Aspects of the invention are defined in the independent claims. Some optional features of the invention are defined in the dependent claims.

Therefore, it may be possible to provide a suitable material, for example as an insulation material for electrodes or electrode leads of medical implants, which has a greater wear resistance and/or lower sliding friction or static friction than silicone or TPU, for example.

A material according to claim 1 is therefore provided. The material comprises a silicone, wherein a polymer is arranged on the surface of the silicone, wherein the polymer is characterised by a higher wear resistance than silicone, and the polymer is attached to the surface of the silicone by non-covalent bonds.

In particular, the polymer is attached to the surface of the silicone exclusively by non-covalent bonds.

The term “silicone” in the context of the present disclosure particularly refers to polysiloxanes with the general formula $[R_2SiO]_n$, with R being a carbon bond, in particular an alkyl, such as methyl or ethyl, or an aryl, such as phenyl.

The term “wear resistance” in the context of the present disclosure particularly refers to the capability of a solid surface to resist mechanical loading, in particular friction.

The expression “arranging the polymer on the surface of the silicone” in the sense of the disclosure means in particular that the polymer is attached to the silicone surface non-covalently or physically. The polymer is preferably arranged on or physically attached to the silicone surface by non-covalent interactions, such as electrostatic or hydrophobic interactions, hydrogen bridges or Van-der-Waals forces, or by looping of the chains of the silicone with the chains of the polymer.

In particular, the surface of the silicone is coated with the polymer.

Therefore, it may be possible to provide a silicone which not only has good friction values, but also is extremely resistant to wearing through. Due to the surface coating or the attaching of the

polymer to the silicone in a manner achieved by a less complex method, the production of a cover sleeve for example and also the fitting of the cover sleeve on the main body of electrode leads of implantable devices are spared. This, combined with the excellent properties of silicone, makes the material combination or the base material an improved alternative to conventional materials.

In accordance with an exemplary material, the polymer is a copolymer formed of two or more monomers.

In accordance with a further exemplary material, one or more monomers of the polymer are selected from the group comprising

- an aromatic diphenol, in particular bisphenol A or 1,4-dihydroxybenzene, and a bis(halophenyl)sulfone, in particular 4,4-dichlorodiphenylsulfone,
- vinylidene fluoride, and
- an acrylate, a methacrylate (MAA) and/or a methyl methacrylate (MMA).

In accordance with a further exemplary material, the polymer comprises 2-methacryloyloxyethyl phosphorylcholine (CAS no.: 67881-98-5) as monomer, preferably in combination with acrylate, methacrylate and/or methyl methacrylate.

In accordance with a further exemplary material, the polymer is a polyvinylidene fluoride, a polyarylsulfone, in particular a polysulfone, a polyacrylate, a polymethyl acrylate, or a polymethyl methacrylate.

In accordance with a further exemplary material, the polymer is a polysulfone (CAS no. 25135-51-7), a polyether sulfone (CAS no. 25608-63-3), a polyphenylene sulfone (CAS no. 25608-64-4) or polyphenylene ether sulfone, (PPSP, CAS no. 25608-63-3).

In accordance with a further exemplary material, the polymer is a polytetrafluoroethylene (PTFE), ethylene-tetrafluoroethylene (ETFE), polyamide, or polyether ether ketone (PEEK).

In accordance with a further exemplary material, the polymer is attached to the surface of the silicone by an entanglement, looping or intermolecular interlooping of the chains of the silicone and the chains of the polymer.

In the sense of the present disclosure an entanglement (looping, intermolecular interlooping) is understood to mean in particular a physical/geometrical connection of two or more polymer chains which is created by crossing over the polymer chains. As a result of the entanglement, one polymer chain may be separated from the other polymer chain or the other polymer chains only with difficulty by applying force, or even may not be separated at all.

In accordance with a further exemplary material, the silicone is a methyl silicone, in particular a polydimethylsiloxane, a vinyl-methyl silicone, a phenyl-vinyl-methyl silicone, a phenyl-modified silicone, a fluoroalkyl silicone or a fluoro-vinyl-methyl silicone.

In accordance with a further exemplary material, the polymer is a copolymer of

a. an acrylate (acrylic acid), a methacrylate (methacrylic acid) and/or a methyl methacrylate; and
b. a zwitterionic compound, selected from phosphorylcholine, sulfobetaine, carboxybetaine, sulfopyridium betaine, cysteine, or a sulfobetaine siloxane, preferably comprising methyl or ethyl groups.

In accordance with a further exemplary material, the polymer is a methacrylic acid-methyl methacrylate copolymer, which comprises a residue of a zwitterionic compound, wherein the zwitterionic compound is selected from the group comprising phosphorylcholine, sulfobetaine, carboxybetaine, sulfopyridium betaine, cysteine, phosphatidyl ethanolamine or a sulfobetaine siloxane.

In accordance with a further exemplary material, it is provided that in the polymer the methacrylic acid monomer is provided in relation to the methyl methacrylate monomer in a molar ratio in the range of from 1:1 (1 part methacrylic acid monomer to 1 part methyl methacrylate monomer) to 1:3 (1 part methacrylic acid monomer to 3 parts methyl methacrylate monomer), preferably 1:2 (1 part methacrylic acid monomer to 2 parts methyl methacrylate monomer).

In accordance with a further exemplary material, the polymer comprises methacrylic acid as monomer with a mole fraction in the range of from 25% to 45%, in particular approximately 33%.

The zwitterionic compound preferably comprises at least one polymerizable molecular group, such as a vinyl group or an acryl group.

In accordance with a further exemplary arrangement, a medical implant is provided, wherein the medical implant comprises the material as set out in the claims.

In accordance with an exemplary medical implant, the medical implant comprises an electrode lead.

In the sense of the disclosure, an electrode lead is understood to mean in particular a device which comprises at least one elongate electrically conductive element, in particular a wire, which extends over the length of the electrode lead. In particular the electrode lead comprises an electrical, in particular tubular insulation, wherein the lumen of the insulation surrounds the at least one elongate element with the exception of the two ends. Such an insulation is also referred to as a cover sleeve.

In accordance with a further exemplary medical implant, the electrode lead, in particular the elongate conductive element, is sheathed at least in part with the material as herein described.

In accordance with a further exemplary medical implant, the medical implant comprises a current-generating or current-emitting component (generator component, battery) and/or a current-detecting component (diagnosis component) which is connected to the electrode lead.

In accordance with a further exemplary medical implant it is provided that the medical implant is designed as a cardiac pacemaker, a cardioverter-defibrillator, or a neurostimulator, in particular a spinal cord stimulator.

A cardiac pacemaker is in particular a device which comprises an implantable electronic pulse generator which is connected to a patient’s heart by an electrode lead.

An implantable cardioverter-defibrillator (ICD) is in particular a device which comprises a stimulation part (pulse generator) and a diagnostics part (for identifying any threat of arrhythmias), wherein the stimulation/diagnostics part, usually implanted beneath the skin in

the vicinity of the left pectoral muscle, is connected to the right ventricle by an electrode lead. The electrode lead is typically guided here into the right ventricle via the upper vena cava.

The spinal cord stimulator is in particular a device for treating chronic neuropathic pain, in which a pulse generator is connected by an electrode lead to the part of the nervous system that is to be treated, for example to the posterior funiculus of the spinal cord.

In accordance with a further exemplary medical implant it is provided that the medical implant comprises a fixing sleeve for fixing an implantable electrode lead (electrode fixing sleeve, EFS), wherein the electrode fixing sleeve comprises substantially of the material as herein described.

In the sense of the disclosure the electrode fixing sleeve is understood in particular to be a special fixing sleeve which is arranged fixedly on the electrode lead at a defined point and which is then secured in the human body at a suitable position, for example by being sewn in place in the region of a muscle or a vessel.

In accordance with a further exemplary arrangement, a method for producing the material as herein described is provided. The method comprises the steps:

- providing a silicone, and
- arranging a polymer on the surface of the silicone, wherein the polymer is characterised by a greater wear resistance than the silicone, and the polymer is attached to the surface of the silicone by non-covalent bonds.

The silicone and the polymer are a silicone and a polymer according to one of the above-mentioned exemplary aspects or embodiments.

The expression “arranging a polymer” in the sense of the disclosure means in particular the physical attaching of the polymer to the surface of the silicone by non-covalent bonds. In particular the surface of the silicone is coated at least in part with the polymer.

In accordance with an exemplary method, arranging of the polymer on the surface of the silicone comprises the following steps:

- dissolving the polymer in a suitable solvent yielding a polymer solution;

- applying the polymer solution to the silicone, preferably by spraying or immersion; and
- drying the silicone at a temperature in the range from room temperature to approximately 300°C, preferably at temperatures from 180°C to 260°C, and more preferably at approximately 220°C.

In accordance with a further exemplary method, arranging of the polymer on the surface of the silicone comprises the following steps:

- swelling the silicone in an organic solvent yielding a swollen silicone,
- contacting the swollen silicone with the polymer, wherein the polymer is present dissolved in a suitable solvent, and
- drying the silicone.

Alternatively, the arranging of the polymer on the surface of the silicone comprises the following steps:

- swelling the silicone in an organic solvent yielding a swollen silicone;
- contacting the swollen silicone with one or more precursors of the polymer, wherein the precursor of the polymer is present dissolved in a suitable solvent (inert reaction partner) or one precursor of the polymer is present dissolved in another precursor of the polymer (reactive reaction partner);
- reacting or polymerising the one or more precursors to form the polymer; and
- drying the silicone.

In the sense of the disclosure, “swelling the silicone” means in particular the infiltration of the organic solvent into the silicone, wherein at least the uppermost layers of the silicone experience an increase in volume. The swelling of the silicone in particular causes the silicone chains of the uppermost layers to be movable, and therefore they may entangle or loop with the polymer chains of the polymer, which is advantageous.

The swelling of the silicone also allows the polymer to be formed within the movable chains of the silicone from monomers by polymerisation, whereby an entanglement or looping of the chains of the polymer and of the silicone may also be attained here, advantageously.

A key advantage of the method is that the method may be performed in any step of a manufacturing process for producing a device or an apparatus which is intended to comprise

the material as herein described. For example, existing electrode leads with customary silicone sheathings already may be processed by the disclosed method so as to obtain electrode leads comprising the material as herein described.

In the sense of the disclosure, “drying the silicone” means in particular the removal of the organic solvent, in particular the technically possible complete removal of the organic solvent, for example by temperature or application of a vacuum.

In order to convert or polymerise the one or more precursors into the polymer, initiators may be used, for example azobis(isobutyronitrile) (AIBN) as initiator of a radical chain reaction, for example during the polymerisation of acrylate, methacrylate (MAA), and/or methyl methacrylate (MMA).

In accordance with a further exemplary method, the one or more precursors are monomers which are selected from the following group:

- an aromatic diphenol, in particular bisphenol A or 1,4-dihydroxybenzene, and a bis(halophenyl)sulfone, in particular 4,4-dichlorodiphenylsulfone,
- vinylidene fluoride,
- an acrylate (acrylic acid, AA), a methacrylate (, methacrylic acid, MAA), and/or a methyl methacrylate (MMA).

In accordance with a further exemplary method, the precursors comprise

a. acrylate, methacrylate and/or methacrylate methyl ester; and
b. a zwitterionic compound selected from phosphorylcholine, sulfobetaine, carboxybetaine, sulfopyridium betaine, cysteine, phosphatidyl ethanolamine, or a sulfobetaine siloxane, preferably comprising methyl or ethyl groups,

wherein the zwitterionic compound preferably comprises a polymerizable group, for example a vinyl group or an acryl group.

Advantageously, antimicrobial surfaces preferably may be produced with the above-described zwitterionic compounds as copolymer.

The precursors preferably comprise methacrylate, ethyl methacrylate and phosphorylcholine or 2-methacryloyloxyethyl phosphorylcholine.

In accordance with a further exemplary method, the organic solvent is toluene, xylene, chloroform, dichloromethane, dimethyl acetamide, dimethyl formamide, dimethyl sulfoxide, cresol, ortho-dichlorobenzene, sulfolane, tetrahydrofuran, trichlorethylene, N-methyl-2-pyrrolidone, or a methacrylate or methyl methacrylate solution. A preferred solvent for swelling the silicone is N-methyl-2-pyrrolidone, in particular in combination with n-heptane.

Further features and embodiments of the present invention will be explained hereinafter, by way of example only, and with reference to the drawings, in which:

Fig. 1 shows suitable polymers for use in the material according to the invention;

Fig. 2 schematically shows a possible method for producing the material according to the invention;

Fig. 3 shows an embodiment of an implant according to the invention comprising an electrode lead;

Fig. 4 shows a further embodiment of a medical implant according to the invention comprising an electrode fixing sleeve; and

acetamide and N-methyl-2-pyrrolidone were used as particularly preferred solvents. In this example, it was not a monomer that was added, but a polymer, so as to produce an IP network by diffusion. PESU and PSU were used as polymers.

To this end, the silicone matrix was swollen for 48 h in the solvent at room temperature. The polymer was added as solid substance and was dissolved in the solvent at room temperature over 24 h in the presence of the silicone samples to be treated. The silicone samples were then incubated in this solution for a further 24 h and were then removed, freed from any adhering solution, and were pre-dried at 40°C for 8 h and were then freed from residual material at 40°C and 0.01 bar under vacuum.

Exemplary embodiment of the electrode lead

An embodiment of the implant according to the invention is shown in Figure 3 and has an electrode lead 1. The electrode lead comprises a plurality of conductors 10, 11, which extend longitudinally along the z-axis of the electrode lead 1. The conductors 10, 11 are wound here in the form of a helix around the longitudinal axis z of the electrode lead.

The electrode lead 1 has an outer (for example tubular) electrical insulation 100, which extends along the longitudinal axis z of the electrode lead 1 and surrounds the conductors 10, 11. The electrical insulation 100 here at least substantially comprises the material according to the current disclosure.

The conductors 10, 11 are preferably formed as cables which may comprise a plurality of wires, which for example may at least substantially comprise silver or tantalum.

In the detailed view of the region A shown in Figure 3 it is clear that the conductors 10, 11 forming a helix may be wound along the z-axis with different pitch p, p' of the helix (see reference signs 10a, 10b and 11b).

The electrode lead 1 in its distal region 1a comprises electrode terminals E1 to E8 for contacting bodily tissue. In its proximal region 1b the electrode lead also has contacts C1 to C8, by which the electrode lead may be connected to an active electrical implant, such as an implantable pulse generator – for example an implantable cardiac pacemaker or an implantable neurostimulator –

or an ICD. The contacts C1 to C8 are connected here to the electrode terminals E1 to E8 by means of electrical conductors 10, 11. For this purpose the electrode lead may have more than two conductors 10, 11, as shown schematically in Figure 3. In particular, the electrode lead may have a dedicated electrical conductor for connection of the electrode pole E1 to the contact C1. The same is true also for the other electrode terminal-contact pairs E2 and C2, E3 and C3, etc.

Exemplary embodiment of the electrode fixing sleeve

Another embodiment of the implant according to the invention relates to an electrode fixing sleeve 2, as shown by way of example in Figure 4. The fixing sleeve is used to fix an elongate element 2, here for example in the form of an implantable electrode lead 1. The electrode lead 1 has an elongate lead body, in which, in the known manner, there is arranged at least one electrical conductor - not shown here - which is connected in particular to an electrode contact, which may be arranged on a surface of the lead body so as to contact tissue of the patient. In the example according to Figure 4 the electrode lead 1 pierces a vessel G of the patient and is connected to muscle tissue MG of the patient by fixing elements 41, 42, which are secured to the fixing sleeve 2. The fixing elements 41, 42 are also used to compress or constrict the fixing sleeve 2, in such a way that the electrode lead 1 is securely clamped in a lumen 30 of the sleeve 3. The electrode lead 1 bears against an inner side 3a of the sleeve 2. The fixing elements 41, 42 are placed around the sleeve 2 in order to exert a force into corresponding grooves 31, 32, such that the sleeve may be constricted by means of the fixing elements 41, 42, resulting in a compression of the sleeve 3, at least in the region of the grooves 31, 32, such that the electrode lead 1 is securely clamped in the lumen 30 of the sleeve 2. It is provided in accordance with the invention that the electrode sleeve and/or the electrode lead comprises the material according to the invention. In particular it is provided that the electrode lead has an electrical insulation which comprises the material according to the invention, in particular on the outer surface, or the electrical insulation comprises substantially of the material according to the invention. It is also provided in particular that the electrode fixing sleeve is produced substantially from the material according to the invention.

Antimicrobial properties of the material according to the invention

Claims

1. A material comprising a silicone, characterised in that a polymer is arranged on the surface of the silicone, wherein the polymer is characterised by a higher wear resistance than the silicone, and the polymer is attached to the surface of the silicone by non-covalent bonds, wherein
the polymer is a methacrylic acid-methyl methacrylate copolymer which comprises a residue of a zwitterionic compound, wherein the zwitterionic compound is selected from the group comprising phosphorylcholine, sulfobetaine, carboxybetaine, sulfopyridium betaine, cysteine, phosphatidyl ethanolamine or a sulfobetaine siloxane.

2. The material according to claim 1, characterised in that in the polymer the methacrylic acid monomer is present in relation to the methyl methacrylate monomer in a molar ratio in the range of from 1:1 to 1:3, preferably 1:2.

3. The material according to any one of the preceding claims, characterised in that the polymer is attached to the surface of the silicone by an entanglement of the chains of the silicone and the chains of the polymer.

4. The material according to any one of the preceding claims, characterised in that the silicone is a methyl silicone, in particular a polydimethylsiloxane, a vinyl-methyl silicone, a phenyl-vinyl-methyl silicone, a phenyl-modified silicone, a fluoroalkyl silicone, or a fluoro-vinyl-methyl silicone.

5. A medical implant comprising material according to any one of the preceding claims.

6. The medical implant according to claim 5, characterised in that the medical implant comprises an electrode lead.

7. The medical implant according to claim 6, characterised in that the electrode lead comprises an electrically insulating sheathing which comprises substantially of the material according to any one of claims 1 to 5.

8. The medical element according to claim 6 or 7, characterised in that the medical implant comprises a current-generating or current-emitting component and/or a current-detecting component which is connected to the electrode lead, wherein the medical implant is in particular a cardiac pacemaker, a cardioverter-defibrillator or a neurostimulator.

9. The medical implant according to any one of claims 6 to 8, characterised in that the implant comprises a fixing sleeve for fixing an implantable electrode lead, wherein the fixing sleeve comprises substantially of a material according to any one of claims 1 to 5.

- 10. A method for producing a material according to any one of claims 1 to 4, comprising arranging a polymer on the surface of a silicone, wherein the polymer is characterised by a greater wear resistance than the silicone, and the polymer is attached to the surface of the silicone by non-covalent bonds, wherein the polymer is a methacrylic acid-methyl methacrylate copolymer which comprises a residue of a zwitterionic compound, wherein the zwitterionic compound is selected from the group comprising phosphorylcholine, sulfobetaine, carboxybetaine, sulfopyridium betaine, cysteine, phosphatidylethanolamine or a sulfobetaine siloxane.

11. The method according to claim 10, characterised in that the arranging of the polymer on the surface of the silicone comprises the following steps:
- dissolving the polymer in a suitable solvent yielding a polymer solution;
- applying the polymer solution to the silicone, preferably by spraying or immersion; and
- drying the silicone at a temperature in the range from room temperature to approximately 300°C, preferably at temperatures from 180°C to 260°C, and more preferably at approximately 220°C.

12. The method according to claim 11, characterised in that the arranging of the polymer on the surface of the silicone comprises the following steps:
- swelling the silicone in an organic solvent yielding a swollen silicone;
- contacting the swollen silicone with the polymer, wherein the polymer is present dissolved in a suitable solvent, or

- contacting the swollen silicone with the precursors of the polymer, wherein the one or more precursors of the polymer are present dissolved in a suitable solvent, and reacting the one or more precursors to form the polymer; and
- drying the silicone.

wherein the precursors of the polymer comprise methacrylic acid, methyl methacrylate and a polymerisable compound with the zwitterionic compound or residue thereof.

13. The method according to claim 12, characterised in that the organic solvent is toluene, chloroform, dichloromethane, dimethyl acetamide, dimethyl formamide, dimethyl sulfoxide, cresol, ortho-dichlorobenzene, sulfolane, tetrahydrofuran, trichlorethylene, N-methyl-2-pyrrolidone, in particular N-methyl-2-pyrrolidone, preferably in combination with n-heptane or a methacrylate or methyl methacrylate solution.