations of the above-mentioned radiological contrast medias are also conceivable, including combinations of all ionic radiological contrast medias and combinations of ionic radiological contrast medias with non-ionic radiological contrast medias.

According to another aspect, there is provided a method for operating an actuator in an electrochemical system. The method comprises providing an operating current to the actuator, a counter electrode or a
reference electrode, through a conducting wire, need not be insulatingly coated as described with respect to Fig. 8a-8f, and that is inserted into a tubular device. Such a tubular device may be an elongate casing, in which a wire is removably, or at least displacably insertable. The actuator may be arranged directly or indirectly on or in the tubular device. There may be sealing means for sealing the wire relative to the tubular device. Such sealing means may comprise an actuator device as described herein.

The tubular device may be electrically insulating. The tubular device, with or without the conducting wire inserted therein, may be adapted for insertion into a body lumen, and may thus form part of a catheter. The conducting wire may thus be a guide wire.
1. A device comprising:
   a first part (101);
   a second part (102); and
   an actuator (114), comprising an electroactive polymer material (106),
   wherein said first and second parts are separated by a gap and the actuator is operable in the gap.

2. The device as claimed in claim 1, wherein the actuator presents a substantially annular shape.

3. The device as claimed in claim 1 or 2, wherein the first part is substantially encircled by the second part.

4. The device as claimed in claim 3, wherein said first and second parts are substantially concentrically arranged.

5. The device as claimed in any one of the preceding claims, wherein the gap is substantially annular.

6. The device as claimed in any one of the preceding claims, wherein said first and second parts are arranged as inner and outer parts, respectively.

7. The device as claimed in any one of the preceding claims, wherein said first and second parts are axially displaceable relative each other.
8. The device as claimed in any one of the preceding claims, wherein one of the first and second parts forms a shaft, relative to which the other one of the first and second parts is rotatably and/or slidably arranged.

9. The device as claimed in any one of the preceding claims, wherein one of the first and second parts comprises, or forms part of, an inflatable body.

10. The device as claimed in any one of the preceding claims, wherein the electroactive polymer material changes volume upon activation.

11. The device as claimed in claim 10, wherein the electroactive polymer material is arranged such that its major expansion is to occur in a direction from said first part towards said second part.

12. The device as claimed in any one of the preceding claims, wherein said first part is substantially electrochemically passive.

13. The device as claimed in any one of the preceding claims, wherein the second part is substantially electrochemically passive.

14. The device as claimed in any one of the preceding claims, wherein the actuator is arranged to control a size of the gap.

15. The device as claimed in any one of the preceding claims, wherein the actuator is arranged to
counteract relative movement between said first and second parts.

16. The device as claimed in any one of the preceding claims, wherein the actuator is arranged to lock said first and second part relative to each other.

17. The device as claimed in any one of the preceding claims, wherein an edge portion of the electroactive polymer material is passivated.

18. The device as claimed in any one of the preceding claims, wherein said actuator comprises a substrate base (105), on which the electroactive polymer material is arranged,

   said substrate base (105, 105a, 105b, 105c, 105d, 105e, 105f, 105g, 105h, 105i) being arranged on one of the first and second parts.

19. The device as claimed in claim 18, wherein said substrate base comprises a carrier layer and optionally an adhesion layer, which is arranged between said carrier layer and said electroactive polymer material.

20. The device as claimed in claim 18 or 19, wherein the substrate base (105b) has a thickness, in a direction perpendicular to a surface of said one of the first and second parts, on which surface the actuator is arranged, which is less than one half the thickness of the electroactive polymer material (106b).

21. The device as claimed in claim 18 or 19, wherein the substrate base (105c) has a thickness, in a direction
perpendicular to a surface of said one of the first and second parts, on which surface the actuator is arranged, which is larger than the thickness of the electroactive polymer material (106c).

22. The device as claimed in claim 18 or 19, wherein said substrate base, as seen in a longitudinal section of the device, presets a width, which is larger than a thickness thereof.

23. The device as claimed in claim 18 or 19, wherein the substrate base (105g, 105h) is integrated with said one of the first and second parts.

24. The device as claimed in any one of claims 18-23, wherein the substrate base is formed in one piece with said one of the first and second parts.

25. The device as claimed in any one of claims 18-24, wherein the substrate base is arranged in a recess in said one of the first and second parts.

26. The device as claimed in any one of claims 18-25, wherein the substrate base (105d) is exposed in at least one direction parallel with a surface of said one of the first and second parts, on which surface the actuator is arranged.

27. The device as claimed in any one of claims 18-26, wherein the substrate base (105, 105e) presents a varying thickness.
28. The device as claimed in claim 27, wherein the substrate base (105e), in a direction perpendicular to a surface of said one of the first and second parts, on which surface the actuator is arranged, presents a curved section.

29. The device as claimed in claim 27 or 28, wherein the substrate base (105) has at least one tapering edge portion.

30. The device as claimed in claim 18 or 19, wherein the substrate base (105f) extends in a direction perpendicular to a surface of said one of the first and second parts, on which surface the actuator is arranged, and wherein the electroactive polymer material (106f) is arranged such that its major expansion is to occur in a direction substantially parallel with said surface.

31. The device as claimed in any one of claims 18-30, wherein the actuator is at least partially arranged in a recess in said one of the first and second parts.

32. The device as claimed in any one of claims 18-31, wherein the substrate base has a thickness which is less than 0.1 μm, less than 1.0 μm, less than 20 μm, less than 50 μm, less than 100 μm, or less than 500 μm.

33. The device as claimed in any one of the preceding claims, further comprising a counter electrode (115).
34. The device as claimed in claim 33, wherein said counter electrode is positioned on a proximal (103) or distal (104) side of the actuator.

35. A device as claimed in claim 33 or 34, wherein said counter electrode (115, 115a, 115b, 115c, 115d, 115e, 115f, 115g, 115h, 115i, 115j, 115k) is positioned in the gap.

36. The device as claimed in claim 35, wherein said counter electrode is positioned on one of said first and second parts (101, 102).

37. The device as claimed in claim 35, wherein said counter electrode is positioned on a third part.

38. The device as claimed in claim 37, wherein said third part is substantially electrochemically passive.

39. The device as claimed in any one of claims 35-38, wherein the counter electrode is positioned on a proximal side (103) of the actuator.

40. The device as claimed in any one of claims 35-38, wherein the counter electrode is positioned on a distal side of the actuator.

41. The device as claimed in any one of claims 35-40, wherein the counter electrode is positioned across the gap from the actuator.
42. The device as claimed in any one of claims 35-41, wherein the device comprises at least two counter electrodes.

43. The device as claimed in claim 42, wherein the counter electrodes are positioned on a respective proximal and distal side (103, 104) of the actuator.

44. The device as claimed in claim 43, wherein the counter electrodes are positioned on one of said first and second parts, and wherein at least one further counter electrode is positioned on the other one of said first and second parts.

45. The device as claimed in claim 42, wherein the counter electrodes are positioned on a respective one of said first and second parts.

46. The device as claimed in any one of claims 35-45, wherein the device comprises at least two actuators and wherein at least one counter electrode is positioned between the actuators.

47. The device as claimed in any one of claims 33-46, wherein the counter electrode is positioned not more than 60 mm, preferably not more than 30 mm, 10 mm, 5 mm, 2 mm, 1 mm, 0.5 mm, 0.1 mm from the electroactive polymer material.

48. The device as claimed in any one of claims 33-47, wherein the actuator is arranged on one of said first and second parts and the counter electrode, or at least
one of the counter electrodes, is arranged on the other one of said first and second parts.

49. The device as claimed in any one of claims 33-48, wherein the counter electrode is integrated with a catheter, a guide wire, a sheath, a lead, an outer tubing, an inner tubing, a trocar, a stylet, an embolic coil, a part of a filter device, a part of an endoscope, or a part of a gastroscope.

50. The device as claimed in any one of claims 33-49 in combination with claim 8, wherein said counter electrode is arranged on said inflatable body, or on a part protruding therefrom.

51. The device as claimed in claim 50, wherein said counter electrode is at least partially integrated with said inflatable body, or on said part protruding therefrom.

52. The device as claimed in claim 50 or 51, wherein said counter electrode at least partially extends along the inflatable body into said gap.

53. The device as claimed in claim 50, wherein the counter electrode is arranged across the gap, on a part protruding from the inflatable body.

54. The device as claimed in any one of claims 50-53, wherein the actuator is arranged on the one of the first and second parts, which is associated with the inflatable body.
55. The device as claimed in any one of claims 50-53, wherein the actuator is arranged on the one of the first and second parts, which is not associated with the inflatable body.

56. The device as claimed in any one of claims 33-55, wherein the counter electrode is substantially annular.

57. The device as claimed in any one of claims 33-55, wherein the counter electrode forms at least one segment of an annulus.

58. A device as claimed in any one of claims 33-57, wherein the counter electrode is at least partially formed from an organic material.

59. The device as claimed in claim 58, wherein said device further comprises a surgical tool, which is at least partially controlled by said actuator, and wherein said counter electrode is arranged on said surgical tool.

60. The device as claimed in claim 59, wherein said surgical tool is selected from a group consisting of a dilation balloon, a knife, a needle, a scissors, a pliers, a tweezers, a clamp, a guide wire and a catheter, a sheath, a lead, an outer tubing, an inner tubing, a trocar, a stylet, an embolic coil, a part of a filter device a part of an endoscopes, or a part of a gastroscopy.
61. The device as claimed in any one of the preceding claims, further comprising a reference electrode (116).

62. The device as claimed in claim 61, wherein the reference electrode is positioned in the gap.

63. The device as claimed in claim 61 or 62, wherein the reference electrode is positioned across the gap from the actuator.

64. The device as claimed in any one of claims 61-63, wherein the device comprises at least two actuators and wherein the reference electrode is positioned between said actuators.

65. The device as claimed in any one of claims 61-64, in combination with claim 33, wherein a reference electrode is positioned between the actuator and a counter electrode (115).

66. The device as claimed in any one of claims 61-64, in combination with claim 33, wherein the counter electrode is positioned between a reference electrode (116) and the actuator (114).

67. The device as claimed in any one of claims 61-67, wherein the actuator is positioned between a reference electrode (116) and the counter electrode (115).

68. The device as claimed in any one of claims 61-67, wherein the reference electrode is positioned not
more than 30 mm, preferably not more than 10 mm, 5 mm, 2
mm, 1 mm, 0.5 mm, or 0.1 mm from the electroactive
polymer material.

69. The device as claimed in any one of claims 61-
68, wherein the reference electrode is substantially
annular.

70. The device as claimed in any one of claims 61-
10 68, wherein the reference electrode forms at least one
segment of an annulus.

71. The device as claimed in any one of claims 61-70
15 in combination with claim 33, wherein said counter
electrode and said reference electrode are angularly
spaced apart.

72. The device as claimed in any one of claims 61-
20 71, wherein the actuator is arranged on one of said first
and second parts and the reference electrode is arranged
on the other one of said first and second parts.

73. The device as claimed in any one of the
25 preceding claims, wherein the actuator presents a fast
expanding portion (195) and a slow expanding portion
(196), which, upon actuation, expands slower than the
fast expanding portion.

74. The device as claimed in claim 73, wherein a
distance between an actuator surface and a surface of the
one of the first and second parts against which the
actuator operates diminishes in a direction away from the fast expanding portion (195).

75. The device as claimed in claim 73 or 74, wherein the actuator tapers in thickness in a direction towards the fast expanding portion (195).

76. The device as claimed in any one of claims 73-75, wherein a distance between said first and second parts tapers in a direction away from the fast expanding portion (195).

77. The device as claimed in any one of claims 73-76, wherein the actuator presents first and second fast expanding portions (195), and a slow expanding portion (196) arranged between said fast expanding portions (195).

78. The device as claimed in claim 77, wherein the actuator tapers in thickness from the slow expanding portion (196) towards the respective fast expanding portion (195).

79. The device as claimed in claim 77 or 78, wherein the actuator presents an actuator portion, wherein the distance between the actuator surface and the one of the first and second parts against which the actuator operates increases in a direction from the slow expanding (196) portion towards the respective fast expanding portion (195).
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80. The device as claimed in any one of claims 73-79, wherein said fast and slow expanding portions (195, 196) are longitudinally juxtaposed.

81. The device as claimed in any one of claims 73-80, wherein the actuator comprises at least two juxtaposed actuator portions, and wherein an actuator portion that is further away from the fast expanding portion (195) is more expanded than an actuator portion that is closer to the fast expanding portion, such that said gap tapers in depth in a direction away from the fast expanding portion only upon activation of the actuator.

82. The device as claimed in any one of claims 73-81, wherein the actuator comprises at least two juxtaposed actuator portions, which are individually actuatable.

83. The device as claimed in claim 82, further comprising means for actuating a second one (114-1, 114-2, 114-3) of said actuator portions such that a finally applied potential applied thereto occurs before a finally applied potential of a first one (114-4) of said actuator portions occurs.

84. The device as claimed in claim 82 or 83, further comprising means for actuating a second one of said actuator portions with a time delay relative to a first one of said actuator portions.

85. The device as claimed in claim 82 or 83, further comprising means for actuating a second one of said
actuator portions with a lower increase rate in applied potential, relative to a first one of said actuator portions.

86. The device as claimed in any one of the preceding claims, wherein the actuator is positioned near a portion of the device, where a distance between the first and second parts (102-1, 102-2) begins to increase.

87. The device as claimed in claim 86, wherein the actuator is positioned less than 5 mm from said portion of the device.

88. The device as claimed in any one of the preceding claims, wherein at least one of said first and second parts form a channel, and wherein the actuator is situated near an end of said channel.

89. The device as claimed in claim 88, wherein the actuator is positioned less than 5 mm from said end.

90. The device as claimed in any one of the preceding claims, wherein the device presents a first portion, wherein a distance between said first and second parts is substantially constant, and a second portion, wherein the distance between said first and second parts increases or decreases, wherein said actuator is arranged where said first and second portions intersect.

91. A device as claimed in any one of the preceding claims, in combination with claim 10,
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wherein said device is arranged for sealing or locking the first part relative to the second part, and
wherein said actuator comprises at least two separate actuator sections (114a, 114b, 114c).

92. The device as claimed in claim 91, wherein said actuator sections are spaced apart in a longitudinal direction of the device.

93. The device as claimed in claim 91 or 92, wherein said actuator sections are arranged on a respective one of said first and second parts.

94. The device as claimed in any one of claims 91-93, in combination with claim 5, wherein the actuator sections are aligned in an axial direction of the annular gap.

95. The device as claimed in any one of claims 91-94 in combination with claim 33, wherein said actuator portions are angularly spaced apart.

96. A device as claimed in any one of the preceding claims, in combination with claim 10,
wherein said device is arranged for sealing or locking the first part relative to the second part, and wherein said actuator is arranged on one of said first and said second parts and is expandable towards a protrusion (125) on the other one of said first and said second parts.

97. The device as claimed in claim 96, wherein the actuator and the protrusion are contactable.
98. The device as claimed in claim 96 or 97, wherein the protrusion is formed in one piece with said other one of said first and second parts.

99. The device as claimed in claim 96 or 97, wherein the protrusion is formed as a separate part and attached to said other one of said first and second parts.

100. The device as claimed in any one of claims 96-99, wherein at least two protrusions are provided and separated in a longitudinal direction of the device.

101. A device as claimed in any one of the preceding claims, in combination with claim 10, wherein said device is arranged for sealing or locking the first part relative to the second part, and wherein said actuator has an extent in a longitudinal direction of the gap, which is more than twice its extent in a thickness direction of the gap.

102. A device as claimed in any one of the preceding claims, in combination with claim 10, wherein said device is arranged for sealing or locking the first part relative to the second part, wherein said device comprises means (127, 128, 125) for counteracting or limiting relative axial movement between said first and second parts.

103. A device as claimed in claim 102, wherein a protrusion (127) of a first one of said first and second parts is arranged to engage a recess in the other one of said first and second parts.
104. The device as claimed in claim 103, wherein the actuator is arranged on one of said first and second parts, and spaced from said protrusion in a longitudinal direction of the device.

105. A device as claimed in claim 102, wherein a first protrusion on one of said first and second parts is arranged to engage a second protrusion on the other one of said first and second parts.

106. The device as claimed in claim 105, wherein the actuator is arranged on one of the protrusions.

107. The device as claimed in claim 106, wherein actuators are arranged on both of said protrusions.

108. The device as claimed in any one of claims 105-107, wherein said protrusions are complimentarily shaped.

109. A device as claimed in any one of the preceding claims, in combination with claim 10, wherein said device is arranged for sealing or locking the first part relative to the second part, and wherein said actuator is arranged on one of said first and second parts and arranged for interaction with a recess in the other one of said first and second parts.

110. The device as claimed in claim 109, wherein the actuator is expandable towards said recess.

111. The device as claimed in claim 109 or 110, wherein the recess is formed by a pair of protrusions,
extending from the other one of said first and second parts.

112. The device as claimed in any one of claims 109-111, wherein the recess is provided in a protrusion which is aligned with the actuator.

113. The device as claimed in any one of claims 109-112, wherein the recess and the actuator are complimentarily shaped.

114. The device as claimed in any one of claims 109-112, wherein the actuator, in a direction perpendicular to a surface of said one of the first and second parts, on which surface the actuator is arranged, presents a curved section.

115. The device as claimed in claim 114, wherein the protrusion presents a recess having a substantially V-shaped section.

116. The device as claimed in claim 114 or 115, wherein the actuator presents a substantially V-shaped section.

117. The device as claimed in any one of claims 109-116, wherein at least two longitudinally spaced-apart actuator sections are arranged for interaction with respective longitudinally spaced-apart recesses.

118. The device as claimed in claim 109, wherein the actuator extends into the recess, and is expandable in a
substantially longitudinal direction, towards side edges of the recess.

119. A device as claimed in any one of the preceding claims, in combination with claim 10,
wherein said device is arranged for sealing or locking the first part relative to the second part, and
wherein said actuator is arranged on one of said first and second parts and arranged for interaction with
a protrusion arranged on the other one of said first and second parts, and
wherein at least one of the actuator and the protrusion presents a substantially wedge-shaped cross-
section.

120. The device as claimed in claim 119, wherein both said actuator and the protrusion present wedge-
shaped cross-sections.

121. A device as claimed in any one of the preceding claims, wherein a hydrophobic surface portion (137-1, 137-2) is provided on at least one of the first and second parts, adjacent said actuator.

122. The device as claimed in claim 121, wherein hydrophobic surface portions are provided on both proximal and distal sides (103, 104) of said actuator.

123. The device as claimed in claim 121 or 122, wherein hydrophobic surface portions are provided on both first and second parts.
124. The device as claimed in any one of claims 121-123, wherein the hydrophobic surface portion is provided on at least one of the first and second parts, on a first side of the actuator, and wherein a hydrophilic surface portion is provided on at least one of the first and second parts, on a second side of the actuator.

125. The device as claimed in any one of claims 121-124, wherein the hydrophobic surface portion is provided across the gap from the actuator.

126. A device as claimed in any one of the preceding claims, wherein a hydrophilic surface portion (137-1, 137-2) is provided on at least one of the first and second parts, adjacent said actuator.

127. The device as claimed in claim 126, wherein hydrophilic surface portions are provided on both proximal and distal sides (103, 104) of said actuator.

128. The device as claimed in claim 126 or 127, wherein hydrophilic surface portions are provided on both first and second parts.

129. The device as claimed in any one of claims 126-128, wherein the hydrophilic surface portion is provided across the gap from the actuator.

130. A device as claimed in any one of the preceding claims, in combination with claim 10, wherein said actuator is arranged on one of said first and second members, and
wherein the device further comprises means (147, 148) for detecting contact between the actuator and the other one of said first and second members.

131. The device as claimed in claim 130, wherein said detection means comprises an electrically conducting portion arranged on the other one of said first and second members.

132. The device as claimed in claim 130 or 131, wherein said detection means comprises a plurality of separate electrically conducting portions, arranged on the other one of said first and second members.

133. The device as claimed in any one of claims 130-132, wherein the detection means comprises a pressure sensor arranged to detect pressure between the actuator and the other one of said first and second members.

134. The device as claimed in any one of claims 130-133, wherein the detection means comprises a pressure sensing arrangement arranged to detect a pressure difference between proximal and distal sides (103, 104) of the actuator.

135. The device as claimed in any one of claims 130-134, wherein the detection means comprises a flow meter for detecting a flow in the gap.

136. A device as claimed in any one of the preceding claims, in combination with claim 10, wherein said actuator is arranged on one of said first and second parts,
wherein said actuator presents first and second opposite surfaces, the first one of which faces the other one of said first and second parts, and wherein means are provided for supplying ions to the second surface of the actuator.

137. The device as claimed in claim 136, wherein said first surface is provided with a covering layer (140).

138. The device as claimed in claim 137, wherein said covering layer is arranged to protect the electroactive polymer material from an environment in the gap.

139. The device as claimed in claim 136-138, wherein the actuator is arranged on an ion conducting material (139).

140. The device as claimed in any one of claims 136-139, wherein the actuator is arranged on a porous material.

141. The device as claimed in any one of claims 136-140, wherein the second surface is directly contactable by the ions.

142. The device as claimed in claim 141, wherein substantially all of the second surface is contactable by the ions.

143. The device as claimed in any one of claims 136-142, wherein the first part is substantially hollow.
144. The device as claimed in any one of claims 136-143, wherein the first part comprises an electrolyte supply channel (142).

145. A device, as claimed in any one of the preceding claims, in combination with claim 10, further comprising spacing means (144), arranged to control a relative position of said first and second parts.

146. The device as claimed in claim 145, wherein the spacing means comprises at least one spacer part, arranged to position said first and second parts in a predetermined position relative to each other.

147. The device as claimed in claim 145 or 146, wherein the first and second parts are substantially concentrically arranged.

148. A device as claimed in any one of the preceding claims, in combination with claim 10, wherein:
   said first part constitutes an inner member,
   said second part constitutes an outer member, which at least partially encircles said inner member, and
   said actuator presenting a tapering radial thickness.

149. The device as claimed in claim 148, wherein a contact surface of one of the inner and outer members, which contact surface faces said actuator, presents a substantially conical surface portion.
150. The device as claimed in claims 148 or 149, wherein the actuator presents a substantially conical surface facing the outer member.

151. The device as claimed in any one of claims 148-150, wherein the actuator presents a substantially conical surface facing the inner member.

152. The device as claimed in any one of claims 148-151, wherein the actuator presents a substantially cylindrical surface facing the outer member.

153. The device as claimed in any one of claims 148-152, wherein the actuator comprises first and second actuator sections, which are positioned on a respective one of said inner and outer members.

154. The device as claimed in claim 153, wherein said actuator sections present interacting conical surfaces.

155. A device as claimed in any one of the preceding claims, wherein the actuator is mechanically modified to reduce its bending stiffness.

156. The device as claimed in claim 155, wherein the actuator comprises a substantially cylindrical body, comprising portions of removed material.

157. The device as claimed in claim 156, wherein said portions of removed material comprise at least one substantially annular groove (192).
158. The device as claimed in claim 156 or 157, wherein said portions of removed material comprise at least one slot (190), extending in an axial direction of the actuator.

159. The device as claimed in any one of claims 156-158, wherein said portions of removed material comprise at least one substantially helical groove.

160. The device as claimed in any one of claims 156-159, wherein said portions of removed material comprise at least one slot (190) extending along a partial circumference of the actuator.

161. The device as claimed in any one of claims 156-160; wherein said portions of removed material comprise recess (191a, 191b) in the actuator.

162. A device as claimed in any one of the preceding claims, in combination with claim 10, wherein the actuator is arranged on one of said first and second parts, and one of said first and second parts is flexible, so as to compensate for thickness deviations of the electroactive polymer material or of the underlying substrate.

163. The device as claimed in claim 162, wherein the second part comprises a portion (146) made from a flexible material, which is softer than the electroactive polymer material.

164. The device as claimed in claim 162 or 163, wherein the first part comprises a portion made from a
flexible material, which is softer than the electroactive polymer material.

165. A device as claimed in any one of the preceding claims, in combination with claim 10, wherein:
said first part constitutes an inner member (131),
said second part constitutes an outer member (130),
which at least partially encircles said inner member, and
at least one of said inner member and outer member
presents an attachment portion for attachment of at least
one further tubular part (123, 132).

166. The device as claimed in claim 165, wherein
said inner member is substantially tubular.

167. The device as claimed in claim 165 or 166, wherein said outer member is substantially tubular.

168. The device as claimed in any one of claims 165-167, wherein said inner member comprises an attachment portion for a tubular surgical device (123).

169. The device as claimed in any one of claims 165-168, wherein said outer member comprises a balloon attachment portion (132).

170. The device as claimed in any one of claims 165-169, further comprising means for retaining said inner and outer members in a substantially fixed axial position relative to each other.

171. A tubular surgical device comprising a device as claimed in any one of claims 165-170.
172. The tubular surgical device as claimed in claim 171, wherein a catheter portion is attached to said inner member.

173. The tubular surgical device as claimed in claim 171 or 172, wherein an inflatable member is attached to said outer member.

174. A bushing for connecting a pair of tubular devices to each other, so as to form a device as claimed in any one of claims 1-164, the bushing comprising:

- a tubular body (131) having an attachment portion for receiving at least one of said tubular devices (123, 132), and an actuator (114), comprising an electroactive polymer material,
- wherein the actuator is arranged to interact in a sealing and/or locking manner with the other one of said tubular devices (132, 123).

175. The bushing as claimed in claim 174, wherein the actuator is arranged on an outside of the tubular body.

176. The bushing as claimed in claim 174, wherein the actuator is arranged on the inside of the tubular body.

177. A bushing arrangement for connecting a pair of tubular devices to each other, so as to form a device as claimed in any one of claims 1-164, the bushing arrangement comprising:
a tubular body (130) having an attachment portion for receiving at one of said tubular devices (123, 132), and
an actuator (114), arranged on the other one of said tubular devices, and comprising an electroactive polymer material,
wherein the actuator is arranged to interact in a sealing and/or locking manner with the other one of said tubular devices.

178. The bushing arrangement as claimed in claim 177, wherein the actuator is arranged on an outside of the tubular body.

179. The bushing arrangement as claimed in claim 177, wherein the actuator is arranged on the inside of the tubular body.

180. A bushing comprising a device as claimed in any one of claims 1-164.

181. A valve comprising a device as claimed in any one of claims 1-1-164.

182. An elongate medical device for insertion into the body, comprising a conducting part which is covered by an insulating material,
wherein the insulating material (120) is partially removed to expose the conducting part (121).

183. The elongate medical device as claimed in claim 182, wherein the conducting part is arranged as a layer (121-3) encircling a central axis of the device.
184. The elongate medical device as claimed in claim 183, wherein the layer is a sheet layer.

185. The elongate medical device as claimed in claim 183, wherein the layer is formed from a plurality of filaments.

186. The elongate medical device as claimed in claim 182, wherein the conducting part is a solid core (121).

187. The elongate medical device as claimed in claim 186, wherein the insulating material is fixedly attached to the conducting core.

188. The elongate medical device as claimed in claim 186 or 187, wherein said conducting core comprises at least two separate conducting cores (121-1, 121-2), which are electrically insulated from each other, and wherein the insulating material is partially removed to expose both of said separate conducting cores.

189. The elongate medical device as claimed in any one of claims 186-188, wherein a transducer (114) is arranged on the device.

190. The elongate medical device as claimed in claim 189, wherein the transducer comprises an electroactive polymer material.

191. The elongate medical device as claimed in claim 189 or 190, wherein the transducer forms part of a device as claimed in any one of claims 1-164.
192. The elongate medical device as claimed in any one of claims 182-191, wherein the device is at least partially hollow.

193. Use of an elongate medical device as claimed in any one of claims 182-192, as a conductor for providing electrical connection to a transducer or electrode.

194. The use as claimed in claim 193, wherein electrical connection is provided to an electrode in an electrochemical system comprising at least one electroactive polymer material.

195. A hollow, elongate medical device for insertion into the body, comprising an insulating tubular body (123), in which a wire is insertable, wherein an opening (124) is provided in the tubular body to expose the wire.

196. The hollow, elongate medical device as claimed in claim 195, wherein the wire comprises a conducting core (121), covered by an insulating material.

197. The hollow, elongate medical device as claimed in claim 196, wherein said conducting core comprises at least two separate conducting cores (121-1, 121-2), which are electrically insulated from each other, and wherein at least one of the conducting cores is exposed through at least one opening.

198. The hollow, elongate medical device as claimed in claim 197, wherein separate openings (122-1, 122-2)
are provided for exposing the respective conducting cores.

199. The hollow, elongate medical device as claimed in any one of claims 195-199, wherein the conducting wire core is covered with an insulating material (120), and wherein the insulating material is partially removed to expose the conducting core.

200. The hollow, elongate medical device as claimed in any one of claims 195-199, wherein a transducer (114) is arranged on the device.

201. The hollow, elongate medical device as claimed in claim 199, wherein the transducer comprises an electroactive polymer material.

202. The hollow, elongate medical device as claimed in claim 200 or 201, wherein the transducer forms part of a device as claimed in any one of claims 1-164.

203. Use of a hollow, elongate medical device as claimed in any one of claims 195-202, for housing a conductor for providing electrical connection to a transducer or electrode.

204. The use as claimed in claim 203, wherein electrical connection is provided to an electrode in an electrochemical system comprising at least one electroactive polymer material.

205. A system comprising:

a device as claimed in any one of claims 1-164; and
an electrolyte arranged to interact with the actuator.

206. The system as claimed in claim 205, wherein an ion concentration of the electrolyte on one of the proximal and distal sides (103, 104) of the actuator is higher than an ion concentration on the other one of the proximal and distal sides.

207. The system as claimed in claim 206, wherein the gap increases in size in a direction towards the one of the proximal and distal sides (103, 104) of the actuator where the ion concentration is highest.

208. An actuator system, comprising: a substrate (101), an electrolyte-conducting polymer material (106), arranged on the substrate an electrode (105), in contact with said electrolyte-conducting polymer material, an aqueous electrolyte, contacting said electrolyte-conducting polymer material, drive means for providing a voltage sufficient to provide gas production in an interface between the electrolyte-conducting polymer material and the electrode, wherein the electrolyte conducting polymer material is attached, at perimeter portions thereof, to the substrate, and wherein a central portion of the electrolyte conducting polymer material is inflatable by said gas production.
209. The actuator system as claimed in claim 208, wherein said substrate forms part of a first member, which is separated by a gap from a second member, and wherein said electrolyte conducting polymer material is arranged to control a size of the gap.

210. The actuator system as claimed in claim 208 or 209, wherein said electrolyte conducting polymer material is gas impermeable.

211. The actuator system as claimed in claim 208 or 209, wherein said electrolyte conducting polymer material is enclosed in a protection layer (184).

212. The actuator system as claimed in claim 211, wherein said protection layer is a semi-permeable membrane, allowing electrolyte influx, but preventing gas outflux.

213. The actuator system as claimed in any one of claims 208-212, wherein the gap is substantially annular.

214. The actuator system as claimed in any one of claims 209-213, wherein said first member is an inner part and said second member is an outer part, wherein said inner and outer parts are substantially concentrically arranged.

215. A method for measuring a dimension or change in dimension of an object, comprising:
positioning, between a source of electromagnetic radiation (162) and a sensor (163), a liquid container
(165), which is at least partially transparent to said electromagnetic radiation,
positioning the object (164) in said liquid container,
5 exposing said object to said electromagnetic radiation,
recording an amount of received electromagnetic radiation at the sensor, and
determining said dimension or change in dimension of an object, based on a signal from said sensor.

216. The method as claimed in claim 215, wherein said electromagnetic radiation source comprises a laser source.

217. The method as claimed in claim 215 or 216, wherein said object is elongate, and wherein the electromagnetic radiation is applied in a direction substantially perpendicular to a longitudinal axis of the substrate.

218. The method as claimed in claim 215 or 216, wherein the electromagnetic radiation is applied along a direction substantially parallel with a cross section of the object.

219. The method as claimed in claim 215 or 216, wherein said object is substantially planar, and wherein the electromagnetic radiation is applied in a direction which is substantially parallel with a main plane of said object.
220. The method as claimed in claim 215 or 216, wherein the object comprises a conveyor-like structure, which is deflected by a pulley or the like, and wherein the electromagnetic radiation is applied in a direction perpendicular to an axis about which the object is deflected.

221. The method as claimed in any one of claims 215-216, wherein the object comprises at least one through hole, and wherein said electromagnetic radiation is applied through said through hole.

222. The method as claimed in any one of claims 215-221, further comprising forming, based on a compound present in said liquid, a layer on said object.

223. The method as claimed in claim 222, wherein the recording is carried out while forming said layer.

224. The method as claimed in claim 222 or 223, wherein said forming comprises synthesizing an electroactive polymer material.

225. The method as claimed in claim 222 or 223, wherein said forming comprises electroplating said object.

226. The method as claimed in any one of claims 215-225, further comprising actuating an electroactive polymer material, which changes volume upon actuation, and which is arranged on said object.
227. A liquid electrolyte for use with a body-insertable electroactive polymer actuator, said electrolyte comprising radiological contrast media.

228. The liquid electrolyte as claimed in claim 227, wherein said liquid electrolyte consists of an ion-containing radiological contrast media.

229. The liquid electrolyte as claimed in claim 228, wherein said radiological contrast media comprises at least one radiological contrast media selected from a group consisting of Acetrizoate Sodium, Barium Sulfate, Diatrizoate Meglumine, Diatrizoate Meglumine and Diatrizoate Sodium, Diatrizoate Meglumine and Iodipamide Meglumine, Diatrizoate Sodium, Ethiodized Oil, Gadopenetetate Dimeglumine, Iocetamic Acid, Iodamide Meglumine, Iodipamide Meglumine, Ioglicate, Iopanoic Acid, Iothalamate Meglumine and Iothalamate Sodium, Iothalamate Sodium, Ioxaglate Meglumine and Ioxaglate Sodium, Ioxithalamate, Ipodate Calcium, Ipodate Sodium, Isosulfan Blue, Metrizoate, Propyliodone, and Tyropanoate Sodium.

230. The liquid electrolyte as claimed in claim 228, wherein said liquid electrolyte consists of a radiological contrast media, which per se is substantially free from ions, and added ions of at least one type.

231. The liquid electrolyte as claimed in claim 230, wherein the radiological contrast media comprises at least one radiological contrast media selected from a
group consisting of Iodixanol, Iohexol, Iopamidol, Iopentol, Iopromide, Ioversol, Ioxilan and Metrizamide.

232. A method for making an electrolyte for use with a body-insertable polymer actuator, the method comprising adding ions to a substantially non-ionic radiological contrast media.

233. An ion-containing radiological contrast media for use as an electrolyte for a body-insertable electroactive polymer actuator.

234. Use of an ion-containing radiological contrast media as an electrolyte for a body-insertable electroactive polymer actuator.

235. A method for operating an actuator in an electrochemical system, the method comprising providing an operating current to the actuator, a counter electrode or a reference electrode, wherein said current is provided through a conducting wire that is inserted into a tubular device.

236. The method as claimed in claim 235, wherein the conducting wire is displaceably inserted in to the tubular device.

237. The method as claimed in claim 235 or 236, wherein the actuator is arranged on or in the tubular device.
238. The method as claimed in claim 237, wherein the actuator, the tubular device and the conducting wire form part of a device as claimed in any one of claims 1-164.

239. The method as claimed in any one of claims 235-238, wherein the tubular device is at least partially electrically insulating.

240. The method as claimed in any one of claims 235-239, wherein the tubular device is adapted for insertion into a body lumen.

241. The method as claimed in any one of claims 235-240, wherein the actuator forms part of a device or system as claimed in any one of claims 1-214.
Fig. 20

Fig. 21a

Fig. 21b

Fig. 22
PATENT COOPERATION TREATY

PCT

DECLARATION OF NON-ESTABLISHMENT OF INTERNATIONAL SEARCH REPORT

(PCT Article 17(2)(a), Rules 13ter.1(c) and Rule 39)

<table>
<thead>
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<th>Applicant's or agent's file reference</th>
<th>IMPORTANT DECLARATION</th>
<th>Date of mailing (day/month/year)</th>
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<th>International filing date (day/month/year)</th>
<th>(Earliest) Priority date (day/month/year)</th>
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International Patent Classification (IPC) or both national classification and IPC

B81B3/00H2, A61F2/0628B, A61M25/10

Applicant

MICROMUSCLE AB

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This International Searching Authority hereby declares, according to Article 17(2)(a), that no international search report will be established on the international application for the reasons indicated below:

1. ☐ The subject matter of the international application relates to:
   a. ☐ scientific theories
   b. ☐ mathematical theories
   c. ☐ plant varieties
   d. ☐ animal varieties
   e. ☐ essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes
   f. ☐ schemes, rules or methods of doing business
   g. ☐ schemes, rules or methods of performing purely mental acts
   h. ☐ schemes, rules or methods of playing games
   i. ☐ methods for treatment of the human body by surgery or therapy
   j. ☐ methods for treatment of the animal body by surgery or therapy
   k. ☐ diagnostic methods practised on the human or animal body
   l. ☐ mere presentations of information
   m. ☑ computer programs for which this International Searching Authority is not equipped to search prior art

2. ☑ The failure of the following parts of the international application to comply with prescribed requirements prevents a meaningful search from being carried out:
   a. ☐ the description
   b. ☑ the claims
   c. ☐ the drawings

3. ☐ A meaningful search could not be carried out without the sequence listing; the applicant did not, within the prescribed time limit:
   a. ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
   b. ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

4. ☐ A meaningful search could not be carried out without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

5. Further comments:

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Authorized officer

Klaus Meierwert

Form PCT/ISA/203 (April 2005)
The present application contains 241 claims, of which 12 are independent. There are so many claims, and they are drafted in such a way that the claims as a whole are not in compliance with the provisions of clarity and conciseness of Article 6 PCT, as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought.

The non-compliance with the substantive provisions is to such an extent that a meaningful search of the whole claimed subject-matter could not be carried out (Article 17(2) PCT and PCT Guidelines 9.30).

The description doesn't contain any clear indication as to which subject-matter might be expected to form the subject of the claims later in the procedure. In particular, the description doesn't contain a single embodiment, but so many embodiments that in view of the drafting of the claims, an expected fall back position could not be determined.

Therefore, no search at all was deemed possible.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2)PCT declaration be overcome.