

Claims

1. A balloon catheter provided on an outer surface of a balloon with a plurality of elongate bodies which are crystals of a water-insoluble drug extending while
5 having independent long axes,

wherein the balloon catheter has a base layer including a water-soluble low-molecular compound disposed in a layer form on the outer surface of the balloon, the water-soluble low molecular compound having a molecular
10 weight of 50 to 2,000, being dissolved in water in an amount of not less than 5 mg/mL, and being dissolved in water without swelling,

at least part of the elongate bodies is located inside of the base layer, and

15 the elongate bodies include a first elongate body whose proximal end portion is separate from the outer surface of the balloon, the outer surface being smooth and non-porous, and is located inside of the base layer.

20 2. The balloon catheter according to claim 1, wherein the elongate bodies include a second elongate body extending from the outer surface of the balloon and/or a third elongate body extending from an outer surface of the base layer toward an outside of the

surface.

3. A balloon catheter provided on an outer surface of a balloon with a plurality of elongate bodies which
5 are crystals of a water-insoluble drug extending while having independent long axes,

wherein the balloon catheter has a base layer including a water-soluble low-molecular compound disposed in a layer form on the outer surface of the balloon, the
10 water-soluble low molecular compound having a molecular weight of 50 to 2,000, being soluble in water in an amount of not less than 5 mg/mL, and being soluble in water without swelling,

at least part of the elongate bodies is located
15 inside of the base layer, and

the elongate bodies include a second elongate body extending from the outer surface of the balloon, the outer surface being smooth and non-porous.

4. The balloon catheter according to claim 3,
20 wherein the elongate bodies include a first elongate body whose proximal end portion is separate from the outer surface of the balloon and is located inside of the base layer and/or a third elongate body extending from an outer surface of the base layer toward an outside of the

surface.

5. The balloon catheter according to any one of claims 1 to 4, wherein the water-soluble low molecular compound is at least one of serine ethyl ester, citric acid esters, polysorbates, sugars, amino acid esters, or glycerol esters of short-chain monocarboxylic acids.

6. The balloon catheter according to any one of claims 1 to 5, wherein the balloon is formed by using a polyamide.

10 7. The balloon catheter according to any one of claims 1 to 6, wherein the water-soluble low-molecular compound included in the base layer is a crystal, an amorphous phase or a mixture of them.

15 8. The balloon catheter according to any one of claims 1 to 7, wherein the water-insoluble drug is rapamycin, paclitaxel, docetaxel, or everolimus.

9. The balloon catheter according to any one of claims 1 to 8, wherein the base layer has a rugged surface.

20 10. The balloon catheter according to any one of claims 1 to 9, wherein the outer surface of the balloon has a portion which is not covered with the base layer but is exposed to an outside, in at least part of a region where the elongate bodies are not provided.

11. The balloon catheter according to any one of claims 1 to 10, wherein adjacent ones of the elongate bodies are structurally separate from each other.

12. The balloon catheter according to any one of
5 claims 1 to 10, wherein adjacent ones of part of the plurality of elongate bodies are in contact with each other.

13. A method of manufacturing a balloon catheter provided on an outer surface of a balloon with a
10 plurality of elongate bodies which are crystals of a water-insoluble drug extending while having independent long axes, the method comprising:

a step of supplying a coating solution containing the drug, a water-soluble low-molecular compound which
15 has a molecular weight of 50 to 2,000, is soluble in water in an amount of not less than 5 mg/mL and is soluble in water without swelling, an organic solvent, and water from a dispensing tube for supplying the coating solution, while keeping the dispensing tube in
20 contact with the outer surface of the balloon which outer surface is smooth and non-porous, and giving a physical stimulus to the coating solution to cause formation of crystal nuclei of the water-insoluble drug;

a step of volatilizing the organic solvent while

leaving water to cause growth of the elongate bodies
based on the crystal nuclei; and

a step of evaporating water to form a base layer
including the water-soluble low-molecular compound.

5 14. The method of manufacturing a balloon catheter
according to claim 13, wherein the water-insoluble low-
molecular compound is at least one of serine ethyl ester,
citric acid esters, polysorbates, sugars, amino acid
esters, and glycerol esters of short-chain monocarboxylic
10 acids.

15 15. The method of manufacturing a balloon catheter
according to claim 13 or 15, wherein the balloon is
formed by using a polyamide.

 16. The method of manufacturing a balloon catheter
15 according to any one of claims 13 to 15, wherein the
water-soluble low-molecular compound included in the base
layer is a crystal, an amorphous phase or a mixture of
them.

 17. The method of manufacturing a balloon catheter
20 according to any one of claims 13 to 16, wherein the
elongate bodies include at least one of a first elongate
body whose proximal end portion is separate from the
outer surface of the balloon, the outer surface being
smooth and non-porous, and is located inside of the base

layer, a second elongate body extending from the outer surface of the balloon, or a third elongate body extending from an outer surface of the base layer toward an outside of the surface