The above-described, known methods have the disadvantage that they require relatively long heating and cooling times and are complex on account of the necessary mounting of the sleeve over the assembly. In addition, there is a risk of cross-contamination in the case of implants with a medicament layer.

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

Therefore, it may be possible to create a device which allows a quick and thus economical embedding of an implant in a balloon. It may also be possible to provide an associated embedding method which avoids cross-contamination.

An exemplary device has, in particular, an embedding mould to be arranged in the heating element, which mould has a high heat flux and a cylindrical cavity, preferably a tubular geometry with a continuous cavity, which is dimensioned in such a way (in particular in respect of length and diameter), that an assembly consisting of the catheter with the balloon to be embedded in the implant and with the implant mounted, preferably crimped, on the outer side of the balloon can be introduced into the cavity of the embedding mould and can be arranged in the cavity, wherein a protective film is provided between an inner wall of the cavity of the embedding mould and the assembly.

The protective film of the solution facilitates the insertion and removal of the assembly into and from the cavity of the embedding mould. The low thickness, that is to say the thin wall, of the protective film means that the heat insulation between heating element and assembly is minimal, so that the assembly is quickly heated and cooled. As a result, the process as a whole is thus accelerated and production costs are consequently saved. The protective film preferably has a thickness of less than 25 µm, particularly preferably of less than 20 µm. The thickness of the protective film is the smallest dimension of the measurements of the protective film.

In one exemplary arrangement, the protective film is strip-like. The assembly can thus be particularly easily introduced into and removed from the embedding mould. Alternatively,

the protective film can be formed as a layer arranged on the inner wall of the embedding mould. This is a particularly economical solution for the embedding mould.

The insertion and removal of the assembly and also the embedding are designed particularly simply and in an automatable manner if the cavity of the embedding mould runs parallel to the longitudinal direction of the embedding mould and is formed continuously, wherein the strip-like protective film bears loosely against the inner wall of the embedding mould, that is to say is not connected to the inner wall, and can be wound and/or unwound around the assembly and preferably protrudes beyond the continuous cavity of the embedding mould on both sides in the longitudinal direction of the cavity. The strip-like protective film can preferably be unwound from a roll, guided through the continuous cavity of the embedding mould, and wound onto a roll after use. A new portion of the protective film is used with each assembly in which the implant is to be embedded in the balloon, so that each portion of the protective film is used only once for the embedding. Contaminations and mechanical damage to the externally arranged elements of the assembly are thus avoided.

In order to ensure that the protective film securely surrounds the entire assembly, the width of the strip-like protective film in a preferred exemplary arrangement is greater than the circumference of the cavity of the embedding mould. It is thus ensured that the entire inner wall of the embedding mould is covered. The width of the protective film is measured perpendicularly to the longitudinal direction of the strip. By way of example, the width of the protective film is at least 105% of the circumference, preferably at least 110% of the circumference of the cavity of the embedding mould. Particularly good properties with regard to the insertion and removal of the assembly into/from the cavity of the embedding mould are ensured if the protective film consists of a plastic material, preferably at least one material of the group comprising fluoropolymers (for example polytetrafluoroethylene, perfluoroalkoxy polymers) and polyolefins (for example polyethylene, polypropylene).

It has already been explained above that it is advantageous if the embedding mould has a high heat flux. This requirement can be achieved primarily by a thin-walled geometry (low mass) and by a material having a high thermal conduction coefficient, preferably having a thermal conduction coefficient of more than 10 W/(m*K). On account of the high strength

of metallic materials, metallic embedding moulds can be designed with particularly thin walls, and therefore a metallic material is preferred for the embedding mould. By way of example, a wall thickness of less than 0.2 mm is possible for aluminium alloys, or less than 0.1 mm for high-grade steel (for example 1.4310). In addition, metallic materials offer high thermal conduction coefficients of more than 10 W/(m*K), whereby quick heating and cooling times and therefore minimal process times are made possible. By way of example, high-grade steel (for example 1.4301, 1.4310), aluminium or aluminium alloy can be used as a material for the embedding mould.

For quick cooling and therefore a reduced process time, a cooling element is arranged beneath the heating element, which cooling element has, on its upper side, at least one recess for the conduction of a cooling fluid (for example water or a gas, for example in the form of cooled nitrogen). The heating element can preferably be formed in two parts, wherein both parts are joined together to heat the assembly and to close the embedding mould. After the embedding, the two parts of the heating element can be opened again, so that the embedding mould with the assembly is accessible for the cooling fluid.

One or more of the above advantages may also be achieved by an exemplary method for embedding a balloon, arranged on a catheter, in an implant having an open-work structure, said method having the following steps:

- producing an assembly consisting of a catheter with balloon and the implant mounted on the outer side of the balloon, preferably by crimping the implant onto the balloon, in particular onto a middle portion of the balloon,
- inserting the assembly into a cavity of an embedding mould, which is lined on its inner wall with a protective film,
- connecting the catheter to a fluid source,
- heating the embedding mould with assembly in a heating element for a predefined time,
- applying a predefined first internal pressure to the balloon by means of the fluid source connected to the catheter,
- cooling the embedding mould with the assembly with a predefined second internal pressure in the balloon, said pressure being applied by means of the fluid source,
- deflating (deaerating) the balloon after cooling the embedding mould with the assembly,

- removing the assembly from the embedding mould.

The method may allow a quick and economical embedding of the implant in the balloon.

It is also advantageous if, prior to the introduction of the assembly into the cavity of the embedding mould, a strip-like protective film is wound around the assembly. The insertion of the assembly into the cavity of the embedding mould is facilitated as a result.

The removal is facilitated, and mechanical damage and cross-contamination are reduced if, when introducing the assembly into the embedding mould and/or removing the assembly from the embedding mould, the assembly is introduced into the cavity of the embedding mould and/or is removed from the cavity of the embedding mould together/jointly with the strip-like protective film. This means that the relative speed between assembly and protective film is zero in each case, that is to say that the assembly and protective film move at the same speed during introduction and/or removal. The protective film is more preferably unwound from the assembly following the removal.

As has already been described above, the embedding method is facilitated in that the strip-like protective film is unwound from a roll, is guided through the cavity of the embedding mould, and is wound up again onto a further roll, preferably after use for a single assembly.

Further objectives, features, advantages and possible applications of the disclosed techniques will become clear from the following description of an exemplary device with reference to the drawings. Here, all features described and/or depicted in the drawings form the subject matter of the present techniques, both individually and in any combination, also independently of their summary in the individual claims and the dependency references of the claims.

The drawings schematically show

Fig. 1 a device according in a perspective view from the side,

Fig. 2 the embedding mould with protective film of the device according to Fig. 1 in a perspective view from the side,

Fig. 3a a first step of an exemplary method on the basis of a longitudinal section through the embedding mould and protective film,

Fig. 3b a second step of the method according to Fig. 3a with a longitudinal section through an assembly, and

Fig. 3c a third step of the method according to Fig. 3a with a longitudinal section through an assembly.

The device shown in Fig. 1 for embedding a balloon 30 of a catheter 29 in an open-work implant, for example a stent 31, has a two-part heating element 3, in which a hollow-cylindrical embedding mould 5 is arranged. For this purpose, corresponding cavities 7 are provided in each part of the heating element 3. The heating element 3 is designed so that it can transfer heat to the embedding mould 5, for example by means of radiation, convection, or contact. For this purpose, the heating element 3 can be designed for example as a resistance heater, induction heating element, capacitive heating element, or as a heating element that works with infrared radiation.

In order to embed a balloon 30, arranged in a catheter 29, in an implant in the form of a stent 31 which has an open-work structure (gaps) at least in portions, an assembly consisting of the stent 31 mounted on the balloon 30 and of the balloon 30 with catheter 29

As has already been explained above, the protective film 11 is moved further through the continuous cavity 9 of the embedding mould 5 for the next embedding process, so that a new portion of the protective film 11 is used for the next embedding process. The used protective film is, for example, wound up again on a roll after having been guided through the cavity 9 of the embedding mould 5.

The protective film 11 can consist for example of a plastic material, such as PTFE, PFA, PE, PP, PA, etc. In particular, fluoropolymers have suitable properties with regard to temperature resistance and coefficient of friction.

The above-described device and the may allow a quick and economical embedding of a stent 31 in a balloon 30.