

[54] **IMPLANTABLE INDUSION PUMP**
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Related U.S. Application Data

[63] Continuation of Ser. No. 38,356, May 18, 1970, abandoned.

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[51] Int. Cl.A61m 05/00

[58] Field of Search.....128/214 R, 214 F, 128/214.2, 216, 1 R, 260; 222/386.5; 3/1

[57] **ABSTRACT**

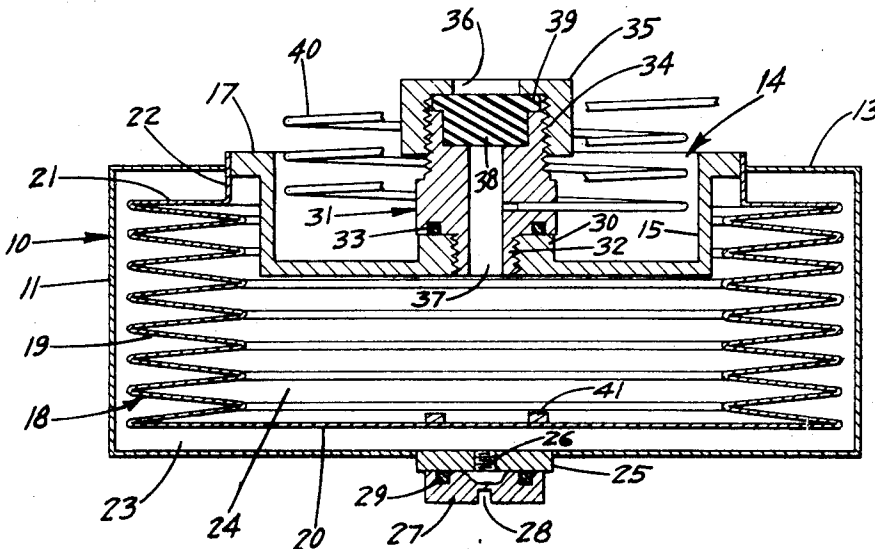
An implantable pump for infusing drugs or other chemicals or solutions into the body at a uniform slow flow rate. The pump comprises a housing divided into two chambers separated by a bellows, diaphragm or other pressure-communicating interphase. A volatile liquid partially filling one chamber provides a constant pressure energy source to act upon the interphase to force liquid infusate from the other chamber through a capillary tube or other flow-regulating resistance element to the infusion site. The infusate chamber is closed as by means of a self puncture sealing refill stopper. The pump is implanted with the refill stopper disposed under the skin and the pump is refilled periodically by injection through the skin.

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17 Claims, 4 Drawing Figures



SHEET 1 OF 2

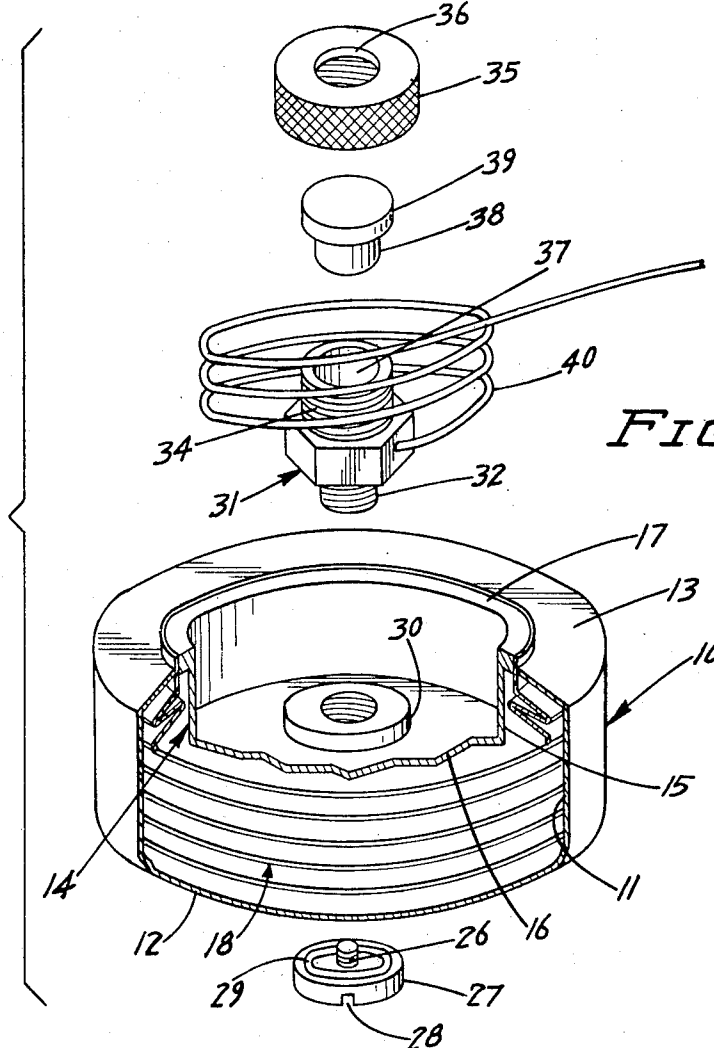


FIG. 1

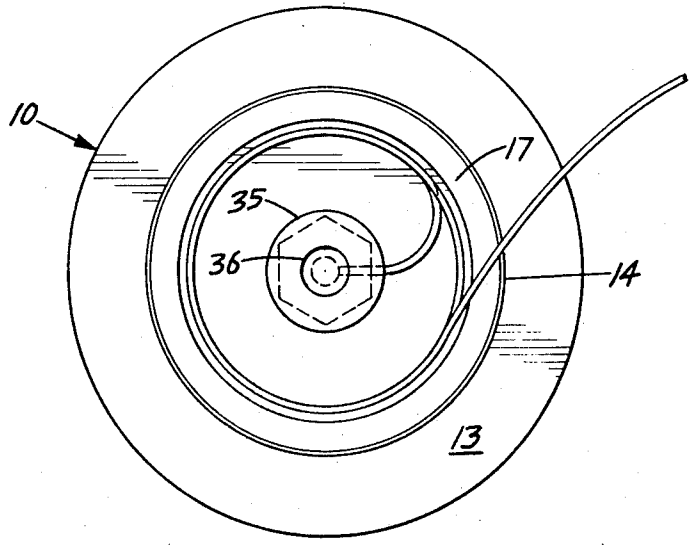


FIG. 2

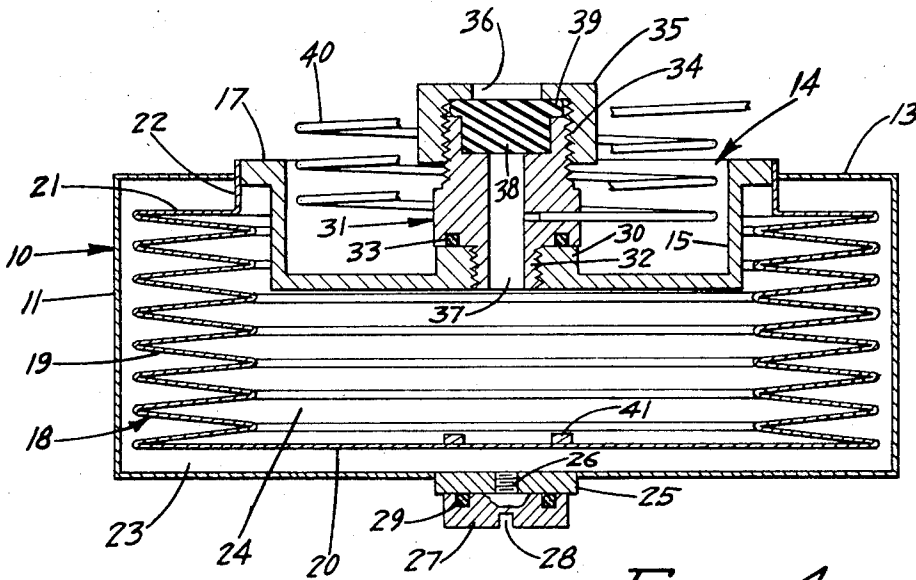


FIG. 4

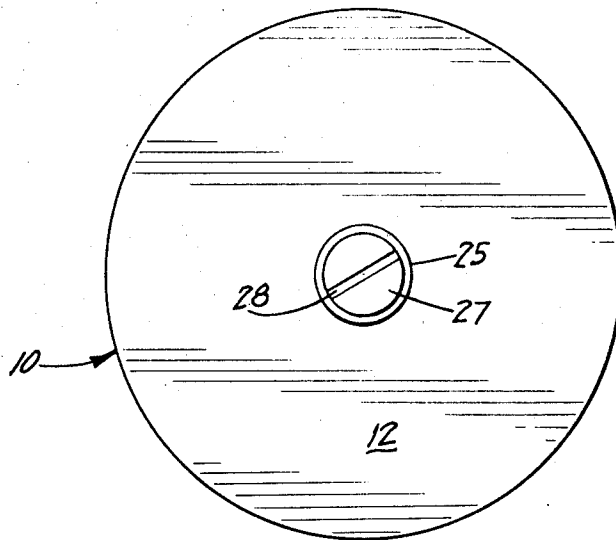


FIG. 3

IMPLANTABLE INFUSION PUMP

This application is a continuation of application, Ser. No. 38,356, filed May 18, 1970, and now abandoned.

The invention described herein was made in the course of work under a grant or award from the Department of Health, Education and Welfare.

This invention is directed to a permanently implantable self-recycling low-flow constant rate multi-purpose infusion pump of simple design. The pump is percutaneously refillable. It operates without any kind of intrinsic or extrinsic electrical power source. It can function independently of Vascular pressure to provide continuous uniform rate infusion. Drugs or other chemical substances or fluids can be infused intravenously, intra-arterially or into a body cavity or tissue at a constant volume slow flow delivery rate. It may be used for such purposes as continuous heparinization, artificial pancreas insulin injection, chemotherapeutic organ infusion, anti-hyperlipidemic agent infusion, regional vasodilator infusion, and the like.

Previous methods of infusion have required external connections and tubing. No completely permanently implantable infusion pump with percutaneous refilling access has been known. The pump of the present invention utilizes a recycling chemical vapor-liquid constant pressure energy source, avoiding the disadvantages of any electrically powered pump, whether operated from an external or internal power pack, atomic powered pump, magnetic powered pump, or the like. The present pump utilizes the pressure used to fill the inner chamber as the kinetic energy source for restoring the potential energy to the chemical pump. Operation of the pump depends upon the physical concept that a vapor in equilibrium with its liquid phase exerts a constant vapor pressure at a given temperature, regardless of volume.

The invention is illustrated in the accompanying drawings in which the corresponding parts are identified by the same numerals and in which:

FIG. 1 is a perspective view of the implantable infusion pump, partly broken away and partly in section, and showing the components in exploded relation;

FIG. 2 is a top plan view of the pump;

FIG. 3 is a bottom plan view; and

FIG. 4 is a transverse sectional view, on a slightly enlarged scale, of the assembled pump.

Referring now to the drawings, the infusion pump according to the present invention comprises an outer cylindrical housing, indicated generally at 10, and having a cylindrical side wall 11, circular bottom wall 12 and annular top wall 13. A shallow cup-like member, indicated generally at 14, of lesser diameter than housing 10, is fitted into the space within annular housing top wall 13. Cup-like member 14 is open at the top and includes a cylindrical side wall 15, generally circular bottom wall 16 and outwardly extending annular flange 17. The elements of housing 10 and cup-like member 14 are formed and secured together in liquid-tight vapor-tight junctions.

A bellows, indicated generally at 18, and comprised of a stack of plurality of concentric flat annular rings 19, a circular bottom wall 20, an annular top wall 21 and a cylindrical mouth or lip 22 is positioned within housing 10. Lip 22 is secured to the inner periphery of top wall 21 and to flange 17 of cup-like member 14 in

liquid-tight vapor-tight relation. Adjacent rings 19 are secured together alternately at their inner and outer peripheries, the bottom-most ring is secured to the outer periphery of bottom wall 20 and the topmost ring is secured to the outer periphery of top wall 21, all in liquid-tight vapor-tight relation, in the usual manner to form an expandable-contractible bellows structure. The annular space between the housing wall and the cup-like member provides a recess into which the bellows may be collapsed.

Bellows 18 divides the interior of housing 10 into an outer chamber 23 and inner chamber 24 of varying volume. As chamber 23 becomes larger through contraction of the bellows, chamber 24 becomes smaller, and vice versa. Housing bottom wall 12 is provided with a screw-threaded fitting 25 defining a central inlet port or aperture to chamber 23 to receive a threaded plug 26. The head 27 of screw plug 26 is provided with a transverse slot 28 on its outer surface to facilitate closing of the opening, and an annular channel on its inner surface to receive a resilient O-ring 29 to form a liquid-tight vapor-tight seal.

The bottom wall 16 of cup-like member 14 is provided with a central aperture and annular fitting 30 internally threaded to receive one end 32 of nipple 31. The central portion of nipple 31 is of greater diameter than threaded portion 32, and is desirably hexagonal or other polygonal shape. Its bottom surface is provided with an annular groove or channel to receive an O-ring 33 adapted to be compressed against the upper surface of fitting 30 to form a liquid-tight seal.

The upper portion 34 of nipple 31 is of somewhat greater diameter than the lower portion 32 and is externally threaded to receive an internally threaded knurled cap 35 having a central top opening 36. A longitudinal passage 37 extends through nipple 31. The upper end of passage 37 receives a plug or stopper 38 formed of elastic self-puncture-sealing material, which serves as an entry port to chamber 24. Stopper 38 has an outwardly flanged top 39 which engages the upper end of nipple 31, the stopper being secured by knurled ring 35 in liquid-tight relation.

The fitting enclosing passage 37 may also be elongated, or bent, as in the case where the pump itself would lie some distance under the skin, i.e. in a body cavity, between two muscle planes, etc. The liquid-tight closure apparatus, 35-39, would necessarily lie at the end of this extension directly underneath the skin for percutaneous refilling ease. This closure apparatus is not limited to a puncture-sealing rubber stopper as shown, but may be replaced by any displaceable self-sealing mechanism, such as a ball valve.

The expressions "upper," "lower," "top," "bottom," etc. are relative and refer only to positions as shown in the drawings. These relationships may vary in use when the pump is implanted in the body with the opening 36 of cap 35 and stopper 38 accessible under the skin for injection of refills of the drug or other chemical to be infused.

One end of a thin small-diameter flexible capillary tube 40 (preferably within a larger protective tube) is secured in a radial discharge passage in the body of nipple 31 so as to be in direct fluid communication with the longitudinal passage through the nipple and with chamber 24 to serve as a discharge therefrom. Tube 40

serves primarily as the pressure-drop flow regulator (e.g. may be replaced by a porous plug or other flow regulating device) and is of variable length and diameter. It is coiled around nipple 31 and fits within cup-like member 14. Tubing 40 extends to the infusion site where the infused material is dispensed from its opposite end. This capillary is preferably enclosed in a larger polyethylene or Silastic cannula to facilitate placement.

The capillary tubing 40 serves a two-fold function, as a flow-regulating resistance element and a discharge port into the site of infusion. This may be replaced by a combination of any two devices accomplishing the same end; for example, the resistance element may be a porous metal plug or other filter, or any other type of flow regulator, in direct fluid communication with the infusion site by means of a conduit, such as a catheter or cannula. Also, these resistance elements may number more than one, as in the case of more than one site of infusion.

Bellows 18 is one form of liquid-tight, vapor-tight, pressure-communicating interphase means which can be used to separate the two chambers of the pump. Alternatively the chambers may be separated by a resilient diaphragm which is compatible with the substances within the chambers; or the second chamber may be formed, in part at least, from a flexible bladder which is compatible with the materials and capable of expanding and contracting under influence of the infusate and vapor-producing material in the first chamber, and the like.

A vapor in equilibrium with its liquid phase exerts a constant vapor pressure at a given temperature regardless of volume. The outer pump chamber 23 at its minimum volume is partially filled with a stable volatile liquid that exerts a vapor pressure of greater than one atmosphere at physiological temperatures (approximately 37° C) to form the vapor-liquid mixture of the chemical power source. Volatile liquids among the members of this very large group of compounds include: Perfluoro pentane, Tetramethyl silane, Ethyl ether, Methyl formate, Ethanethiol, Dimethyl sulfide, Ethylamine, 2-Methyl butane, Hydrocyanic acid, Trichlorofluoro methane, and Nitrogen tetroxide. These compounds, of course, should be compatible with the substance serving as the enclosure for chamber 23. The inner chamber 24 contains the displaceable infusate. The flow rate of the infusate is varied through the use of the capillary tubing 40 for the pressure drop, which is governed by the equation: $Q = (\pi D^4 \Delta P) / 128 \mu L$, where Q = flow in ml/sec., D = diameter in cm., μ = viscosity in poise, ΔP = pressure in dynes/cm², and L = length in cm. The most readily adjustable parameters are the length and diameter of the capillary and the viscosity of the infusate. Refills of infusate are injected into the inner chamber through the self-sealing stopper 38. The pressure generated by this injection is sufficient to recycle the pump by condensing the volatile vapor phase within outer chamber 23.

One or more spacer members 41 are desirably provided on the inside of bellows bottom wall 20 (or cup bottom wall 16) to prevent wall members 20 and 16 from becoming adhered through surface tension of the infusate. Desirably a filter is installed on both the inlet and outflow sides of the pump to reduce the possibility

of particulate contamination. The pump is constructed of materials non-toxic to the host animal and compatible with both the infusate and the chemical power source. Stainless steel is a desirable material for forming the housing, bellows, fittings, etc. All exposed parts of the pump are covered with Silastic, Teflon, or similar material, compatible with body fluids and well-known for the coating of devices to be implanted within the body.

In-vitro tests in an incubator at 37° C have shown a high degree of constancy in infusion rates at adjusted levels of extremely low flow over various time increments. Representative mean adjusted flow rates \pm standard error for different time periods include: 0.078 \pm 0.0017 ml/hr for a 39 hour period; 0.101 \pm 0.00035 ml/hr for an 82 hour trail; 0.183 \pm 0.0073 ml/hr for a 68 hour trial; 0.363 \pm 0.0046 ml/hr for a 43 hour trial; 0.373 \pm 0.013 ml/hr for a 44 hour trial; and 0.613 \pm 0.020 ml/hr for a 13 hour trial. The capacity of a unit in which the housing 10 measures about 2½ by 7 cm. is approximately 20 ml. This means that low flow may be maintained over 10 days before refilling is necessary.

In-vivo trials in dogs, utilizing chronic heparinization as the measureable parameter, have confirmed in-vitro pump specifications. The pump is placed beneath the external oblique muscle with the delivery catheter threaded into the inferior vena cava through the femoral vein and the refill nipple or stopper is placed subcutaneously to be readily accessible to percutaneous needle injection. Constant infusion flows have been maintained so that the daily Lee White clotting times and activated partial thromboplastin times have remained at twice control values.

It is apparent that many modifications and variations of this invention is hereinbefore set forth may be made without departing from the spirit and scope thereof. The specific embodiments described are given by way of example only and the invention is limited only by the terms of the appended claims.

We claim:

1. An infusion pump for implantation in a living body comprising:

A. a housing,

B. means for dividing the housing into first and second fluid-tight chambers, the dividing means being movable relative to the housing so as to vary the volumes of the chambers in a reciprocal manner,

C. an inlet conduit located at a first position on the housing leading to the second chamber,

D. at least one outlet conduit located at a second position on the housing adjacent to but spaced from said inlet conduit communicating with the second chamber and for leading to an infusion site in the body,

E. means in the first chamber for moving the dividing means to reduce the volume of the second chamber so that a fluid in the second chamber may be forced through the outlet conduit, and

F. a self-sealing, penetrable member in said inlet conduit, said member being unobstructed so that the pump can be implanted in the body with the unobstructed penetrable member situated adjacent a surface area of the body whereby the second chamber can be refilled with fluid periodically by injection through the skin.

2. The pump defined in claim 1 wherein the moving means is comprised of a volatile fluid in the first chamber which exerts a sufficient vapor pressure at physiological temperatures to move the dividing means and force the contents of the second chamber through the outlet conduit. 5

3. The pump defined in claim 2 and further including:

A. an entry port to the chamber from the outside of the housing, and 10

B. a fluid-tight closure for the entry port.

4. The pump defined in claim 1 and further including fluid flow regulating means in the outlet conduit.

5. An infusion pump for implantation in a living body comprising: 15

A. a housing including an inlet means,

B. a metal bellows within the housing, the bellows

1. having a closed end wall,

2. being sealed with respect to the interior of the housing, and 20

3. being compressible in response to pressure exerted on the outside of the end wall,

C. an inlet conduit leading to the interior of the bellows from the outside of the housing, 25

C. an outlet conduit communicating with the interior of the bellows for conducting fluid from the interior of the bellows to an infusion site in the body, and

E. a self-sealing, penetrable member in the inlet conduit, said penetrable member being unobstructed so that the pump can be implanted in the body with the unobstructed member situated adjacent a surface area of the body whereby the bellows can be refilled with fluid periodically by injection through the skin. 30 35

6. The pump defined in claim 5 and further including a volatile liquid in the housing outside the bellows which exerts a sufficient vapor pressure at physiological temperatures to compress the bellows and force the bellows contents through the outlet conduit. 40

7. The pump defined in claim 5 and further including means for controlling the rate of flow of fluid through the outlet conduit.

8. The pump defined in claim 5 wherein the penetrable member is comprised of a penetrable self-sealing stopper. 45

9. The pump defined in claim 5 and further including means for limiting the extent to which the bellows can be compressed in response to the pressure exerted on its end wall. 50

10. An infusion pump for implantation in a living body comprising:

A. a housing,

B. first and second chambers within the housing, 55

C. a liquid-tight, vapor-tight, pressure-communicating metal bellows separating the chambers, said bellows having an open mouth at one end and closed wall at the other end, the mouth of the bellows being secured in liquid-tight, vapor-tight relation, the first chamber being provided with an inlet means and lying between the inside walls of the housing and the bellows and the second chamber lying within the bellows, 60

D. an entry port into the second chamber and liquid-tight closure means therefor, the closure means being penetrable from the outside of a living body 65

after implantation therein by injection through the skin, and

E. at least one discharge port from the second chamber spaced from but adjacent to said entry port.

11. A pump according to claim 10 further characterized in that:

A. a recessed, cup-like member is disposed in one end of the housing extending within the mouth of the bellows,

B. an aperture is provided in the cup-like member with a fitting therein having a channel in communication with the second chamber, and

C. the bellows is collapsible into an annular space between the cup-like member and the housing wall.

12. The pump according to claim 10 and further characterized in that:

A. the penetrable closure means is an elastic member, and

B. an annular retainer having a central aperture is secured to the external end of the fitting in engagement with the elastic member.

13. The pump according to claim 12 and further characterized in that:

A. the housing and the fitting having contours conforming generally to the contours of the implantation site in the body, and

B. a conduit is connected to the discharge port for conducting infusate from the bellows to an infusion site in the body.

14. The pump according to claim 13 wherein the conduit is a length of capillary tubing.

15. The pump according to claim 10 and further characterized in that the first chamber is partially filled with a stable, volatile liquid that exerts a vapor pressure of greater than 1 atmosphere at physiological temperatures, whereby the pump is self-powered through body warmth.

16. The method of infusing liquids into a living body, said method comprising:

A. implanting a self-powered pump according to claim 15 in a living body, with the closure means to the entry port of the second chamber of the pump underlying and facing the skin,

B. connecting the discharge port to at least one infusion site in the body,

C. injecting infusate through the skin of the body and through the closure means to fill the second chamber thereby condensing the vapor within the first chamber to charge the power source, and

D. expanding the vapor in the first chamber through body warmth to gradually collapse the second chamber to expel the infusate in the second chamber through the discharge port to the infusion site.

17. The method of infusing fluids into a living body, said method comprising the steps of:

A. charging the power cell of a vapor pressure pump with a stable, volatile liquid that exerts an appreciable vapor pressure at physiological temperatures,

B. forming a self-sealing, penetrable member in the discharge port of the pump,

C. implanting the pump in the body so that the penetrable member underlies the skin,

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D. expanding the pressure-exerting vapor in the power cell through body warmth to pump infusate through the discharge port to an infusion site in the body, and

E. injecting additional fluid through the skin and 5

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through the penetrable member periodically to refill the pump with infusate and, at the same time, condense the pressure-exerting vapor so as to recharge the power cell.

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