

coated on the microneedle array and delivered directly through the skin after the stratum corneum has been punctured.

[0005] Microneedle arrays can be used in conjunction with an injection and infusion apparatus (i.e., an “applicator” that applies the hollow microneedles to the skin and facilitates infusion of a substance through the hollow microneedles) capable of being used several times or as a single-use device. The microneedle arrays are generally used once and then discarded.

SUMMARY

[0006] It has now been found that an interaction between an article comprising a plurality of hollow microneedles and a skin surface against which the article is urged can result in undesirable effects on the penetration of at least one microneedle of the plurality into the skin. It has further been found that, when the article comprises an array of microneedles, one of the effects can be significant variability in the depth of penetration into the skin by one or more of the microneedles in the array. The present inventors recognized the consistency of penetration depth can be controlled by including several features into the design of the article. The inventive design features result in the ability to rapidly, effectively and consistently insert the needles to a desired depth in the skin and quickly deliver a pharmaceutically-effective dose in a variety of skin locations. In addition, certain features of the disclosure design permit simpler, more robust processes to be used for the manufacture of the articles.

[0007] The present disclosure generally relates to articles comprising microneedles and their use to deliver materials through the surface of skin or remove biological fluids through the surface of skin. In particular, the present disclosure relates to an article comprising an array of a plurality of microneedles that is configured to provide consistent depths of penetration for each microneedle of the plurality of microneedles by facilitating the contact between microneedles and skin and by reducing the possibility of contact between skin and non-microneedle surfaces during the use of the articles.

[0008] The present disclosure provides an article. The article can comprise a first side, a second side opposite the first side, and at least three hollow microneedles. The first side can comprise a central cavity portion and a platform portion that projects from the first side and that is not coplanar with the central cavity portion. The microneedles can extend from the platform portion in a first direction. The platform portion can substantially surround the central cavity portion and can comprise an inner perimeter proximate the central cavity portion and an outer perimeter distal the central cavity portion. Each of the at least three microneedles comprises a body that comprises an outer surface; a base segment having a base and a first shape that is defined by a first section of the outer surface; a tip segment having a tip and a second shape that is defined by a second section of the outer surface, wherein the second shape is

distinct from the first shape; a transition plane that delineates the base segment and the tip segment; and a central axis. A first angle, defined by the central axis of each of the at least three microneedles and a shortest line extending from the outer perimeter of the platform and through the transition plane of the at least one microneedle, is greater than 50° and less than or equal to about 85°. In any embodiment, the first angle can be about 65° to about 75°, inclusive. In any of the above embodiments, the first angle can be about 70°.

[0008a] In one aspect, there is provided an article, comprising: a first side comprising a central cavity portion and a platform portion that projects from the first side and that is not coplanar with the central cavity portion; a second side opposite the first side; and at least three hollow microneedles extending from the platform portion in a first direction; wherein the platform portion substantially surrounds the central cavity portion; wherein the platform portion comprises an inner perimeter proximate the central cavity portion and an outer perimeter distal the central cavity portion; wherein the at least three hollow microneedles each comprise a body that comprises: an outer surface; a base segment having a base and a first shape that is defined by a first section of the outer surface; a tip segment having a tip and a second shape that is defined by a second section of the outer surface, wherein the second shape is distinct from the first shape; a transition plane that delineates the base segment and the tip segment; and a central axis; wherein a first angle, defined by the central axis of each of the at least three hollow microneedles and a shortest line extending from the outer perimeter of the platform and through the transition plane of the microneedle, is greater than 50° and less than or equal to about 85°.

[0009] The present disclosure also provides an article. The article can comprise a first side, a second side opposite the first side, and at least three hollow microneedles. The first side can comprise a central cavity portion and a platform portion that projects from the first side and that is not coplanar with the central cavity portion. The microneedles can extend from the platform portion in a first direction. The platform portion can substantially surround the central cavity portion and can comprise an inner perimeter proximate the central cavity portion and an outer perimeter distal the central cavity portion. Each of the at least three microneedles comprises a body that comprises an outer surface; a base segment having a base and a first shape that is defined by a first section of the outer surface; a tip segment having a tip and a second shape that is defined by a second section of the outer surface, wherein the second shape is distinct from the first shape; a transition plane that delineates the base segment and the tip segment; and a central axis. Each of the at least three microneedles comprises a height measured from the base to the tip. The tip segment of each of the at least three microneedles can define at least about 45% of the height of the microneedle. In any embodiment, the tip segment of each of the at least three microneedles can define at least about 70-80% of the height of the microneedle.

[0009a] In another aspect, there is provided use of the article as defined herein for injecting fluid into a body.

[0009b] In another aspect, there is provided the article, as defined herein, for extracting fluid from a body.

5 [0009c] In another aspect, there is provided an injection and infusion apparatus, comprising: a hollow-microneedle array article as defined herein; a hollow-microneedle array article holder; a first stored energy component configured to move the hollow-microneedle array article from a first position to a second position; and a reservoir containing a fluid, the reservoir being in fluid communication with the hollow microneedles; wherein the apparatus is
10 configured to propel the article in a predetermined direction at a predetermined velocity.

[0009d] In another aspect, there is provided a method, comprising: providing the injection and infusion apparatus as defined herein; actuating the actuator so as to insert the hollow microneedles through a surface of a skin.

[0010] The phrase "injection apparatus" refers to an integrated device capable of delivering
15 or extracting a fluid over a certain period and is not limited to devices intended solely for an infusion. Accordingly, an injection apparatus may be used, for example, for injecting fluid into the dermis or extracting fluid from tissue.

[0011] The term "transdermally" and variations thereof, is generally used to refer to any type of delivery of an active ingredient that crosses any portion of skin. That is, transdermally
20 can generally include systemic delivery (i.e., where the active ingredient is transported across, or substantially through, the dermis such that the active ingredient is delivered into the bloodstream), as well as intradermal delivery (i.e., where the active ingredient is transported partially through the dermis, e.g., across the outer layer (stratum corneum) of the skin, where the active ingredient is delivered into the skin, e.g., for treating psoriasis or for local anesthetic
25 delivery). That is, transdermal delivery as used herein includes delivery of an active ingredient that is transported across at least a portion of skin (but not necessarily all of the layers of skin), rather than merely being topically applied to an outer layer of the skin.