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(54) **Biodegradable sterilization wrap**

Biologisch abbaubare Sterilisationshülle

Enveloppe de stérilisation biodégradable

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Description

Technical field

[0001] The present invention, in particular, relates to sterilization wraps. Sterilization wraps are mainly used in CSSD (Central Sterilization & Supplies Department) of hospitals and healthcare facilities for the packaging, the sterilization and the maintenance of the sterile state of re-usable, freshly washed, and disinfected medical devices such as scalpels, pliers, scissors, endoscopes, bedpans, tongue depressors or stents.

[0002] The invention also concerns a set comprising a medical device and a sterilization wrap according to the invention, said sterilization wrap containing said medical device, in particular in a sterilized state.

Prior art

[0003] Sterilization wraps are generally made of special papers. Several types of papers for use in medical packaging are described in the patent literature.

[0004] WO 2007/058822 describes papers having enhanced microbial barrier properties for use in sterile packaging.

[0005] US 6 349 826 describes papers comprising non-biodegradable binders.

[0006] JP 4 334 448 describes a biodegradable composite material comprising a layer of vegetal fibers covered with a layer of polylactic acid.

[0007] The sterilization wraps performances are described in the European Standard (EN 868-2:09): "Packaging for terminally sterilized medical devices - Part 2: Sterilization Wrap - Requirements and tests methods ".

[0008] This document also describes the properties that a sterilization wrap must present. In order to be in conformity with EN 868-2:09 standard, a nonwoven sterilization wrap should meet:

- the general requirements described in the 11607-1:06 : "Packaging for terminally sterilized medical devices - Part 1 : Requirements for materials, sterile barrier systems and packaging systems" defining, in particular, the microbial barrier properties and the compatibility with the sterilization process, and
- the general and the specific performance requirements of EN 868-2:09 #4.2.1 and #4.2.2.3 for nonwoven wrapping material, as summerized in the following table 1 :

TABLE 1

EN 868-2	UNITS	STANDARDS OR METHODS	Specifications
SUBSTANCE	g/m^2	ISO 536	+ or -5% nominal
TENSILE STRENGTH MD	KN/m	ISO 1924-2	1.00 <
TENSILE STRENGTH CD	KN/m	ISO 1924-2	0.65 <
WET TENSILE STRENGTH MD	KN/m	ISO 1924-2	0.75 <
WET TENSILE STRENGTH CD	KN/m	ISO 1924-2	0.50 <
STRETCH MD	%	ISO 1924-2	5 <
STRETCH CD	%	ISO 1924-2	7 <
BURST STRENGTH	kPa	ISO 2758	130 <
WET BURST	kPa	ISO 3689	90 <
TEARING STRENGTH MD	mN	ISO 1974	750 <
TEARING STRENGTH CD	mN	ISO 1974	1000 <
Drape MD	mm	EN 868-2D	To be measured
Drape CD	mm	EN 868-2D	To be measured
HYDROSTATIC TEST	cm	ISO 811	To be measured
pH OF AQUEOUS EXTRACT		ISO 6588	5 < pH < 8
SULFATE CONTENT	% w	ISO 9197-1	< 0.25

(continued)

EN 868-2	UNITS	STANDARDS OR METHODS	Specifications
CHLORIDE CONTENT	% w	ISO 9197-1	< 0.05
FLUORESCENCE	%	DIN 58953-6	5 spots of maximum diameter of 1 mm/100 cm^2

[0009] The fabrication of a sterilization wrap meeting the requirements of the EN 868-2:09 #4.2.2.3 is well known by a man skilled in the art. For example, it is well known that:

- increasing the grammage, and/or
- adding non-biodegradable reinforcing fibers (e.g. polyester, polyamide or polypropylene fibers), and/or
- adding a non-biodegradable binder (e.g. acrylic binder),

may improve the mechanical properties of a wrap so as to meet the required strength standards.

[0010] The known sterilization wraps may be nonwoven and may be made of:

• a mixture of cellulosic wood pulp, binders, fibers and hydrophobic additives. Except the cellulosic wood pulp, those compounds are usually non biodegradable and made from non renewable raw materials (materials of fossil origin). Those nonwovens are known as "wet laid nonwovens", or
• 100% synthetic fossil based fibers such as polypropylene. Those nonwovens are known as "SMS" (Spunbond - Meltblown - Spunbond) nonwovens.

[0011] These sterilization wraps may have a grammage of 80g/m^2 or less, usually below 70g/m^2.

[0012] The Applicant has surprisingly found that the use of biodegradable compounds in a sterilization wrap may allow the meeting of the EN 868-2 requirements while allowing the maintain of the grammage of the formed sheet.

[0013] Further, the use of biodegradable compounds may enhance the ability of the formed products to be recycled or decomposed.

[0014] It is an object of the present invention to provide a sterilization wrap meeting the EN 868-2:09 requirements, including the barrier properties requirements, and having a relatively low grammage.

[0015] It is another object of the invention to provide a sterilization wrap which is easy to get rid of.

Summary of the invention

[0016] The invention provides a medical material, intended to be sterilized, the medical material for producing a product chosen in the group consisting of: a surgical drape, optionally provided with a hole, a container filter, a sterile field, in particular to be used as a mayo or table cover, a gown, a sterilization wrap or a sterile barrier system as per ISO 11607 standard definition, said material comprising or consisting of a, preferably nonwoven, sheet:

- comprising at least 80%, preferably at least 90%, more preferably at least 95%, in percentage by dry weight on the basis of said sheet, of biodegradable compounds,
- having a bio-based content of 60%, preferably 80%, more preferably 90%, or more, and
- having a grammage of 75 g/m^2 or less, preferably of 70g/m^2 or less, said sheet comprising or consisting of a layer comprising, for a total of more than 80%, in particular more than 85 %, in particular more than 90%, in percentages by dry weight on the basis of said layer, 15 % or more of cellulose fibers and:

  - at least 1%, preferably 1% to 80%, preferably 1 to 50%, preferably 2% to 20%, more preferably 3 % to 10%, of synthetic biodegradable fibers having an average length of at least 2.5 mm, preferably 3 mm, said synthetic biodegradable fibers preferably being selected from fibers of plastified cereal flour based polymers, optionally modified with copolyesters, fibers of plastified starch, such as corn starch, wheat starch or potatoe starch optionally modified with copolyesters, fibers of polylactic acid, fibers of polyhydroxyvalerate, fibers of polyhydroxybutyrate, fibers of polyhydroxyalkanoate, fibers of polyhydroxyhexanoate, fibers of polycaprolactone, fibers of polybutylene succinate, fibers of polybutylene succinate adipate or mixtures thereof, and/or
  - 20% to 100%, preferably 30% to 100%, preferably 40% to 100%, preferably 55% to 85%, more preferably 65% to 85%, of natural biodegradable fibers having an average length of at least 1.5 mm, preferably 2.5 mm, more

preferably 3 mm, preferably selected from abaca, bamboo, cotton, sisal fibers or mixtures thereof, and/or
- a biodegradable binder.

[0017] The cellulose fibers may be refined.

[0018] The sheet may have a grammage lying in the range 25g/m^2 to 75g/m^2, preferably 50g/m^2 to 75g/m^2, more preferably 55 g/m^2 to 65 g/m^2.

[0019] A sheet according to the invention may advantageously present a relatively low grammage and an enhanced biodegradability while still meeting the strong requirements of EN 868-2:09 and presenting satisfying barrier properties, in particular to microorganisms.

[0020] The sheet may be considered as a paper and may be, as described hereunder, manufactured by papermaking methods.

Definitions

[0021] According to the invention, a compound is "biodegradable" when the ratio of its biodegradation percentage on the biodegradation percentage of cellulose fibers is at least 75 %, more preferably at least 80 %, more preferably at least 90 %. The biodegradation percentages may be measured according to ISO 14855 (2005) method: *"Determination of the ultimate aerobic biodegradability and disintegration of plastic materials under controlled composting conditions",* after 24 days as described in the examples.

[0022] Preferably, a compound is regarded as "biodegradable" if it is decomposed, when exposed to the outside natural environment, under the climate of Paris (France), in less than 10 years, less than 5 years, preferably less than 1 year, preferably less than 6 months, preferably less than 2 months.

[0023] The "bio-based content" of a material is the ratio of its amount of organic carbon produced by the biomass or "bio-carbon" (i.e. from biologic origin, therefore excluding fossil or geologic materials) to its total amount of organic carbon.

[0024] The bio-based content quantifies, in a given material, the concentration of young (i.e. renewable) organic carbon in comparison with the concentration of old fossil organic carbon based resources.

[0025] The bio-based content may in particular be determined according to ASTM D6866-10.

[0026] A "fiber" is, in particular, presenting a ratio L/l of its length "L" to its width (largest dimension in a transversal cross-section) "1" of at least 10.

[0027] According to the invention, the expression "synthetic fiber" means a fiber produced artificially by a chemical or biochemical synthesis. A "synthetic fiber" is synonymous of a man-made fiber.

[0028] According to the invention, a "natural fiber" is a fiber which is not a "synthetic fiber" as defined above. A natural fiber may, in particular, be a cellulose-based fiber.

[0029] Unless otherwise stated, the amount, by dry weight, of cellulose fibers includes the amount, by dry weight, of the natural biodegradable fibers which are mainly cellulosic. Thus, if a sterilization wrap comprises 80%, by dry weight, of biodegradable fibers which are cellulosic (i.e. bamboo fibers) and 20%, by dry weight, of wood pulp, the amount, by dry weight, of cellulose fibers is 100 %.

[0030] According to the invention, the fibers of a "layer" are intimately entangled. Woven or non woven mats are examples of layers.

[0031] According to the invention, the "binder" binds the fibers together thus improving the cohesiveness and mechanical properties of the sheet.

[0032] The invention also provides a product comprising a material as described above, said product being chosen in the group consisting of:

- a sterilization wrap,
- a container filter,
- a sterilized surgical drape, optionally provided with a hole,
- a sterilized sterile field, in particular to be used as a mayo or table cover,
- a sterilized gown,
- a sterilized sterile barrier system as per ISO 11607 standard definition.

[0033] The invention also provides a kit comprising:

- a sterilization wrap as described above, said sterilization wrap defining a closed inner volume, and
- a sterilized medical device disposed inside said inner volume, said sterilized medical device being, in particular, chosen from sterilized scalpels, pliers, scissors, endoscopes, bedpans, tongue depressors or stents.

[0034] The invention also provides a method for manufacturing a material as described above comprising:

a) preparing a furnish:

- comprising at least 80%, preferably 90%, more preferably 95%, by dry weight, of biodegradable compounds,
- having a bio-based content of 60%, preferably 80%, more preferably 90%, or more, said furnish further comprising:
- for a total of more than 80 %, in particular more than 85 %, in particular more than 90 %, in percentages by dry weight of said furnish, at least 15 percent of cellulose fibers and:

  i. at least 1%, preferably 1% to 80%, preferably 1 to 50%, preferably 2% to 20%, more preferably 3% to 10%, of synthetic biodegradable fibers having an average length of at least 2.5 mm, preferably 3 mm, said synthetic biodegradable fibers preferably being selected from fibers of plastified cereal flour based polymers, optionally modified with copolyesters, fibers of plastified starch, such as corn starch, wheat starch or potatoe starch optionally modified with copolyesters, fibers of polylactic acid, fibers of polyhydroxyvalerate, fibers of polyhydroxybutyrate, fibers of polyhydroxyalkanoate, fibers of polyhydroxyhexanoate, fibers of polycaprolactone, fibers of polybutylene succinate, fibers of polybutylene succinate adipate or mixtures thereof, and/or
  ii. 20% to 100%, preferably 30% to 100%, preferably 40% to 100%, preferably 55% to 85%, more preferably 65% to 85%, of natural biodegradable fibers having an average length of at least 1.5 mm, preferably 2.5 mm, more preferably 3 mm, preferably selected from abaca, bamboo, cotton, sisal fibers or mixtures thereof, and/or
  iii. a biodegradable binder,

b) forming a sheet from the furnish in a wet-laid process, in particular selected from one of a fourdrinier process, an inclined wire process, a mold table process, a former process and a mold cylinder process;
c) preferably pressing and drying the sheet; and
d) optionally forming a pattern on and/or within the sheet via a softening process, performed on-line or off-line, configured to result in a softening of the sheet and a barrier performance of the sheet according to the EN 868-2:09 standard, said softening process being, in particular, selected from at least one of creping, micro-creping and/or an embossing,
said method being, preferably, deprived of a hydro-entangling step.

[0035] As used herein the term "on-line" shall mean a period during which the material is formed (e.g., on the wire), and includes any process from wet laying through finishing (e.g., drying, calendaring, sizing, etc.). The term "off-line" shall mean any period after the on-line period.
[0036] The above-mentioned steps a) to d) may have a positive impact on the obtaining of the desired barrier properties.
[0037] The cellulose fibers present in the furnish described in a) may be refined.
[0038] A refining step may be carried out before step a). The refining step may advantageously densify the fiber network and improve its cohesion.
[0039] The invention also provides a method of sterilization of a medical device, in particular chosen from scalpels, pliers, scissors, endoscopes, bedpans, tongue depressors or stents, comprising at least the following steps consisting in:

- providing a sterilization wrap according to the invention,
- wrapping in said sterilization wrap a medical device to obtain a kit,
- introducing said kit into a sterilizing unit, and
- sterilizing said kit.

[0040] The kit described above may, in particular, be wrapped in an additional sterilization wrap before being introduced in the sterilizing unit.
[0041] The sterilizing unit may subject the kit to high pressure saturated steam (the sterilizing unit may be an autoclave), low temperature formaldehyde steam (LTFS), gamma-rays, electron beams, ethylene oxide or to a dry heat process.
[0042] The invention also provides the use of a sheet as described above as a component of a product having barrier properties, in particular to microorganisms.

Brief description of the drawings

[0043] Other features of the invention will become apparent when reading the following description in view of the drawings, wherein:

- Figure 1 shows the evolution of the biodegradation percentage of a sterilization wrap according to the invention and of cellulose in average of the 3 corresponding replicates,
- Figures 2 and 3 respectively show the evolution of the biodegradation percentage of cellulose and of a sterilization wrap according to the invention, for each of the three corresponding replicates (RN1-RN6).

Detailed description

Fibers comprised in the sheet

[0044] The sheet may comprise biodegradable fibers selected from at least one of following ones: bleached wood pulp, semi-bleached wood pulp, unbleached wood pulp, cotton, abaca, straw, bamboo, viscose, hemp, jute, sisal, flax, kenaf, esparto or fibers from biodegradable or biocompostable polymers, according to EN 13432 standard, such as polylactic acid, polyhydroxyvalerate, polyhydroxybutyrate, polyhydroxyalkanoate, polyhydroxyhexanoate, polycaprolactone, polybutylene succinate, polybutylene succinate adipate or copolymers of them, optionally modified with starch based polymer, plastified cereal flour based polymers, optionally modified with copolyesters, plastified starch, such as corn starch, wheat starch or potatoe starch optionally modified with copolyesters.

[0045] Any suitable pulps may be utilized for obtaining the cellulose, for example, kraft pulps from coniferous and/or deciduous trees. Portions of the cellulose may be mechanically, chemically, thermo-mechanically, and/or chemi-thermo-mechanically pulped, as desired.

[0046] The natural biodegradable fibers may, in particular, be selected from at least one of the following ones: bleached wood pulp, semi-bleached wood pulp, unbleached wood pulp, cotton, abaca, straw, bamboo, hemp, jute, sisal, flax, kenaf or esparto.

[0047] The synthetic (i.e. man-made) biodegradable fibers may preferably be selected from at least one of the following ones: polylactic acid fibers, fibers of polyhydroxyalkanoate, fibers of polyhydroxyhexanoate, fibers of polycaprolactone, fibers of polybutylene succinate, fibers of polybutylene succinate adipate, viscose fibers, fibers of plastified starch, such as corn starch, wheat starch or potatoe starch optionally modified with copolyesters, or fibers of plastified cereal flour polymer.

[0048] The biodegradable fibers may have an average length lying in the range 0.1 mm to 30 mm, preferably 1 to 15 mm.

[0049] The biodegradable synthetic fibers may, in particular, have an average length of at least 2.5 mm, preferably 3 mm, more preferably 5 mm.

[0050] The biodegradable synthetic fibers may, in particular, have an average length of less than 12 mm.

[0051] The biodegradable natural fibers may have an average length of at least 1.5 mm, preferably 2.5 mm, more preferably 3 mm.

[0052] The biodegradable natural fibers may, in particular, have an average length of less than 10 mm.

[0053] The "average length" is, unless otherwise specified, the median length.

[0054] When the sheet comprises synthetic biodegradable fibers, the cellulose fibers may be present in an amount of 30 % or more, preferably of 50 % or more, in particular of 70 % or more, by dry weight of the layer.

[0055] In one embodiment, the sheet may comprise, for a total of more than 80 %, in particular more than 85 %, in particular more than 90 %, in percentages by dry weight on the basis of the layer:

- 3 to 10% of synthetic biodegradable fibers, preferably selected from polylactic acid fibers, fibers of plastified starch, such as corn starch, wheat starch or potatoe starch optionally modified with copolyesters, fibers of polyhydroxyvalerate, fibers of polyhydroxybutyrate or fibers of plastified cereal flour polymers, and
- 70 % or more of cellulose fibers.

[0056] When the sheet comprises a biodegradable binder, the cellulose fibers may be present in an amount of 30 % or more, preferably of 50 % or more, in particular of 70 % or more, by dry weight of the layer.

[0057] In one embodiment, the sheet may comprise in percentages by dry weight on the basis of the layer:

- 1 to 10% of a biodegradable binder, preferably selected from potatoe starch, and
- 90 % or more of cellulose fibers.

[0058] When the sheet comprises natural biodegradable fibers, the cellulose fibers may be present in an amount of 50 % or more, preferably of 70 % or more, more preferably of 85 % or more, by dry weight of the layer.

[0059] In one embodiment, the sheet may comprise, in percentages by dry weight on the basis of the layer, 60% or more of biodegradable fibers selected from abaca, sisal, cotton, bamboo fibers or mixtures thereof, the total amount of cellulose fibers in the layer being more than 85%.

[0060] In a particularly preferred embodiment, the layer of the sheet comprises cellulose fibers and synthetic biode-

gradable fibers.

Biodegradable binder and additive

[0061] The sheet may comprise a biodegradable binder, in particular in an amount of 2 % or more, in percentage by dry weight of the layer.

[0062] The biodegradable binder may, in particular, be non-fibrous.

[0063] The biodegradable binder may, in particular, be an adhesive.

[0064] The biodegradable binder may, in particular, be polymeric.

[0065] The sheet may, in particular, comprise at least 2 %, and/or less than 30 %, preferably less than 25%, preferably less than 20 %, preferably less than 15 %, preferably less than 10 %, more preferably less than 5%, in percentage by dry weight of the layer, of a biodegradable binder and/or of an additive providing wet strength, cohesiveness or softness, for example chosen from potatoe, wheat, tapioca or corn starch, proteins of vegetal origin, such as soya protein or silk protein, proteins of animal origin, such as milk proteins, egg derivatives or algae derivatives, gelatin, collagen, chitine, the natural rubber latex, preferably of low protein grade, or a mixture of these compounds.

[0066] The sheet may comprise less than 20 %, preferably less than 15%, preferably less than 12 %, in percentage by dry weight of the layer, of a biodegradable hydrophobic additive, for example a vegetal modified oil, providing liquid repellency.

Non-biodegradable compounds

[0067] The sheet may have an amount less than 20 %, preferably less than 15%, preferably less than 12%, preferably less than 10%, preferably less than 6%, in percentage by dry weight of the layer, of non-biodegradable compounds, said non-biodegradable compounds being, in particular, chosen from pigments, non-biodegradable hydrophobic additives or binders either acrylic or vinylic, polyurethane, polyvinyl alcohol, polyvinylacetate, styrene butadiene rubber, ethylene propylene heteropolymers or a mixture thereof.

[0068] The non-biodegradable binder may, in particular, be incorporated via a size-press process, a spraying process, a saturating process or a precipitating process.

[0069] The non-biodegradable binder may, in particular, be a film-forming non-biodegradable binder.

[0070] The concentration in the layer of eco-toxic substances, in particular fluorocarbon compounds additives, is preferably less than 200 parts per million.

Structure of the products according to the invention

[0071] The products according to the invention may have, when completely unfold, a greatest dimension comprised between 15 cm and 180 cm, for example 60 cm and 150 cm.

[0072] When the product is a container filter, its greatest dimension may, in particular, be comprised between 15 cm and 60 cm.

[0073] The thickness of the gowns, sterilization wraps or sterile fields according to the invention may, in particular, lie in the range 100 μm to 250 μm, preferably 125 μm to 175 μm.

[0074] The sterilization wrap may have a density of 0.8 g/cm^3 or less.

[0075] The sterilization wrap may have at least a portion comprising a softening process pattern, formed on-line or off-line, configured to soften said sterilization wrap, said softening process pattern being, in particular, selected from one of a creped pattern, micro-creped pattern, and an embossing pattern.

[0076] The sterilization wrap is preferably a monolayer material.

[0077] The sterilization wrap may be provided in a non-sterilized state and may be sterilized after.

[0078] The sterilization wrap may, when completely unfold, be of any shape for e.g.: circular, elliptical or polygonal.

[0079] The sterilization wrap, when completely unfold, may be of square shape and, in particular, have a length of about 60cm, 75cm or 90cm.

[0080] The invention also concerns a sterilized sterile barrier system as per ISO 11607 standard definition comprising a sterilization wrap as described above.

Functional properties of the products according to the invention

[0081] The sterilization wrap, container filter and sterile field according to the invention may present at least one, preferably all of, the following features:

- a barrier meeting at least level 2 performance requirements based on the standard defined by AAMI PB70,

- a Log Reduction Value of at least 1, preferably at least 2, in particular lying in the range 1 to 4, in particular 1 to 3, the Log Reduction Value being determined by ASTM F 1608,
- a barrier filtration efficiency; according to ASTM F2101-01, higher than 90%, preferably higher than 96%, when the product comprises a single layer according to the invention and higher than 95%, preferably higher than 99.5%, when it comprises two or more layers according to the invention.

[0082] The sterilization wrap may comprise less than 0.1 % of biocide agents, by dry weight.

[0083] The sterilization wrap may be in the sterilized state.

[0084] The sterilization wrap may be sterilized and provided in a sterilized packaging following its manufacture.

[0085] The sterilization wrap and the field according to the invention may present at least one, preferably all of, the following features:

- some tensile strength values, according to ISO 1924-2, higher than 1.0 kN/m in machine direction and higher than 0.65 kN/m in cross direction, preferably higher than 3.0 kN/m in machine direction and higher than 1.5 kN/m in cross direction,
- some wet tensile strength values according to ISO 1924-2 higher than 0.75 kN/m in machine direction and higher than 0.50 kN/m in cross direction, preferably higher than 1.0 kN/m in machine direction and higher than 0.6 kN/m in cross direction,
- some stretch values, according to ISO 1924-2, higher than 5% in machine direction and higher than 7% in cross direction, preferably higher than 10% in machine direction and higher than 8% in cross direction,
- some burst values, according to ISO 2758, higher than 130 kPa, preferably higher than 180 kPa,
- some wet burst values, according to ISO 3689, higher than 90 kPa, preferably higher than 105 kPa,
- some tear strength values, according to ISO 1974, higher than 750 inN in machine direction and higher than 1000 mN in cross direction, preferably higher than 850 mN in machine direction and higher than 1150 mN in cross direction,
- the softening process pattern resulting in a cross direction drape value lower than 200 mm, preferably lower than 140 mm,
- the softening process pattern resulting in a machine direction drape value lower than about 120 mm, preferably lower than 90 mm.

[0086] The sterilization wrap may have a linting value, according to ISO 9073-10, of less than 10, preferably less than 6.

[0087] The sterilization wrap may have water penetration resistance values, according to ISO 811, higher than 20 mbar, preferably higher than 40 mbar.

Method of manufacture of the sheet

[0088] The sheet may be manufactured according to steps a) to d) as described above.

[0089] At step a), the furnish may comprise an aqueous solution, according to some embodiments, a coloring agent (e.g., a pigment and/or a dye) may be introduced into the aqueous solution where desired and/or the sheet may be printed or otherwise colored following formation on the wire. For example, where a color match is desired, an appropriate pigment and/or dye (e.g., a blue pigment) may be added to cause the dried sheet to have a desired color. The pigments and/or dyes may be natural and/or synthetic, and combinations thereof, and such pigments may be biodegradable and/or may be inert towards the environment. The pigments may, in particular, be organic or inorganic, and when they are inorganic, they may, in particular, be inert towards the environment.

[0090] As such, the sheet according to the invention may, in particular, comprise for example green or blue, inorganic pigments which are inert towards the environment.

[0091] Alternatively, the sheet may be void of any coloring agent and may be colored based substantially on the fibers used to manufacture said sheet and other environmental conditions.

[0092] At step c), the drying can be carried out at a temperature between about 75 °C and about 200 °C.

[0093] At step d), sheet may undergo one or more off line or on-line finishing processes. For example one or more softening processes (e.g., mechanical finishing) may be applied to the sheet as desired. Such softening processes may be configured to effect a softening of the sheet, an increase in strength, an increase in breathability, and/or an increase in conformability. Such softening processes may therefore be effective to at least reduce drape values (i.e., increase conformability).

[0094] Softening processes may include, for example, mechanical processes such as creping, micro-creping, flexage, embossing, etc. Micro-creping, for example, may act on the web associated with the sheet by compacting it, particularly in the machine direction (MD). Therefore, when exposing to a micro-crepe finishing process, it may be desirable to have a certain percentage of fibers of the web oriented in the machine direction, thereby allowing more fibers to be creped.

[0095] According to some embodiments, the finishing processes (e.g., softening) may be configured to form a pattern

on and/or within the structure of sheet resulting in, for example, a softening process pattern on and/or within the structure of sheet. Such a pattern may be a visible pattern, semi-visible, or not visible to the naked eye (e.g., microscopic pattern), as desired, and/or combinations thereof. The mechanical finishing processes may be executed on any suitable processor, for example, when micro-creping sheet, a mechanical microcreper may be utilized. According to some embodiments, a Micrex® Microcreper may be implemented to micro-crepe the formed sheets. For example, a microcreper having rigid retarders, and/or comb roll cavity, and/or two rolls cavity, and/or flat blade cavity, or bladeless microcreper may be utilized.

[0096] According to some embodiments, coloring agents may be added to provide color to the sheet after the mechanical finishing process, particularly where coloring agents may affect the mechanical finishing process (e.g., depending on sensitivity of a creping machine). For example, a blue pigment may be introduced into the aqueous solution prior to formation on the wire. Additionally, it may be possible to provide designs and/or text, among other things, via printing on the sheet. Alternatively, no coloring agents may be used.

Examples

Manufacturing method of sterilization wraps according to the present invention

[0097] A single layer sheet according to example 4 (see Table 2 below) was manufactured on a Fourdrinier paper machine in the following manner: 89.5% by dry weight of cellulose fibers were suspended in an aqueous medium with 5.1% by dry weight of polylactic acid fibers. A synthetic acrylic binder was added in a concentration of 3.5% by dry weight. A biodegradable binder was added in a concentration of 0.7% by dry weight, a non-biodegradable hydrophobic additive was added in a concentration of 0.3% by dry weight and an additive of unknown degradability was added in a concentration of 0.9% by dry weight. The suspension was dewatered on the wire of the paper machine in order to form the sheet. The sheet was dried at around 120 degrees C and the resulting sheet had a grammage of approximately 64.1 g/m^2.

The sheet was then micro-creped to effect a softening of the sheet. The micro-creping was performed resulting in a conformability value of approximately 75 in the machine direction.

[0098] A single layer sheet according to example 5 (see Table 2 below) was manufactured on a Fourdrinier paper machine in the following manner: 86.6% by dry weight of cellulose fibers were suspended in an aqueous medium with 7.4% by dry weight of polylactic acid fibers. A synthetic acrylic binder was also added in a concentration of 3.5% by dry weight. A non-biodegradable hydrophobic additive was added at a concentration of 0.3% by dry weight, an additive of unknown degradability was added at a concentration of 1.5% by dry weight and a biodegradable binder was added at a concentration of 0.7% by dry weight. The suspension was dewatered on the wire of the paper machine in order to form the sheet. The sheet was dried at around 120 degrees C and the resulting sheet had a grammage of approximately 63 g/m^2.

[0099] The sheet was then micro-creped to effect a softening of the sheet. The micro-creping was performed resulting in a conformability value of approximately 79 in the machine direction.

Compositions and results

[0100]

TABLE 2

Component	Ref (supplier)	Nature		Ex.1	Ex.2	Ex.3	Ex.4	Ex.5
Wood cellulose	-	Bleached or semi-bleached or unbleached hardwood or softwood cellulosic fibers		95.4%	82.1%	22.5%	89.5%	86.6%
Natural bioD fibers	AK 102S (Ogura Trading)	Abaca cellulosic fibers		0.0%	0.0%	76.2%	0.0%	0.0%
Non BioD hydrophobic additive		Alkyl Keten Dimer		0.6%	0.2%	0.3%	0.3%	0.3%
BioD hydrophobic additive	Topscreen DS13 (Topchim)	Vegetal modified oil		0.0%	10.7%	0.0%	0.0%	0.0%
Non BioD Binder	Vinacryl 4333 (Celanese)	Acrylic binder		0.0%	0.0%	0.0%	3.5%	3.5%
BioD binder N°1	Emcol KF1000 (Emsland)	Modified potatoe starch		2.4%	0.0%	0.0%	0.0%	0.0%
Additive of unknown degradability	-	Wet strength additive, pigment, defoamer...		0.9%	0.8%	0.5%	0.9%	1.5%
BioD binder N°2	Hicat 1164A (Roquette)	Potatoe starch		0.7%	0.0%	0.5%	0.7%	0.7%
Fluoro-chemical additives	-	-		0%	0%	0%	0%	0%
Synthetic Bio D fibers	Grade 811 (FIT)	PLA (Poly Lactic Acid) fibers		0.0%	6.2%	0.0%	5.1%	7.4%
softening process		microcreping		either in-line or off-line				
EN 868-2 part 4.2.1 requirements	**Units**	**Standards or TM**	**Objective**	Ex.1	Ex.2	Ex.3	Ex.4	Ex.5
Substance	g/m^2	ISO 536	+ or -5% nominal	70.7	60.6	65.8	64.1	63.0
pH OF AQUEOUS EXTRACT		ISO 6588	5 < pH < 8	5 < pH < 8	5 < pH <8	5 < pH < 8	5 < pH < 8	5 < pH < 8
SULFATE CONTENT	%	ISO 9197-1	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25
CHLORIDE CONTENT	%	ISO 9197-1	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05
FLUORESCENCE	%	DIN 58953-6	5 spots of maximum diameter of 1 mm/100 cm^2	Nil	Nil	Nil	Nil	Nil
Drape MD	mm	EN 868-2D	To be measured			79	75	79

(continued)

Component	Ref (supplier)	Nature		Ex.1	Ex.2	Ex.3	Ex.4	Ex.5
Drape CD	mm	EN 868-2D	To be measured			148	156	170
Surface Resistivity	oms	BS 6524	To be measured	<10e13	<10e13	<10e13	<10e13	<10e13
EN 868-2 part 4.2.3 requirements	**Units**	**Standards or TM**	**Objective**	Ex.1	Ex.2	Ex.3	Ex.4	Ex.5
TENSILE STRENGTH MD	KN/m	ISO 1924-2	> 1.00	3.6	3.6	6.2	3.1	3.1
TENSILE STRENGTH CD	KN/m	ISO 1924-2	> 0.65	2.4	1.6	2.5	1.8	1.8
WET TENSILE STRENGTH MD	KN/m	ISO 1924-2	> 0.75	1.0	1.1	0.9	1.2	1.2
WET TENSILE STRENGTH CD	KN/m	ISO 1924-2	> 0.50	0.7	0.6	0.6	0.6	0.6
STRETCH MD	%	ISO 1924-2	> 5	17	7	7	15	13.0
STRETCH CD	%	ISO 1924-2	> 7	7.4	8.5	8.9	8.1	7.5
BURST STRENGTH	kPa	ISO 2758	> 130	212	187	350	190	210.0
WET BURST	kPa	ISO 3689	> 90	92	95	115	105	110.0
TEARING STRENGTH MD	mN	ISO1974	> 750	910	1005	949	796	840.0
TEARING STRENGTH CD	mN	ISO1974	> 1000	1155	1172	1250	1205	1130.0
AAMI PB 70		PB70		2	2	2	2	2
Linting Spray impact test	log 10 g	ISO 9073- 10 AATCC42		<5 <1	<5 <1	<5 <1	<5 <1	<5 <1
HYDROSTATIC TEST	mbar	ISO 811		69	40	65	52	60
11607-1 Barrier claims								
Din test (Dry/Wet)	OK/Not OK	Din 58953/6		OK/ OK	OK/ OK	OK/OK	OK/ OK	OK/ OK
BFE single	%	ASTM F2101-01		> 98%	> 98%	> 98%	98.4	98.9%
BFE double	%	ASTM F2101-01		> 99%	> 99%	> 99%	99.9%	99.5%
Cytotoxicity	OK/Not OK	ISO 10993-5		OK	OK	OK	OK	OK
Biodegradability claims								
Biobased content (estimates)	%	ASTM D6866		98.5%	98.9%	99.2%	95.2%	94.6%
Biobased content (measured values) (when available)	%			N/A	N/A	N/A	N/A	96.0%

(continued)

Component	Ref (supplier)	Nature	Ex.1	Ex.2	Ex.3	Ex.4	Ex.5
OK bio based	numbers of *	Vincotte	****	****	****	****	****
Biodegradability	OK/Not OK	ISO14855	OK	OK	OK	OK	OK

Biodegradability test

[0101] The biodegradability of a sterilization wrap consisting in a sheet according to example 5 is tested according to ISO 14855 (2005) method: *"Determination of the ultimate aerobic biodegradability and disintegration of plastic materials under controlled composting conditions".*

[0102] The test item is prepared by milling said sterilization wrap in particles having a size less than 4 mm.

[0103] The reference item is native cellulose powder for thin layer chromatography (cellulose Avicel, Merck).

[0104] The test details are reported in table 3.

TABLE 3

Treatment	Number of replicates	Compost Inoculum (g)	Test item (g)
Compost (control)	3	1200	-
Cellulose powder (reference item)	3	1200	80
test item	3	1200	80

[0105] During the test, the incubation temperature is continuously kept on 58°C ± 2°C and the test lasts 24 days.

[0106] The net CO_2 production of the item under consideration (reference item or test item) is obtained by substracting the CO_2 production of the control to the CO_2 production of said item.

[0107] The biodegradation percentage is the ratio of the net CO_2 production of the item under consideration to the original amount of carbon comprised in said item. When the ratio of the biodegradation percentage of the item under consideration to the biodegradation percentage of cellulose is higher than 75%, the item under consideration is regarded as "biodegradable".

[0108] An overview of the evolution of the biodegradation percentage of the different materials is given in Figure 1, while Figures 2 up to 3 show the biodegradation of the replicates of reference and test items.

[0109] Table 4 illustrates the assessment of biodegradability for example 5.

TABLE 4

Items	**Net CO_2 production (mg/g item)**	**Biodegradation (%)**		
		AVG.	**STD.**	**REL.**
Reference item	1314	84.4	1.3	100.0
Test item	1204	76.9	1.5	91.1

[0110] Throughout the description, including the claims, the term "comprising a" should be understood as being synonymous with "comprising at least one" unless otherwise stated. In addition, any range set forth in the description, including the claims should be understood as including its end value(s) unless otherwise stated. Specific measurement values for described elements should be understood to be within generally accepted manufacturing or industry tolerances, and any use of the terms "substantially" and "approximately" should be understood to mean falling within such generally accepted tolerances. Component ratios throughout the disclosure shall be understood to be by dry weight unless otherwise specified.

Claims

1. A medical material, intended to be sterilized, the medical material for producing a product chosen in the group consisting of: a surgical drape, optionally provided with a hole, a container filter, a sterile field, in particular to be used as a mayo or table cover, a gown, a sterilization wrap or a sterile barrier system as per ISO 11607 standard definition, said material comprising or consisting of a, preferably nonwoven, sheet:

- comprising at least 80%, preferably at least 90%, more preferably at least 95%, in percentage by dry weight on the basis of said sheet, of biodegradable compounds, a biodegradable compound having a ratio of its biodegradation percentage on the biodegradation percentage of cellulose fibers of at least 75%, the biodegradation percentages being measured according to ISO 14855 (2005) method: *"Determination of the ultimata aerobic biodegradability and disintegration of plastic materials under controlled composting conditions* ", after

24 days,
- having a bio-based content of 60%, preferably 80%, more preferably 90%, or more, and
- having a grammage of 75 g/m^2 or less, preferably of 70g/m^2 or less, said sheet comprising or consisting of a layer comprising, for a total of more than 80%, in particular more than 85 %, in particular more than 90%, in percentages by dry weight on the basis of said layer, 15 % or more of cellulose fibers and:

- at least 1%, preferably 1% to 80%, preferably 1 to 50%, preferably 2% to 20%, more preferably 3 % to 10%, of synthetic biodegradable fibers having an average length of at least 2.5 mm, preferably 3 mm, said synthetic biodegradable fibers preferably being selected from fibers of plastified cereal flour based polymers, optionally modified with copolyesters, fibers of plastified starch, such as corn starch, wheat starch or potatoe starch optionally modified with copolyesters, fibers of polylactic acid, fibers of polyhydroxyvalerate, fibers of polyhydroxybutyrate, fibers of polyhydroxyalkanoate, fibers of polyhydroxyhexanoate, fibers of polycaprolactone, fibers of polybutylene succinate, fibers of polybutylene succinate adipate or mixtures thereof, and/or
- 20% to 100%, preferably 30% to 100%, preferably 40% to 100%, preferably 55% to 85%, more preferably 65% to 85%, of natural biodegradable fibers having an average length of at least 1.5 mm, preferably 2.5 mm, more preferably 3 mm, preferably selected from abaca, bamboo, cotton, sisal fibers or mixtures thereof, and/or
- a biodegradable binder.

2. The material according to claim 1, the sheet comprising biodegradable fibers selected from at least one of following ones: bleached wood pulp, semi-bleached wood pulp, unbleached wood pulp, cotton, abaca, straw, bamboo, viscose, hemp, jute, sisal, flax, kenaf, esparto or fibers from biodegradable or biocompostable polymers, according to EN 13432 standard, such as polylactic acid, polyhydroxyvalerate, polyhydroxybutyrate, polyhydroxyalkanoate, polyhydroxyhexanoate, polycaprolactone, polybutylene succinate, polybutylene succinate adipate or copolymers of them, optionally modified with starch based polymer, plastified cereal flour based polymers, optionally modified with copolyesters, plastified starch, such as corn starch, wheat starch or potatoe starch optionally modified with copolyesters.

3. The material according to claims 1 or 2, the sheet comprising less than 30 %, preferably less than 10%, more preferably less than 5%, in percentage by dry weight of the layer, of a biodegradable binder or additive providing wet strength, cohesiveness or softness, for example chosen from potatoe, wheat, tapioca or corn starch, proteins of vegetal origin, such as soya protein or silk protein, proteins of animal origin, such as milk protein, egg derivatives or algae derivatives, gelatin, collagen, chitine, the natural rubber latex, preferably of low protein grade, or a mixture of these compounds.

4. The material according to any preceding claim, the sheet having an amount less than 20 %, preferably less than 6%, in percentage by dry weight of the layer, of non-biodegradable compounds, in particular chosen from pigments, non-biodegradable hydrophobic additives or binders either acrylic or vinylic, polyurethane, polyvinyl alcohol, polyvinylacetate, styrene butadiene rubber, ethylene propylene heteropolymers or a mixture thereof.

5. The material according to any preceding claim, the sheet having a concentration in the layer of fluorocarbon compounds additives of less than 200 parts per million.

6. The material according to any preceding claim, the sheet having a grammage lying in the range 25 g/m^2 to 75 g/m^2, preferably 50 g/m^2 to 75 g/m^2, more preferably 55 g/m^2 to 65 g/m^2.

7. The material according to any preceding claim, the sheet having at least a portion comprising a softening process pattern, formed on-line or off-line, configured to soften said sheet, said softening process pattern being, in particular, selected from one of a creped pattern, micro-creped pattern, and an embossing pattern.

8. The material according to any preceding claim, having a density of 0.8 g/cm^3 or less.

9. The material according to any preceding claim, being a monolayer material.

10. The material according to any preceding claim, the product being a sterilization wrap.

11. A product chosen in the group consisting of: a surgical drape, optionally provided with a hole, a container filter, a sterile field, in particular to be used as a mayo or table cover, a gown, a sterilization wrap or a sterile barrier system

as per ISO 11607 standard definition, said product comprising a material as defined in any of the preceding claim.

12. A kit comprising:

- a sterilization wrap according to claim 10, said sterilization wrap defining a closed inner volume, and
- a sterilized medical device present inside said inner volume, said sterilized medical device being, in particular, chosen from sterilized scalpels, pliers, scissors, endoscopes, bedpans, tongue depressors or stents.

13. A method for manufacturing a material according to any of claims 1 to 11 comprising:

a) preparing a furnish:

- comprising at least 80%, preferably 90%, more preferably 95%, by dry weight, of biodegradable compounds, a biodegradable compound having a ratio of its biodegradation percentage on the biodegradation percentage of cellulose fibers of at least 75%, the biodegradation percentages being measured according to ISO 14855 (2005) method: *"Determination of the ultimate aerobic biodegradability and disintegration of plastic materials under controlled composting conditions*", after 24 days,
- having a bio-based content of 60%, preferably 80%, more preferably 90%, or more, said furnish further comprising:
- for a total of more than 80 %, in particular more than 85 %, in particular more than 90 %, in percentages by dry weight of said furnish, at least 15 percent of cellulose fibers and:

i. at least 1%, preferably 1% to 80%, preferably 1 to 50%, preferably 2% to 20%, more preferably 3% to 10%, of synthetic biodegradable fibers having an average length of at least 2.5 mm, preferably 3 mm, said synthetic biodegradable fibers preferably being selected from fibers of plastified cereal flour based polymers, optionally modified with copolyesters, fibers of plastified starch, such as corn starch, wheat starch or potatoe starch optionally modified with copolyesters, fibers of polylactic acid, fibers of polyhydroxyvalerate, fibers of polyhydroxybutyrate, fibers of polyhydroxyalkanoate, fibers of polyhydroxyhexanoate, fibers of polycaprolactone, fibers of polybutylene succinate, fibers of polybutylene succinate adipate or mixtures thereof, and/or
ii. 20% to 100%, preferably 30% to 100%, preferably 40% to 100%, preferably 55% to 85%, more preferably 65% to 85%, of natural biodegradable fibers having an average length of at least 1.5 mm, preferably 2.5 mm, more preferably 3 mm, preferably selected from abaca, bamboo, cotton, sisal fibers or mixtures thereof, and/or
iii. a biodegradable binder,

b) forming a sheet from the furnish in a wet-laid process, in particular selected from one of a fourdrinier process, an inclined wire process, a mold table process, a former process and a mold cylinder process;
c) preferably pressing and drying the sheet; and
d) optionally forming a pattern on and/or within the sheet via a softening process, performed on-line or off-line, configured to result in a softening of the sheet and a barrier performance of the sheet according to the EN 868-2:09 standard, said softening process being, in particular, selected from at least one of creping, micro-creping and/or an embossing,
said method being, preferably, deprived of a hydro-entangling step.

14. A method of sterilization of a medical device, in particular chosen from scalpels, pliers, scissors, endoscopes, bedpans, tongue depressors or stents, comprising at least the following steps consisting in:

- providing a sterilization wrap according to claim 10,
- wrapping in said sterilization wrap a medical device to form a kit,
- introducing said kit into a sterilizing unit, and
- sterilizing said kit.

Patentansprüche

1. Medizinisches Material, das sterilisierbar sein soll und zur Herstellung eines Produkts geeignet ist, das aus der aus folgendem bestehenden Gruppe ausgewählt ist: einer Operationsabdeckung, die wahlweise mit einem Loch ver-

sehen ist, einem Behälterfilter, einem sterilen Bereich insbesondere zur Verwendung als Mayo oder Tischabdeckung, einem Kittel, einer Sterilisationshülle oder einem sterilen Barrieresystem in der Standarddefinition von ISO 11607, wobei das Material eine vorzugsweise ungewebte Lage umfasst oder aus dieser besteht und die Lage:

- mindestens 80%, vorzugsweise mindestens 90%, weiter vorzugsweise mindestens 95% bezogen auf das Trockengewicht der Lage biologisch abbaubare Stoffe umfasst, wobei ein biologisch abbaubarer Stoff ein Verhältnis seines biologischen Abbauprozentsatzes zum biologischen Abbauprozentsatz von Zellulosefasern von mindestens 75% aufweist, wobei die biologischen Abbauprozentsätze nach dem Verfahren "Bestimmung der vollständigen aeroben Bioabbaubarkeit und Zersetzung von Kunststoff-Materialien unter den Bedingungen kontrollierter Kompostierung" nach ISO 14855 (2005) nach 24 Tagen gemessen werden,
- einen biobasierten Gehalt von 60%, vorzugsweise 80%, weiter vorzugsweise 90% oder mehr aufweist, und
- ein Flächengewicht von 75 g/m^2 oder weniger, vorzugsweise 70g/m^2 oder weniger aufweist,

wobei die Lage eine Schicht umfasst oder aus dieser besteht, die für insgesamt mehr als 80%, insbesondere mehr als 85%, insbesondere mehr als 90%, bezogen auf das Trockengewicht der Schicht, 15% oder mehr Zellulosefasern und folgendes umfasst:

- mindestens 1%, vorzugsweise 1% bis 80%, vorzugsweise 1 bis 50%, vorzugsweise 2% bis 20%, weiter vorzugsweise 3% bis 10% synthetische biologisch abbaubare Fasern mit einer durchschnittlichen Länge von mindestens 2,5 mm, vorzugsweise 3 mm, wobei die synthetischen biologisch abbaubaren Fasern vorzugsweise aus folgendem ausgewählt sind: Fasern aus plastifizierten Getreidemehl-basierten Polymeren, die wahlweise mit Copolyestern modifiziert sind, Fasern aus plastifizierter Stärke wie Maisstärke, Weizenstärke oder Kartoffelstärke, die wahlweise mit Copolyestern modifiziert ist, Fasern aus Polylactid, Fasern aus Polyhydroxyvalerat, Fasern aus Polyhydroxybutyrat, Fasern aus Polyhydroxyalkanoat, Fasern aus Polyhydroxyhexanoat, Fasern aus Polycaprolacton, Fasern aus Polybutylen-Succinat, Fasern aus Polybutylen-Succinat-Adipat oder Mischungen daraus, und/oder
- 20% bis 100%, vorzugsweise 30% bis 100%, vorzugsweise 40% bis 100%, vorzugsweise 55% bis 85%, weiter vorzugsweise 65% bis 85% natürliche biologisch abbaubare Fasern mit einer durchschnittlichen Länge von mindestens 1,5 mm, vorzugsweise 2,5 mm, weiter vorzugsweise 3 mm, die vorzugsweise aus Abaca-, Bambus-, Baumwoll-, Sisalfasern oder Mischungen daraus ausgewählt sind, und/oder
- ein biologisch abbaubares Bindemittel.

2. Material nach Anspruch 1, wobei die Lage biologisch abbaubare Fasern umfasst, die aus mindestens einer der folgenden Fasern ausgewählt sind: gebleichter Holzpulpe, halbgebleichter Holzpulpe, ungebleichter Holzpulpe, Baumwolle, Abaca, Stroh, Bambus, Viskose, Hanf, Jute, Sisal, Flachs, Kenaf, Esparto oder Fasern aus biologisch abbaubaren oder biologisch kompostierbaren Polymeren nach dem Standard von EN 13432 wie Polylactid, Polyhydroxyvalerat, Polyhydroxybutyrat, Polyhydroxyalkanoat, Polyhydroxyhexanoat, Polycaprolacton, Polybutylen-Succinat, Polybutylen-Succinat-Adipat oder Copolymeren daraus, die wahlweise mit Stärke-basiertem Polymer modifiziert sind, plastifizierten Getreidemehl-basierten Polymeren, die wahlweise mit Copolyestern modifiziert sind, plastifizierter Stärke wie Maisstärke, Getreidestärke oder Kartoffelstärke, die wahlweise mit Copolyestern modifiziert sind.

3. Material nach Anspruch 1 oder 2, wobei die Lage weniger als 30%, vorzugsweise weniger als 10%, weiter vorzugsweise weniger als 5% bezogen auf das Trockengewicht der Schicht eines biologisch abbaubaren Bindemittels oder Additivs, das Nassfestigkeit, Bindefähigkeit oder Weichheit liefert, umfasst, beispielsweise ausgewählt aus Kartoffel-, Weizen-, Tapioka- oder Maisstärke, Proteinen pflanzlichen Ursprungs wie Sojaprotein oder Seidenprotein, Proteinen tierischen Ursprungs wie Milchprotein, Eiderivaten oder Algenderivaten, Gelatine, Collagen, Chitin, natürlichem Gummilatex vorzugsweise mit niedrigem Proteingehalt oder Mischungen dieser Stoffe.

4. Material nach einem der vorhergehenden Ansprüche, wobei die Lage eine Menge von weniger als 20%, vorzugsweise 6% bezogen auf das Trockengewicht der Schicht nicht biologisch abbaubare Stoffe aufweist, die insbesondere aus folgendem ausgewählt sind: Pigmenten, nicht biologisch abbaubaren hydrophoben Additiven oder Bindemitteln, die entweder akrylisch oder vinylisch sind, Polyurethan, Polyvinylalkohol, Polyvinylacetat, Styrol-Butadien-Gummi, Ethylen-Propylen-Heteropolymeren oder einer Mischung daraus.

5. Material nach einem der vorhergehenden Ansprüche, wobei die Lage in der Schicht eine Konzentration von Fluorkohlenstoffverbindungs-Additiven von weniger als 200 Teilen pro Millionen aufweist.

6. Material nach einem der vorhergehenden Ansprüche, wobei die Lage ein Flächengewicht aufweist, das im Bereich

von 25 g/m^2 bis 75 g/m^2, vorzugsweise 50 g/m^2 bis 75 g/m^2, weiter vorzugsweise 55 g/m^2 bis 65 g/m^2 liegt.

7. Material nach einem der vorhergehenden Ansprüche, wobei die Lage mindestens einen Abschnitt aufweist, der ein Muster eines weichmachenden Prozesses umfasst, das mitlaufend oder separat ausgebildet ist und eingerichtet ist, die Lage weicher zu machen, wobei das Muster des weichmachenden Prozesses insbesondere aus einem Kreppmuster, einem Mikrokreppmuster und einem Prägemuster ausgewählt ist.

8. Material nach einem der vorhergehenden Ansprüche, das eine Dichte von 0,8 g/cm^3 oder weniger aufweist.

9. Material nach einem der vorhergehenden Ansprüche, das ein einlagiges Material ist.

10. Material nach einem der vorhergehenden Ansprüche, wobei das Produkt eine Sterilisationshülle ist.

11. Produkt, das aus der aus folgendem bestehenden Gruppe ausgewählt ist: einer Operationsabdeckung, die wahlweise mit einem Loch versehen ist, einem Behälterfilter, einem sterilen Bereich insbesondere zur Verwendung als Mayo oder Tischabdeckung, einem Kittel, einer Sterilisationshülle oder einem sterilen Barrieresystem nach der Standarddefinition von ISO 11607, wobei das Produkt ein Material nach einem der vorhergehenden Ansprüche umfasst.

12. Kit, umfassend:

- eine Sterilisationshülle nach Anspruch 10, die einen geschlossenen Innenraum festlegt, und
- einen sterilisierten medizinischen Gegenstand, der in dem Innenraum vorliegt und insbesondere aus sterilisierten Skalpellen, Pinzetten, Scheren, Endoskopen, Bettpfannen, Mundspateln oder Stents ausgewählt ist.

13. Verfahren zum Herstellen eines Materials nach einem der Ansprüche 1 bis 11, umfassend:

a) Bereitstellen einer Zubereitung, die:

- mindestens 80%, vorzugsweise 90%, weiter vorzugsweise 95% bezogen auf das Trockengewicht biologisch abbaubare Stoffe umfasst, wobei ein biologisch abbaubarer Stoff ein Verhältnis seines biologischen Abbauprozentsatzes zum biologischen Abbauprozentsatz von Zellulosefasern von mindestens 75% aufweist, wobei die biologischen Abbauprozentsätze nach dem Verfahren "Bestimmung der vollständigen aeroben Bioabbaubarkeit und Zersetzung von Kunststoff-Materialien unter den Bedingungen kontrollierter Kompostierung" nach ISO 14855 (2005) nach 24 Tagen gemessen sind,
- einen biobasierten Gehalt von 60%, vorzugsweise 80%, weiter vorzugsweise 90% oder mehr aufweist, wobei die Zubereitung außerdem folgendes umfasst:
- für insgesamt mehr als 80%, insbesondere mehr als 85%, insbesondere mehr als 90%, bezogen auf das Trockengewicht der Zubereitung, mindestens 15% Zellulosefasern und:

  i. mindestens 1%, vorzugsweise 1% bis 80%, vorzugsweise 1 bis 50%, vorzugsweise 2% bis 20%, weiter vorzugsweise 3% bis 10% synthetische biologisch abbaubare Fasern mit einer durchschnittlichen Länge von mindestens 2,5 mm, vorzugsweise 3 mm, wobei die synthetischen biologisch abbaubaren Fasern vorzugsweise aus folgendem ausgewählt sind: Fasern aus plastifizierten Getreidemehl-basierten Polymeren, die wahlweise mit Copolyestern modifiziert sind, Fasern aus plastifizierter Stärke wie Maisstärke, Weizenstärke oder Kartoffelstärke, die wahlweise mit Copolyestern modifiziert ist, Fasern aus Polylactid, Fasern aus Polyhydroxyvalerat, Fasern aus Polyhydroxybutyrat, Fasern aus Polyhydroxyalkanoat, Fasern aus Polyhydroxyhexanoat, Fasern aus Polycaprolacton, Fasern aus Polybutylen-Succinat, Fasern aus Polybutylen-Succinat-Adipat oder Mischungen daraus, und/oder
  ii. 20% bis 100%, vorzugsweise 30% bis 100%, vorzugsweise 40% bis 100%, vorzugsweise 55% bis 85%, weiter vorzugsweise 65% bis 85% natürliche biologisch abbaubare Fasern mit einer durchschnittlichen Länge von mindestens 1,5 mm, vorzugsweise 2,5 mm, weiter vorzugsweise 3 mm, die vorzugsweise aus Abaca-, Bambus-, Baumwoll-, Sisalfasern oder Mischungen daraus ausgewählt sind, und/oder
  iii. ein biologisch abbaubares Bindemittel,

b) Ausbilden einer Lage aus der Zubereitung in einem Nassverfahren, das insbesondere aus einem der folgenden ausgewählt ist: einem Fourdrinier-Prozess, einem Schrägsieb-Prozess, einem Formtisch-Prozess, einem

Formungsprozess und einem Formzylinder-Prozess;
c) vorzugsweise Pressen und Trocknen der Lage; und
d) wahlweise Ausbilden eines Musters auf und/oder innerhalb der Lage mittels eines weichmachenden Prozesses, der mitlaufend oder separat ausgeführt wird und eingerichtet ist, ein Erweichen der Lage und eine Barriereleistung der Lage nach dem Standard EN 868-2:09 zu bewirken, wobei der weichmachende Prozess insbesondere aus mindestens einem der folgenden ausgewählt ist: Krepp-Bildung, Mikrokrepp-Bildung und einem Prägen,
wobei das Verfahren vorzugsweise frei von einem Wasserverfestigungsschritt ist.

14. Verfahren zur Sterilisation eines medizinischen Gegenstands, der insbesondere aus Skalpellen, Pinzetten, Scheren, Endoskopen, Bettpfannen, Mundspateln oder Stents ausgewählt ist, mit mindestens den aus folgendem bestehenden Schritten:

- Bereitstellen einer Sterilisationshülle nach Anspruch 10,
- Einhüllen eines medizinischen Gegenstands in der Sterilisationshülle unter Bildung eines Kits,
- Einführen des Kits in eine Sterilisationseinheit, und
- Sterilisieren des Kits.

Revendications

1. Matériau médical, destiné à être stérilisé, le matériau médical étant destiné à la fabrication d'un produit choisi dans le groupe constitué : des champs opératoires, présentant facultativement un trou, d'un filtre à réservoir, d'un champ stérile, devant en particulièrement être utilisé en tant que housse Mayo ou protection de table, d'une blouse, d'une enveloppe de stérilisation ou d'un système de protection stérile selon la définition de la norme ISO 11607, ledit matériau comprenant une feuille, de préférence de nontissé, ou étant constitué d'une telle feuille :

- comprenant au moins 80 %, de préférence au moins 90 %, plus préférablement au moins 95 %, en pourcentage en poids sec sur la base de ladite feuille, de composés biodégradables, un composé biodégradable ayant un rapport de son pourcentage de biodégradation au pourcentage de biodégradation des fibres cellulosiques d'au moins 75 %, les pourcentages de biodégradation étant mesurés selon la méthode de la norme ISO 14855 (2005) : « *Détermination* de *la biodégradabilité aérobie ultime et de la désintégration des matériaux plastiques dans des conditions contrôlées de compostage »,* après 24 jours,
- ayant une teneur en produits biosourcés de 60 %, de préférence de 80 %, plus préférablement de 90 % ou plus, et
- ayant un grammage de 75 g/m^2 ou moins, de préférence de 70 g/m^2 ou moins, ladite feuille comprenant une couche ou étant constituée d'une couche comprenant, pour un total de plus de 80 %, en particulier de plus de 85 %, en particulier de plus de 90 %, en pourcentages en poids sec sur la base de ladite couche, 15 % ou plus de fibres cellulosiques et :

  - au moins 1 %, de préférence de 1 % à 80 %, de préférence de 1 à 50 %, de préférence de 2 % à 20 %, plus préférablement de 3 % à 10 %, de fibres biodégradables synthétiques ayant une longueur moyenne d'au moins 2,5 mm, de préférence de 3 mm, lesdites fibres biodégradables synthétiques étant de préférence choisies parmi les fibres de polymères à base de farine de céréales plastifiée, facultativement modifiés par des copolyesters, les fibres d'amidon plastifié, tel que l'amidon de maïs, l'amidon de blé ou l'amidon de pomme de terre facultativement modifiés par des copolyesters, les fibres d'acide polylactique, les fibres de polyhydroxyvalérate, les fibres de polyhydroxybutyrate, les fibres de polyhydroxyalcanoate, les fibres de polyhydroxyhexanoate, les fibres de polycaprolactone, les fibres de polybutylène succinate, les fibres de polybutylène succinate-adipate ou leurs mélanges, et/ou de 20 % à 100 %, de préférence de 30 % à 100 %, de préférence de 40 % à 100 %, de préférence de 55 % à 85 %, plus préférablement de 65 % à 85 %, de fibres biodégradables naturelles ayant une longueur moyenne d'au moins 1,5 mm, de préférence de 2,5 mm, plus préférablement de 3 mm, de préférence choisies parmi les fibres d'abaca, de bambou, de coton, de sisal ou leurs mélanges, et/ou
  - un liant biodégradable.

2. Matériau selon la revendication 1, la feuille comprenant des fibres biodégradables choisies parmi au moins l'une des fibres suivantes : pâte de bois blanchie, pâte de bois semi-blanchie, pâte de bois non blanchie, coton, abaca, paille, bambou, viscose, chanvre, jute, sisal, lin, kenaf, sparte ou des fibres de polymères biodégradables ou biocompostables, conformes à la norme EN 13432, tels que l'acide polylactique, le polyhydroxyvalérate, le polyhy-

droxybutyrate, le polyhydroxyalcanoate, le polyhydroxyhexanoate, la polycaprolactone, le polybutylène succinate, le polybutylène succinate-adipate ou leurs copolymères, facultativement modifiés par un polymère à base d'amidon, des polymères à base de farine de céréales plastifiée, facultativement modifiés par des copolyesters, un amidon plastifié, tel que l'amidon de maïs, l'amidon de blé ou l'amidon de pomme de terre facultativement modifié par des copolyesters.

3. Matériau selon les revendications 1 ou 2, la feuille comprenant moins de 30 %, de préférence moins de 10 %, plus préférablement moins de 5 %, en pourcentage en poids sec de la couche, d'un liant ou d'un additif biodégradable offrant résistance à l'état humide, cohésion ou moelleux, par exemple choisi parmi l'amidon de pomme de terre, de blé, de tapioca ou de maïs, les protéines d'origine végétale, telles que la protéine de soja ou la protéine de soie, les protéines d'origine animale, telles que la protéine de lait, les dérivés d'oeuf ou les dérivés d'algues, la gélatine, le collagène, la chitine, le latex de caoutchouc naturel, de préférence à faible teneur protéique, ou un mélange de ces composés.

4. Matériau selon l'une quelconque des revendications précédentes, la feuille ayant une quantité inférieure à 20 %, de préférence inférieure à 6 %, en pourcentage en poids sec de la couche, de composé non biodégradables, en particulier choisis parmi les pigments, les additifs hydrophobes non biodégradables ou les liants, soit acryliques soit vinyliques, le polyuréthane, l'alcool polyvinylique, le polyvinylacétate, le caoutchouc de styrène-butadiène, les hétéropolymères d'éthylène-propylène ou un mélange de ceux-ci.

5. Matériau selon l'une quelconque des revendications précédentes, la feuille ayant une concentration dans la couche d'additifs constitués de composés fluorocarbonés de moins de 200 parties par million.

6. Matériau selon l'une quelconque des revendications précédentes, la feuille ayant un grammage situé dans la plage de 25 g/m^2 à 75 g/m^2, de préférence de 50 g/m^2 à 75 g/m^2, plus préférablement de 55 g/m^2 à 65 g/m^2.

7. Matériau selon l'une quelconque des revendications précédentes, la feuille ayant au moins une partie comprenant un motif obtenu par un procédé d'assouplissement, formé en ligne ou hors ligne, configuré pour assouplir ladite feuille, ledit motif obtenu par un procédé d'assouplissement étant, en particulier, choisi parmi l'un d'un motif crêpé, d'un motif micro-crêpé et d'un motif de gaufrage.

8. Matériau selon l'une quelconque des revendications précédentes, ayant une densité de 0,8 g/cm^3 ou moins.

9. Matériau selon l'une quelconque des revendications précédentes, étant un matériau monocouche.

10. Matériau selon l'une quelconque des revendications précédentes, le produit étant une enveloppe de stérilisation.

11. Produit choisi dans le groupe constitué : des champs opératoires, présentant facultativement un trou, d'un filtre à réservoir, d'un champ stérile, devant en particulièrement être utilisé en tant que housse Mayo ou protection de table, d'une blouse, d'une enveloppe de stérilisation ou d'un système de protection stérile selon la définition de la norme ISO 11607, ledit produit comprenant un matériau tel que défini dans l'une quelconque des revendications précédentes.

12. Kit comprenant :

- une enveloppe de stérilisation selon la revendication 10, ladite enveloppe de stérilisation définissant un volume interne fermé, et
- un dispositif médical stérilisé présent à l'intérieur dudit volume interne, ledit dispositif médical stérilisé étant, en particulier, choisi parmi les scalpels, pinces, ciseaux, endoscopes, bassins, abaisse-langue ou stents stérilisés.

13. Procédé de fabrication d'un matériau selon l'une quelconque des revendications 1 à 11 comprenant :

a) la préparation d'une pâte :

- comprenant au moins 80 %, de préférence 90 %, plus préférablement 95 %, en poids sec, de composés biodégradables, un composé biodégradable ayant un rapport de son pourcentage de biodégradation au pourcentage de biodégradation des fibres cellulosiques d'au moins 75 %, les pourcentages de biodégra-

dation étant mesurés selon la méthode de la norme ISO 14855 (2005) : « *Détermination de la biodégradabilité aérobie ultime et de la désintégration des matériaux plastiques dans des conditions contrôlées de compostage »,* après 24 jours,
- ayant une teneur en produits biosourcés de 60 %, de préférence de 80 %, plus préférablement de 90 %, ou plus, ladite pâte comprenant en outre :
- pour un total de plus de 80 %, en particulier de plus de 85 %, en particulier de plus de 90 %, en pourcentages en poids sec de ladite pâte, au moins 15 pour cent de fibres cellulosiques et :

i. au moins 1 %, de préférence de 1 % à 80 %, de préférence de 1 à 50 %, de préférence de 2 % à 20 %, plus préférablement de 3 % à 10 %, de fibres biodégradables synthétiques ayant une longueur moyenne d'au moins 2,5 mm, de préférence de 3 mm, lesdites fibres biodégradables synthétiques étant de préférence choisies parmi les fibres de polymères à base de farine de céréales plastifiée, facultativement modifiés par des copolyesters, les fibres d'amidon plastifié, tel que l'amidon de maïs, l'amidon de blé ou l'amidon de pomme de terre facultativement modifiés par des copolyesters, les fibres d'acide polylactique, les fibres de polyhydroxyvalérate, les fibres de polyhydroxybutyrate, les fibres de polyhydroxyalcanoate, les fibres de polyhydroxyhexanoate, les fibres de polycaprolactone, les fibres de polybutylène succinate, les fibres de polybutylène succinate-adipate ou leurs mélanges, et/ou
ii. de 20 % à 100 %, de préférence de 30 % à 100 %, de préférence de 40 % à 100 %, de préférence de 55 % à 85 %, plus préférablement de 65 % à 85 %, de fibres biodégradables naturelles ayant une longueur moyenne d'au moins 1,5 mm, de préférence de 2,5 mm, plus préférablement de 3 mm, de préférence choisies parmi les fibres d'abaca, de bambou, de coton, de sisal ou leurs mélanges, et/ou
iii. un liant biodégradable,

b) la formation d'une feuille à partir de la pâte dans un procédé par voie humide, en particulier choisi parmi l'un d'un procédé à table Fourdrinier, d'un procédé à toile inclinée, d'un procédé à table de moulage, d'un procédé à machine à former et d'un procédé à cylindre de moulage ;
c) de préférence la compression et le séchage de la feuille ; et
d) facultativement la formation d'un motif sur et/ou dans la feuille via un procédé d'assouplissement, réalisé en ligne ou hors ligne, configuré pour conduire à un assouplissement de la feuille et à une performance de protection de la feuille conformes à la norme EN 868-2:09, ledit procédé d'assouplissement étant, en particulier, choisi parmi au moins l'un du crêpage, du micro-crêpage et/ou d'un gaufrage,
ledit procédé étant, de préférence, dépourvu d'étape hydro-entremêlement.

14. Procédé de stérilisation d'un dispositif médical, en particulier choisi parmi les scalpels, pinces, ciseaux, endoscopes, bassins, abaisse-langue ou stents, comprenant au moins les étapes suivantes consistant à :

- fournir une enveloppe de stérilisation selon la revendication 10,
- envelopper dans ladite enveloppe de stérilisation un dispositif médical pour former un kit,
- introduire ledit kit dans une unité de stérilisation, et
- stériliser ledit kit.

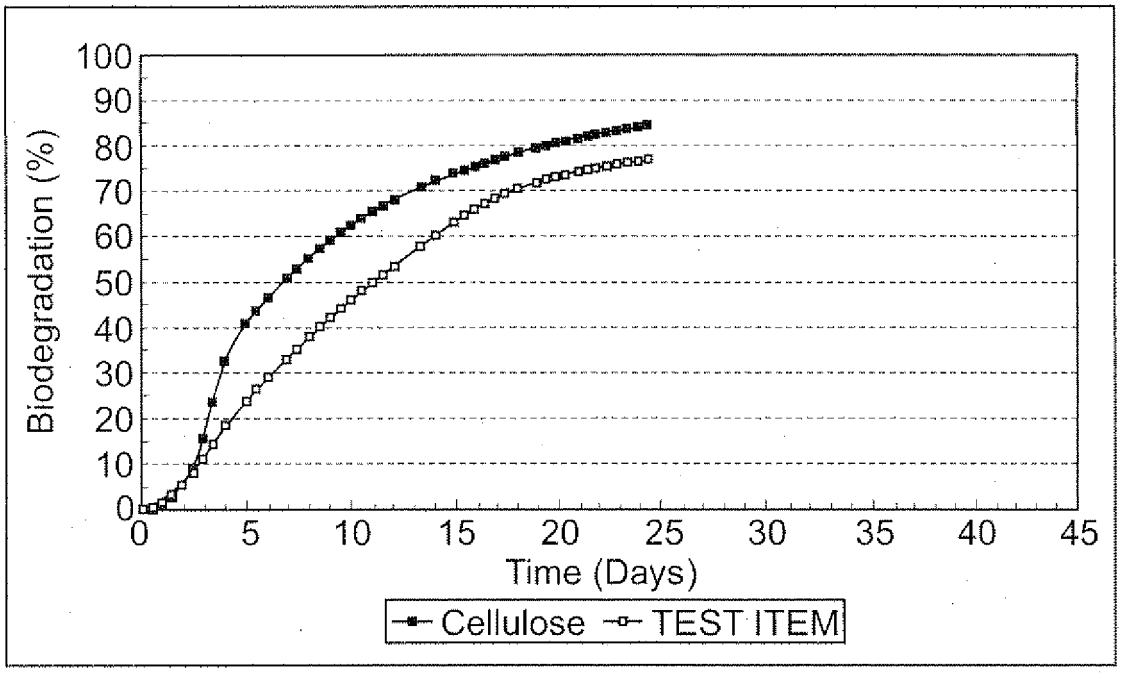
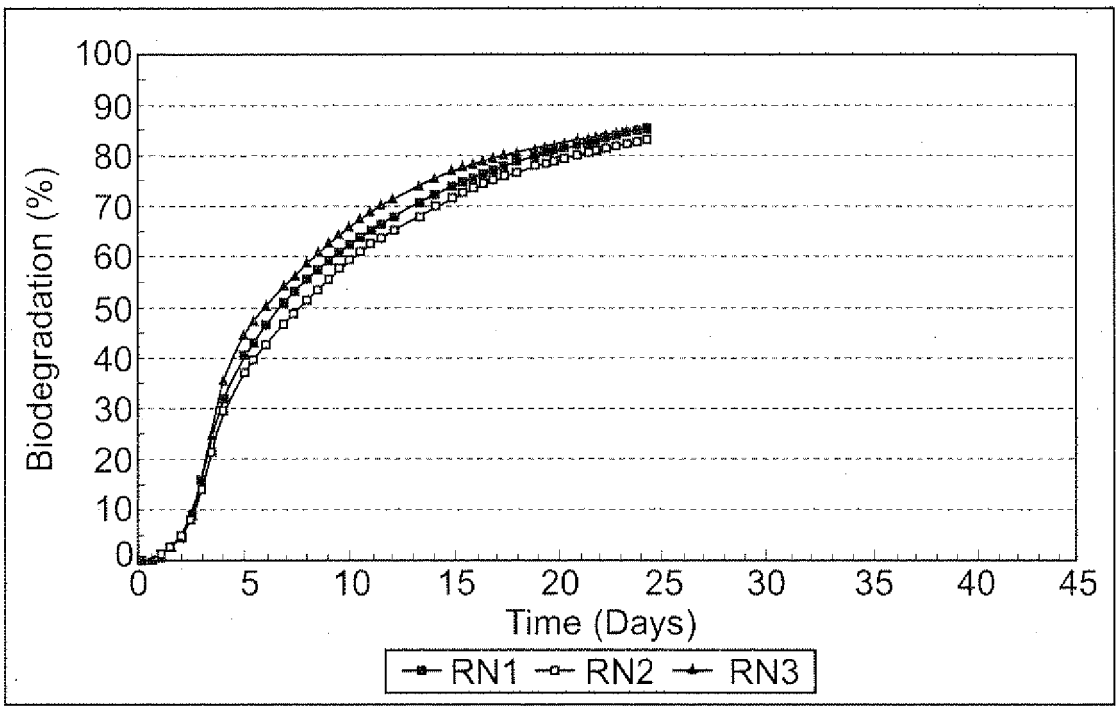

Biodegradation (%)
100
90
80
70
60
50
40
30
20
10
0
0
5
10
15
20
25
30
35
40
45
Time (Days)
Cellulose
TEST ITEM

Fig. 1


Biodegradation (%)
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90
80
70
60
50
40
30
20
10
0
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5
10
15
20
25
30
35
40
45
Time (Days)
RN1
RN2
RN3

Fig. 2

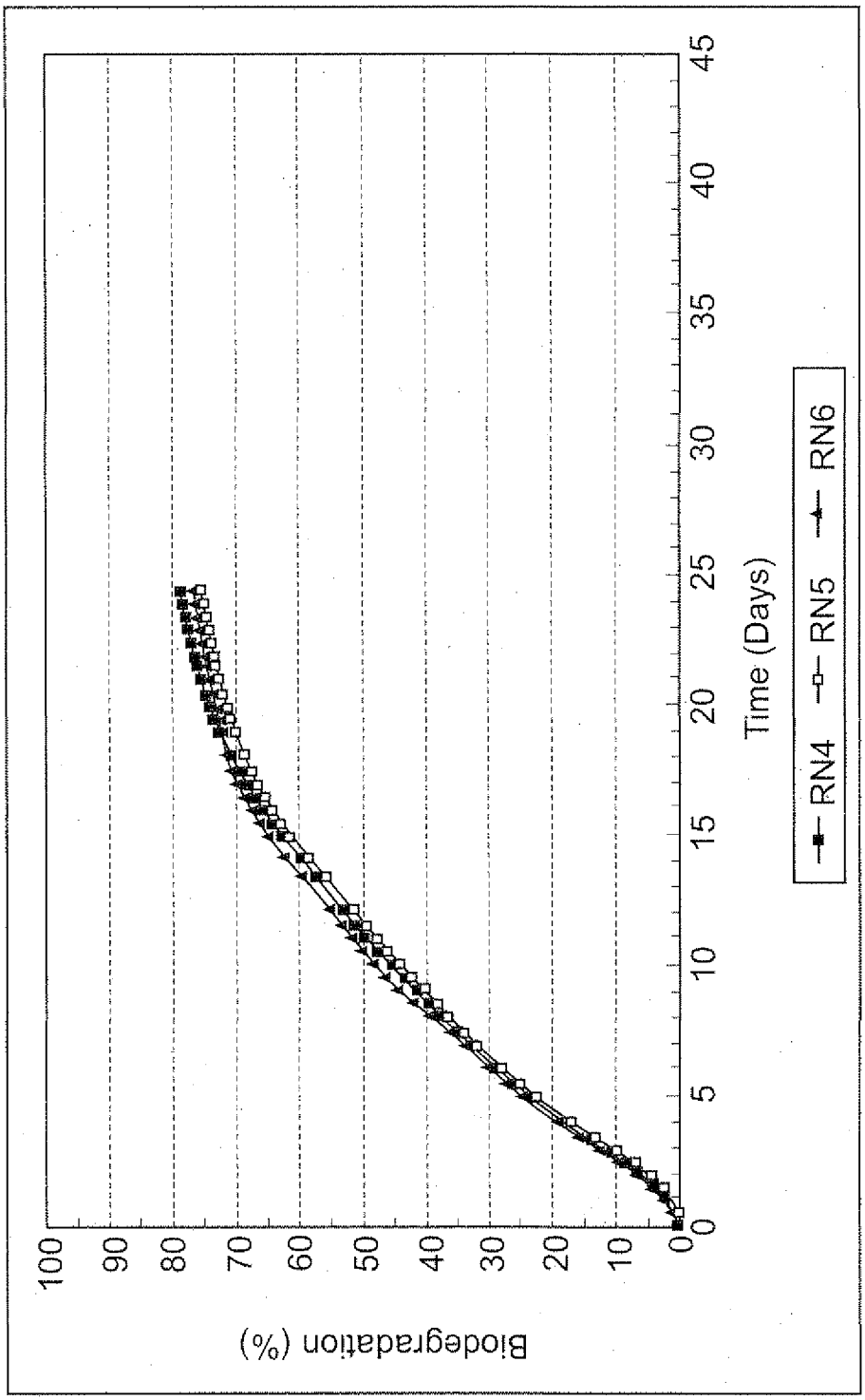
Biodegradation (%)
100
90
80
70
60
50
40
30
20
10
0
0
5
10
15
20
25
30
35
40
45
Time (Days)
RN4
RN5
RN6

Fig. 3

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO 2007058822 A **[0004]**
- US 6349826 B **[0005]**
- JP 4334448 B **[0006]**

Non-patent literature cited in the description

- *Packaging for terminally sterilized medical devices - Part 2: Sterilization Wrap - Requirements and tests methods* **[0007]**
- *Packaging for terminally sterilized medical devices - Part 1 : Requirements for materials, sterile barrier systems and packaging systems* **[0008]**