CONTRACEPTIVE MEDICAL DEVICES

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application No. 62/934,090, filed November 12, 2019, and U.S. Provisional Patent Application No. 63/019,884, filed May 4, 2020, which each application is herein incorporated in its entirety for all purposes.

TECHNICAL FIELD

[0002] The present disclosure relates to medical devices for contraception, particularly disclosing an intravaginal medical device comprising a ring, an injection molding guide and a barrier material.

BACKGROUND

[0003] Effective contraceptive medical devices or pharmaceuticals are desired by fertile humans worldwide. The success rate of a contraceptive medical device depends not only upon the efficacy of a contraceptive method, but also upon a user's preference, the reversibility of the method's medical device or pharmaceutical; convenience for the user, and compliance by the user. The need for effective contraceptive methods, including pharmaceutical or medical devices, continues to be a critical need. It is estimated that fifty percent of pregnancies are unintended, and worldwide, a woman dies every two minutes from pregnancy and childbirth related issues.

[0004] Hormone-based pharmaceutical contraceptives have been used widely, but are now known to affect users systemically, and are contraindicated for individuals with a variety of cardiovascular conditions. Therefore, it is desirable to provide new and improved contraceptive medical devices that provide localized administration of active agents, and that are easier to use than are conventional devices and methods. Accordingly, there is a need to provide local administration of one or more active agents, biocompatible, non-invasive, cost-effective, reversible and convenient contraceptive medical devices to prevent pregnancy. The present disclosure provides contraceptive medical devices and related devices and methods to meet this need.

SUMMARY

[0005] Briefly stated, the present disclosure provides contraceptive medical devices, components thereof, methods of making and using the contraceptive devices and components thereof, and compositions contained therein. ~~In one aspect, the~~The present disclosure provides a

contraceptive device comprising a porous barrier material and an injection molding guide, the injection molding guide optionally affixed to the barrier material The injection molding guide and the porous barrier material may each be at least partially encased within a polymeric ring that encircles the porous barrier material, and in one ~~embodiment~~example the injection molding guide is completely encased within the polymeric ring and the porous barrier material is partially encased within the polymeric ring. Thus, ~~in one aspect~~ the present disclosure provides a contraceptive device comprising a porous barrier material, an injection molding guide, and a polymeric ring, where the injection molding guide is entirely encased within the polymeric ring and the porous barrier material is partially encased within the polymeric ring. In one aspect, the present disclosure provides a contraceptive device comprising a polymeric ring, a porous barrier material and an injection molding guide, both of the injection molding guide and the porous barrier material at least partially embedded within the polymeric ring. The injection molding guide may have symmetry so that two or more pins may equally engage with the injection molding guide during an injection molding process. The injection molding guide may have a plurality of planar surfaces, e.g., 3, or 4, or 5, or 6, or 7, or 8 planar surfaces. The injection molding guide is at least partially encased within a polymeric ring structure, and in one ~~embodiment~~example the injection molding guide is encased within the polymeric ring structure. For example, the present disclosure provides a contraceptive device comprising a polymeric ring, a porous barrier material and an injection molding guide, the injection molding guide comprising a plurality of planar surfaces, each of the injection molding guide and the porous barrier material at least partially embedded within the polymeric ring, where optionally the injection molding guide is completely embedded within the polymeric ring and the porous barrier material is partially embedded within the polymeric ring. As another example, the present disclosure provides a contraceptive device comprising a polymeric ring, a porous barrier material and an injection molding guide, the injection molding guide having a symmetrical appearance when viewed in cross-section, such that the left side of the cross sectional view is the mirror image of the right side of the cross sectional view, each of the injection molding guide and the porous barrier material at least partially embedded within the polymeric ring, where optionally the injection molding guide is completely embedded within the polymeric ring and the porous barrier material is partially embedded within the polymeric ring.

[0006] Optionally, the contraceptive device may be further characterized by features disclosed herein, e.g., it may be further characterized by one or more of the following features: the barrier material is a mesh; the barrier material is a fibrous mesh; the barrier material is fibrous; the barrier material is circular; the barrier material is substantially circular; the barrier material has a diameter, e.g., a diameter of about 40 mm to about 60 mm, for example, about 45 mm to about 53 mm; the injection molding guide is non-fibrous; the injection molding guide has a

melting point above the temperature used for injection molding, e.g., above 120°C; the injection molding guide has a uniform cross-section at all locations around the injection molding guide; the injection molding guide has a corner formed by two planar surfaces intersecting at an angle, optionally an angle between 45 degrees and 135 degrees, e.g., of 85-95 degrees, e.g., a 90 degree angle; the injection molding guide has a polymeric coating; the injection molding guide is uncoated; the injection molding guide does not contain a sizing polymer; the injection molding guide has a single composition throughout the support ring; the injection molding guide is biodegradable; the injection molding guide is located along an edge of the barrier material; the injection molding guide is located close to an edge of the barrier material; the injection molding guide extends into the porous barrier material; the injection molding guide is 3D-printed on the barrier material; the injection molding guide is injection molded onto the barrier material; the ring structure comprises an elastomeric polymer, e.g., a siloxane; the contraceptive device includes a biologically active agent located within the polymeric ring structure; the contraceptive device includes a ferrous compound located within the polymeric ring structure; the contraceptive device includes ferrous gluconate or a hydrate thereof located within the polymeric ring structure; the contraceptive device includes a ferrous compound and ascorbic acid, each located within the polymeric ring structure. These and other features and options for the contraceptive device of the present disclosure are described herein.

[0007] In ~~one~~ another aspect, the present disclosure provides a kit comprising a contraceptive device as described herein, e.g., as described above, the kit further comprising at least one of a lubricant, a spermicidal gel, a spermicidal film, a contraceptive gel and an applicator.

[0008] ~~In one aspect, the~~The present disclosure provides a construct that can be used to form a contraceptive device of the present disclosure. The construct comprises a porous barrier material affixed to an injection molding guide, where the injection molding guide has a plurality of planar surfaces. Thus, in another aspect, the present disclosure provides a construct for forming a contraceptive device, the construct comprising a porous barrier material affixed to an injection molding guide. Optionally, the construct may be further characterized by a feature described herein, e.g., one or more of the following features: the barrier material is a mesh; the barrier material is a fibrous mesh; the barrier material is fibrous; the barrier material is circular; the barrier material is substantially circular; the barrier material has a diameter of about 40 mm to about 60 mm, e.g., about 45 mm to about 53 mm; the injection molding guide

is non-fibrous; the injection molding guide has a melting point above the temperature used for injection molding, e.g., above 120°C; the injection molding guide has a uniform cross-section at all locations around the injection molding guide; the injection molding guide has a corner formed by two planar surfaces intersecting at an angle, such as an angle of about 45 degrees to about 135 degrees, such as 85-95 degrees, e.g., a 90 degree angle; the injection molding guide

is uncoated; the injection molding guide does not contain a sizing polymer; the injection molding guide has a single composition; the injection molding guide is biodegradable; the injection molding guide is located along an edge of the barrier material; the injection molding guide is located close to an edge of the barrier material; the injection molding guide extends into the porous barrier material; the injection molding guide is 3D-printed on the barrier material; the injection molding guide is injected molded onto the barrier material.

[0009] ~~In one aspect, the~~The present disclosure provides methods of forming a construct and a contraceptive device of the present disclosure. In another aspect, the present disclosure provides a method of forming a contraceptive device, the method comprising: a. providing a construct comprising a porous barrier material affixed to an injection molding guide; b. placing the construct into a die; c. adjusting a location of at least one pin within the die so that the at least one pin contacts a surface of the injection molding guide; and d. injecting a molten polymer into the die to form a polymeric ring, where each of the injection molding guide and the porous barrier material is at least partially embedded within the polymeric ring. For example, the present disclosure provides a method of forming a contraceptive device, the method comprising: (a) providing a construct comprising a porous barrier material affixed to an injection molding guide, the injection molding guide comprising a plurality of planar surfaces; (b) placing the construct into a die; (c) adjusting a location of at least one pin within the die so that the at least one pin contacts a surface of the injection molding guide; and (d) injecting a molten polymer into the die to form a ring structure that encases the injection molding guide. As another example, the present disclosure provides a method of forming a construct, the method comprising: 3D-printing an injection molding guide onto a porous barrier material. As yet another example, the present disclosure provides a method of forming a construct, the method comprising forming an injection molding guide, optionally by an injection molding process; and then affixing the injection molding guide to the porous barrier material. In another aspect, the present disclosure provides a method of forming a contraceptive device, the method comprising: a. providing a construct comprising a porous barrier material affixed to an injection molding guide; b. placing the construct into a heated die; c. adjusting a location of at least one pin within the die so that at least one pin contacts a surface of the injection molding guide; d. injecting a mixture of a two part heat curable polymer into the die to form a polymeric ring, where each of the injection molding guide and the porous barrier

material is at least partially embedded within the polymeric ring; e. allowing the mixture of a two part heat curable polymer to cure in the mold such that the mixture of a two part heat curable polymer is transformed from a liquid state to a solid state; and f. ejecting the molded product from the die. As a further example, the present disclosure provides a method of forming a contraceptive device, the method comprising: (a) providing a construct comprising a porous barrier material affixed to an injection molding guide, the injection molding guide having symmetry and comprising a plurality of planar surfaces; (b) placing the construct into a die, optionally a heated die; (c) adjusting a location of at least one pin within the die so that the at least one pin contacts a surface of the injection molding guide; (d) injecting a mixture of a two part heat curable polymer into the die to form a polymeric ring, where each of the injection molding guide and the porous barrier material is at least partially embedded within the polymeric ring; allowing the mixture of a two part heat curable polymer to cure in the mold such that the mixture of a two part heat curable polymer is transformed from a liquid state to a solid state; and (f) ejecting the contraceptive device from the die.

[0010] The present disclosure provides various aspects and ~~embodiments~~examples of contraceptive devices, constructs useful in forming contraceptive devices and related methods for forming and using same, where these various aspects and ~~embodiments~~examples may be combined to describe a contraceptive device, construct, and related method of the present disclosure. For example, ~~in~~

~~an aspect,~~ the contraceptive device comprises a polymeric ring structure, an injection molding guide and a porous barrier material, where the polymer of the polymeric ring structure comprises silicone, and the polymeric ring structure further comprises ferrous gluconate, ascorbic acid, glycine and particles of poly(glycolic acid). The device may be further described by saying that encased within the silicone ring structure is an injection molding guide that comprises a lactide trimethylene carbonate polymer in which the lactide comprises greater than about 70% (w/w), e.g., 80% (w/w) of the polymer, and where the guide has a melting point above the temperature used for injection molding. The device may be further described by saying that the injection molding guide has at least one planar surface. The device may be further described by saying that it comprises a porous barrier material that is partially embedded within the polymeric ring structure, where the barrier material completely traverses the inner diameter of the ring. The device may be further described by saying that the barrier material can comprise a fibrous multifilament mesh, formed at least in part from a lactide trimethylene carbonate polymer in which the lactide comprises greater than 70% (w/w), or greater than 80% (w/w) of the polymer. The contraceptive device may be further described by saying that is has an outer diameter of about 40 mm to about 60 mm, e.g., about 45m to about 53 mm. The device may be further described by saying that the device is not contaminated with Pseudomonas aeruginosa, Staphylococcus aureus or Candida albicans, and optionally has a bacterial endotoxin level of less than or equal to 20 EU. The device may further be described in terms of its performance properties, e.g., ~~in an aspect~~ the contraceptive device, when placed in simulated vaginal fluid will release ferrous ions for at least 35 days. ~~In an aspect, the~~The present disclosure provides a kit, containing a contraceptive device having aspects and ~~embodiments~~examples as described herein, where the device is packaged, optionally with written instructions for use.

[0011] The present disclosure provides the following exemplary and non-exhaustive ~~embodiments~~examples, which are numbered for convenience:

1) A contraceptive device comprising a polymeric ring, a porous barrier material and an injection molding guide, each of the injection molding guide and the porous barrier material at least partially embedded within the polymeric ring.
2) The contraceptive device of ~~embodiment~~ example 1 wherein the barrier material is a mesh.
3) The contraceptive device of ~~embodiment~~ example 1 wherein the barrier material is fibrous.
4) The contraceptive device of ~~embodiments~~examples 1-3 wherein the barrier material is circular or substantially circular.
5) The contraceptive device of ~~embodiments~~examples 1-4 wherein the barrier material has a diameter of about 40 mm to about 60 mm, e.g., from about 45 mm to about 53 mm.

6) The contraceptive device of ~~embodiments~~examples 1-5 wherein the injection molding guide is symmetrical.
7) The contraceptive device of ~~embodiments~~examples 1-6 wherein the injection molding guide comprises a plurality of planar surfaces.
8) The contraceptive device of ~~embodiments~~examples 1-7 wherein the injection molding guide comprises a plurality of planar surfaces, and has a corner formed by intersection of two planar surfaces, optionally wherein the injection molding guide has a corner formed by two planar surfaces intersecting at an angle, where the angle is between a 45 degree angle and a 135 degree angle, e.g., a 90 degree angle.
9) The contraceptive device of ~~embodiments~~examples 1-8 wherein the injection molding guide is at least one of non-fibrous and non-porous.
10) The contraceptive device of ~~embodiments~~examples 1-9 wherein the injection molding guide is completely embedded within the polymeric ring and the porous barrier material is partially embedded within the polymeric ring.
11) The contraceptive device of ~~embodiments~~examples 1-10 wherein the injection molding guide is uncoated and/or does not contain a sizing polymer.
12) The contraceptive device of ~~embodiments~~examples 1-11 wherein the injection molding guide is affixed to the porous barrier material.
13) The contraceptive device of ~~embodiments~~examples 1-12 wherein the injection molding guide has a composition, and the composition is constant at each location of the injection molding guide.
14) The contraceptive device of ~~embodiments~~examples 1-13 wherein the injection molding guide is biodegradable.
15) The contraceptive device of ~~embodiment~~ examples 1-14 wherein the injection molding guide is located along an edge of the porous barrier material.
16) The contraceptive device of ~~embodiments~~examples 1-14 wherein the injection molding guide is located close to an edge of the porous barrier material.
17) The contraceptive device of ~~embodiments~~examples 1-16 wherein the injection molding guide extends into the porous barrier material.
18) The contraceptive device of ~~embodiments~~examples 1-17 wherein the injection molding guide is 3D-printed on the porous barrier material.
19) The contraceptive device of ~~embodiments~~examples 1-17 wherein the injection molding guide is injected molded onto the porous barrier material.

20) The contraceptive device of ~~embodiments~~examples 1-19 wherein the polymeric ring comprises an elastomeric polymer.
21) The contraceptive device of ~~embodiments~~examples 1-20 wherein the polymeric ring encircles the porous barrier material.
22) The contraceptive device of ~~embodiments~~examples 1-21 further comprising a biologically active agent located within the polymeric ring.
23) The contraceptive device of ~~embodiments~~examples 1-21 further comprising a ferrous compound located within the polymeric ring.
24) The contraceptive device of ~~embodiments~~examples 1-21 further comprising ferrous gluconate or a hydrate thereof located within the polymeric ring, optionally also further comprising ascorbic acid located within the polymeric ring.
25) A kit comprising the contraceptive device of ~~embodiments~~examples 1-24, the kit further comprising at least one of a lubricant, a spermicidal gel, a spermicidal film, a contraceptive gel and an applicator.
26) A construct for forming a contraceptive device, such as a contraceptive device of any of ~~embodiments~~examples 1-24, the construct comprising a porous barrier material affixed to an injection molding guide.
27) The construct of ~~embodiment~~ example 26 wherein the barrier material is a mesh.
28) The construct of ~~embodiments~~examples 26-27 wherein the barrier material is fibrous.
29) The construct of ~~embodiments~~examples 26-28 wherein the barrier material is circular or is substantially circular.
30) The construct of ~~embodiments~~examples 26-29wherein the barrier material has a diameter of about 40 mm to about 60 mm, e.g., about 45 mm to about 53mm.
31) The construct of ~~embodiments~~examples 26-30 wherein the injection molding guide is symmetrical.
32) The construct of ~~embodiments~~examples 26-31 wherein the injection molding guide has a uniform cross-section at all locations around the injection molding guide.
33) The construct of ~~embodiments~~examples 26-32 wherein the injection molding guide comprises a plurality of planar surfaces.
34) The construct of ~~embodiments~~examples 26-33 wherein the injection molding guide has a corner formed by intersection of two planar surfaces, optionally wherein the injection molding guide has a corner formed by two planar surfaces intersecting at an angle, where the angle is between about 45 degrees and about 135 degrees, for example an angle of about 90 degrees.

35) The construct of ~~embodiments~~examples 26-34 wherein the injection molding guide is non-fibrous and optionally is non-porous.

36) The construct of ~~embodiments~~examples 26-35 wherein the injection molding guide has a melting point above 120°C.

37) The construct of ~~embodiments~~examples 26-36 wherein the injection molding guide is uncoated.

38) The construct of ~~embodiments~~examples 26-37 wherein the injection molding guide does not contain a sizing polymer.

39) The construct of ~~embodiments~~examples 26-38 wherein the injection molding guide has a single composition at each location of the injection molding guide .

40) The construct of ~~embodiments~~examples 26-39 wherein the injection molding guide is biodegradable.

41) The construct of ~~embodiments~~examples 26-40 wherein the injection molding guide is located along an edge of the porous barrier material.

42) The construct of ~~embodiments~~examples 26-40 wherein the injection molding guide is located close to an edge of the barrier material.

43) The construct of ~~embodiments~~examples 26-42 wherein the injection molding guide extends into the porous barrier material.

44) The construct of ~~embodiments~~examples 26-43 wherein the injection molding guide is 3D-printed on the porous barrier material.

45) The construct of ~~embodiments~~examples 26-43 wherein the injection molding guide is injected molded onto the porous barrier material.

46) A method of forming a contraceptive device, such as a contraceptive device of any of ~~embodiments~~examples 1-24, the method comprising:

   a. providing a construct comprising a porous barrier material affixed to an injection molding guide;
   b. placing the construct into a die;
   c. adjusting a location of at least one pin within the die so that the at least one pin contacts a surface of the injection molding guide; and
   d. injecting a molten polymer into the die to form a polymeric ring, where each of the injection molding guide and the porous barrier material is at least partially embedded within the polymeric ring.

47) The method of ~~embodiment~~ example 46 wherein the construct is provided by a method comprising 3D-printing the injection molding guide onto the porous barrier material.

48) The method of ~~embodiment~~ example 46 wherein the construct is provided by a method comprising:

a. forming an injection molding guide by an injection molding process;

b. affixing the injection molding guide to the porous barrier material.

49) A method of forming a contraceptive device, such as a contraceptive device of any of ~~embodiments~~examples 1-24, the method comprising:

a. providing a construct comprising a porous barrier material affixed to an injection molding guide;

b. placing the construct into a heated die;

c. adjusting a location of at least one pin within the die so that the at least one pin contacts a surface of the injection molding guide;

d. injecting a mixture of a two part heat curable polymer into the die to form a polymeric ring, where each of the injection molding guide and the porous barrier material is at least partially embedded within the polymeric ring;

e. allowing the mixture of a two part heat curable polymer to cure in the mold such that the mixture of a two part heat curable polymer is transformed from a liquid state to a solid state; and

f. ejecting the molded product from the die.

50) The method of ~~embodiment~~ example 49 wherein the construct is provided by a method comprising 3D-printing the injection molding guide onto the porous barrier material.

[0012] The above-mentioned and additional features of the present ~~invention~~disclosure and the manner of obtaining them will become apparent, and the ~~invention~~disclosure will be best understood by reference to the following more detailed description. All references disclosed herein are hereby incorporated by reference in their entirety as if each was incorporated individually.

[0013] This Brief Summary has been provided to introduce certain concepts in a simplified form that are further described in detail below in the Detailed Description. Except where otherwise expressly stated, this Brief Summary is not intended to identify key or essential features of the claimed subject matter, nor is it intended to limit the scope of the claimed subject matter.

[0014] The details of one or more ~~embodiments~~examples and aspects are set forth in the description below. The features illustrated or described in connection with one ~~exemplary embodiment~~example or aspect may be combined with the features of other ~~embodiments~~examples or aspects. Thus, any of the various ~~embodiments~~examples or aspects described herein can be combined to provide further ~~embodiments~~examples of the present disclosure. Features of the ~~embodiments~~examples and aspects can be

modified, if necessary, to employ concepts of the various patents, applications and publications as identified herein to provide yet further ~~embodiments~~examples. Other features, objects and advantages will be apparent from the description, the drawings, and the claims.

BRIEF DESCRIPTION OF THE FIGURES

[0015] Exemplary features of the present disclosure, its nature and various advantages will be apparent from the accompanying drawings and the following detailed description of various embodiments. Non-limiting and non-exhaustive embodiments are described with reference to the accompanying drawings, wherein like labels or reference numbers refer to like parts throughout the various views unless otherwise specified. The sizes and relative positions of elements in the drawings are not necessarily drawn to scale. For example, the shapes of various elements are selected, enlarged, and positioned to improve drawing legibility. The particular shapes of the elements as drawn have been selected for ease of recognition in the drawings. One or more embodiments are described hereinafter with reference to the accompanying drawings in which:

[0016] FIG. 1 shows a top view of an exemplary contraceptive medical device disclosed herein, illustrating an injection molding guide (1), a porous barrier material (2), and a ring structure (3).

[0017] FIG. 2 shows a schematic of a side view of a portion of an exemplary contraceptive medical device disclosed herein, and more specifically the portion identified by "A" in FIG. 1, illustrating an injection molding guide (1), a porous barrier material (2), and a ring structure (3).

[0018] FIGs. 3A, 3B, 3C, 3D, 3E, 3F, 3G, 3H and 3I each show a cross-section of a portion of a schematic of an exemplary injection molding guide (1) provided on a porous barrier material (2) of an exemplary construct disclosed herein.

[0019] FIG. 4 shows a schematic of an exemplary injection molding guide (1) provided on a porous barrier material (2) of an exemplary contraceptive medical device disclosed herein.

[0020] FIGs. 5A and 5B each show a schematic of an exemplary injection molding guide (1) provided on a porous barrier material (2) of an exemplary contraceptive medical device disclosed herein.

[0021] FIGs. 6A, 6B and 6C show schematics of an exemplary construct, where FIG. 6A provides a top view of the construct, FIG. 6B shows a full cross-sectional view of the construct of FIG. 6A as viewed through the line B shown in FIG. 6A, and FIG. 6C shows a partial cross-sectional view of the construct of FIG. 6A, and in particular the part of the cross-sectional view enclosed within the area denoted C in FIG. 6B.