
THREE-DIMENSIONAL IMPLANT WITH HYDROPHILIC SURFACE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the right of priority of European patent application 23183089.4 filed with the European Patent Office on 03 July 2023, the entire content of which is incorporated herein for all purposes.

FIELD OF THE INVENTION

[0002] The present invention relates to a tissue reconstruction implant, the implant having a hydrophilic implant surface, wherein the implant is a three-dimensional (3D) implant consisting of a bio-resorbable material, and wherein the implant surface is considered hydrophilic when assessed using an ink test following ISO 8296:2003 and adapted to a three-dimensional (3D) surface, wherein said ink test comprises incubating the implant for 1 min in a solution consisting of an ink with a surface tension of 72 mN/m and water and wherein after incubation of the implant in said solution an ink colored implant surface is indicative for a hydrophilic implant surface. The present invention relates further to said tissue reconstruction implant for use in tissue reconstruction, (soft) tissue support, tissue augmentation and/or implant revision, wherein the implant is inserted into a patient, as well as to a use of said tissue reconstruction implant for reconstructing, augmenting and/or revising a tissue and/or supporting a (soft) tissue, wherein the implant is inserted into a patient. Further, the present invention relates to a method of manufacturing a tissue reconstruction implant with a hydrophilic implant surface, comprising exposing a surface of an implant to a surface treatment, wherein the surface treatment is suitable for making the surface of the implant hydrophilic, whereby a hydrophilic implant surface is obtained, wherein the implant is a three-dimensional (3D) implant consisting of a bio-resorbable material, and wherein the implant surface is considered hydrophilic when assessed using an ink test following ISO 8296:2003 and adapted to a three-dimensional (3D) surface, wherein said ink test comprises incubating the implant for 1 min in a solution consisting of an ink with a surface tension of 72 mN/m and water and wherein after incubation of the implant in said solution an ink colored implant surface is indicative for a hydrophilic implant surface. The present invention relates also to a kit comprising the tissue reconstruction implant

according to the present invention and/or an implant obtainable or obtained by the method according to the present invention comprised in a packaging, preferably a multiple layer packaging, wherein preferably at least one of the layers is a moisture barrier and/or comprises or consists of polyethylene lined with aluminum.

BACKGROUND

[0003] Tissue reconstruction, (soft) tissue support, tissue augmentation and implant revision are often realized using an implant. This holds true for various tissues including e.g. soft tissues and bone tissues.

[0004] Tissues requiring reconstruction, support, augmentation and/or revision may be soft tissues with breast tissues being a prominent example. For tissue reconstruction, support, augmentation and/or revision of breasts, silicone implants are primarily used. However, silicone implants have several drawbacks including, capsular contracture, delayed and/or chronic seroma, hematoma and implant-associated anaplastic large cell lymphoma. Additionally, silicone implants are subject to potential rupture, displacement and/or deformation. Undesired tissue stretching may be observed due to the implant's heavy load, especially in case of traditional silicone implants that may be filled with an incompressible fluid. Over time, silicone implants may also lead to the requirement of additional (corrective) surgeries or even may cause severe health issues when bursting. In view of the drawbacks of silicone implants, alternatives are currently under development. Some implants may include, e.g., space-occupying structures which may be filled with fluid. For example, International Patent Application WO 2016/038083 and Chhaya et al. (Transformation of Breast Reconstruction via Additive Biomanufacturing. Sci. Rep. 6, 28030; doi: 10.1038/srep28030; 2016) disclose an implant having a three-dimensional (3D) scaffold structure having voids, all of which are filled with space-occupying structures. The space-occupying structures are removable attached to the 3D scaffold structure and are configured to prevent invasion of tissue and/or of individual cells. For example, 6 to 8 weeks after implantation, the space-occupying structures are removed in a further surgery from the residual parts of the implant and the site of implantation. Thus, the use of such implants requires additional surgeries posing a further risk to the patients. Implants that do require the removal of such space-occupying structures have meanwhile also been described, e.g., in International Patent Application WO 2021/043950 and in International Patent Application WO 2022/018124.

[0005] In case of bone tissue, an example may be an application in the context of orbital fractures. In this context a study reported for example results of a retrospective comparative

interventional series of patients who had undergone orbital fracture repair (Seen et al., Orbital Implants in Orbital Fracture Reconstruction: A Ten-Year Series, Craniomaxillofac Trauma Reconstr., 2021 Mar;14(1):56-63, doi: 10.1177/1943387520939032). Said study discloses, e.g., that currently available alloplastic implants were made of materials such as titanium, porous polyethylene or silicone elastomers. These implants were readily available, easy to handle, and underwent minimal or no resorption at the cost of being permanent foreign bodies. Thus, these implants may be susceptible to infection, migration, palpability, and exposure over time. The article further discloses that bio-resorbable implants may offer advantages over permanent implants including an ability to contour (in case of polylactides) and to provide mechanical integrity (in case of polycaprolactone (PCL) for small fractures) while the polymer resorbs. Accordingly, it is further reported that most common implants were observed to be bio-resorbable implants, such as PCL mesh implants, and that both bio-resorbable and porous polyethylene implants were stable, biocompatible, and easy to be shaped two-dimensionally, thus making them suitable for simple 1-walled blowout fractures. In the same line, research is also going in the field of soft tissue reconstruction, investigating e.g. the potential of electrospun nanofibrous membranes and electrospun fiber mats of materials like PCL for e.g. cardiovascular applications, as such substantially two-dimensionally (2D) implants may be capable of resembling at least partially the extracellular matrix (ECM) of some tissues.

[0006] However in view of 3D tissue reconstruction implants clinical challenges persist, e.g., relating to a successful cell adhesion, cell invasion and/or vascularization after implantation. This requires that cells can attach to the implant surface and migrate into the implant structure. Thus, there is still a need to provide 3D implants that overcome short comings, like (long-term) foreign body responses, while being capable of leading to a (long-term) successful tissue reconstruction, (soft) tissue support, and/or tissue augmentation.

SUMMARY

[0007] The present invention relates to a tissue reconstruction implant, the implant having a hydrophilic implant surface, wherein the implant is a three-dimensional (3D) implant consisting of a bio-resorbable material, and wherein the implant surface is considered hydrophilic when assessed using an ink test following ISO 8296:2003 and adapted to a three-dimensional (3D) surface, wherein said ink test comprises incubating the implant for 1 min in a solution consisting of an ink with a surface tension of 72 mN/m and water and wherein after incubation of the implant in said solution an ink colored implant surface is indicative for a hydrophilic implant surface.

[0008] It is preferred that i) the bio-resorbable material comprises, or is, a polymer selected from the group consisting of polycaprolactone, poly(1,3-trimethylene carbonate), polylactide, polyglycolide, poly(ester amide), poly(ethylene glycol)/poly(butylene terephthalate), poly(4-hydroxybutyrate), polydiacoxane, poly(glycerol sebacate), poly(1,8-octanediol-co-citric acid), poly(1,10-decanediol-co-D,L-lactic acid), poly(diol citrate), poly(glycolide-co-caprolactone), poly(1,3-trimethylene carbonate-co-lactide), poly(1,3-trimethylene carbonate-co-caprolactone) and a copolymer of at least two of said polymers, ii) the bio-resorbable material comprises polycaprolactone, and/or iii) the bio-resorbable material is capable of being resorbed by a patient, preferably within less than 15 years upon insertion of the implant into said patient.

[0009] Alternatively or additionally, it is preferred that the implant is an additively manufactured implant, preferably a 3D printed implant, and/or wherein the filaments of the 3D printed implant have an average diameter between 25 μm and 7.5 mm, preferably between 50 μm and 5 mm or between 50 μm and 600 μm .

[0010] Alternatively or additionally, it is preferred that the implant has a resting volume between 0.5 cm^3 and 40,000 cm^3 , preferably between 5 cm^3 and 25,000 cm^3 or between 5 cm^3 and 3,000 cm^3 or between 5 cm^3 and 800 cm^3 .

[0011] Alternatively or additionally, it is preferred that the implant comprises a 3D lattice structure, wherein the 3D lattice structure preferably i) defines a resting volume of the implant, ii) has a bulk porosity of at least 50%, and/or iii) is a reversibly compressible 3D lattice structure, preferably wherein the 3D lattice structure is compressible to at least 80% of its resting volume.

[0012] Alternatively or additionally, it is preferred that the implant is i) a reversibly compressible 3D implant, ii) a soft tissue implant and/or a soft tissue support implant, wherein the soft tissue is preferably a soft tissue of a) a breast region, pectoral region, malar region, gluteal region or genital region and/or of b) a tendon and/or a ligament, iii) for insertion into a patient, and/or iv) a single-piece reconstruction implant.

[0013] Alternatively or additionally, it is preferred that the implant is suitable for being folded and/or compressed such that it can be inserted into a patient minimal invasively.

[0014] The present invention further provides the tissue reconstruction implant of the invention for use in tissue reconstruction, (soft) tissue support, tissue augmentation and/or implant revision, wherein the implant is inserted into a patient.

[0015] The present invention further provides a use of the tissue reconstruction implant of the invention for reconstructing, augmenting and/or revising a tissue and/or supporting a (soft) tissue, wherein the implant is inserted into a patient.

[0016] The present invention further provides a method of manufacturing a tissue reconstruction implant with a hydrophilic implant surface, comprising exposing a surface of an implant to a surface treatment, wherein the surface treatment is suitable for making the surface of the implant hydrophilic, whereby a hydrophilic implant surface is obtained, wherein the implant is a three-dimensional (3D) implant consisting of a bio-resorbable material, and wherein the implant surface is considered hydrophilic when assessed using an ink test following ISO 8296:2003 and adapted to a three-dimensional (3D) surface, wherein said ink test comprises incubating the implant for 1 min in a solution consisting of an ink with a surface tension of 72 mN/m and water and wherein after incubation of the implant in said solution an ink colored implant surface is indicative for a hydrophilic implant surface.

[0017] It is preferred that the implant is manufactured by sequentially printing layers to form a 3D printed lattice structure comprising a plurality of unit cells, preferably wherein i) each printed layer comprises a lattice arrangement of two-dimensional (2D) unit cells, ii) the unit cells are connected to each other, and/or iii) the filaments of the 3D printed lattice structure have an average diameter between 25 μm and 7.5 mm, preferably between 50 μm and 5 mm or between 50 μm and 600 μm .

[0018] Alternatively or additionally, it is preferred that the surface treatment is i) an etching treatment, preferably an acid or alkaline etching treatment, more preferably a sodium hydroxide treatment, or ii) a plasma treatment, preferably an oxygen plasma treatment.

[0019] Alternatively or additionally, it is preferred that the plasma treatment i) is a low frequency plasma treatment, preferably at about 40 kHz, ii) is performed for at least 10 sec or at least 15 sec or at least 30 sec, and/or for a period of time ranging between 10 sec and 240 min or between 15 sec and 240 min or between 15 sec and 90 min or between 15 sec and 60 min or between 15 sec and 30 min, iii) is performed by applying a used power of less than 70 watts (W) or of less than 40 W, and/or between 20 W and 70 W, preferably between 20 W and 40 W or between 50 W and 70 W, iv) is performed by applying a pressure of about 0.3 mbar, and/or v) is performed by putting the implant on a glass tray in a plasma treatment device.

[0020] Alternatively or additionally, it is preferred that in case of the method of the invention or the implant of the invention the solution used in the ink test consists of the ink with

the surface tension of 72 mN/m and distillate water, preferably in a ratio of ink:distillate water of between (about) 1:15 and (about) 1:75, more preferably in a ratio of ink:distillate water of (about) 1:60 or of (about) 1:30.

[0021] The present invention further provides a kit comprising the tissue reconstruction implant according to the present invention and/or obtainable or obtained by the method according to the present invention comprised in a packaging, preferably a multiple layer packaging, wherein preferably at least one of the layers is a moisture barrier and/or comprises or consists of polyethylene lined with aluminum.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] The foregoing and other features of the present disclosure will become more fully apparent from the following description and appended claims, taken in conjunction with the accompanying drawings. It is understood that the accompanying drawings depict only several embodiments in accordance with the present disclosure and are, therefore, not to be considered limiting of its scope. The disclosure will be described with additional specificity and detail through use of the accompanying drawings, such that the advantages of the present disclosure can be more readily ascertained, in which:

[0023] **Figure 1** shows solvents of the test protocol published by the International Organization for Standardization (ISO) (second edition 2003-09-01, reviewed and confirmed in 2018) with reference number ISO 8296:2003(E). It is noted here that the **Figure 1** is copy-right protected material. It is also noted here that **Figure 1** does not expressly recites the solvent (named “test mixture” in **Figure 1**) that are being using to test whether a surface has a surface tension of 72 mN/m (named “wetting tension” in the ink test of ISO 8296:2003). However, Table 1 explains that a mixture of 10 ml methanol and 90 ml water (that means a mixture of 90 % (v/v) water and 10 % methanol) is being used to measure a surface tension of 70 mN/m while water is used as the sole solvent for measuring a surface tension of 73 mN/m. Thus, it is clear that either pure water (as done in the Experimental Section of the present application) or a mixture of at least 90 % water (v/v) with the remainder being methanol, for example 95 % (v/v) water 5 % methanol (v/v) can be used for measuring a surface tension of 72 mN/m using the ink test of ISO 8296:2003. In this context, it is noted that (blue) inks formulated for measuring a surface tension of 72 mN/m according to ISO 8296 are commercially available from a wide range of providers. See, for example, Test ink blue (in the ranges) 60 to 70 mN/m of Fischer Test Tinten, 76479 Steinmauern, Germany, the “BLUE Test Inks” of Arcotest GmbH, 71297 Moensheim, Germany (for, example, the ink set with article number 40.302XX.0), the “Series B” inks of Tigres GmbH, 21436 Marschacht, Germany, the Dynelevel test ink in the ranges 28 to 72 mN/m (available in 10ml, 30ml, 50ml, 100ml and 1000ml PET bottles) from SEST Messtechnik, 79588 Efringen-Kirchen,

Germany, or the blue formamide test inks available from Fischer Test Tinten, 76479 Steinmauern, Germany that are used to determine surface tensions and are liquids according to DIN 53364 or ISO 8296. Any of these test inks can be used in determining the surface tension of an implant as described herein using ISO 8296 that is being herein to measure the surface tension of surfaces of “three-dimensional objects” instead of plastic sheets and films, meaning rather “two-dimensional” objects.

Plastics — Film and sheeting — Determination of wetting tension

1 Scope

1.1 This International Standard specifies a method for determining the wetting tension of surfaces of plastic film and sheeting in contact with drops of specific test solutions.

1.2 The ability of plastic films to retain inks, coatings, adhesives, etc., is primarily dependent on the character of their surfaces, and can be improved by one of several surface-treatment techniques. These same treatment techniques have been found to increase the wetting tension of a plastic film surface in contact with mixtures of solvents. It is therefore possible to relate the wetting tension of a plastic film surface to its ability to accept and retain inks, coatings, adhesives, etc. The measured wetting tension of a specific film surface can only be related to acceptable ink, coating, or adhesive retention through experience. Wetting tension, in itself, is not a completely acceptable measure of ink, coating or adhesive adhesion.

1.3 Any contamination of the film surface and any trace of surface-active impurities in the liquid reagents may affect the wetting tension. It is therefore important that the portion of the film surface to be tested is not touched or rubbed, that all equipment be scrupulously clean, and that reagent purity be carefully controlled. Glass apparatus, in particular, is likely to be contaminated with detergents having very strong surface tension reducing ability, unless specific precautions are taken to ensure their absence such as by cleaning with an oxidizing agent, for example chromic-sulfuric acid or sulfuric acid-ammonium peroxydisulfate, and rinsing with distilled water.

1.4 The test is not applicable when the surface of the material to be tested reacts chemically with the test solution.

1.5 It should be noted that surface properties of plastic film and sheeting may change by ageing processes. The measurements must therefore be related to the age of the film.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 291, Plastics — Standard atmospheres for conditioning and testing

3 Principles

A series of mixtures of solvents of gradually increasing surface tension are applied to the surface of the plastic film until a mixture is obtained that just wets the film surface. The wetting tension of the surface under test is approximated by the surface tension of this particular mixture.

4 Apparatus

Ordinary laboratory apparatus and the following:

4.1 Hand-coater, with a wire bar depositing a film. Alternatively, cotton-tipped wood sticks or brushes may be used, provided that they give the same test result.

4.2 Brown-glass dropper bottles.

5 Test mixtures

Test mixtures of graduated wetting tension shall be prepared by mixing reagent grades of ethylene glycol monoethyl ether (Cellosolve), formamide, methanol and water in accordance with Table 1.

The test mixtures shall be stored in the brown-glass dropper bottles (4.2). If well protected, the mixtures change very little with time. If used frequently, they shall be renewed after 3 months.

SAFETY PRECAUTIONS — When handling the solvents, the appropriate laboratory safety precautions must be taken.

6 Sampling

Whether a film is presented in the form of rolls or in the form of piled sheets, two surfaces are in contact (as a rule, front with reverse). When sampling, care shall be taken that the surfaces to be tested do not come into contact with any other material. In the case of a roll, this is achieved by discarding the outer layer and unwinding a sample without touching the areas to be tested. In the case of a pile, some sheets are taken together and the outermost sheets discarded before testing. The actual specimens for testing shall be taken from these samples immediately before the tests are carried out. Normally, a specimen measuring is sufficient.

7 Procedure

7.1 Conduct the test in standard laboratory atmosphere 23/50 (see ISO 291).

7.2 Place the test specimen on the ground plate of the hand-coater (4.1). Apply a few drops of the test mixture (Clause 5) to the film in front of the wire bar and spread immediately by drawing the bar.

If a brush or cotton-tipped stick is used for spreading the test mixtures, the liquid shall be spread rapidly over an area of at least . The quantity of liquid shall be such that it forms a thin film without pools.

Observe the liquid film of the test mixture under glancing illumination and note the time taken for the continuous liquid film to break up into droplets. If the liquid film holds together for more than 2 s, repeat the test on a new specimen with a mixture of the next higher surface tension, until the liquid film breaks up in less than 2 s. If the liquid film holds for less than 2 s, proceed to lower surface tensions until the film persists for 2 s.

7.3 For each test, use a new cotton applicator. Clean the brush or wire bar after each use by rinsing in methanol and drying, because the liquid remaining on these spreaders will change in composition and surface tension by evaporation.

7.4 Note the mixture that comes nearest to wetting the surface for 2 s, based on at least three determinations with that mixture. The surface tension of this mixture shall be reported as the wetting tension of the plastic film.

8 Test report

The test report shall include the following particulars:

- a) a reference to this International Standard;
- b) all details necessary for identification of the plastic film and, if known, its approximate age;
- c) the side and location tested;
- d) the wetting tension of the film.

[0024] **Figure 2A** shows a cross-sectional longitudinal side view of an implant 200, and **Figure 2B** shows a top view (plan view) of the first outer surface region 105 of said implant.

[0025] **Figure 3** shows a test object used for process development, said test object being a material piece like a scaffold with a big structure compared to an implant.

[0026] **Figure 4** shows ink test results of long and strong life stability tests, respectively. **Figure 4A** shows long life stability test results using an ink test, exemplarily showing results for 11 weeks of storage (15%P refers to a used power of 30W, and 30%P refers to a used power of 60W). **Figure 4B** shows strong life stability test results using an ink test, exemplarily showing results for exposure to 40 °C for 5 min (left) and 1h (right), while **Figure 4C** shows results for exposure to 50 °C for 1 h, and **Figure 4D** shows results for exposure to 60 °C for 1 h.

[0027] **Figure 5** shows results of an ink test following ISO 8296:2003 and adapted to a three-dimensional (3D) surface as disclosed herein using a solution consisting of a blue ink with a surface tension of 72 mN/m and assessing whether the implant surface homogenously adsorbed and/or absorbed the blue ink. A blue coloured implant is indicative for the implant surface being hydrophilic, whereas a colourless or white implant is indicative for the implant surface being hydrophobic. Shown are in **Figure 5A** the first outer surface region of a breast implant before (upper implant) and after surface treatment (implant at the bottom) and in **Figure 5B** the second outer surface region of a breast implant before (left) and after surface treatment (right implant), respectively.

[0028] **Figure 6** shows two negative examples of a surface treatment using oxygen plasma treatment. An unfavourable parameter combination resulted in a damage of the implant as indicated by a faint colouring of the implant (yellowish coloured regions of the implant). Shown are in **Figure 6A** an implant with a faint yellowish discoloured surface region, and in

Figure 6B another implant with a faint yellowish discoloured surface region (in **Figure 6B** indicated by a line surrounding the discoloured surface region), respectively.

[0029] **Figure 7** shows surface treated breast implants cut into two pieces so that the ink colored inner surfaces are visible). **Figure 7A** shows an implant cut along an axis orthogonal to the first outer surface region of the breast implant, and **Figure 7B** shows an implant cut along an axis substantially parallel to the first outer surface region of the breast implant.

[0030] **Figure 8** shows an exemplarily contact angle measurement of breast tissue reconstruction implant with the three white (with black surrounding) circles indicating potential measurement positions and/or regions at three different outer surface positions.

DETAILED DESCRIPTION

[0031] In the following detailed description, reference is made to the accompanying drawings that show, by way of illustration, specific embodiments in which the claimed subject matter may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the subject matter. It is to be understood that the various embodiments, although different, are not necessarily mutually exclusive. For example, a particular feature, structure, or characteristic described herein, in connection with one embodiment, may be implemented within other embodiments without departing from the spirit and scope of the claimed subject matter. References within this specification to “one embodiment” or “an embodiment” mean that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one implementation encompassed within the present description. Therefore, the use of the phrase “one embodiment” or “in an embodiment” does not necessarily refer to the same embodiment. In addition, it is to be understood that the location or arrangement of individual elements within each disclosed embodiment may be modified without departing from the spirit and scope of the claimed subject matter. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the subject matter is defined only by the appended claims, appropriately interpreted, along with the full range of equivalents to which the appended claims are entitled. In the drawings, like numerals refer to the same or similar elements or functionality throughout the several views, and that elements depicted therein are not necessarily to scale with one another, rather individual elements may be enlarged or reduced in order to more easily comprehend the elements in the context of the present description.

[0032] The present invention addresses the need to have at hand alternative solutions to currently available 3D implants that overcome, e.g. silicone implant associated, problems like (long-term) foreign body responses including, e.g., capsular contracture, while allowing long-term success of the intended tissue reconstruction, (soft) tissue support, tissue augmentation and/or implant revision.

[0033] In particular, the present invention relates to a method of manufacturing a three-dimensional (3) tissue reconstruction implant having a hydrophilic implant surface and consisting of a bio-resorbable material, a 3D tissue reconstruction implant having a hydrophilic implant surface and consisting of a bio-resorbable material, as well as uses of said implant and/or said implant for use in reconstructing, augmenting and/or revising a tissue and/or supporting a (soft) tissue, wherein the implant is inserted into a patient.

[0034] More specifically, implants made of bio-resorbable materials may exhibit suboptimal cell attachment due to their hydrophobic surfaces. The inventor found that the surface wettability of bio-resorbable materials like polycaprolactone (PCL) may be improved by exposing a 3D implant to a surface treatment like (e.g. oxygen) plasma treatment, thereby obtaining a hydrophilic surface. Surprisingly, the inventor found that the “net effect” of different surface treatment parameter combinations may be crucial to obtain an implant with hydrophilic surface without surface treatment related damage. Herein, illustrative surface treatment parameter combinations are disclosed to illustrate the inventor’s surprising findings about net effects of different surface treatment parameters, and the complexity of finding a “sweet spot” of parameter combinations that allow a balance between desired surface treatment effect and structural and/or chemical integrity of surface treated 3D implants. Disclosed herein is further an ink test developed by the inventor to overcome the hurdle of validating hydrophilicity of 3D surfaces as existing methods like contact angle measurements were developed for 2D surfaces.

[0035] Furthermore, disclosed herein is a new generation of tissue reconstruction implants, said implants being bio-resorbable 3D implants with hydrophilic surface that may facilitate cell attachment, cell invasion and/or natural tissue regeneration. The implant according to the present invention overcomes challenges associated with implants like silicone implants that result in a permanent positioning of foreign material into the patient’s body. Wearing comfort perceived by the patient may be positively affected by the implant according to the present invention preferably being a lightweight single-piece tissue reconstruction implant that may have only about e.g. 5 to 15 % of a same-sized silicone implant. Moreover, the implant according to the present invention may have an e.g. 3D printed porous structure that may provide

structural and/or mechanical support for natural tissue regeneration as well as a reversible compressibility, thus enabling minimal-invasive implant insertion.

I. Method of manufacturing

[0036] The present invention relates to a method of manufacturing a tissue reconstruction implant with a hydrophilic implant surface, comprising exposing a surface of an implant to a surface treatment, wherein the surface treatment is suitable for making the surface of the implant hydrophilic, whereby a hydrophilic implant surface is obtained, wherein the implant is a three-dimensional (3D) implant consisting of a bio-resorbable material, and wherein the implant surface is considered hydrophilic when assessed using an ink test following ISO 8296:2003 and adapted to a three-dimensional (3D) surface, wherein said ink test comprises incubating the implant for 1 min in a solution consisting of an ink with a surface tension of 72 mN/m and wherein after incubation of the implant in said solution an ink colored implant surface is indicative for a hydrophilic implant surface.

[0037] The tissue reconstruction implant exposed to a surface treatment according to the present invention and/or the tissue reconstruction implant according to the present invention is a three-dimensional (3D) implant. A 3D object like a 3D implant may be characterized by having a spatial extent in a 3D space. Herein, a 3D space may relate to a mathematical space in which three values (coordinates) are required to determine a position of a point within said 3D space. The 3D space may be described using three axes, e.g. an x-, y-, and z-axis, with the three coordinates of a point within said 3D space referring to a value per axis. In case of 3D objects, such as 3D implants, said object may be described referring to its spatial extent per axis, for example given in cm. Herein, a 3D object may have a spatial extent per axis of at least 0.5 mm or 0.75 mm, preferably of at least 0.75 mm. For example, a 3D object may have a spatial extent per axis e.g. of at least 1 mm, or e.g. of at least 1.25 mm, or e.g. of at least 1.5 mm, or e.g. of at least 1.75 mm, or e.g. of at least 2 mm, or e.g. of at least 2.25 mm, or e.g. of at least 2.5 mm. Contrarily, a two-dimensional (2D) object may have a spatial extent only along two of the three axes of a 3D space. Herein, the term “2D object” may include a substantially 2D object having a spatial extent per axis of a 3D space under the constraint that the spatial extent along at least one of the three axes may not exceed 0.5 mm or 0.75 mm or 1 mm, preferably it may not exceed 0.75 mm. Thus, the 3D implant may have a spatial extent in three directions within a 3D space and/or may have a (3D) size that may be described by a spatial extent per each of the three axes.

[0038] For example, a 3D implant may have a (3D) size (volume) between 0.1 cm x 0.5 cm x 0.5 cm and 30 cm x 30 cm x 50 cm. The (3D) size of the implant may vary depending on the patient's body part to be reconstructed by the 3D implant. For example, a 3D implant being a malar region implant may have a (3D) size/dimensions between 0.1 cm x 0.5 cm x 0.5 cm and 2.5 cm x 7.0 cm x 7.0 cm, e.g. between 0.3 cm x 1.0 cm x 3.0 cm and 2.0 cm x 5.0 cm x 7.0 cm or e.g. between 0.8 cm x 1.0 cm x 3.0 cm and 2.0 cm x 5.0 cm x 7.0 cm. For example, a 3D implant being a breast implant may have a (3D) size/dimensions between 4.0 cm x 4.0 cm x 1.0 cm and 20.0 cm x 20.0 cm x 10.0 cm, e.g. between 4.0 cm x 4.0 cm x 1.0 cm and 20.0 cm x 20.0 cm x 7.0 cm. For example, a 3D implant being a pectus implant may have a (3D) size/dimensions between 4.0 cm x 4.0 cm x 1.0 cm and 20.0 cm x 20.0 cm x 10.0 cm, e.g. between 4.0 cm x 4.0 cm x 1.0 cm and 20.0 cm x 20.0 cm x 7.0 cm. For example, a 3D implant being a gluteal region implant may have a (3D) size/dimensions between 4.0 cm x 4.0 cm x 1.0 cm and 20.0 cm x 20.0 cm x 10.0 cm, e.g. between 4.0 cm x 4.0 cm x 1.0 cm and 20.0 cm x 20.0 cm x 7.0 cm. For example, a 3D implant being a genital region implant, a (soft) tissue support implant, a tendon implant and/or a ligament implant may have a (3D) size/dimensions 0.1 cm x 0.5 cm x 0.5 cm and 20.0 cm x 20.0 cm x 10.0 cm, e.g. between 2.0 cm x 2.0 cm x 1.0 cm and 20.0 cm x 20.0 cm x 7.0 cm. For example, a 3D implant being a bone implant may have a (3D) size/dimensions between 4.0 cm x 4.0 cm x 1.0 cm and 30 cm x 30 cm x 50 cm, e.g. between 4.0 cm x 4.0 cm x 1.0 cm and 20 cm x 20 cm x 30 cm.

[0039] For example, a 3D implant may have a (3D) size described by the volume of the implant. For example, the implant may have a volume between 0.5 cm³ and 40,000 cm³, preferably between 5 cm³ and 25,000 cm³ or between 5 cm³ and 3,000 cm³ or between 5 cm³ and 800 cm³. For example, in case of an implant being an implant for or suitable for a breast region or a pectoral region, the volume of the implant may be between 15 cm³ and 3,000 cm³, e.g. between 40 cm³ and 800 cm³ or between 30 cm³ and 800 cm³. For example, in case of an implant being an implant for or suitable for a malar region, the volume of the implant may be between 0.5 cm³ and 75 cm³, e.g. between 5 cm³ and 50 cm³ or between 5 cm³ and 15 cm³. For example, in case of an implant being an implant for or suitable for a gluteal region, the volume of the implant may be between 15 cm³ and 3,000 cm³, e.g. between 50 cm³ and 800 cm³. For example, in case of an implant being an implant for or suitable for a genital region, a soft tissue support, a tendon and/or a ligament, the volume of the implant may be between 2.5 cm³ and 3,000 cm³, e.g. between 5 cm³ and 200 cm³. For example, in case of an implant being an implant for or suitable for a bone region, the volume of the implant may be between 15 cm³ and 40,000 cm³, e.g.

between 40 cm³ and 25,000 cm³ or between 100 cm³ and 25,000 cm³ or between 40 cm³ and 16,000 cm³.

[0040] The method according to the present invention may comprise a step of manufacturing and/or providing a 3D reconstruction implant consisting of a bio-resorbable material. Different methods exist for manufacturing and/or providing said implant.

[0041] The implant, a surface of which is exposed to a surface treatment in the method of manufacturing a tissue reconstruction implant with a hydrophilic implant surface according to the present invention, may be an implant manufactured using a method suitable for manufacturing a (bio-) resorbable implant such as melt extrusion, selective laser sintering, vat polymerization etc. or any combination and/or modification thereof. The implant may be an implant manufactured e.g. according to the disclosure of one or more of the group consisting of EP application number 22189015, WO 2021/043950, WO 2022/018124, WO 2023/094674, WO 2019/238716 and WO 2021/156292. Thus, the implant, a surface of which is exposed to a surface treatment according to the present invention, may be an implant obtainable and/or obtained by the method of manufactured according to the disclosure of one or more of the group consisting of EP application number 22189015, WO 2021/043950, WO 2022/018124, WO/2023/094674, WO/2019/238716 and WO/2021/156292. It may be preferred that the implant is an implant manufactured according to the disclosure of (at least) WO 2021/043950 (PCT/EP2020/074690; e.g. A1).

[0042] The implant may be an additively manufactured implant. For example, the implant may be a 3D printed implant. For example, the implant may be an implant 3D printed using a melt extrusion-based method and/or a selective-laser-sintering method. Additive manufacturing may also be referred to as additive layer manufacturing and relates to a computer-controlled process to deposit a material, e.g. layer by layer, thereby creating a 3D object. Additive manufacturing such as 3D printing may be advantageous, e.g., in view of cost effectivity, easy handling, processing speed and/or possibility of customization. Herein, it may be preferred that the implant is a 3D printed implant.

[0043] For example, the implant may be manufactured by sequentially printing layers, preferably layers of filaments. For example, the implant may have been manufactured and/or may be formed using 3D printing to control filament deposition. For example, the implant may be a 3D printed implant comprising or consisting of filaments. For example, a diameter of a filament, preferably of each of the filaments, may be selected so that the filament(s) is/are

flexible. In case of a material like PCL, for example, a filament may have an elastic modulus of 216 MPa, a tensile strength of 10 MPa, and/or a breaking stress of 26.5 MPa. For example, filaments of a 3D printed implant may have an average diameter between 25 μm and 7.5 mm, preferably between 25 μm and 5 mm or between 50 μm and 5 mm or between 50 μm and 750 μm or between 50 μm and 600 μm or between 25 μm and 750 μm or between 500 μm and 7.5 mm. For comparison, in case of electrospun filaments, average filament diameters may be between 0.1 μm and 50 μm . As in case of electrospinning between 1 and 15 layers may be put on top of each other due to technical constraints limiting the number of layers to about 15 layers, electrospinning may be suitable for manufacturing substantially two-dimensional (2D) objects like membranes and/or meshes. For illustration, 10 to 15 layers of electrospun filaments on top of each other may not exceed 0.5 mm to 0.75 mm. Thus, electrospinning may not be considered suitable for manufacturing a 3D tissue reconstruction implant that may be suitable for reconstructing e.g. a patient's breast as a single-piece implant.

[0044] Herein, it may be preferred that the filaments of the (e.g. 3D printed) implant have an average diameter between 25 μm and 7.5 mm, preferably between 50 μm and 5 mm or between 50 μm and 750 μm or between 50 μm and 600 μm . For example, in case of an implant being an implant for or suitable for a breast region, pectoral region, malar region, and/or gluteal region, an average diameter of a filament, preferably of each of the filaments, may be between 50 μm and 750 μm , e.g. between 250 μm and 400 μm or e.g. between 200 μm and 450 μm or e.g. between 100 μm and 600 μm . For example, in case of an implant being an implant for or suitable for a genital region, a soft tissue support, a tendon and/or a ligament, an average diameter of a filament, preferably of each of the filaments, may be between 25 μm and 750 μm , e.g. between 50 μm and 600 μm . For example, in case of an implant being an implant for or suitable for a bone region, an average diameter of a filament, preferably of each of the filaments, may be between 500 μm and 7500 μm , e.g. between 800 μm and 5000 μm or e.g. between 700 μm and 5000 μm or e.g. between 600 μm and 5000 μm . Thus, 3D implants may be manufactured and/or provided with e.g. sizing and mechanical stability as required for reconstructing, supporting, augmenting and/ or revising a patient's tissue.

[0045] For example, the implant may be formed and/or manufactured by sequentially printing layers to form a 3D printed lattice structure. Thus, the implant may comprise, or consist of, a 3D lattice structure. The layers may be successively stacked on top of each other. Each layer of such an arrangement of layers may include a 2D lattice arrangement of a plurality of (2D) unit cells. A unit cell may be a 2D basic unit of a 3D lattice structure. The unit cells may be

connected to each other. The sequential arrangement (e.g. by printing) of layers on top of each other may lead to the forming of a 3D structure. The lattice structure may thus include a plurality of (e.g. directly) adjacent unit cells, connected to each other throughout the lattice structure. Thus, the implant may be manufactured by sequentially printing layers to form a 3D printed lattice structure comprising a plurality of unit cells, preferably wherein each printed layer comprises a lattice arrangement of 2D unit cells. For example, individual unit cells of the plurality of unit cells may be reversibly compressible spring-like unit cells. Thus, the individual unit cells of the plurality of unit cells may be spring-like unit cells. A spring-like unit cell may be compressible to at least 80% (or e.g. at least 70%, or e.g. at least 60%, or e.g. at least 50%, or e.g. at least 30%, or e.g. at least 20%, or e.g. at least 10%) of its original volume. As used herein, compressible to at least 80% refers to being compressible to 80% or less of its original volume. The spring-like unit cells may be reversibly compressible. By being reversibly compressible, each unit cell may be able to recover or return to its original (resting) volume after a compression force has been removed (even at the same ambient pressure and temperature). A reversibly compressible spring-like unit cell may be configured to recover to at least 80% (or e.g. at least 90%, or e.g. at least 95%, or e.g. at least 98%, or e.g. up to 100%) of its original volume, after the compression force exerted on the implant and/or the implant's 3D lattice structure is removed. As used herein, recover to at least 80% refers to being able to recover to 80% or more of its original volume.

[0046] The 3D printed lattice structure may define the resting volume of the implant. The resting volume may be the volume of the implant described herein above in the context of the implant's (3D) size. Accordingly, the implant may have a resting volume between 0.5 cm³ and 40,000 cm³, preferably between 5 cm³ and 25,000 cm³ or between 5 cm³ and 3,000 cm³ or between 5 cm³ and 800 cm³. The resting volume (e.g. given in cm³) of the implant may be the volume of the implant before inserting the implant into a patient. The resting volume of the implant may be the volume of the implant when only one outer surface of the implant experiences an external force. For example, when the implant is at rest on (or in contact with) a carrier surface (e.g. a table surface, or e.g. a board). In other words, the resting volume of the implant may be the volume of the implant without a (physical or mechanical) compression force being exerted on more than one outer surface of the implant (e.g. opposing compressive forces acting on the surfaces of the implant).

[0047] When a (physical or mechanical) compression force is exerted on more than one outer surface of the implant, the implant may be compressible to at least 80% (or e.g. to at least

75%, or e.g. to at least 70%, or e.g. to at least 65%, or e.g. to at least 60%, or e.g. to at least 55%, or e.g. at least 50%, or e.g. to at least 45%, or e.g. to at least 40%, or e.g. to at least 35%, or e.g. at least 30%, or e.g. to at least 25%, or e.g. at least 20%, or e.g. to at least 15%, or e.g. at least 10%, or e.g. to at least 5%) of its resting volume. Being compressible to at least 80% refers to the implant being able to attain 80% or smaller of its resting volume (e.g. because of compression). Preferably, the implant is configured to recover at least 80% (e.g. equal to or larger than 80%), or e.g. at least 85%, or e.g. at least 90%, or e.g. at least 95%, or e.g. at least 98%, or e.g. up to 100%, of its original volume (e.g. original resting volume), after the compression force exerted on the implant is removed. Preferably, the implant is a reversibly compressible 3D implant. Alternatively or additionally, the 3D lattice structure is preferably a reversibly compressible 3D lattice structure. For example, the implant and/or the 3D lattice structure may be (preferably reversibly) compressible to at least 80% of its resting volume. For example, the 3D lattice structure may be a reversibly compressible 3D lattice structure comprising the plurality of reversibly compressible, e.g. spring-like, unit cells. Thus, the implant may provide shape stability. The implant may deform if a force is applied to the implant, and the implant may recover its shape when or after the force is released. For example, once a compressive force is released, the energy stored during this process may act in the opposite direction as when the compressive force was; this may help the shape of the implant to spring back and recover its original shape (e.g. at least 80% of its resting volume). Thus, the ability of the implant to recover its shape may avoid pore obstruction and/or any extra forces, e.g. being exerted on the patient's body region the implant may be in contact after implant insertion into the patient's body such as in case of a breast implant the patient's chest cavity, which may cause damages to the patient's tissues and/or to the lungs.

[0048] Compressibility of the 3D lattice structure and/or of the implant may (e.g. at least partially) be based on (or e.g. proportional to) the bulk porosity and/or total void space of the implant. For example, the 3D lattice structure of the implant may be compressible to a minimal compressible volume, V_c based on (or e.g. proportional to) the void space of the implant. For example, the 3D lattice structure may be compressible to $V_c = V_T - V_v$, wherein V_c is the volume of the compressed implant, V_v is the volume of void-space, and V_T is the total resting volume of the 3D lattice structure. In other words, the implant may be compressed by a volume based on (proportional to, or equal to) the volume of void space. The volume of void space may be comprised in the resting volume of the implant. Thus, the resting volume of the implant may comprise a volume of the 3D lattice structure and the void space (e.g. an interstitial volume). The void fraction or percentage (e.g. a measure of the empty space) of the implant before insertion

into a patient may be represented by (or may be) a bulk porosity. The bulk porosity of the implant may be determined by the total void space (cm^3) within the implant divided by the total volume (cm^3) of the 3D lattice structure of the implant. Preferably, the 3D lattice structure has a bulk porosity of at least 50%. Thus, the bulk porosity of the 3D lattice structure of the implant may be at least 50%. A bulk porosity of 3D lattice structure of the implant may be at least 80% (or e.g. at least 50%, or e.g. at least 55%, or e.g. at least 60%, or e.g. at least 65%, or e.g. at least 70%, or e.g. at least 75%, or e.g. at least 85%, or e.g. at least 90%, or e.g. at least 95%). Optionally, a bulk (or overall) porosity of the implant may be between 80% and 99%. The bulk (or overall) porosity of the implant may be, e.g., at least 80%, or at least 85%, or at least 90% or at least 95%.

[0049] Additionally, or alternatively, the implant may have a material density between 0.1 gr/cm^3 and 2 gr/cm^3 . Thus, a material density of the implant may be between 0.1 gr/cm^3 and 2 gr/cm^3 , or e.g. between 0.1 gr/cm^3 and 1 gr/cm^3 , or e.g. between 0.1 gr/cm^3 and 0.75 gr/cm^3 , or e.g. between 0.1 gr/cm^3 and 0.5 gr/cm^3 . The material density may be determined by the weight of the implant divided by the resting volume of the implant before insertion into the patient. In comparison, the material density of silicone is 0.98 gr/cm^3 , and the material density of saline is 1.005 gr/cm^3 . The weight of the implant may be at least 10 times less than its volume value in milliliters, and at least 10 times less than that of a traditional non-porous silicone/saline implant (the weight of which in grams is roughly the same as its volume value in milliliters). For example, an implant having a volume of 250 ml may weigh 25 g, whereas a traditional silicone implant having a volume of 250 ml may weight 240 g, and a saline implant having a volume of 250 ml may weigh 250 g.

[0050] The plurality of unit cells may be arranged to form a porous network of the 3D lattice structure. Said porous network may have an average pore size from 0.15 mm or 0.5 mm up to 5, 6, 8, 10 or 12 mm; for example from 0.15 to 12 mm and/or between 0.5 mm and 2 mm and/or from 0.15 mm or 0.5 mm up to 5, 6, 8, 10 or 12 mm. Said pore sizes may be measured at a surface of the implant, preferably an outer surface region.

[0051] The tissue reconstruction implant has an implant surface. It may be understood that a surface of an implant may refer to (or may be) a surface, a layer, and/or a contour of said implant. The surface of the implant may comprise an outer surface region. It may be understood that an outer surface region of an implant may refer to (or may be) an outermost surface, an outermost layer, and/or an outermost contour of said implant. For example, the 3D implant may have an outer surface region (area) between 0.5 cm^2 and $40,000 \text{ cm}^2$, preferably between 5 cm^2

and 25,000 cm² or between 5 cm² and 3,000 cm² or between 5 cm² and 800 cm². For example, in case of an implant being an implant for or suitable for a breast region or a pectoral region, the outer surface (region / area) of the implant may be between 15 cm² and 3,000 cm², e.g. between 40 cm² and 800 cm² or between 30 cm² and 800 cm² or between 50 cm² and 500 cm². For example, in case of an implant being an implant for or suitable for a malar region, the outer surface (region / area) of the implant may be between 0.5 cm³ and 75 cm³, e.g. between 5 cm³ and 50 cm³ or between 5 cm³ and 15 cm³ or between 10 cm² and 50 cm². For example, in case of an implant being an implant for or suitable for a gluteal region, the outer surface (region / area) of the implant may be between 15 cm³ and 3,000 cm³, e.g. between 50 cm³ and 800 cm³. For example, in case of an implant being an implant for or suitable for a genital region, a soft tissue support, a tendon and/or a ligament, the outer surface (region / area) of the implant may be between 2.5 cm³ and 3,000 cm³, e.g. between 5 cm³ and 200 cm³. For example, in case of an implant being an implant for or suitable for a bone region, the outer surface (region / area) of the implant may be between 15 cm³ and 40,000 cm³, e.g. between 40 cm³ and 25,000 cm³ or between 100 cm³ and 25,000 cm³ or between 40 cm³ and 16,000 cm³ or between 50 cm² and 600 cm².

[0052] The outer surface region may comprise or consist of a first and a second outer surface region. The region and/or volume between the first outer surface region and the second outer surface region may define the resting volume of the implant before implantation into the patient. The outer surface region of the implant may comprise (or consist of) a first outer surface region and a second outer surface region, preferably wherein the second outer surface region is contiguous to the first outer surface region at a perimeter of the first outer surface region. For example, the outer surface region of the implant may comprise (or consist of) a first outer surface region of the implant comprising a first surface curvature, and a second outer surface region of the implant comprising a second surface curvature, preferably wherein the second outer surface region of the implant is contiguous to the first outer surface region of the implant at a perimeter of the first outer surface region. For example, the 3D lattice structure may comprise a first outer surface region of the implant comprising a first surface curvature; and a second outer surface region of the implant comprising a second surface curvature, wherein the second outer surface region of the implant is contiguous to the first outer surface region of the implant at a perimeter of the first outer surface region.

[0053] As regards the first outer surface region, the first outer surface region of the implant and/or the 3D lattice structure of the implant may comprise, or may have, a first surface curvature. The first outer surface region of the implant may be the largest planar (or e.g. flattest)

surface of the implant. For example, the first outer surface region may be a flattest surface of the implant and/or a surface with the least (or smallest) amount of curvature.

[0054] Preferably, a geometry of the first outer surface region represents a geometry of a patient's body part to be brought in contact with the implant upon insertion of the implant into said patient. Thus, the first outer surface may have a geometry that resembles the part of a patient's body the implant is to be brought into contact upon insertion. For example, assuming an implant being a breast implant, then the first outer surface of the implant may be the surface of the implant that comes into contact with the patient's chest wall and/or pectoralis muscle upon insertion of the implant.

[0055] As regards the second outer surface region, the implant and/or its 3D lattice structure may be manufactured and/or formed by sequentially printing layers to form a surface of the 3D printed lattice structure. Edge regions of the successive, sequentially printed layers may form the second outer surface region of the 3D printed structure contiguous to the first outer surface region. The second outer surface region may be defined by edges (or perimeter) of the plurality of layers. Thus, edges of the plurality of layers may define shape and/or geometry of the second outer surface region. Thus, edge regions of the layers may form the second outer surface region of the implant. The second outer surface region of the implant and/or the 3D lattice structure of the implant may comprise, or may have, a second surface curvature different to the first surface curvature. The second surface curvature may be greater than the first surface curvature. The second outer surface region of the implant may be contiguous to (e.g. abutting) the first outer surface region of the implant at a perimeter (e.g. a circumference) of the first outer surface region. For example, the second outer surface region of the implant may abut the first outer surface region, wherein the perimeter of the first outer surface region may be a shared edge (or interface) between the first outer surface region and the second outer surface region.

[0056] Preferably, a geometry of the second outer surface region represents a geometry of a patient's body part to be reconstructed by the implant upon insertion of the implant into said patient. Thus, the second outer surface may have a geometry that resembles the part of a patient's body that is to be reconstructed by upon insertion. For example, assuming an implant being a breast implant, then the second outer surface of the implant may be the surface of the implant that comes into contact with the patient's skin upon insertion of the implant and/or the second outer surface region may represent the shape of the reconstructed breast upon insertion of the implant. For example, the second outer surface region may include an upper pole portion and a lower pole portion. The upper pole portion may have a geometry of an upper portion of the

breast to be constructed by the implant. The upper portion of the breast may be the region of the breast above the nipple region of the patient towards the head of the patient. The lower pole portion may have a geometry of a lower portion of the breast to be constructed by the implant. The lower portion of the breast may be a region of the breast below the nipple region of the patient towards the feet of the patient. The upper pole portion and the lower pole portion may meet (or may be coincident) at an apex region of the second outer surface region. The location (or position) of the apex region at the second outer surface region of the implant may be based on (and/or may coincide with) the location (or position) of the nipple/areola of the breast to be constructed by the implant.

[0057] As regards the patient's body part to be brought into contact with the implant and/or to be reconstructed by the implant upon insertion of the implant into said patient, it is preferred that said patient's body part is i) a breast region, pectoral region, malar region, gluteal region or genital region, ii) a tendon and/or a ligament, or iii) a bone region. Preferably, the implant is an implant for reconstructing i) a breast region, pectoral region, malar region, gluteal region or genital region, ii) a tendon and/or a ligament, or iii) a bone region. Accordingly, it is preferred that the implant is for reconstructing i) a breast region, pectoral region, malar region, gluteal region or genital region, ii) a tendon and/or a ligament, or iii) a bone region. Alternatively or additionally, it is preferred that the implant is for supporting a soft tissue of a breast region, pectoral region, malar region, gluteal region, genital region, tendon and/or ligament. Thus, although the implant is described herein primarily with respect to a breast implant for illustrative purposes, the same description is also valid for other parts of a patient's body, such as the chest, the gluteal region (also known as buttock), the calf, parts of the face such as a cheek (or malar region) or a genital region such as the testicular region, to name only a few illustrative body regions. Thus, an implant according to the present invention can adopt any suitable form, merely depending on the tissue that is to be reconstructed, supported, augmented and/or revised. The implant may, for example, have the form of a gluteal implant as described in US patent 10,004,585, of a chest (such as a pectus implant, e.g. for the reconstruction of a pectoral or chest area of a patient's body), of a malar or cheek region or of a testicular region. Preferably, the implant is a soft tissue implant, wherein the soft tissue is preferably a soft tissue of i) a breast region, pectoral region, malar region, gluteal region or genital region and/or of ii) a tendon and/or a ligament. Alternatively, the implant may be a bone (e.g. bone tissue) implant.

[0058] Preferably, the tissue reconstruction implant is for insertion into a patient. The implant is preferably a reversibly compressible implant and/or an implant that is suitable for being folded and/or compressed such that it can be inserted into a patient minimal invasively.

[0059] The implant may be an implant for reconstructing, supporting, augmenting and/or revising at least a part of a (e.g. soft) tissue. Preferably, the implant is a single-piece reconstruction implant. Thus, the implant may be an implant for reconstructing, supporting, augmenting and/or revising the part of a (e.g. soft) tissue that requires reconstructing, supporting, augmenting and/or revising. Herein, support of a (soft) tissue may also encompass reinforcement of a (soft) tissue. (Soft) Tissue reinforcement may be advantageous e.g. in the context of treating hernia or pelvic organ prolapse and/or for providing prosthesis support e.g. in case of a silicone prosthesis.

[0060] Preferably, the tissue to be reconstructed is naturally rebuild and the implant resorbed upon insertion into a patient's body within some time, such that (substantially) no implant derived material will be therein after e.g. 15 years (or after e.g. 10 years, or after e.g. 5 years) after the implantation. Therefore, the material (composition) of the implant is to be selected accordingly.

[0061] The tissue reconstruction implant consists of a bio-resorbable material. A bio-resorbable material may refer to a material that is degradable and/or resorbable by an organism like a patient. Examples of suitable bio-resorbable materials may include surface-degradable polymers. A surface-degradable polymer may include or may be a polymer that degrades predominantly via a surface degradation mechanism as opposed to bulk degradation. Herein, surface degradation refers to the breakdown of the exterior surface of the polymer material as opposed to the inside of the polymer material. The breakdown of the exterior surface of the polymer material may occur at at least 2 times (or e.g. at least 5 times, or e.g. at least 10 times, or e.g. at least 100 times) the speed of breakdown of the interior of the polymer material. Further herein, bulk degradation refers to the degradation or break down of both the exterior surface and the interior of the material simultaneously, and at the same rate (e.g. the ratio of speed of exterior breakdown to speed of interior breakdown is less than 1.2). For example, the bio-resorbable material may be a material as described in International patent application WO 2016/038083.

[0062] The implant consists of a bio-resorbable material that may be capable of being (e.g. substantially or fully) resorbed by a patient and/or a patient's body, preferably within less than 15 years (or e.g. within less than 10 years or e.g. within less than 5 years) upon insertion of

the implant into said patient. Thus, the implant may serve as a graft for patient cells. For example, natural tissue reconstruction and/or growth may be supported, guided and/or facilitated by the implant for a period of time. Said period of time may depend, e.g., on structure and/or chemical properties of the bio-resorbable material(s) used, filament diameter, implant surface area, implant size, localization of the implant when inserted into a patient and/or properties of the patient the implant is inserted into like age and metabolism. For example, when inserted into a patient an implant consisting of a bio-resorbable material may be resorbed and/or degraded faster when comprising and/or being made of filaments with an on average smaller diameter than with an on average larger diameter. A reason for the latter may be that a larger filament diameter may relate to a larger filament surface that may be affected stronger by surface degradation than a smaller filament surface in case of a smaller filament diameter. As another example, when inserted into a patient an implant consisting of a bio-resorbable material may be resorbed and/or degraded faster when inserted into a patient's body region closer to the chest than when inserted into an extremity of a patient like a leg. A reason for the latter may be that a metabolic activity in the body region closer to the chest is higher than in an extremity and that surface degradation may be affected by the metabolic activity of the patient's body region the implant is inserted into. As a further example, an implant consisting of a bio-resorbable material may be resorbed and/or degraded faster when inserted into a younger patient compared to an older patient. A reason for the latter may be that a metabolic activity in a younger patient may be higher than in an older patient and that surface degradation may be affected by the metabolic activity of the patient the implant is inserted into. As the bio-resorbable material is resorbed over time by the patient, the patient will not comprise non-patient derived material originating from the tissue reconstruction implant after some time.

[0063] The bio-resorbable material may be capable of being resorbed by a patient within less than 15 years upon insertion of the implant into said patient, preferably within less than 10 years or within less than 5 years. As disclosed e.g. in the paragraph before, is understood by the skilled artisan that degradation may depend on various factors like e.g. surface area, patient metabolism, age, location of implant etc. Thus, the implant may be capable of being resorbed by a patient e.g. within less than 10 years, or e.g. within less than 9 years, or e.g. within less than 8 years, or e.g. within less than 7 years, or e.g. within less than 6 years, or e.g. within less than 5 years, or e.g. within less than 4 years, or e.g. within less than 3 years. Optionally, the bio-resorbable material is capable of being resorbed by a patient e.g. after 15 years, or e.g. after 10 years, or e.g. after 5 years, or e.g. after 3 years, or e.g. after 2 years, or e.g. 1 year upon insertion of the implant into said patient. Thus, e.g. 15 years after insertion of the implant (preferably e.g.

within less than 10 years or e.g. within less than 5 years), a patient, into whom the implant was inserted into, may have a reconstructed natural (patient-derived) tissue.

[0064] The bio-resorbable material may comprise, or may be, a polymer selected from the group consisting of polycaprolactone, poly(1,3-trimethylene carbonate), polylactide, polyglycolide, poly(ester amide), poly(ethylene glycol)/poly(butylene terephthalate), poly(4-hydroxybutyrate), polydioxanone, poly(glycerol sebacate), poly(1,8-octanediol-co-citric acid), poly(1,10-decanediol-co-D,L-lactic acid), poly(diols citrate), poly(glycolide-co-caprolactone), poly(1,3-trimethylene carbonate-co-lactide), poly(1,3-trimethylene carbonate-co-caprolactone) and a copolymer of at least two of said polymers. Optionally, the bio-resorbable material may comprise polycaprolactone. Optionally, the bio-resorbable material may comprise, or may be, a copolymer of polycaprolactone and either poly-trimethylene carbonate or polylactide. Optionally, the bio-resorbable material may comprise one or more additives like calcium phosphate, hydroxyapatite, bioactive glass etc. This may be advantageous e.g. in case of a bone implant as such (an) additive(s) may support and/or facilitate bone reconstruction.

[0065] Preferably, the bio-resorbable material comprises, or consists, of polycaprolactone (PCL). PCL may also be referred to as poly- ϵ -caprolactone. PCL relates to synthetic polyester plastic and may be characterized by a melting point of about 60°C and/or a glass transition temperature of about -60°C. PCL can be degraded by hydrolysis of ester linkages under physiological conditions (such as in a patient's body). Compared to other biodegradable polymers PCL may have a comparatively long degradation time. PCL may have beneficial properties in view of defined chemistry and processability, and may have advantageous mechanical properties. PCL may stimulate, e.g., collagen production, and may be beneficial for tissue regeneration. Thus, PCL may be advantageous for tissue reconstruction implants. For example, a bone tissue implant may comprise PCL. As another example, a soft tissue implant like for example a breast implant may comprise or consist of PCL. However, PCL may be hydrophobic and this may hamper cell adhesion and thus, tissue reconstruction.

[0066] According to the method of the present invention, the surface of an implant is exposed to a surface treatment, wherein the surface treatment is suitable for making the surface of the implant hydrophilic, whereby a hydrophilic implant surface is obtained. Different kinds of surface treatments and/or surface treatment parameter combinations may be envisioned under the condition that the surface treatment is suitable for making the surface of the implant hydrophilic. Examples of surface modification techniques may comprise chemical treatments, blending, coatings and/or film deposition, (e.g. ion beam) radiation, and plasma treatment. Herein

preferred examples of a surface treatment may be i) an etching treatment, preferably an acid or alkaline etching treatment, more preferably a sodium hydroxide treatment, and/or ii) a plasma treatment.

[0067] In case of a plasma treatment for example, effects of a surface treatment may vary depending on gas composition, frequency, exposure time, pressure, position within a treatment chamber and/or number of objects within a treatment chamber for example. Herein, the inventor surprisingly found that there may exist sweet spots of parameters and/or parameter combinations of a surface treatment like a plasma treatment that allow obtaining a hydrophilic implant surface without damaging the implant. Such a damage of the implant may be indicated by a change in colour and/or structure of the implant. For example, a change of the implant's colour with the colour being yellowish after a plasma surface treatment compared to the implant's colour before said treatment may be indicative of a damage of the implant due to an undesired strong plasma treatment effect. More specifically, in view of currently available knowledge about surface treatments like plasma treatment it was hypothesized that for example smaller inventive implants would require less surface treatment exposure compared to larger inventive implants. However, the inventor surprisingly found that the opposite holds true for implants according to the present invention. Without being bound by theory it is believed that compared to smaller implants, larger implants have more material and/or structure that is exposed to a surface treatment and that in case of a plasma treatment reflects more plasma, thereby intensifying the surface treatment effect. Thus, larger implants are preferably less exposed to a plasma treatment compared to smaller implants. Accordingly, there may be combination of parameters and/or parameter ranges for a given implant that may depend e.g. on the implant's dimension and/or size, material, and structural complexity as well as the amount of implants in the chamber used for the surface treatment. While the "net effect" of a surface treatment on an implant's (e.g. structural) integrity and surface hydrophilicity may be considered crucial for obtaining a hydrophilic implant surface, any herein disclosed specific combination of surface treatment parameters and/or parameter ranges may be understood as illustrative and/or as dependent on the implant in the context of which it is disclosed herein. For example, a bone implant according to the present invention may require a stronger net effect of a (e.g. plasma) surface treatment compared to an inventive malar region implant. As another example, the net effect of a surface treatment like a plasma treatment may be smaller in case of several inventive bone implants in a plasma treatment chamber compared to the net effect of a plasma treatment required in case of single malar region implant in a plasma treatment chamber. In any case, the surface treatment requires being suitable for making the surface of the implant hydrophilic, whereby a hydrophilic implant surface is

obtained, according to the method of the present invention. Preferably, said surface treatment is being at the same time not suitable for damaging the implant that is exposed to the surface treatment according to the method of the present invention.

[0068] Preferably, the surface treatment is a plasma treatment. Plasma treatment may be an effective surface treatment for improving the surface and/or biological properties of polymeric materials like biodegradable materials, e.g. comprising PCL. Plasma treatment may relate to a non-solvent process involving the use of chemical reagents. Plasma treatment may change chemical composition, wettability, surface energy, refractive index, hardness, chemical inertness and/or biocompatibility of polymeric materials like PCL. In case of PCL for example, weak chemical bonds may be replaced due to plasma treatment exposure with highly reactive chemical groups, like e.g. carboxy, hydroxy and aldehyde groups, by the use of glow discharges of non-deposition gases such as oxygen. Such chemical groups may act as binding sites that may facilitate protein adsorption and/or cell adhesion.

[0069] Preferably, the plasma treatment is an oxygen plasma treatment. An oxygen plasma treatment may increase on the implant's surface the amount of oxygen-comprising polar functional groups and/or C₃ groups due to an oxidation of the implant material on the implant surface for example in case of an implant comprising or consisting of PCL. Such oxygen-comprising groups may result in an increase in total surface energy on the surface of the implant. Thus, oxygen plasma treatment may improve surface hydrophilicity of an implant, preferably of an implant according to the present invention and/or an implant comprising or consisting of PCL.

[0070] Preferably, the plasma treatment is a low frequency plasma treatment, preferably a low frequency plasma treatment at (about) 40 kHz. A low frequency plasma treatment may be suitable for obtaining more evenly distributed plasma within the treatment chamber and thus, a more evenly distributed surface treatment effect across the surface of the exposed implant.

[0071] Suitable oxygen plasma treatment parameters have been identified as disclosed in the following; said parameters and/or parameter ranges may be especially suitable for surface treatment of a soft tissue reconstruction implant like e.g. a breast implant without being limited thereto. For example, a plasma treatment may be performed for at least 10 sec or at least 15 sec or at least 20 sec or at least 25 sec or at least 30 sec, or for at least 1 min or for at least 5 min or for at least 20 min. For example, an oxygen plasma treatment may be performed for a period of time ranging between 10 sec and 240 min or between 15 sec and 240 min or between 15 sec and 90 min or between 15 sec and 60 min or between 15 sec and 30 min or between 15 sec and 15

min. For example, an oxygen plasma treatment may be performed for a period of time ranging between 5 min and 60 min or between 5 min and 30 min. For example, an oxygen plasma treatment may be performed for a period of time ranging between 20 sec and 240 min or between 25 sec and 240 min or between 30 sec and 240 min, or between 5 min and 240 min or between 15 min and 150 min or between 20 min and 125 min. For example, an oxygen plasma treatment may be performed for a period of time ranging between 20 min and 35 min, e.g. for about 25 or about 30 min. For example, an oxygen plasma treatment may be performed for a period of time ranging between 10 sec and 90 min or between 10 sec and 60 min or between 10 sec and 30 min, e.g. between 10 sec and 20 min or between 15 sec and 15 min or between 15 sec and 10 min or between 15 sec and 5 min or between 30 sec and 10 min or between 30 sec and 2 min or between 1 min and 50 min or between 1 min and 35 min or between 1 min and 30 min. For example, in case of a malar region implant, an oxygen plasma treatment may be performed for a period of time ranging between 15 sec and 5 min, preferably between 30 sec and 2 min. For example, in case of a breast region implant, an oxygen plasma treatment may be performed for a period of time ranging e.g. between 10 sec and 90 min or e.g. between 15 sec and 60 min or e.g. between 15 sec and 30 min or e.g. between 15 sec and 15 min, preferably e.g. between 30 sec and 10 min or e.g. between 2.5 min and 45 min or e.g. between 2.5 min and 7.5 min or e.g. between 5 min and 30 min. For example, in case of a bone region implant, an oxygen plasma treatment may be performed for a period of time ranging between 1 min and 50 min, preferably between 2.5 min and 35 min or between 5 min and 30 min. For example, in case of a pectoral region implant, a gluteal region implant, a genital region implant, a soft tissue support implant, a tendon and/or ligament implant, an oxygen plasma treatment may be performed for a period of time ranging between 10 sec and 30 min, preferably between 15 sec and 15 min. For example, the plasma treatment may be performed by applying a used power of less than 70 watts (W) or of less than 50 W or (e.g. preferably) of less than 40 W. For example, the plasma treatment may be performed by applying a used power of between 20 W and 70 W, preferably of between 20 W and 40 W or of between 50 W and 70 W. For example, the plasma treatment may be performed at (about) 30 W. The skilled artisan understands that there may be a relationship between used power and exposure time in order to observe a given “net effect” and/or to apply a given amount of plasma energy to a surface. Accordingly, the skilled artisan understands exposure time and applied power may be given herein for the purpose of illustration and that e.g. in case of a used power differing from the value or range(s) specified herein, the respective exposure time may have to be amended accordingly. For example, a higher used power than specified herein may be combined with less exposure time and vice versa. Also, the plasma treatment may be performed

at a given pressure. For example, the plasma treatment may be performed by applying a pressure of about 0.3 mbar. For example, the plasma treatment may be performed by putting the implant on a glass tray in a plasma treatment device. For example, one or more of these parameters and/or ranges may be applied in combination for a plasma treatment of an implant.

[0072] The tissue reconstruction implant may have an (e.g. hydrophobic) implant surface that is exposed to a surface treatment, wherein the surface treatment is suitable for making the surface of the implant hydrophilic, whereby a hydrophilic implant surface is obtained. It may be understood that hydrophilicity may refer to an affinity for water. It may also be understood that hydrophobicity may refer to a lack of affinity for water. Hydrophobicity and/or hydrophilicity may be assessed, e.g., using a surface tension test according to ISO 8296:2003 and/or measured, e.g., by determining a (e.g. water) contact angle.

[0073] Hydrophilicity may be assessed, e.g., by determining a (e.g. water) contact angle. A contact angle may be measured, e.g. using commercially available devices, like an optical tensiometer, by applying a droplet of liquid, preferably of (e.g. distilled) water, onto a (solid) surface in a gas atmosphere and measuring the angle. The angle may be geometrically defined as the angle formed by the liquid surface at the three-phase contact point where liquid, gas, and (e.g. solid) surface intersect. The angle may be understood as the angle between the (e.g. solid) surface and a tangent to the liquid surface at said three-phase contact point. In case of a (e.g. water) contact angle measurement, a surface may be commonly considered hydrophilic when said angle is $<90^\circ$. However, herein a “hydrophilic surface” may be understood in the context of a (3D) implant according to the present invention as a surface having a (water) contact angle of $<50^\circ$. The reasoning for deviating from the common understanding is based on the following observation. Contact angle measurements are well-optimized for substantially flat surfaces like plastic films, while facing challenges in case of 3D implants according to the present invention that may have a porous structure and/or that may have only small and/or few (substantially) flat surfaces, if any. Upon having identified an outer surface region suitable for obtaining contact angle measurements reproducible between implants of the same structure, size and type, contact angles of (about) 62° (degrees) were observed for untreated PCL, which is commonly considered hydrophobic. Thus, in view of observed “hydrophobic” contact angles of (about) 62° , herein in the context of a (3D) implant according to the present invention a “hydrophilic” surface may have a contact angle of less than (about) 62° , herein in particular a contact angle of less than 50° .

[0074] Preferably, the hydrophilic implant surface has a contact angle of less than 40° , or e.g. of less than 35° , or e.g. of less than 30° , or e.g. of less than 25° . Preferably, the hydrophilic

implant surface as a contact angle between 20° and 40°, or e.g. between 25° and 40°, or e.g. between 20° and 35°, or e.g. between 25° and 35°. The contact angle may be measured at at least two different implant positions, preferably at at least two different outer surface implant positions. For example, the contact angle may be measured at, e.g., three different implant positions on a first outer surface region and/or at, e.g., three different implant positions on a second outer surface region. The contact angle may be measured using a drop (of liquid, preferably of, e.g. distilled, water) with a volume of (about) 1 µl (per measurement). For example, the contact angle may be measured at, e.g., three different implant positions on a first outer surface region and/or at, e.g., three different implant positions on a second outer surface region using at each of said positions a drop (of liquid, preferably of, e.g. distilled, water) with a volume of (about) 1 µl. It may be preferred that the implant surface is assessed hydrophilic when each of the measurements performed at at least two different outer surface regions (using a drop 1 µl liquid per measurement) gives a contact angle of less than 40°, or e.g. of less than 35°, or e.g. of less than 30°, or e.g. of less than 25°, and/or between 20° and 40°, or e.g. between 25° and 40°, or e.g. between 20° and 35°, or e.g. between 25° and 35°.

[0075] However, it may be difficult to (e.g. reproducibly) perform a contact angle measurement on 3D surfaces such as in case of a porous network and/or a surface with a curvature as in case of an implant exposed to a surface treatment according to the present invention and/or an implant according to the present invention. For example, the liquid drop of 1 µl per measurement may run and/or roll down the curved surface. In view of these challenges, a test was required that allows an easy and fast assessment of a hydrophilicity of a 3D surface which may refer herein to a curved and/or porous and/or multi-contoured surface.

[0076] Additionally or alternatively, a test according to surface tension test according to ISO 8296:2003 may be performed. ISO 8296:2003 refers to an international standard that specifies a method for determining the wetting tension of a plastic film or sheeting in contact with drops of specific test solutions comprising one or more solvents. ISO 8296:2003 is shown in **Figure 1**. According to the basic principle of ISO 8296:2003, a series of mixtures of solvents of gradually increasing surface tension may be applied to a surface of a plastic film until a mixture is obtained that just can wet the film surface. The wetting tension of the tested surface may be approximated by the surface tension of said obtained particular mixture. It may be understood that surface tension may be defined as a property of a surface of a liquid that allows said liquid to resist an external force due to the cohesive nature of the liquid's molecules. If the cohesion force within a droplet of the liquid is less than the adhesion force to a surface of a solid

like a plastic film, the droplet may spread over the surface of the solid and the solid may be wetted. In this case, the solid may be considered hydrophilic. If the cohesive force within the liquid droplet is greater than the adhesive force, the liquid droplet may have a spherical shape and the surface may not be or may be hardly wetted. In this case, the solid may be considered hydrophobic.

[0077] More specifically, according to ISO 8296:2003, a test solution with a given surface tension is applied to a test object being a plastic film or sheeting and spread over a surface area of said test object of at least 6 cm², wherein the quantity of the test solution shall be such that it forms a thin film of liquid. The liquid film of the test solution is to be investigated under glancing illumination and the time is to be taken for the applied continuous liquid film to break up into droplets. If the liquid film holds together for more than 2 sec, the test is to be repeated on a new test object with a test solution having a higher surface tension than the previously used test solution until the film breaks up in less than 2 sec. If the film holds for less than 2 sec, the test is to be repeated on a new test object with a test solution having a lower surface tension than the previously used test solution until the film persists for 2 sec. The surface tension of the test solution that comes nearest to wetting the surface of the test object for 2 sec is to be reported as the wetting tension of the plastic film or sheeting. Furthermore, suitable test solutions are given with their respective surface tension in Table 1 of ISO 8296:2003. For example, according to said Table the wetting tension of a plastic film or sheeting is 73.0 mN/m in case of a test solution of 100% water. As a further example, the wetting tension of a plastic film or sheeting is 70.0 mN/m for a test solution of 90% water and 10% formamide. Thus, the ability of plastic films and sheeting to retain e.g. inks may be related to a wettability of their surface and/or a hydrophobicity and/or hydrophilicity of their surface. However, ISO 8296:2003 has been designed for testing a plastic film or sheeting and thus, a substantially two-dimensional test object with an ideally (substantially) planar surface and/or surface region.

[0078] Thus, the inventor developed a qualitative test by adapting the test following ISO 8296:2003 to 3D surfaces. The developed test, herein referred to as “ink test”, can give a binary result (e.g. ink colored test object = hydrophilic test object surface). Moreover, the test can be easily performed and does not require any specific device, as it is the case for a contact angle measurement. Thus, the test may be suitable for routine quality checks and associated with low costs compared to a contact angle measurement.

[0079] Herein, an implant surface is considered hydrophilic when assessed using an ink test following ISO 8296:2003 and adapted herein (as part of the invention) to a three-

dimensional (3D) surface, wherein said ink test comprises incubating the implant for 1 min in a solution consisting of an ink with a surface tension of 72 mN/m and water and wherein after incubation of the implant in said solution an ink colored implant surface is indicative for a hydrophilic implant surface. Preferably, the implant is incubated by dropping the implant into said ink:water solution, preferably ink:distillate water solution. As the implant may be substantially colorless, colorless, substantially white and/or white, an assessment of hydrophilicity of an implant surface may be facilitated by using an ink with a color like blue or green. For example, an implant surface may be considered hydrophilic when in case of a blue colored ink after incubation of the implant in the ink:(e.g. distillate) water solution (and e.g. the implant has been taken out of the solution after said incubation) a blue colored implant surface is observed. Preferably, the implant surface remains (substantially) colored, for example, for more than 10 weeks when the implant is stored at 4°C or less after incubation of the implant in the ink:(e.g. distillate) water solution. An ink with a surface tension of 72 mN/m in accordance with ISO 8296 are commercially widely available, e.g. from Fischer Test Tinten (Rheinstraße 25 A, 76479 Steinmauern, Germany), the “BLUE Test Inks” of Arcotest GmbH, 71297 Moensheim, Germany (for, example, the ink set with article number 40.302XX.0), the “Series B” inks of Tigres GmbH, 21436 Marschacht, Germany, the Dynelevel test ink in the ranges 28 to 72 mN/m (available in 10ml, 30ml, 50ml, 100ml and 1000ml PET bottles) from SEST Messtechnik, 79588 Efringen-Kirchen, Germany) to name only a few examples of such a commercially available ink. By mixing the ink with, preferably distillate, water, costs associated with the ink may be reduced. Optionally, a solution is used consisting of ink and distillate water. Optionally, a solution is used consisting of ink and distillate water in a ratio of ink:distillate water of between (about) 1:15 and (about) 1:75, e.g. of (about) 1:60 or (preferably) of (about) 1:30. Such a ratio may be suitable to reduce costs associated with the ink while still facilitating visual assessment of hydrophilicity of the implant surface. For example, 5 ml of an ink with a surface tension of 72 mN/m may be mixed with 300 ml of (preferably distillate) water in case of a solution consisting of ink and distillate water in a ratio of ink:distillate water of (about) 1:60. For example, 1 ml of an ink with a surface tension of 72 mN/m may be mixed with 30 ml of (preferably distillate) water in case of a solution consisting of ink and distillate water in a ratio of ink:distillate water of (about) 1:30. For example, after incubation the implant may be taken out of the ink:distillate water solution, put on a wipe, such as a “Kimtech wipe” (Kimwipes™ Delicate Task Wipes by Kimtech Science™, available from Kimberly-Clark) or a wipe e.g. from Coventry Econowipes™ (e.g. Articiel 6709), and put on a further wipe, such as a further “Kimtech wipe” or a further wipe e.g. from Coventry Econowipes™, for drying and (e.g. visual) assessment. If

the surface of the implant is (preferably entirely and/or homogeneously) ink colored, the implant surface is preferably considered hydrophilic. Optionally, the implant may be scratched (before the drying step) on a further wipe, such as a further “Kimtech wipe” or a further wipe e.g. from Coventry Econowipes™. In the latter example (comprising the optional step of scratching on a further wipe before drying), the wipe may be (substantially) colorless and the surface of the implant ink colored in case the implant surface is hydrophilic. Additionally, or alternatively, there may be cases where it may be appropriate to include an optional washing step (before the drying step). For example in case of the method comprising an optional washing step, the ink tested implant may be washed with water, for example with distillate water, to assess whether any ink is washed out. If this is the case, the ink test may be considered failed. Using an ink test following ISO 8296:2003 and adapted to a 3D surface as described herein may be especially advantageous in case of the 3D implant being not a compact implant like a silicone or silicone-based implant but comprising a three-dimensional (3D) lattice structure, preferably with a porous network.

[0080] Thus, by exposing a surface of a 3D tissue reconstruction implant to a surface treatment, wherein the surface treatment is suitable for making the surface of the implant hydrophilic, a hydrophilic implant surface can be obtained. Thus, the implant’s surface is amended to facilitate cell adhesion, cell grafting and (natural) tissue reconstruction. Further, an ink test is provided that may be suitable to assess hydrophilicity of the obtained implant surface.

[0081] Hence, by performing the method according to the present invention a 3D tissue reconstruction implant with a hydrophilic implant surface can be obtained.

II. Tissue reconstruction implant

[0082] The present invention relates to a tissue reconstruction implant, the implant having a hydrophilic implant surface, wherein the implant is a three-dimensional (3D) implant consisting of a bio-resorbable material, and wherein the implant surface is considered hydrophilic when assessed using an ink test following ISO 8296:2003 and adapted to a three-dimensional (3D) surface, wherein said ink test comprises incubating the implant for 1 min in a solution consisting of an ink with a surface tension of 72 mN/m and water, and wherein after incubation of the implant in said solution an ink colored implant surface is indicative for a hydrophilic implant surface.

[0083] The tissue reconstruction implant may be obtained by or obtainable by the method according to the present invention. The implant according to the present invention is a 3D

implant that may be for and/or suitable for tissue reconstruction, (soft) tissue support, tissue augmentation and/or implant revision. The implant may be a bio-resorbable implant, which may be used to reconstruct and/or augment and/or support e.g. a patient's breast region, pectoral region, malar region, gluteal region or genital region, or bone region, preferably as a single-piece implant. Accordingly, the implant may be a soft tissue implant, wherein the soft tissue is preferably a soft tissue of i) a breast region, pectoral region, malar region, gluteal region or genital region, and/or of ii) a tendon and/or ligament to be reconstructed, supported, augmented, and/or revised. The implant may be a reversibly compressible implant and/or an implant that is suitable for being folded and/or compressed such that it can be inserted into a patient minimal invasively. Preferably, the implant of the invention is for insertion into a patient.

[0084] As regards the tissue reconstruction implant, the same applies as stated herein above in the context of the tissue reconstruction implant exposed to a surface treatment according to the method of the present invention. Moreover, also the other features of such a tissue reconstruction implant, alone or in combination, can be as described herein above.

[0085] For example, as regards the structure of the implant according to the present invention, said implant may be an implant according to the disclosure(s) of EP application number 22189015, WO 2021/043950, WO 2022/018124, WO/2023/094674, WO/2019/238716 and/or WO/2021/156292, preferably at least of WO 2021/043950. Additionally, or alternatively, the implant may be an additively manufactured implant, preferably a 3D printed implant, preferably 3D printed using a melt extrusion-based method and/or a selective-laser-sintering method. For example, in case of a 3D printed implant, the filaments may have an average diameter between 25 μm and 7.5 mm, preferably between 50 μm and 5 mm or between 50 μm and 600 μm . Said filaments may be arranged to form a 3D lattice structure. For example, filaments may be deposited as intersecting lines that may be configured to form unit cells that may form a 3D lattice structure. Additionally or alternatively, the implant may comprise a 3D lattice structure. The 3D lattice structure may be formed by a plurality of unit cells connected to each other. A unit cell may be a 2D basic unit of the 3D lattice structure. Unit cells may be arranged to form layers successively stacked on top of each other, wherein each layer may comprise a lattice arrangement of 2D unit cells. Individual unit cells of the plurality of unit cells may be reversibly compressible spring-like unit cells.

[0086] Additionally, or alternatively, the implant may comprise a 3D lattice structure, wherein the 3D lattice structure may define a resting volume of the implant. The 3D lattice structure may be a reversibly compressible 3D lattice structure and/or the 3D lattice structure

may be reversibly compressible to at least 80% of its resting volume. Thus, the implant may be a reversibly compressible 3D implant. Preferably, the implant is suitable for being folded and/or compressed such that it can be inserted into a patient minimal invasively.

[0087] Additionally, or alternatively, the plurality of unit cells may be arranged to form a porous network of the 3D lattice structure. For example, the porous network may have an average pore size from 0.15 mm or 0.5 mm up to 5, 6, 8, 10 or 12 mm. For example, the porous network may have an average pore size between 0.15 to 12 mm and/or between 0.5 mm and 2 mm and/or from 0.15 mm or 0.5 mm up to 5, 6, 8, 10 or 12 mm. For example, the porous network may have an average pore size between 0.5 mm and 2 mm, between 0.5 mm and 5 mm, between 0.5 mm and 6 mm, between 0.5 mm and 8 mm, between 0.5 mm and 10 mm, or between 0.5 mm and 12 mm. The 3D lattice structure implant may have a bulk porosity of at least 50%. Additionally or alternatively, the wherein a material density of the implant is between 0.1 gr/cm³ and 2 gr/cm³.

[0088] Additionally or alternatively, as regards the bio-resorbable material, the implant according to the present invention consists of, said bio-resorbable material comprise, or may be, a polymer selected from the group consisting of polycaprolactone, poly(1,3-trimethylene carbonate), polylactide, polyglycolide, poly(ester amide), poly(ethylene glycol)/poly(butylene terephthalate), poly(4-hydroxybutyrate), polydioxanone, poly(glycerol sebacate), poly(1,8-octanediol-co-citric acid), poly(1,10-decanediol-co-D,L-lactic acid), poly(diols citrate), poly(glycolide-co-caprolactone), poly(1,3-trimethylene carbonate-co-lactide), poly(1,3-trimethylene carbonate-co-caprolactone) and a copolymer of at least two of said polymers. It may be preferred that the bio-resorbable material comprises polycaprolactone. Optionally, e.g. in case of a bone implant, the bio-resorbable material may comprise one or more additives like calcium phosphate, hydroxyapatite, bioactive glass etc. Additionally, or alternatively, the bio-resorbable material may be capable of being resorbed by a patient, preferably within less than 15 years (or e.g. within less than 10 years or e.g. within less than 5 years) upon insertion of the implant into said patient.

[0089] As the bio-degradable material may be hydrophobic and/or not hydrophilic to an extent beneficial for cell adhesion, a surface of the implant may have been exposed to a surface treatment according to the method of the present invention. To ensure hydrophilicity of the implant surface e.g. after surface treatment, the implant surface may be assessed using an ink test following ISO 8296:2003 and adapted to a 3D surface, wherein said ink test comprises incubating the implant for 1 min in a solution consisting of an ink with a surface tension of 72

mN/m and water and wherein after incubation of the implant in said solution an ink colored implant surface is indicative for a hydrophilic implant surface. The solution used in the ink test may consist of the ink with the surface tension of 72 mN/m and distillate water, preferably in a ratio of ink:distillate water of between (about) 1:15 and (about) 1:75, more preferably in a ratio of ink:distillate water of (about) 1:60 or of (about) 1:30. Additionally, surface tension may be assessed using a contact angle measurement. For example, the hydrophilic implant surface may have a contact angle of less than 40°, preferably of less than 35° and/or a contact angle between 20° and 40°. The contact angle may be measured at at least 2 different implant positions, preferably at at least 2 different outer surface implant positions. The contact angle may be measured using a drop with a volume of about 1 µl.

[0090] Additionally, or alternatively, the implant according to the present invention may have a resting volume between 0.5 cm³ and 40,000 cm³, preferably between 5 cm³ and 25,000 cm³ or between 5 cm³ and 3,000 cm³ or between 5 cm³ and 800 cm³. As regards illustrative examples of implant (resting) volumes, reference is made to the examples given herein above in the context of the tissue reconstruction implant exposed to a surface treatment according to the method of the present invention. Additionally or alternatively, as regards the surface of the implant according to the present invention, said implant hydrophilic implant surface may comprise an outer surface region of the implant. The implant may have an outer surface region (area) between 0.5 cm² and 40,000 cm², preferably between 5 cm² and 25,000 cm² or between 5 cm² and 3,000 cm² or between 5 cm² and 800 cm². As regards illustrative examples of implant outer surface (regions / areas), reference is made to the examples given herein above in the context of the tissue reconstruction implant exposed to a surface treatment according to the method of the present invention. The outer surface region of the implant may comprise a first and a second outer surface region, wherein edge regions of the layers (formed by unit cells of the 3D lattice structure) may form the second outer surface region of the implant. Accordingly, the 3D lattice structure of the implant may comprise i) a first outer surface region of the implant comprising a first surface curvature. and ii) a second outer surface region of the implant comprising a second surface curvature, wherein the second outer surface region of the implant may be contiguous to the first outer surface region of the implant at a perimeter of the first outer surface region. For example, a geometry of the first outer surface region may represent a geometry of a patient's body part to be brought in contact with the implant upon insertion of the implant into said patient. For example, a geometry of the second outer surface region may represent a geometry of a patient's body part to be reconstructed by the implant upon insertion of

the implant into said patient. The patient's body part may be i) a breast region, pectoral region, malar region, gluteal region or genital region, ii) a tendon and/or a ligament, or iii) a bone region.

[0091] Additionally or alternatively, the implant may be for reconstructing i) a breast region, pectoral region, malar region, gluteal region or genital region, ii) a tendon and/or a ligament, and/or iii) a bone region. The implant may be a soft tissue implant and/or a soft tissue support implant, wherein the soft tissue may be a soft tissue of i) a breast region, pectoral region, malar region, gluteal region or genital region, and/or of ii) a tendon and/or a ligament. The implant may be a single-piece reconstruction implant. The implant may be for insertion into a patient, preferably for minimal-invasive insertion into a patient.

III. Applications of the implant of the invention

[0092] The present invention further relates to a tissue reconstruction implant according to the present invention for use in a method of reconstructing, augmenting and/or revising a tissue and/or supporting a (soft) tissue, wherein the implant is inserted into a patient. As regards the implant, the same applies as stated herein in the context of the implant according to the present invention, including features and advantages – alone or in combination – mentioned herein above (cf. e.g. sections I. and II. above). For example, the implant may be a 3D implant, preferably a 3D single piece implant. For example, the implant may be a reversibly compressible 3D implant. For example, the implant may be inserted into a patient minimal invasively.

[0093] The present invention also relates to a tissue reconstruction implant according to the present invention for use in tissue reconstruction, (soft) tissue support, tissue augmentation and/or implant revision, wherein the implant is inserted into a patient. As regards the implant, the same applies as stated herein in the context of the implant according to the present invention, including features and advantages – alone or in combination – mentioned herein above (cf. e.g. sections I. and II. above). For example, the implant may be a 3D implant, preferably a 3D single piece implant. For example, the implant may be a reversibly compressible 3D implant. For example, the implant may be inserted into a patient minimal invasively.

[0094] The present invention further relates to a use of the tissue reconstruction implant according to the present invention for reconstructing, augmenting and/or revising a tissue and/or supporting a (soft) tissue, wherein the implant is inserted into a patient. As regards the implant, the same applies as stated herein in the context of the implant according to the present invention, including features and advantages – alone or in combination – mentioned herein above (cf. e.g. sections I. and II. above). For example, the implant may be a 3D implant, preferably a 3D single

piece implant. For example, the implant may be a reversibly compressible 3D implant. For example, the implant may be inserted into a patient minimal invasively.

IV. Kit comprising the implant of the invention

[0095] The tissue reconstruction implant according to the present invention may be part of a kit. This may be advantageous for storing, selling, shipping, transferring and/or handling of the implant before the implant is inserted into a patient.

[0096] Accordingly, the present invention further relates to a kit comprising the implant according to the present invention comprised in a packaging, preferably in a multiple layer packaging. A packaging may be beneficial for protecting the enclosed, preferably sterile, implant from environmental influences including (e.g. bacterial) contamination, moisture and/or mechanical forces. Thus, the implant may be safely stored, transferred and/or handled.

[0097] The packaging may comprise or consist of a blister packaging. For example, the packaging may be a blister packaging. As another example, the packaging may be a double blister packaging, preferably a blister-in-a-blister packaging. A blister packaging may comprise a transparent packaging region. This may allow for a visual (e.g. quality) control of the enclosed implant.

[0098] The packaging may also be a multiple layer packaging, wherein preferably at least one of the layers is (or functions as) a moisture barrier. A moisture barrier may advantageously protect the implant that is enclosed in the packaging from a change in hydrophilicity of the implant surface, e.g. due to exposure to moisture, for example during transport or storage. Respective suitable packaging materials may comprise or consist of polyethylene (films) lined with aluminum. Thus, it may be preferred that at least one of the layers of the multiple layer packaging comprises or consists of polyethylene lined with aluminum.

[0099] At least one of the layers of the multiple packaging may comprise or consist of polyethylene, preferably comprising or being made of polyethylene filaments arranged to form a network. A suitable commercially available example of such a packaging layer may be Tyvek®, available from DuPont. A layer comprising or consisting of polyethylene may advantageously protect the in the packaging enclosed implant against mechanical forces. Thus, it may be preferred that at least one of the layers of the multiple layer packaging comprises or consists of polyethylene.

[00100] Preferably, the kit comprises the implant according to the present invention comprised in a multiple layer packaging, said packaging comprising at least i) an inner packaging layer being a moisture barrier and ii) an outer packaging layer providing protection against mechanical forces. An inner packaging layer may be a layer of the multiple layer packaging that is in contact with the implant and/or in contact with the outer layer without being in contact with the environment. Preferably, said inner packaging layer protects sterility of the enclosed implant. An outer packaging layer may be a layer of the multiple layer packaging that is in contact with the environment and/or in contact with the inner layer without being in contact with the implant. For example, the kit may comprise the implant according to the present invention enclosed in a multiple layer packaging, said packaging comprising at least i) an inner packaging layer comprising, or consisting of, polyethylene lined with aluminum and ii) an outer packaging layer comprising, or consisting of, polyethylene.

[00101] The implant may be sterilized before being enclosed in a packaging, like a multiple layer packaging, preferably within the inner packaging layer of a multiple layer packaging. Sterilization may be done, for example, using gamma sterilization.

[00102] Herein, the terms “over”, “to”, “between” and “on” as used herein may refer to a relative position of one layer with respect to other layers. One layer “over” or “on” another layer may be directly in contact with the other layer or may have one or more intervening layers. One layer “between” layers may be directly in contact with the layers or may have one or more intervening layers. As used herein, the singular forms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise.

[00103] As used herein, the term “and/or” includes the meaning of “and,” “or,” and “all or any other combination of the elements connected by said term.”

[00104] It is to be noted that herein the terms “substantially” and/or “about” refer to a deviation of 20% or less, preferably of 15% or less, more preferably of 10% or less, even more preferably of 5% or less, most preferably of 1% or less. Thus, said terms relate to a value that is within a deviation of, e.g., maximal 10% or 5% of a given value or range.

[00105] It is to be noted that in case of any definition given herein, the respective definition of a term, phrase, and/or abbreviation applies vice versa throughout the specification. Furthermore, all definitions given herein are intended to encompass all grammatical forms.

[00106] Additional objects, advantages, and features of this disclosure will become apparent to those skilled in the art upon examination of the following Examples and the attached Figures thereof, which are not intended to be limiting. Thus, it should be understood that although the present disclosure is specifically disclosed by exemplary embodiments and optional features, modification and variation of the disclosures embodied therein herein disclosed may be resorted to by those skilled in the art and that such modifications and variations are considered to be within the scope of this disclosure.

[00107] List of reference signs

- 102: Plurality of unit cells (102)
- 105: First outer surface region
- 106: Second outer surface region
- 107: Perimeter of the first outer surface region 105
- 111: Lower pole portion
- 112: Apex region
- 115: Lower pole interface region
- 116: Arrow denoting, e.g., a z-direction
- 126: Layer of an arrangement of layers
- 128: Lines oriented in a first direction
- 129: Lines oriented in a second direction different to the first direction
- 200: Implant according to the present invention
- w: Pore size of a unit cell 102
- j: Angle between two intersecting lines, 128 and 129, of a unit cell 102

EXAMPLES

Tissue reconstruction implant

[00108] **Figure 2** shows an illustrative example of an implant according to the present invention, namely a 3D breast implant for and/or suitable for insertion into a patient.

[00109] The implant 200 may comprise a plurality of unit cells 102 arranged to form a 3D lattice structure. The 3D lattice structure may comprise a resting volume of the implant 200. The plurality of unit cells 102 may be arranged to form a porous network of the 3D lattice structure, and the 3D lattice structure may be a reversibly compressible 3D structure.

[00110] The 3D lattice structure of the implant 200 may include an arrangement of layers

126. The arrangement of layers 126 may include (or may be) layers (e.g. parallel to the x-y plane) arranged successively over each other in the z-direction (e.g. vertical direction 116). For example, the implant 200 may be formed by sequentially printing layers 126 (e.g. in the z-direction 116) to form the 3D lattice structure of the implant. The sequential arrangement (by printing) of layers 126 on top of each other (e.g. in the z-direction 116) may lead to the forming of the 3D lattice structure, comprising a first and a second outer surface region. The first outer surface region 105 of the implant 200 may be the largest surface of the implant and/or the surface of the implant with the least (or smallest) amount of curvature. For example, the first outer surface region 105 of the implant 200 may be the perimeter of the first outer surface region 107. The shape and/or geometry of the second outer surface region 106 may be defined or formed by edges (or perimeter) of the plurality of layers 126. The second outer surface region 106 may have a geometry (e.g. the shape, curvature, size) which represents a geometry of a patient's breast to be reconstructed by the implant 200.

[00111] For example, the second outer surface region 106 may include an upper pole portion and a lower pole portion 111. The upper pole portion may have a geometry of an upper portion of the breast to be reconstructed by the implant 200. The upper portion of the breast may be the region of the breast above the nipple region of the patient towards the head of the patient. The lower pole portion 111 may have a geometry of a lower portion of the breast to be reconstructed by the implant 200. The lower portion of the breast may be a region of the breast below the nipple region of the patient towards the feet of the patient. The upper pole portion and the lower pole portion 111 may meet (or may be coincident) at an apex region 112 of the second outer surface region 106. The location (or position) of the apex region 112 at the second outer surface region 106 of the implant may be based on (and/or may coincide with) the location (or position) of the nipple/areola of the breast to be constructed by the implant 200.

[00112] Each layer of the arrangement of layers 126 may include a 2D lattice arrangement of a plurality of 2D unit cells 102. A (2D) unit cell 102 may be the smallest and most basic unit of the 3D lattice structure. A (2D) unit cell 102 may be formed by a plurality of lines. Herein, said lines may relate to one or more filaments, preferably filaments the deposition of which are controlled using 3D printing. The plurality of lines may comprise lines oriented in a first direction 128 and lines oriented in a second direction different to the first direction 129. Lines 129 and Lines 129 may represent intersecting lines. For example, a smallest angle, j , between two intersecting lines of a unit cell may be between 5° and 90° (or e.g. between 10° and 80° , or e.g. between 30° and 60°). The intersecting lines of the plurality of lines may be configured to

form repeated unit cells 102 that may form the 3D lattice structure. The 3D lattice structure may include a plurality of adjacent (e.g. directly adjacent) unit cells, connected to each other throughout the 3D lattice structure. For example, the unit cells 102 may be repeated throughout at least (equal to or larger than) 80% (or e.g. at least 85%, or e.g. at least 90%, or e.g. at least 95%) of the resting volume of the 3D lattice structure. The 3D lattice structure may thus include a plurality of adjacent (e.g. directly adjacent) repeated unit cells, connected to each other (e.g. throughout the lattice structure of the implant 200).

[00113] The plurality of unit cells 102 may be arranged to form a porous network of the 3D lattice structure. For example, the (e.g. intersecting) lines may form or define a geometry (e.g. shape, dimension, pore size) of the individual unit cells (e.g. each unit cell) of the 3D lattice structure. The porous network may refer to (and/or may include) the pores of the plurality of unit cells 102 within the 3D lattice structure. The plurality of intersecting lines may form or define a plurality of pores (e.g. forming walls enclosing the individual unit cells). The (e.g. intersecting) lines may be arranged, so that each unit cell formed by said lines may include or may be referred to as a pore, having a pore size. Thus, the intersecting lines may be arranged, so that each unit cell 102 formed from the intersecting lines may include or may be referred to as a pore, having a pore size w , wherein w may be pore specific and/or identical for at least a portion of the unit cells (e.g. of a layer). Each (2D) unit cell 102 may have a pore size w , defining the dimension of the 2D unit cell 102. The pore size, w , of the unit cell 102 of a layer may be the minimal dimension (or width) of the pore, e.g. the smallest distance of the pore measured between two lines (e.g. opposite facing lines) defining a unit cell 102.

[00114] For example, the 3D lattice structure of the implant 200 may be constructed from the plurality of unit cells 102 having a range of different pore sizes w . For example, a surface pore size, w , at the lower pole portion 111 of the second outer surface region 106 may increase (gradually, or e.g. step-wise, or e.g. layer-wise) from the lower pole interface region 115 towards the apex region 112 of the second outer surface region 106, wherein the lower pole interface region 115 may be an interface (or edge) region of the 3D lattice structure at which the lower pole portion 111 of the second outer surface region 106 meets a portion of the perimeter 107 of the first outer surface region 105.

Illustrative examples of tissue reconstruction implants

[00115] **Table 1** shows illustrative examples of an implant according to the present invention, namely 3D implants for and/or suitable for insertion into a patient. Of note, resting

volumes given in Table 1 are illustrative and may be upon insertion into a patient's body also up to e.g. 10% or up to e.g. 20% smaller than the resting volume of the implant before being inserted into the patient's body (as given in **Table 1**) as the implant may be compressed in the patient's body due to e.g. mechanical forces resulting e.g. from the patient's anatomy.

Table 1: Illustrative examples of implants according to the present invention. Given are for an illustrative purpose exemplarily ranges of respective values. As implants are preferably porous, outer surface (areas) [cm²] were approximated assuming a "closed" (non-porous) shell around the respective implant.

Implant (suitable for or for ...)	Sizing (variable, illustrative ranges) [cm x cm x cm]	Resting volume [cm³]	Outer surface [cm²]	Filament diameter [μm]
Breast region	4 x 4 x 1 – 20 x 20 x 7	15-3000 e.g. 30-800	15-3000 e.g. 30-800	50-750 e.g. 100-600 or e.g. 200-450 or e.g. 250-400
Pectoral region	4 x 4 x 1 – 20 x 20 x 7	15-3000 e.g. 30-800	15-3000 e.g. 30-800	50-750 e.g. 100-600 or e.g. 200-450 or e.g. 250-400
Malar region	3 x 1 x 0.3 - 7 x 5 x 2	0.5-75 e.g. 5-50	0.5-75 e.g. 5-50	50-750 e.g. 100-600 or e.g. 200-450 or e.g. 250-400
Gluteal region	4 x 4 x 1 – 20 x 20 x 7	15-3000 e.g. 50-800	15-3000 e.g. 50-800	50-750 e.g. 100-600 or e.g. 200-450 or e.g. 250-400
Genital region	2 x 2 x 1 – 20 x 20 x 7	2.5-3000 e.g. 5-200	2.5-3000 e.g. 5-200	25-750 e.g. 50-600
Soft Tissue Support	2 x 2 x 1 – 20 x 20 x 7	2.5-3000 e.g. 5-200	2.5-3000 e.g. 5-200	25-750 e.g. 50-600
Tendon and/or Ligament	2 x 2 x 1 – 20 x 20 x 7	2.5-3000 e.g. 5-200	2.5-3000 e.g. 5-200	25-750 e.g. 50-600
Bone Region	4 x 4 x 1 – 20 x 20 x 30	15-40000 e.g. 100- 25000	15-40000 e.g. 100- 25000	500-7500 e.g. 600-5000 or e.g. 700-5000 or e.g. 800-5000

General remarks to following experiments

[00116] All experiments described in the following were conducted with the following parameters being identical across individual experiments. Surface treatment was a plasma surface treatment using as a plasma treatment device a Pico UHP SN 111302 with a glass electrode in a clean room (Iso Class 8), using the following general parameters: Pressure: 0.3 mbar, plasma generator: 40 kHz, power of the generator: 200 W. Tested were material pieces and implants with the implants being implants according to the present invention (breast implants).

[00117] Experiments V1.1 to V2.3 were performed in accordance with the following basic protocol per experiment. Per experiment, in total 55 test objects from at least 3 different batches of production were assessed. Before plasma treatment, contact angle measurements were performed to ensure that the test objects had a hydrophobic surface before plasma treatment and thus, to be able to validate the effect of plasma treatment on the surface of the test objects. Plasma treatment was performed with in total 5 test objects per plasma treatment run (i.e. per run 5 test objects in a chamber underwent plasma treatment in parallel in a given treatment chamber). Out of these 5 test objects per plasma treatment run, one test object was ink tested. The developed ink test was found to be advantageous to quantitatively assess hydrophilicity of a surface of a test object. This holds especially true in case of highly porous structures of the implants. Such 3D surfaces were found to hamper an accurate quantitative determination of a contact angle. For example, a liquid drop used for contact angle measurement may fall off the curved surface formed by filaments of the 3D lattice structure of an implant for example. Also an incorrect positioning of the liquid droplet may result in an incorrect contact angle measurement. Contrarily, the developed ink test allowed a qualitative assessment of a 3D surface's hydrophilicity with the test providing reliable results.

Contact angle measurement

[00118] Test objects like material pieces and implants were additionally investigated using contact angle measurements. In brief, a contact angle measurement device (Krüss Scientific Drop shape analyser - DSA 100) was used with the software "SCA210_U" (Krüss ADVANCE image analysis software; version V2017). The dosing volume for the dispense unit was set to 1 µl distillate water per measurement. A test object adapted holder was used to hold test objects with substantial curvature as in case of the breast implants. Per outer surface region (first and second, respectively) three measurements were done at different outer surface positions as, for example, indicated in **Figure 8** in case of a second outer surface region of a breast implant. Herein reported results represent average contact angles per test object and thus across six measurement per test object. A drop picture was taken per measurement. Measurements were not

deviating by more than 2% across the six measurements per test object.

Ink test

[00119] The in Examples V1.1 to V2.3 investigated test objects like material pieces were made of PCL which is commonly considered hydrophobic. Unexpectedly, e.g. in Experiment V1.1 for an untreated material piece made of PCL a contact angle of 61.9° was observed. As a surface may be commonly considered hydrophilic when the observed contact angle is <90°, the observed contact angle of untreated PCL would have indicated a hydrophilic surface in contrast to the common understanding of (untreated) PCL being hydrophobic. However, contact angle measurements are optimized for 2D surfaces like measurements of contact angles on (substantially) flat plastic films, whereas herein 3D test objects like material pieces and implants were investigated. Thus, in view of 3D surface and porous structure of the test objects, herein the definition of hydrophilicity was adapted in case of 3D objects. Further, a new test was developed (ink test) to assess hydrophilicity of a 3D surface and/or a 3D object like a 3D implant.

[00120] Ink tests were performed in case of experiments V1.12 to V2.3 shown in **Table 2**. Ink tests were performed as follows. In brief, a solution was prepared by mixing 300 ml distillate water with 5 ml of a commercially available standardized blue ink with a surface tension of 72 mN/m (obtained from Fischer Test Tinten, Rheinstraße 25 A, 76479 Steinmauern, Germany), meaning the solution was prepared at a mixing ratio of 1:60 (volume ink to volume distilled water); or a solution was prepared by mixing 30 ml distillate water with 1 ml of said commercially available standardized blue ink with a surface tension of 72 mN/m (obtained from Fischer Test Tinten), meaning the solution was prepared at a mixing ratio of 1:30. Test objects (in the experiments herein: material pieces and implants) were put into the solution ensuring that the respective test object was fully covered in the solution and incubated therein for 1 min. After said one minute, the test object was taken out of the solution, laid down on a “Kimtech wipe” (Kimwipes™ Delicate Task Wipes by Kimtech Science™) or a wipe e.g. from Coventry Econowipes™ (Article 6709), and put on a further wipe (“Kimtech wipe” or from Coventry Econowipes™) for drying and (visual) assessment. If the surface of the test object was (preferably entirely and/or homogenously) ink colored, the respective surface was considered hydrophilic. Hence, the ink test result was considered positive in case the test object was (ink) colored (here: blue) indicating that the colored solution was adsorbed and/or absorbed. This was considered indicative for a hydrophilic surface. In some experiments, an additional assessment was done for which, before drying of the test object, said test object was scratched over another (fresh) “Kimtech wipe” to investigate whether blue solution can be seen on the wipe upon

scratching. If this optional assessment was performed, it was assessed whether any color was observed on the wipe upon scratching, as this could have been indicative for an instable and/or incomplete surface treatment process. Further, in some experiments an additional (visual) check was performed before the drying step. In the latter cases, the ink tested test object was washed with clean distilled water and it was observed whether any ink was washed out – in case of any ink being washed out, the ink test was considered failed. It is to be noted that the in the following given ink test results were reported positive (e.g. “+” in **Table 1**) in case of the test object being colored (blue) and, if any of the additional assessments was performed, the wipe being uncolored upon scratching and/or no ink being washed out.

Process development – material pieces

[00121] In a first set of experiments (V1.1 to V1.15), material pieces with big structure (e.g. scaffolds; **Figure 3**) were investigated. Said material pieces represented (approximately cubic) 1.5 cm cut pieces from implants, wherein said implants were made of PCL using melt-extrusion-based additive manufacturing, had average pore sizes between 600 μm and 10 mm, and were (approximately) 8.0 cm x 8.0 cm x 2.5 cm. For this first set of experiments, the material pieces were laid directly on the bottom of the glass chamber of the plasma treatment device. Investigated were the effects of the following parameters: exposure time in minutes (min), used power in watts (W) and gas composition. As regards the used power parameter: the max power of the machine used was 200 W and a parameter was set per experiment (relating to a percentage of power used; “%P”) to obtain a “used power in watts” as energy provided to test objects exposed to a given surface treatment in the respective experiment.

[00122] As it can be seen in **Table 2**, effects of surface parameter combinations varied resulting in contact angles after surface treatment of between about 30° and about 55°. For comparison, in Experiment V1.1 an untreated piece exhibited a contact angle of 61.9°. Thus, surface treatment using plasma may be considered suitable for modifying hydrophilicity of a surface of an implant according to the present invention. Furthermore, investigated surface treatment parameter combinations resulted in a reduction of the observed contact angle in all experiments (except for V1.6 wherein the test piece melted).

[00123] The experiments indicated that a contact angle of e.g. between about 30° and about 35° (degree) may be indicative for a hydrophilic surface of an implant. As it can be seen in **Table 2**, the experiments of the first set (V1.1 to V1.15) indicated that parameter combinations applied in experiments V1.12 to V1.15 may be (e.g. especially) suitable for the method

according to the present invention. The parameter combination of experiment V1.15 was chosen as starting point for the second set of experiments.

Table 2: Overview of first and second set of experiments. Column headers: Experiments are abbreviated with “Exp.”, and “Position” refers to positioning of test objects within a treatment chamber. As regards the gas (composition) used for plasma treatment, oxygen is abbreviated with O₂ and argon with Ar. Contact angles reported in the last right column refer to contact angles measured after surface treatment. “(+)” indicates a positive ink test result indicative for a hydrophilic surface but discolored (e.g. became yellowish) indicative for an unfavorable damage (e.g. due to a (suspected) pyrolysis reaction, which would be undesirable e.g. in case of a medical application and/or implantation). It is to be noted that contact angle measurements were performed in case of experiments V1.1 to V1.11; ink tests were developed and applied in case of experiments V1.12 to V2.3 in Table 2. Of note experimental conditions were identical for experiments V1.9 and V1.13.

Exp.	Type	Exposure time [min]	Used power [W]	Position	Gas	Ink test	Contact angle [°]
V1.1	Piece	5	30W	Bottom	100% O ₂		54.1
V1.2	Piece	10	30W	Bottom	100% O ₂		51.9
V1.3	Piece	15	30W	Bottom	100% O ₂		42.5
V1.4	Piece	20	30W	Bottom	100% O ₂		39.7
V1.5	Piece	20	100W	Bottom	100% O ₂		55
V1.6	Piece	20	200W	Bottom	100% O ₂		Melt
V1.7	Piece	30	100W	Bottom	100% O ₂		46
V1.8	Piece	40	48W	Bottom	100% O ₂		33.1
V1.9	Piece	60	30W	Bottom	100% O ₂		30.5
V1.10	Piece	45	30W	Bottom	50% O ₂ , 50% Ar		56.4
V1.11	Piece	45	30W	Bottom	100% O ₂		50.6
V1.12	Piece	120	30W	Bottom	100% O ₂	+	
V1.13	Piece	60	30W	Bottom	100% O ₂	+	
V1.14	Piece	90	30W	Bottom	100% O ₂	+	
V1.15	Piece	30	60W	Bottom	100% O ₂	+	
V2.1	Implant	30	60W	Bottom	100% O ₂	(+)	
V2.2	Implant	30	30W	Bottom	100% O ₂	(+)	
V2.3	Implant	30	30W	Glass tray	100% O ₂	+	

Stability

[00124] In addition, long life stability and strong life stability of the surface treated material pieces were investigated. For the long life stability tests, surface treated material pieces

(following parameter combinations of V1.1. to V1.15) were stored at a temperature <40°C for several weeks (in **Figure 4A**) are shown exemplarily results obtained after 11 weeks of storage) before an ink test was performed to assess hydrophilicity of the surfaces. For the strong life stability tests, surface treated material pieces (following parameter combinations of V1.13 and V1.15) were heated for different time periods in an oven to different temperatures before (60 min after heat exposure) an ink test was performed to assess hydrophilicity of the surfaces. **Figure 4 B) to D)** show exemplarily results obtained after heat exposure to 40 °C, 50 °C and 60 °C, respectively.

[00125] As it can be seen in **Figure 4A**, even after several weeks, e.g. 11 weeks, of storage obtained ink test results indicated hydrophilic surfaces of the treated material pieces. Shown are results of experiments V1.9/V1.13 (upper left), V1.14 (upper right), V1.12 (lower left), and V1.15 (lower right). Thus, plasma treatment may ensure hydrophilic surfaces over weeks indicative for a stable long life effect.

[00126] As it can be seen in **Figures 4B to D**, the obtained ink test results indicated hydrophilic surfaces of the treated material pieces after heat exposure at different temperatures and durations. Thus, plasma treatment may ensure hydrophilic surfaces over a range of heat exposure regimes indicative for strong life stability of the obtained hydrophilic surfaces.

Process development – implants

[00127] In a second set of experiments (V2.1 to V2.3), instead of material pieces implants were used to investigate the effect of a plasma treatment on said implants using the parameter combination of experiment V1.15 (first set of experiment) as starting point for optimization. Said implants were made of PCL using melt-extrusion-based additive manufacturing, and had average pore sizes between 600 µm and 10 mm. The implants were (approximately) 8.0 cm x 8.0 cm x 2.5 cm. One single implant was put in the treatment chamber per run.

[00128] As it can be seen in **Table 2**, plasma treatment effects varied between the material pieces investigated in the first set of experiments and the implants investigated in the second set of experiments. Furthermore, experiments of the second set (V2.1 to V2.3) indicated that the parameter combination applied in experiment V2.3 may be suitable for the method according to the present invention.

Surprising findings/insights from negative examples

[00129] Non-working examples of a surface treatment are illustratively shown in **Figure**

6. In **Figure 6**, two negative examples of an oxygen plasma treatment are shown, wherein an unfavourable parameter combination (treatment parameters were as in case of V2.1 to V2.3 as described above except that for a given treatment run not one single implant was in the treatment chamber but three implants) resulted in a damage of the implants as indicated by a faint colouring (yellowish coloured regions of the implants; the implants were (about) 8.0 cm x 8.0 cm x 2.5 cm and of identical structure, design, manufacturing and material as the implants used in experiments V2.1 to V2.3). Such damage may have been occurred due to the fact that the used power was too high and/or the exposure time too long. However, it was assumed initially that identical surface treatment parameters like used power and/or exposure time were used as identified as suitable on a working example before. Thus, further potential pitfalls and/or challenges were considered.

[00130] Without being bound by theory, it was hypothesized that the damage may have occurred due to initially not considered surface treatment parameters being the following: i) a change (here: increase) in the size of the implants investigated compared to the ones, for which the surface treatment parameters were initially identified as being suitable, and/or ii) a change (here: increase) in the number of implants in the treatment chamber. Thus, it was hypothesized that the damage was caused by the fact that in the non-working experiment multiple implants of larger size and/or with larger surface area were exposed together in a treatment chamber to oxygen plasma compared to the initially working experiment. Moreover, in contrast to currently available knowledge it was further hypothesized that an increase of the number, size and/or structure of implants exposed to oxygen plasma treatment in a single treatment chamber may have resulted not in a lower, but in a higher surface reflection within said treatment chamber. Such a higher surface reflection may have caused an increase in the net effect of the identical parameter combination compared to the net effect observed and optimized in the initial experiment wherein the surface treatment parameters were optimized for some implants. Accordingly, it was hypothesized that a higher plasma reflection may be obtained the more (total) surface area is exposed to a surface treatment within a treatment chamber. Said (total) surface area may be increased by increasing the number of implants exposed to the surface treatment within a given treatment chamber and/or by increasing the implant size and/or the numbers of filaments. Thus, the hypothesis was the following: the higher the (total) surface area in a treatment chamber, the higher the reflection of the plasma and the higher the effect of the surface treatment on the exposed implant(s) - up to negative effects due to an implant damage in case of a too strong (net) effect. Following this surprising hypothesis, in a subsequent experiment only one implant of the larger implants was surface treated at a time by putting only one implant

in the treatment chamber for exposure to an oxygen plasma treatment. In said subsequent experiment oxygen plasma treatment was successful using again the identical surface treatment parameter combination: implants with a hydrophilic implant surface were obtained without damage of the implant.

[00131] Thus, “sweet spots” of suitable surface treatment parameters and/or parameter combinations are preferably identified per implant design, preferably in view of technique specific parameters like used power, exposure time, plasma composition etc., as well as in view of implant specific features like material, structural complexity, implant surface and implant size, as well as parameters like number of implants in a treatment chamber. Hence, any of the herein illustratively disclosed surface treatment parameter combinations may not be considered trivial.

Surface treatment effect

[00132] In a further example, the effect of a surface treatment on an implant surface was assessed using an ink test following ISO 8296:2003 and adapted to a surface of a 3D (bulk) object under the constraint that three implants were to be exposed to a plasma treatment at a time in the same treatment chamber. The constraint was made to increase throughput e.g. in view of a potential serial production of implants according to the present invention. A blue coloured ink was used.

[00133] Surface treatment parameters were applied as in case of process development experiment V 2.3 except the following modification. In view of findings from negative examples as the ones disclosed herein above, exposure time was adapted from 30 min to 25 min.

[00134] As shown in **Figure 5** (exemplarily for a result as obtained after a surface treatment exposure of 25 min; sizing 8.0 cm x 8.0 cm x 2.5 cm as in experiments disclosed herein above), an implant without or prior to plasma treatment did not adsorb and/or absorb the blue ink. Contrarily, an implant, the surface of which was exposed to a plasma treatment according to the present invention, turned blue as indicated by the darker colour of the implant compared to the colour of an untreated implant or the colour of the implant before plasma treatment exposure. Thus, the blue (darker) colour of the implant verified that the implant surface became hydrophilic upon oxygen plasma treatment.

[00135] As illustratively shown in **Figure 7** (exemplarily for a result as obtained after a surface treatment exposure of 25 min; sizing 14 cm x 14 cm x 4.1 cm, (about) 450 cc), the experiment resulted in implants having a hydrophilic surface as indicated by the blue (dark)

colouring of the implants upon oxygen plasma treatment. Also, the implants did not exhibit a damage indicating a suitable surface treatment parameter combination. Moreover, as shown in **Figure 7**, inner and outer surfaces of the implants were coloured indicating that not only outer regions of the implants turned hydrophilic but also the inner core regions. Hence, the plasma treatment was suitable for making the (entire) surface of the implant hydrophilic. It is noted here that the wettability (hydrophobicity and hydrophilicity) of cell adhesion surfaces can affect surface protein adsorption and cell adhesion. As reported, for example, by Cai et al “Recent advance in surface modification for regulating cell adhesion and behaviors” Nanotechnology Reviews, 9(1), 2020, 971-989) cells are more likely to adhere to hydrophilic surfaces. It is thus expected that the (increased) hydrophilicity of the implants will in turn lead to an improved cell invasion and/or revascularization after implantation of the implant, thereby providing a functionally improved 3D implant for tissue reconstruction and/or tissue augmentation and/or (soft) tissue support.

[00136] It will be readily apparent to a person skilled in the art that varying substitutions and modifications may be made to the invention disclosed herein without departing from the scope and spirit of the invention.

[00137] All patents, patent applications and publications are herein incorporated by reference to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference.

[00138] The invention illustratively described herein may suitably be practiced in the absence of any element or elements, limitation or limitations, not specifically disclosed herein. Thus, for example, the terms "comprising", "including", "containing", etc. shall be read expansively and without limitation. Additionally, the terms and expressions employed herein have been used as terms of description and not of limitation, and there is no intention in the use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof, but it is recognized that various modifications are possible within the scope of the invention claimed. Thus, it should be understood that although the present invention has been specifically disclosed by preferred embodiments and optional features, modification and variation of the inventions embodied therein herein disclosed may be resorted to by those skilled in the art, and that such modifications and variations are considered to be within the scope of this invention. The invention has been described broadly and generically herein. Each of the

narrower species and subgeneric groupings falling within the generic disclosure also form part of the invention. This includes the generic description of the invention with a proviso or negative limitation removing any subject matter from the genus, regardless of whether or not the excised material is specifically recited herein. In addition, where features or aspects of the invention are described in terms of Markush groups, those skilled in the art will recognize that the invention is also thereby described in terms of any individual member or subgroup of members of the Markush group. Further embodiments of the invention will become apparent from the following claims.

[00139] Equivalents: Those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, many equivalents to the specific embodiments of the invention described herein. Such equivalents are intended to be encompassed by the following claims.

[00140] The invention is further characterized by the following items:

1. Tissue reconstruction implant, the implant having a hydrophilic implant surface, wherein the implant is a three-dimensional (3D) implant consisting of a bio-resorbable material, and wherein the implant surface is considered hydrophilic when assessed using an ink test following ISO 8296:2003 and adapted to a three-dimensional (3D) surface, wherein said ink test comprises incubating the implant for 1 min in a solution consisting of an ink with a surface tension of 72 mN/m and water (a mixture of said ink with a surface tension of 72 mN/m with water) and wherein after incubation of the implant in said solution an ink colored implant surface is indicative for a hydrophilic implant surface.
2. The implant of item 1, wherein the bio-resorbable material comprises, or is, a polymer selected from the group consisting of polycaprolactone, poly(1,3-trimethylene carbonate), polylactide, polyglycolide, poly(ester amide), poly(ethylene glycol)/poly(butylene terephthalate), poly(4-hydroxybutyrate), polydiacxonone, poly(glycerol sebacate), poly(1,8-octanediol-co-citric acid), poly(1,10-decanediol-co-D,L-lactic acid), poly(diol citrate), poly(glycolide-co-caprolactone), poly(1,3-trimethylene carbonate-co-lactide), poly(1,3-trimethylene carbonate-co-caprolactone) and a copolymer of at least two of said polymers, preferably wherein the bio-resorbable material comprises polycaprolactone.

3. The implant of item 1 or 2, wherein the bio-resorbable material is capable of being resorbed by a patient, preferably within less than 15 years or within less than 10 years or within less than 5 years upon insertion of the implant into said patient.
4. The implant of any one of the preceding items, wherein a material density of the implant is between 0.1 gr/cm^3 and 2 gr/cm^3 .
5. The implant of any one of the preceding items, wherein the implant is a reversibly compressible 3D implant.
6. The implant of any one of the preceding items, wherein the hydrophilic implant surface comprises an outer surface region of the implant.
7. The implant of item 6, wherein the implant has a resting volume between 0.5 cm^3 and $40,000 \text{ cm}^3$, preferably between 5 cm^3 and $25,000 \text{ cm}^3$ or between 5 cm^3 and $3,000 \text{ cm}^3$ or between 5 cm^3 and 800 cm^3 .
8. The implant of any one of the preceding items, wherein the solution used in the ink test consists of the ink with the surface tension of 72 mN/m and distillate water, preferably in a ratio of ink:distillate water of between (about) 1:15 and (about) 1:75, more preferably in a ratio of ink:distillate water of (about) 1:60 or of (about) 1:30.
9. The implant of any one of the preceding items, wherein the hydrophilic implant surface has a contact angle of less than 40° , preferably of less than 35° and/or wherein the hydrophilic implant surface preferably has a contact angle between 20° and 40° .
10. The implant of item 9, wherein the contact angle is measured at at least 2 different implant positions, preferably at at least 2 different outer surface implant positions.
11. The implant of item 9 or 10, wherein the contact angle is measured using a drop with a volume of about $1 \mu\text{l}$.
12. The implant of any one of the preceding items, wherein the implant is an additively manufactured implant, preferably a three-dimensionally (3D) printed implant, preferably 3D printed using a melt extrusion-based method and/or a selective-laser-sintering method.
13. The implant of any one of the preceding items, wherein the filaments of the 3D printed implant have an average diameter between $25 \mu\text{m}$ and 7.5 mm , preferably between $50 \mu\text{m}$ and 5 mm or between $50 \mu\text{m}$ and $600 \mu\text{m}$.
14. The implant of any one of the preceding items, wherein the implant comprises a three-dimensional (3D) lattice structure.

15. The implant of item 14, wherein the 3D lattice structure defines a resting volume of the implant.
16. The implant of item 14 or 15, the 3D lattice structure is a reversibly compressible 3D lattice structure.
17. The implant of any one of items 14 to 16, wherein the 3D lattice structure is reversibly compressible to at least 80% of its resting volume.
18. The implant of any one of items 14 to 17, wherein the 3D lattice structure is formed by a plurality of unit cells connected to each other.
19. The implant of item 18, wherein the unit cell is a two-dimensional (2D) basic unit of the 3D lattice structure.
20. The implant of item 18 or 19, wherein the unit cells are arranged to form layers successively stacked on top of each other.
21. The implant of item 20, wherein each layer comprises a lattice arrangement of 2D unit cells.
22. The implant of any one of the preceding items, wherein the outer surface region of the implant comprises a first and a second outer surface region.
23. The implant of item 22, wherein edge regions of the layers form the second outer surface region of the implant.
24. The implant of any one of items 18 to 23, wherein the plurality of unit cells is arranged to form a porous network of the 3D lattice structure.
25. The implant of item 24, wherein the porous network has an average pore size from 0.15 mm or 0.5 mm up to 5, 6, 8, 10 or 12 mm.
26. The implant of item 24 or 25, wherein a bulk porosity of the 3D lattice structure of the implant is at least 50%.
27. The implant of any one of items 18 to 26, wherein individual unit cells of the plurality of unit cells are reversibly compressible spring-like unit cells.
28. The implant of any one of items 14 to 27, wherein the 3D lattice structure comprises a first outer surface region of the implant comprising a first surface curvature; and a second outer surface region of the implant comprising a second surface curvature,

wherein the second outer surface region of the implant is contiguous to the first outer surface region of the implant at a perimeter of the first outer surface region.

29. The implant of item 28, wherein a geometry of the first outer surface region represents a geometry of a patient's body part to be brought in contact with the implant upon insertion of the implant into said patient.
30. The implant of item 28 or 29, wherein a geometry of the second outer surface region represents a geometry of a patient's body part to be reconstructed by the implant upon insertion of the implant into said patient.
31. The implant of item 29 or 30, wherein the patient's body part is i) a breast region, pectoral region, malar region, gluteal region or genital region, ii) a tendon and/or a ligament, or iii) a bone region.
32. The implant of any one of the preceding items, wherein the implant is for reconstructing i) a breast region, pectoral region, malar region, gluteal region or genital region, ii) a tendon and/or a ligament, or iii) a bone region and/or wherein the implant is for supporting a soft tissue.
33. The implant of any one of the preceding items, wherein the implant is a soft tissue implant and/or a soft tissue support implant, wherein the soft tissue is preferably a soft tissue of i) a breast region, pectoral region, malar region, gluteal region or genital region and/or of ii) a tendon and/or a ligament.
34. The implant of any one of the preceding items, wherein the implant is for insertion into a patient.
35. The implant of any one of the preceding items, wherein the implant is a single-piece reconstruction implant.
36. The implant of any one of the preceding items, wherein the implant is suitable for being folded and/or compressed such that it can be inserted into a patient minimal invasively.
37. The implant of any one of items 1 to 36 for use in a method of reconstructing, augmenting and/or revising a tissue and/or (soft) tissue support, wherein the implant is inserted into a patient.
38. The implant of any one of items 1 to 36 for use in tissue reconstruction, (soft) tissue support, tissue augmentation and/or implant revision, wherein the implant is inserted into a patient.

39. Use of the tissue reconstruction implant of any one of items 1 to 36 for reconstructing, augmenting and/or revising a tissue and/or supporting a (soft) tissue, wherein the implant is inserted into a patient.
40. Implant for use according to item 37 or 38, or use according to item 39, wherein the implant is a 3D implant, preferably a 3D single piece implant.
41. Implant for use according to item 37, 38 or 40, or use according to item 39 or 40, wherein the implant is a reversibly compressible 3D implant.
42. Implant for use according to item 37, 38, 40 or 41, or use according to any one of items 39 to 41, wherein the implant is inserted into a patient minimal invasively.
43. A method of manufacturing a tissue reconstruction implant with a hydrophilic implant surface, comprising
exposing a surface of an implant to a surface treatment, wherein the surface treatment is suitable for making the surface of the implant hydrophilic, whereby a hydrophilic implant surface is obtained,
wherein the implant is a three-dimensional (3D) implant consisting of a bio-resorbable material, and
wherein the implant surface is considered hydrophilic when assessed using an ink test following ISO 8296:2003 and adapted to a three-dimensional (3D) surface,
wherein said ink test comprises incubating the implant for 1 min in a solution consisting of an ink with a surface tension of 72 mN/m and and wherein after incubation of the implant in said solution an ink colored implant surface is indicative for a hydrophilic implant surface.
44. The method of item 43, wherein the solution used in the ink test consists of the ink with the surface tension of 72 mN/m and distillate water, preferably in a ratio of ink:distillate water of between (about) 1:15 and (about) 1:75, more preferably in a ratio of ink:distillate water of (about) 1:60 or of (about) 1:30.
45. The method of item 43 or 44, wherein the implant is the implant is a reversibly compressible 3D implant.
46. The method of any one of items 43 to 45, wherein the implant is an additively manufactured implant, preferably wherein the implant is a 3D printed implant, preferably 3D printed using a melt extrusion-based method and/or a selective-laser-sintering method.

47. The method of any one of items 43 to 46, wherein the filaments of the 3D printed implant have an average diameter between 25 μm and 7.5 mm, preferably between 50 μm and 5 mm or between 50 μm and 600 μm .
48. The method of any one of items 43 to 47, wherein the surface treatment is i) a plasma treatment or ii) an etching treatment, preferably an acid or alkaline etching treatment, more preferably a sodium hydroxide treatment,
49. The method of item 48, wherein the plasma treatment is an oxygen plasma treatment.
50. The method of item 47 or 49, wherein the plasma treatment is a low frequency plasma treatment, preferably at about 40 kHz.
51. The method of any one of items 47 to 50, wherein the plasma treatment is performed for at least 10 sec or at least 15 sec or at least 30 sec.
52. The method of any one of items 47 to 51, wherein plasma treatment is performed for a period of time ranging between 10 sec and 240 min or between 15 sec and 240 min or between 15 sec and 90 min or between 15 sec and 60 min or between 15 sec and 30 min.
53. The method of any one of items 47 to 52, wherein plasma treatment is performed by applying a used power of less than 70 watts (W) or of less than 40 W.
54. The method of any one of items 47 to 53, wherein plasma treatment is performed by applying a used power of between 20 W and 70 W, preferably of between 20 W and 40 W or of between 50 W and 70 W.
55. The method of any one of items 47 to 54, wherein plasma treatment is performed by applying a pressure of about 0.3 mbar.
56. The method of any one of items 47 to 55, wherein plasma treatment is performed by putting the implant on a glass tray in a plasma treatment device.
57. The method of any one of items 43 to 56, wherein the implant surface comprises an outer surface region of the implant.
58. The method of item 57, wherein the implant has a resting volume between 0.5 cm^3 and 40,000 cm^3 , preferably between 5 cm^3 and 25,000 cm^3 or between 5 cm^3 and 3000 cm^3 or between 5 cm^3 and 800 cm^3
59. The method of any one of items 43 to 58, wherein the implant surface has a contact angle of less than 40°, preferably of less than 35°.

60. The method of any one of items 43 to 59, wherein the implant surface as a contact angle between 20° and 40°.
61. The method of item 59 or 60, wherein the contact angle is measured at at least 2 different implant positions, preferably at at least 2 different outer surface implant positions.
62. The method of any one of items 59 to 61, wherein the contact angle is measured using a drop with a volume of about 1 µl.
63. The method of any one of items 43 to 62, wherein the bio-resorbable material comprises, or is, a polymer selected from the group consisting of polycaprolactone, poly(1,3-trimethylene carbonate), polylactide, polyglycolide, poly(ester amide), poly(ethylene glycol)/poly(butylene terephthalate), poly(4-hydroxybutyrate), polydioxanone, poly(glycerol sebacate), poly(1,8-octanediol-co-citric acid), poly(1,10-decanediol-co-D,L-lactic acid), poly(diols citrate), poly(glycolide-co-caprolactone), poly(1,3-trimethylene carbonate-co-lactide), poly(1,3-trimethylene carbonate-co-caprolactone) and a copolymer of at least two of said polymers, preferably wherein the bio-resorbable material comprises polycaprolactone.
64. The method of any one of items 43 to 63, wherein the bio-resorbable material is capable of being resorbed by a patient, preferably within less than 15 years or within less than 10 years or within less than 5 years upon insertion of the implant into said patient.
65. The method of any one of items 43 to 64, wherein a material density of the implant is between 0.1 gr/cm³ and 2 gr/cm³.
66. The method of any one of items 43 to 65, wherein the implant is manufactured by sequentially printing layers to form a 3D printed lattice structure comprising a plurality of unit cells.
67. The method of item 66, wherein each printed layer comprises a lattice arrangement of 2D unit cells.
68. The method of item 66 or 67, wherein the unit cells are connected to each other.
69. The method of any one of items 66 to 68, wherein the unit cell is a 2D basic unit of the 3D lattice structure.
70. The method of any one of items 66 to 69, wherein the 3D printed lattice structure defines a resting volume of the implant.

71. The method of any one of items 66 to 70, wherein the layers are successively stacked on top of each other.
72. The implant of any one of items 66 to 71, wherein the outer surface region of the implant comprises a first and a second outer surface region.
73. The implant of item 72, wherein edge regions of the layers form the second outer surface region of the implant.
74. The method of item 72 or 73, wherein the plurality of unit cells is arranged to form a porous network of the 3D lattice structure.
75. The method of item 74, wherein the porous network has an average pore size from 0.15 mm or 0.5 mm up to 5, 6, 8, 10 or 12 mm.
76. The method of item 74 or 75, wherein a bulk porosity of the 3D lattice structure of the implant is at least 50%.
77. The method of any one of items 66 to 76, wherein the 3D lattice structure is a reversibly compressible 3D lattice structure.
78. The method of any one of items 66 to 77, wherein individual unit cells of the plurality of unit cells are reversibly compressible spring-like unit cells, wherein the 3D lattice structure is compressible to at least 80% of its resting volume.
79. The method of any one of items 66 to 78, wherein the 3D lattice structure comprises a first outer surface region of the implant comprising a first surface curvature; and a second outer surface region of the implant comprising a second surface curvature, wherein the second outer surface region of the implant is contiguous to the first outer surface region of the implant at a perimeter of the first outer surface region,
80. The method of item 79, wherein a geometry of the first outer surface region represents a geometry of a patient's body part to be brought in contact with the implant upon insertion of the implant into said patient.
81. The method of item 79 or 80, wherein a geometry of the second outer surface region represents a geometry of a patient's body part to be reconstructed by the implant upon insertion of the implant into said patient, preferably a breast region.
82. The method of items 79 or 81, wherein the patient's body part is i) a breast region, pectoral region, malar region, gluteal region or genital region, ii) a tendon and/or a ligament, or iii) a bone region.

83. The method of any one of items 43 to 82, wherein the implant is for reconstructing i) a breast region, pectoral region, malar region, gluteal region or genital region, ii) a tendon and/or a ligament, or iii) a bone region and/or wherein the implant is for supporting a soft tissue.
84. The method of any one of items 43 to 83, wherein the implant is a soft tissue implant and/or a soft tissue support implant, wherein the soft tissue is preferably a soft tissue of i) a breast region, pectoral region, malar region, gluteal region or genital region, and/or of ii) a tendon and/or a ligament.
85. The method of any one of items 43 to 84, wherein the implant is for insertion into a patient.
86. The method of any one of items 43 to 85, wherein the implant is a single-piece reconstruction implant.
87. The method of any one of items 43 to 86, wherein the implant is suitable for being folded and/or compressed such that it can be inserted into a patient minimal invasively.
88. Kit comprising the tissue reconstruction implant according to any one of items 1 to 36 and/or obtainable or obtained by the method according to any one of items 43 to 87 comprised in a packaging.
89. The kit of item 88, wherein the packaging comprises or consists of a blister packaging, wherein the blister packaging is preferably a blister-in-a-blister packaging.
90. The kit of item 88 or 89, wherein the packaging is a multiple layer packaging.
91. The kit of item 90, wherein at least one of the layers is a moisture barrier and/or comprises or consists of polyethylene lined with aluminum.
92. The kit of item 90 or 91, wherein the multiple layer packaging comprises at least i) an inner packaging layer being a moisture barrier and ii) an outer packaging layer providing protection against mechanical forces.
93. The kit of any one of items 90 to 92, wherein the multiple layer packaging comprises at least i) an inner packaging layer comprising or consisting of polyethylene lined with aluminum and ii) an outer packaging layer comprising or consisting of polyethylene.

Claims

What is claimed is:

1. A tissue reconstruction implant, the implant having a hydrophilic implant surface, wherein the implant is a three-dimensional (3D) implant consisting of a bio-resorbable material, and wherein the implant surface is considered hydrophilic when assessed using an ink test following ISO 8296:2003 and adapted to a three-dimensional (3D) surface, wherein said ink test comprises incubating the implant for 1 min in a solution consisting of an ink with a surface tension of 72 mN/m and water, and wherein after incubation of the implant in said solution, an ink colored implant surface is indicative for a hydrophilic implant surface; wherein the implant comprises a three-dimensional (3D) lattice structure, wherein the 3D lattice structure
 - i) defines a resting volume of the implant,
 - ii) has a bulk porosity of at least 50%, and
 - iii) is a reversibly compressible 3D lattice structure, wherein the 3D lattice structure is compressible to at least 80% of its resting volume.
2. The implant of claim 1, wherein
 - i) the bio-resorbable material comprises, or is, a polymer selected from the group consisting of polycaprolactone, poly(1,3-trimethylene carbonate), polylactide, polyglycolide, poly(ester amide), poly(ethylene glycol)/poly(butylene terephthalate), poly(4-hydroxybutyrate), polydiacxonone, poly(glycerol sebacate), poly(1,8-octanediol-co-citric acid), poly(1,10-decanediol-co-D,L-lactic acid), poly(diols citrate), poly(glycolide-co-caprolactone), poly(1,3-trimethylene carbonate-co-lactide), poly(1,3-trimethylene carbonate-co-caprolactone) and a copolymer of at least two of said polymers, or
 - ii) the bio-resorbable material comprises polycaprolactone, and/or
 - iii) the bio-resorbable material is capable of being resorbed by a patient, preferably within less than 15 years upon insertion of the implant into said patient.
3. The implant of claim 1 or 2, wherein
 - i) the implant is an additively manufactured implant, preferably a three-dimensionally (3D) printed implant, and/or

- ii) the filaments of the 3D printed implant have an average diameter between 25 μm and 7.5 mm, preferably between 50 μm and 5 mm or between 50 μm and 600 μm .
- 4. The implant of any one of the preceding claims, wherein the implant has a resting volume between 0.5 cm^3 and 40,000 cm^3 , preferably between 5 cm^3 and 25,000 cm^3 or between 5 cm^3 and 3000 cm^3 or between 5 cm^3 and 800 cm^3 .
- 5. The implant of any one of the preceding claims, wherein the porous network has an average pore size from 0.15 mm up to 12 mm or an average pore size from 0.5 mm up to 12 mm.
- 6. The implant of any one of the preceding claims, wherein the implant is
 - i) a soft tissue implant and/or a soft tissue support implant,
 - ii) for insertion into a patient, and/or
 - iii) a single-piece reconstruction implant.
- 7. The implant of claim 6, wherein the soft tissue is a soft tissue of
 - a) a breast region, pectoral region, malar region, gluteal region or genital region and/or
 - b) a tendon and/or a ligament.
- 8. The implant of claim 6 or claim 7, wherein the soft tissue is a soft tissue of a breast region, pectoral region, malar region or gluteal region.
- 9. The implant of any one of the preceding claims, wherein the implant is suitable for being folded and/or compressed such that it can be inserted into a patient minimally invasively.
- 10. The tissue reconstruction implant of any one of claims 1 to 9 for use in tissue reconstruction, (soft) tissue support, tissue augmentation and/or implant revision, wherein the implant is inserted into a patient.
- 11. Use of the tissue reconstruction implant of any one of claims 1 to 9 for reconstructing, augmenting and/or revising a tissue and/or supporting a (soft) tissue, wherein the implant is inserted into a patient.
- 12. A method of manufacturing a tissue reconstruction implant with a hydrophilic implant surface, comprising
 - exposing a surface of an implant to a surface treatment, wherein the surface treatment is suitable for making the surface of the implant hydrophilic, whereby a hydrophilic implant surface is obtained,
 - wherein the implant is a three-dimensional (3D) implant consisting of a bio-resorbable material, and

wherein the implant surface is considered hydrophilic when assessed using an ink test following ISO 8296:2003 and adapted to a three-dimensional (3D) surface,
wherein said ink test comprises incubating the implant for 1 min in a solution consisting of an ink with a surface tension of 72 mN/m and water, and wherein after incubation of the implant in said solution an ink colored implant surface is indicative for a hydrophilic implant surface;
wherein the implant is manufactured by sequentially printing layers to form a 3D printed lattice structure comprising a plurality of unit cells,
wherein the 3D printed lattice structure defines a resting volume of the implant,
wherein a bulk porosity of the 3D lattice structure of the implant is at least 50%,
wherein individual unit cells of the plurality of unit cells are reversibly compressible spring-like unit cells, wherein the 3D lattice structure is compressible to at least 80% of its resting volume.

13. The method of claim 12, wherein the implant is manufactured by sequentially printing layers to form a 3D printed lattice structure comprising a plurality of unit cells, wherein
 - i) each printed layer comprises a lattice arrangement of 2D unit cells,
 - ii) the unit cells are connected to each other, and/or
 - iii) the filaments of the 3D printed lattice structure have an average diameter between 25 μm and 7.5 mm, preferably between 50 μm and 5 mm or between 50 μm and 600 μm .
14. The method of claim 12 or 13, wherein the surface treatment is i) an etching treatment, preferably an acid or alkaline etching treatment, more preferably a sodium hydroxide treatment, or ii) a plasma treatment, preferably an oxygen plasma treatment.
15. The method of any one of claims 12 to 14, wherein the plasma treatment
 - i) is a low frequency plasma treatment, preferably at about 40 kHz,
 - ii) is performed for at least 10 sec or at least 15 sec or at least 30 sec and/or for a period of time ranging between 10 sec and 240 min or between 15 sec and 240 min or between 15 sec and 90 min or between 15 sec and 60 min or between 15 sec and 30 min,
 - iii) is performed by applying a used power of less than 70 watts (W) or of less than 40 W, and/or between 20 W and 70 W, preferably between 20 W and 40 W or between 50 W and 70 W,
 - iv) is performed by applying a pressure of about 0.3 mbar, and/or

- v) is performed by putting the implant on a glass tray in a plasma treatment device.
- 16. The method of any one of claims 12 to 15 or the implant of any one of claims 1 to 10, wherein the solution used in the ink test consists of the ink with the surface tension of 72 mN/m and distillate water, preferably in a ratio of ink:distillate water of between (about) 1:15 and (about) 1:75, more preferably in a ratio of ink:distillate water of (about) 1:60 or of (about) 1:30.
- 17. A kit comprising the tissue reconstruction implant according to any one of claims 1 to 10 and/or obtainable or obtained by the method according to any one of claims 12 to 16 comprised in a packaging, preferably a multiple layer packaging, wherein preferably at least one of the layers is a moisture barrier and/or comprises or consists of polyethylene lined with aluminum.