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(54) **Title:** ADAPTER CAPS FOR SAMPLE COLLECTION CONTAINERS AND ASSOCIATED MOLDS WITH CORE PINS AND RELATED METHODS

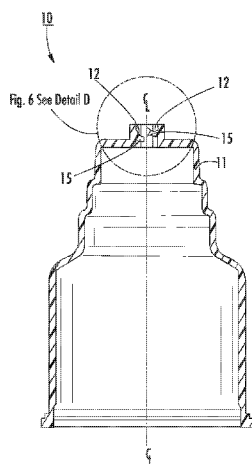


FIG. 2

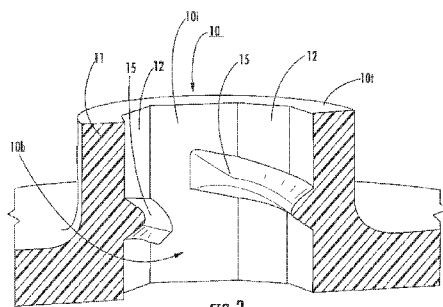


FIG. 3

(57) **Abstract:** Adapter caps for sample collection containers have a monolithic elongate body with an upper neck portion that merges into a larger lower body portion with an open internal cavity. The upper neck portion has an open needle bore that is concentrically aligned with the open internal cavity. The monolithic elongate body has an axially extending centerline. The needle bore has a downwardly extending wall with an inner surface that comprises a plurality of circumferentially spaced apart longitudinally extending flat surfaces.



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## **ADAPTER CAPS FOR SAMPLE COLLECTION CONTAINERS AND ASSOCIATED MOLDS WITH CORE PINS AND RELATED METHODS**

### **Related Applications**

This application claims the benefit of and priority to U.S. Provisional Application Serial Number 61/815,395, filed April 24, 2013, the contents of which are hereby incorporated by reference as if recited in full herein.

### **Field of the Invention**

The instant invention relates to the collection of biological fluid specimens and particularly the collection of bodily fluids such as, for example, blood from a patient and the transfer of the bodily fluid from the patient to fluid collection containers.

### **Background of the Invention**

A biosample such as blood can be withdrawn from a patient and stored in a culture collection bottle. Bottles for collection and culturing of blood and other biological or industrial samples are known in the art. *See*, e.g., U.S. Pat. Nos. 4,945,060; 5,094,955; 5,860,329; 4,827,944; 5,000,804; 6,123,211; 7,211,430 and U.S. Patent Publication Nos. 2005/0037165 and 2011/0081714, the contents of which are incorporated by reference as if recited in full herein.

To collect blood, an intravenous needle is inserted to the vein of the patient after it is connected to an adapter cap to which the top of the blood culture bottle can be mated. Examples of such holders are described in U.S. Patent Nos. 5,374,264; 7,261,698 and 5,360,423, the contents of which are hereby incorporated by reference as if recited in full herein. An example of a commercially available adapter cap is the Saf-T Holder® adapter cap from bioMérieux, Inc., Durham, NC. The adapters can prevent accidental needle pricks of a contaminated needle. The adapter cap is attached to the culture collection bottle and pressed down so that the needle held in the needle bore of the adapter cap penetrates the septum of the collection container and initiates blood flow into the collection bottle.

Despite the above, there remains a need for cost-effective adapter caps that can accommodate and seal to multiple needles from different manufacturers.

### **Summary of Embodiments of the Invention**

Embodiments of the invention are directed to adapter caps for sample collection containers. The adapter caps have a needle bore with a plurality of longitudinally extending flat surfaces.

Embodiments of the invention are directed to adapter caps for a sample collection container. The adapter caps include a monolithic elongate body having an upper neck portion with an open needle bore. The needle bore has a downwardly extending wall with an inner surface that includes (i) a plurality of circumferentially spaced apart longitudinally extending flat surfaces and (ii) first and second circumferentially spaced apart threads that extend radially inward from the inner surface so that respective innermost edges reside on opposing sides of an axially extending centerline of the elongate body.

The upper neck portion can merge into a larger lower body portion with an open internal cavity. The upper neck portion can be concentrically aligned with the open internal cavity.

The flat surfaces can extend a distance above and below the threads.

The threads can have a respective injection molded thread configuration and the thread on one side of the needle bore resides above the thread on an opposing side of the needle bore.

The plurality of flat surfaces can be between 2-6 flat surfaces.

The elongate body can include a molded polymeric material with a substantially constant wall thickness of between about 0.5 mm to about 2 mm.

The wall thickness can be about 1 mm.

The polymeric material can be polypropylene.

The flat surfaces can define wall segments with increased wall thickness of between .01 mm and .03 mm, average, relative to adjacent segments of the inner wall.

The plurality of longitudinally extending flat surfaces can be four flat surfaces that are symmetrically circumferentially spaced apart.

The plurality of longitudinally extending flat surfaces can have a common substantially constant width that is between about 5%-30% of a major diameter of the needle bore.

The needle bore can have a major diameter of about 4.60 mm.

The plurality of longitudinally extending flat surfaces can have a width that is between about 0.25 mm to about 1 mm.

At least some of the flat surfaces can have a length that is between about 2- 2.8 mm.

The needle bore can have a major diameter of about 4.60 mm. Opposing pairs of the longitudinally extending flat surfaces can have a thickness sufficient to define a nominal diameter therebetween of about 4.40 mm.

The adapter cap can include a culture collection container with an upper portion thereof residing in the cavity of the elongate body under the needle bore.

Some embodiments are directed to an injection mold assembly. The assembly includes: (a) an injection mold cavity defining a shape of an adapter cap having an elongate body with an upper neck portion that merges into a larger lower body portion with an open internal cavity; and (b) a core pin having a length in the mold cavity, the core pin having a segment with a reduced diameter that extends to an end thereof. The end has an external thread configuration. The reduced diameter segment has a plurality of longitudinally extending spaced apart flat surfaces.

The core pin flat surfaces can terminate prior to the thread configuration and/or extend longitudinally above and below the thread configuration.

The mold assembly can also include a cavity pin having a length that is less than the length of the core pin, aligned with the core pin in the mold cavity.

The cavity pin can have an end portion with a reduced diameter that extends to an end thereof. The end can have a thread configuration. The reduced diameter segment can have a plurality

of longitudinally extending spaced apart flat surfaces that terminate prior to the thread configuration.

The core pin and the cavity pin can be configured to reside in the mold cavity with aligned flat surfaces across the respective ends to define an injection molded needle bore inner surface with longitudinally extending flat surfaces.

The core pin flat surfaces can longitudinally extend a distance between about 0.10 mm -0.11 mm.

The plurality of flat surfaces can define an outer surface with a nominal diameter that is less than a nominal diameter of adjacent outer surface segments by between 5-10%.

Still other embodiments are directed to methods of fabricating an adaptor cap. The methods include: (a) providing an injection mold cavity; (b) placing a core pin in the mold cavity, wherein the core pin has an end portion with a plurality of longitudinally extending spaced apart flat surfaces and a thread configuration; (c) introducing a moldable polymer material into the injection mold cavity having the core pin; (d) injection molding a monolithic adapter cap with a needle bore having threads and longitudinally extending flat surfaces; and (e) using a straight pull to remove the core pin thereby exposing the injection molded adapter cap with the needle bore without requiring spinning to form the threads.

The method can also include placing a cavity pin in the mold cavity aligned with the core pin. The cavity pin can optionally have a plurality of longitudinally extending spaced apart flat surfaces and a thread configuration.

The injection molding can be carried out to form a needle bore having longitudinally extending flat surfaces that extend above and below the threads.

The collection container body can have a wall thickness of between about 1-5 mm (on average). The container body can be a transparent polycarbonate body or a transparent cyclic olefin copolymer body.

It is noted that aspects of the invention described with respect to one embodiment, may be incorporated in a different embodiment although not specifically described relative thereto. That is, all embodiments and/or features of any embodiment can be combined in any way and/or combination. Applicant reserves the right to change any originally filed claim or file any new claim accordingly, including the right to be able to amend any originally filed claim to depend from and/or incorporate any feature of any other claim although not originally claimed in that manner. These and other objects and/or aspects of the present invention are explained in detail in the specification set forth below.

Other systems and/or methods according to embodiments of the invention will be or become apparent to one with skill in the art upon review of the following drawings and detailed description. It is intended that all such additional systems, methods, and/or devices be included within this description, be within the scope of the present invention, and be protected by the accompanying claims.

#### Brief Description of the Drawings

Other features of the present invention will be more readily understood from the following detailed description of exemplary embodiments thereof when read in conjunction with the accompanying drawings.

**Figure 1** is a front perspective view of an exemplary adapter cap according to embodiments of the present invention.

**Figure 2** is a section view of the adapter cap shown in **Figure 1** taken along lines 2-2 of **Figure 5**.

**Figure 3** is an enlarged section view of the tip or neck of the adapter cap shown in **Figure 1** according to embodiments of the present invention.

**Figure 4** is an enlarged top perspective view of the adapter cap shown in **Figure 1**.

**Figure 5** is a top enlarged view of the adapter cap shown in **Figure 1**.

**Figure 6** is an enlarged section view of Detail D of **Figure 2** according to embodiments of the present invention.

**Figure 7** is an enlarged view of a top medial portion of the adapter cap shown in **Figure 5** according to embodiments of the present invention.

**Figure 8** is a partial section view of an injection mold assembly according to embodiments of the present invention.

**Figure 9** is a side view of two cooperating pins that can be used in the mold assembly shown in **Figure 8** according to embodiments of the present invention.

**Figure 10** is a side view of another embodiment of a core pin that can be used in the injection mold assembly according to embodiments of the present invention.

**Figure 11** is a schematic illustration of a series of actions that can be carried out using the adapter cap according to embodiments of the present invention.

**Figures 12A and 12B** are tables of different measured dimensions of external and internal threads and pitches of various adaptor cap insert needles. The "New Draw" measurements show examples of dimensional variation that can be successfully accommodated by adapter caps having internal flat surfaces and threads according to embodiments of the present invention.

#### Detailed Description of Embodiments of the Invention

The present invention now is described more fully hereinafter with reference to the accompanying drawings, in which embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

Like numbers refer to like elements throughout. In the figures, the thickness of certain lines, layers, components, elements or features may be exaggerated for clarity. Broken lines



illustrate optional features or operations unless specified otherwise. One or more features shown and discussed with respect to one embodiment may be included in another embodiment even if not explicitly described or shown with another embodiment.

The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items. As used herein, phrases such as "between X and Y" and "between about X and Y" should be interpreted to include X and Y. As used herein, phrases such as "between about X and Y" mean "between about X and about Y." As used herein, phrases such as "from about X to Y" mean "from about X to about Y."

Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the specification and relevant art and should not be interpreted in an idealized or overly formal sense unless expressly so defined herein. Well-known functions or constructions may not be described in detail for brevity and/or clarity.

It will be understood that when an element is referred to as being "on", "attached" to, "connected" to, "coupled" with, "contacting", etc., another element, it can be directly on, attached to, connected to, coupled with or contacting the other element or intervening elements may also be present. In contrast, when an element is referred to as being, for example, "directly on", "directly attached" to, "directly connected" to, "directly coupled" with or "directly contacting" another element, there are no intervening elements present. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if the device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

It will be understood that, although the terms first, second, etc. may be used herein to describe various elements, components, regions, layers and/or sections, these elements, components, regions, layers and/or sections should not be limited by these terms. These terms are only used to distinguish one element, component, region, layer or section from another region, layer or section. Thus, a first element, component, region, layer or section discussed below could be termed a second element, component, region, layer or section without departing from the teachings of the present invention. The sequence of operations (or steps) is not limited to the order presented in the claims or figures unless specifically indicated otherwise.

The term "about" means that the recited number or value can vary by +/- 20%.

The term "thread" and derivatives thereof refers to a helical structural thread feature that attaches to a threaded needle component.

The term "sample" refers to a target material undergoing testing or analysis for content. The sample can be a food sample, an environmental sample (water, air, soil, etc.) or a biosample. The testing can be for quality control of food produced in a commercial manufacturing facility, for the EPA (Environmental Protection Agency of the U.S. Government), for

environmental toxins or hazardous materials that are man-made, intentional or not, or medical (clinical diagnostic) purposes.

The term "biosample" refers to human or animal tissue, blood, blood plasma or serum, blood fractions, joint fluid, urine, semen, saliva, feces, cerebrospinal fluid, gastric contents, vaginal secretions, tissue homogenates, bone marrow aspirates, bone homogenates, sputum or lavages, aspirates, swabs and swab rinsates, blood products (e.g., platelets, serum, plasma, white blood cell fractions, etc.), donor organ or tissue samples, and the like. In one embodiment, the biological sample tested is a blood sample, urine, cerebral spinal fluid, lavages, mucus or other solid or liquid samples for analysis which may have microbes, microorganisms, toxins and/or cellular material or other constituents of interest. Embodiments of the invention may be suitable for veterinarian use, medical human use or research for human and/or with laboratory animals.

In general, the adapters and cooperating containers can be used for any known test sample (e.g., a biological sample or specimen). For example, the test sample can be a clinical or non-clinical sample suspected of containing one or more microbial agents. Other samples that may be tested include, but not limited to, foodstuffs, beverages, pharmaceuticals, cosmetics, water (e.g., drinking water, non-potable water, and waste water), seawater ballasts, air, soil, sewage, plant material (e.g., seeds, leaves, stems, roots, flowers, and fruit) and biowarfare samples.

The term "sterile" and derivatives thereof mean that the noted device or material meets or exceeds defined (e.g., food or medical) guidelines of sterility so as to be substantially (if not totally) free of contaminants for at least a defined shelf life so as to be suitable for intended uses, e.g., clinical, health, or consumer product testing for the presence of toxins, microbes, microorganisms or other target constituents in a sample undergoing analysis. The sample can undergo analysis while held in the container. The sample may be transferred after transport and/or culturing in the container for analysis.

The term "aseptic" is used interchangeably with the word "sterile." In some embodiments, the aseptic processing or fabrication complies with GMP (Good Manufacturing Practice) industry guidelines such as those associated with Guidance for Industry--Sterile Drug

Products Produced by Aseptic Processing — Current Good Manufacturing Practice, U.S. Department of Health and Human Services Food and Drug Administration, September 2004.

The term "automatic" means that the operation can be carried out using automated electromechanical equipment, rather than with manual labor.

Embodiments of the invention provide an economic adapter cap **10** that can accommodate needles from a plurality of different manufacturers, which can have different tolerances and dimensions, in a manner that maintains sufficient engagement of the needle in the needle bore when punctured through the septum of a collection container during use.

Turning now to the figures, **Figures 1-7** illustrate an adapter cap **10** with a tip **10t** defining a needle bore **10b** with a plurality of longitudinally extending flat surfaces **12** on an inner surface **10i** of a wall of the needle bore. As shown in **Figures 1 and 2**, for example, the cap **10** has an elongate body. The cap **10** can have a series of decreasing diameter outer wall segments from a bottom to the top thereof. The cap **10** can have various form factors and shapes and is not limited to the body shape shown. The cap **10** can have a smaller upper neck portion that provides the needle bore. The neck portion merges into a larger lower portion that is sized and configured to receive an upper portion of a collection container **110** (**Figure 11**).

As shown in **Figure 2**, the cap **10** can have a wall **11** with a substantially constant wall thickness. The cap can be a monolithic, injection molded cap with a single piece construction.

The plurality of flat surfaces **12** are circumferentially spaced apart and can include between 2-10 longitudinally extending flat surfaces **12**, typically between 3-6, such as 3, 4, 5 and 6 flat surfaces **12**. The flat surfaces **12** can be arranged so that at least one resides on each side of a centerline (c/L) of the needle bore **10b** and cap **10**.

The cap **10** can also include two or more internal opposing threads **15**. The threads **15** can extend inwardly to reside on opposing sides of an axially extending centerline (c/L) of the needle bore **10b**. One thread **15<sub>2</sub>** can be closely spaced above the other **15<sub>1</sub>** (**Figure 6**). The threads **15** can be sized and configured to engage luer threads of a collection needle set used to carry out the collection even accounting for dimensional variations manufacturer to

manufacturer and/or lot-to-lot. The innermost ends of the threads **15** can define a nominal diameter therebetween of about 3.60 inches. The inner wall **10i** can have a circumferentially extending gap space **15g** between the first and second threads **15<sub>1</sub>**, **15<sub>2</sub>** as shown in **Figure 7**. The pitch of the thread **15<sub>1</sub>** can be about 2.8 mm.

As shown in **Figures 3** and **6**, for example, the flat surfaces **12** can extend above and below the threads **15**. The flat surfaces **12** typically extend continuously above the threads **15** up to the end of the tip **10t** of the cap **10**. The flat surfaces **12** can have the same length and width and can be symmetrically circumferentially distributed. In other embodiments, the flat surfaces **12** can be asymmetrically positioned and/or have different widths and lengths.

In some embodiments, two flat surfaces **12** can be closer together than another one or more flat surfaces **12**. In some embodiments, two or more flat surfaces **12** can reside on one side of the needle bore **10b** wall and none on the diametrically opposing other side or two can reside on one side and one, two and three on the diametrically opposing side of the needle bore **10b**.

As shown in **Figure 7**, for example, the flat surfaces **12** project out a small distance "**D<sub>1</sub>**" from adjacent segments **13** of the inner surface **10i** of the wall **11** of the cap **10**. The small distance can be such as between about 0.10-0.20 mm, average, typically between about 0.10 and 0.12 mm, average, to define segments with increased wall thicknesses (e.g., a wall thickness of about 1.0 mm in a non-flat inner wall segment transitions to a wall thickness of about 1.10 mm at the flat surface). The flat surfaces **12** can have different thicknesses or the same thicknesses. Diametrically opposed flat surfaces **12** can be spaced apart a distance **D<sub>2</sub>**, which may be between about 3 mm to about 5 mm, typically about 4.4 mm, average.

As also shown in **Figure 7**, in some particular embodiments, the flat surfaces **12** are four flat surfaces, spaced apart at 90 degrees from each other (the broken line arrows are drawn with respect from the centerline of the needle bore **10b** to a center of each of the flat surfaces **12**).

**Figure 8** illustrates an example of an injection mold assembly **200** that can be used to form adapter caps **10**. The injection mold assembly **200** includes at least one injection mold cavity **205** that is configured to provide the desired outerwall shape of the adapter cap **10**. The mold cavity **205** can also cooperate with at least one pin **50**, **60** that extends through a center region of the respective mold cavity to form the flat surfaces **12** on the internal needle bore of the

cap **10**. In the embodiment shown in **Figure 8**, there are two longitudinally aligned pins, a core pin **60** and a cavity pin **50**, but a single pin may be used or more than two pins.

In the embodiment shown in **Figure 8**, mold assembly **200** includes a plurality of adjacent mold cavities **205** for concurrently injection molding a plurality of adaptor caps **10**, e.g., a block of eight, two rows of four mold cavities.

**Figure 9** illustrates an exemplary configuration of cavity and core pins **50**, **60**, each with a reduced diameter end portion **51**, **61** having a tip with a thread configuration **115**. One or both pins **50**, **60** can include a plurality of circumferentially spaced apart longitudinally extending flat surfaces **122** on the reduced diameter end portion **51**, **61** with a reduced nominal diameter relative to adjacent wall segments. The reduced nominal diameter can be between about 0.1 mm to about 0.2 mm less than a neighboring non-flat segment. The plurality of flat surfaces **122** can be between 2-10 and can have similar or corresponding widths, lengths and configurations of the flat surfaces **12** of the adapter cap **10** described above.

**Figure 10** illustrates another embodiment of a core pin **60'** having a reduced diameter end portion **61** with longitudinally extending external flat surfaces **122** that extend above and below at least one thread segment **115**.

The core pin **60**, **60'** can extend into the mold cavity **205** (**Figure 8**) to form the needle bore features, e.g., thread(s) **115** and flat surfaces **12** without requiring the cavity pin **50**.

The molding can be carried out to pull the pin **60**, **60'** straight out of the mold cavity and/or cap without requiring a spinning core for forming the needle bore threads thus reducing tooling costs and complexity.

**Figure 11** illustrates a sequence of operations that can be used to collect a blood sample in a collection/culture container **110** using an adapter cap **10** according to embodiments of the present invention. The adapter cap **10** can be provided with the needle **150** and tube **151** pre-attached to the cap **10** or a user can attach the needle **150** at the draw site (labeled in step 3). As is known, a needle is inserted into a vein (venipuncture) and the adapter cap with needle **150** held therein is pressed onto a container **110** whereby blood is drawn into the container

**110.** An insert **300** can be used to draw blood into another container or to cooperate with a vacuum collection tube (step 7).

In some embodiments, the sealed collection/culture containers **110** are typically substantially impermeable and typically have oxygen transmission rates ("OTR") (cubic centimeter/day/atm air) that are between 0.0001 to about 0.01 or 0.04 after manufacturing and throughout at least a one year shelf life, typically a 1-2 year shelf life. The test conditions for OTR can be at 1 atm, a relative humidity ("RH %") that is 40% and a room temperature that is 20 degrees C. The term "day" means 24 hours. The OTR can be determined using MOCON Oxytran 2/61 Oxygen Permeability Instrument via ASTM F-1307 or other suitable instruments and protocols. An accelerated age test can be carried out at 80 degrees C for seven (7) days. The age test is typically carried out after the container has been filled with sensor and growth media, sealed and autoclaved.

**Figure 11** illustrates an exemplary sample culture container **110**. The container **110** can have a body shape in the form of a standard culture bottle (e.g., a blood culture bottle). However, the description of a culture bottle (e.g., a blood culture bottle) is offered by way of example and not limitation. As shown, the containers **110** are elongated containers with an internal volume and an outer wall having an outermost width dimension (W) being less than a height dimension (H). In some embodiments, the height (H) is greater than twice the width (W), e.g.,  $H > 2W$ . In some embodiments, the containers have tubular bodies with maximum outer diameters between about 1-2 inches and heights of between about 2-5 inches. In some particular embodiments, the containers **110** have an outer diameter of about 1.36 inches (34.6 mm) and a height that is about 4.68 inches (119 mm).

The container **110** may include a bar code label (not shown) for automated reading of patient data and/or test parameters of the content of the container **110**. In some embodiments, the top portion of the container **110** can include a narrow portion or neck **112**. The container **110** may also include an elastomeric stopper optionally having a self-(re)sealing pierceable material and/or septum.

The container **110** can have a headspace that can accommodate a target (non-air) gas or gas mixture. The gas in the headspace can be introduced into the container **110** during manufacture. The gases introduced into the container could be oxygen, nitrogen, carbon

dioxide, helium, or combination of these gases. The gas could be introduced into the container at a vacuum. The vacuum can be between 3-20 inch Hg, such as about 4.5 inch, about 8 inch, or about 17 inch Hg.

In some embodiments, the container **110** may also have an internal sensor **120** (e.g., a Liquid Emulsion Silicone "LES" sensor) formed or placed in the bottom portion of the container **110** for purposes of visual/optic detection of the internal content (e.g., such as via a colorimetric or fluorescent sensor), to detect the presence of microbial or other growth in the container **110**. The container **110** can include a body with an optically/visually transmissive material.

A variety of sensor technologies are available in the art and may suitable. In some embodiments, the detection unit takes colorimetric measurements as described in the U.S. Pat. Nos. 4,945,060; 5,094,955; 5,162,229; 5,164,796; 5,217,876; 5,795,773; and 5,856,175, which are incorporated by reference as if recited in full herein. A positive container can be identified depending upon these colorimetric measurements, as explained in these patents. Alternatively, detection could also be accomplished using intrinsic fluorescence of the microorganism, and/or detection of changes in the optical scattering of the media (as disclosed, for example, in co-pending U.S. Patent Application Ser. No. 12/460,607, filed July 22, 2009 and entitled, "Method and System for Detection and/or Characterization of a Biological Particle in a Sample"), which is also incorporated by reference as if recited in full herein. In yet another embodiment, detection can be accomplished by detecting or sensing the generation of volatile organic compounds in the media or headspace of the container.

Exemplary analytical instruments for analyzing the bottles for presence of organisms include U.S. Pat. Nos. 4,945,060; 5,094,955; 6,709,857 and 5,770,394, U.S. Patent Publication 2011/0124028 and PCT Publication WO 94/26874. The contents of these documents are hereby incorporated by reference as if recited in full herein. As described in more detail in U.S. Patent Publication 2011/0124028 incorporated by reference hereinabove, an automated detection system may contain one or more work-flow stations for obtaining one or more measurements, readings, scans and/or images of a specimen container, thereby providing information, such as container type, container lot number, container expiration date, patient information, sample type, test type, fill level, weight measurement, and the like.



The container **10** may further comprise a growth or culture medium or promoting and/or enhancing microbial or microorganism growth. The use of a growth or culture media (or medium) for the cultivation of microorganisms is well known. A suitable growth or culture medium provides the proper nutritional and environmental conditions for growth of microorganisms and should contain all the nutrients required by the microorganism which is to be cultivated in the specimen container **110**. The growth media can comprise culture growth media for enhancing or promoting microorganism growth. The media can include a growth media for an aerobic organism or an anaerobic organism.

The adapter cap **10** and container **110** can include a body **10b**, **110b** that is molded. The body **10b** and **110b** can be a molded polymeric body (e.g., a thermoplastic material body) made from a single layer of polymeric (plastic) monolithic material. The adapter cap **10** can be formed of polypropylene of between about 1-2 mm.

One of the exemplary uses of the containers **110** is in culturing a test sample to detect microbial growth in test sample (e.g., a blood sample).

The present invention is explained in greater detail in the following non-limiting Examples.

## EXAMPLES

### Example 1

**Figures 12A and 12B** are tables of different dimensions of external and internal threads and pitches of two different versions of a Becton Dickinson(BD) cap insert needle (the needles refer to the BD Vacutainer Safety Lok Blood Collection Kit Reference No. 367283, 23G X 3/4" X 12"). The "New Draw" headers refer to draws undertaken with the noted "new" draw needle and the new adaptor cap with the flat surfaces and the threads in the needle bore. The "Old Draw" headers refer to draws undertaken with an older version of the BD draw needle with larger dimensions from the newer needle configuration. The adaptor cap with the addition of the flat surfaces in the needle bore was found to be able to successfully engage the new smaller insert needle.

Table 1 below is a list of needle sets that were tested with the adapter cap with flat surfaces and threads to verify the different manufacturer needle sets were able to successfully engage the new adapter cap.

**TABLE 1**

BacT/Alert Plastic Bottle Adaptor Cap w/needle set listed below
Greiner Bio-One Vacuette Safety BloodCollection Set with Holder, REF 450184
Greiner Bio-One Vacuette Safety Blood Collection Set, REF 450095
Myco VAKU-8+ Safety Blood Collection System/Infusion Set, REF SVMSP-23L
Sarstedt Safety-Multifly-Set, REF 85.1638.200
BD Vacutainer Safety-Lok Blood Collection Set, REF 367283
BD Vacutainer Multiple-Sample Luer Adapter, REF 367290
Kawasumi K-Shield Winged Needle BloodCollection Set, REF DBM1-23G
Terumo Surshield Safety Winged Blood Collection Set, REF MN-SV521B3
BD Vacutainer Safety-Lok Blood Collection Set, REF 367281

The foregoing is illustrative of embodiments of the present invention and is not to be construed as limiting thereof. Although a few exemplary embodiments of this invention have been described, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel

teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the claims. The invention is defined by the following claims, with equivalents of the claims to be included therein.

## THAT WHICH IS CLAIMED:

1. An adapter cap for a sample collection container, comprising:  
a monolithic elongate body having an upper neck portion with an open needle bore, wherein the needle bore has a downwardly extending wall with an inner surface that comprises (i) a plurality of circumferentially spaced apart longitudinally extending flat surfaces and (ii) first and second circumferentially spaced apart threads that extend radially inward from the inner surface so that respective innermost edges reside on opposing sides of an axially extending centerline of the elongate body.
2. The adapter cap of Claim 1, wherein the upper neck portion merges into a larger lower body portion with an open internal cavity, and wherein the upper neck portion is concentrically aligned with the open internal cavity.
3. The adapter cap of Claim 1 or Claim 2, wherein the flat surfaces extend a distance above and below the threads.
4. The adapter cap of Claim 3, wherein the threads have a respective injection molded thread configuration and the thread on one side of the needle bore resides above the thread on an opposing side of the needle bore.
5. The adapter cap of any of Claims 1-4, wherein the plurality of flat surfaces is between 2-6 flat surfaces.
6. The adapter cap of any of Claims 1-5, wherein the elongate body comprises a molded polymeric material with a substantially constant wall thickness of between about 0.5 mm to about 2 mm.
7. The adapter cap of any of Claims 1- 6, wherein the wall thickness is about 1 mm, and wherein the polymeric material is polypropylene.
8. The adapter cap of any of Claims 1-7, wherein the flat surfaces define wall segments with increased wall thickness of between .01 mm and .03 mm, average, relative to adjacent segments of the inner wall.

9. The adapter cap of any of Claims 1-8, wherein the plurality of longitudinally extending flat surfaces are four flat surfaces that are symmetrically circumferentially spaced apart.

10. The adapter cap of any of Claims 1-9, wherein the plurality of longitudinally extending flat surfaces have a common substantially constant width that is between about 5%-30% of a major diameter of the needle bore.

11. The adapter cap of any of Claims 1-10, wherein the needle bore has a major diameter of about 4.60 mm, and wherein the plurality of longitudinally extending flat surfaces have a width that is between about 0.25 mm to about 1 mm.

12. The adapter cap of any of Claims 1-11, wherein at least some of the flat surfaces have a length of between about 2- 2.8 mm.

13. The adapter cap of any of Claims 1-12, wherein the needle bore has a major diameter of about 4.60 mm, and wherein opposing pairs of longitudinally extending flat surfaces have a thickness sufficient to define a nominal diameter therebetween of about 4.40 mm.

14. The adapter cap of any of Claims 1-13, further comprising a culture collection container with an upper portion thereof residing in the internal cavity of the elongate body under the needle bore.

15. An injection mold assembly comprising:  
an injection mold cavity defining a shape of an adapter cap having an elongate body with an upper neck portion that merges into a larger lower body portion with an open internal cavity; and

a core pin having a length in the mold cavity, the core pin having a segment with a reduced diameter that extends to an end thereof, wherein the end has an external thread configuration, and wherein the reduced diameter segment has a plurality of longitudinally extending spaced apart flat surfaces.

16. The injection mold assembly of Claim 15, wherein the flat surfaces terminate prior to the thread configuration.

17. The injection mold assembly of Claim 15 or Claim 16, further comprising a cavity pin having a length that is less than the length of the core pin, aligned with the core pin in the mold cavity.

18. The injection mold assembly of Claim 17, wherein the cavity pin has an end portion with a reduced diameter that extends to an end thereof, wherein the end has a thread configuration, and wherein the reduced diameter segment has a plurality of longitudinally extending spaced apart flat surfaces that terminate prior to the thread configuration.

19. The injection mold assembly of Claim 17 or 18, wherein the core pin and the cavity pin are configured to reside in the mold cavity with aligned flat surfaces across the respective ends to define an injection molded needle bore inner surface with longitudinally extending flat surfaces.

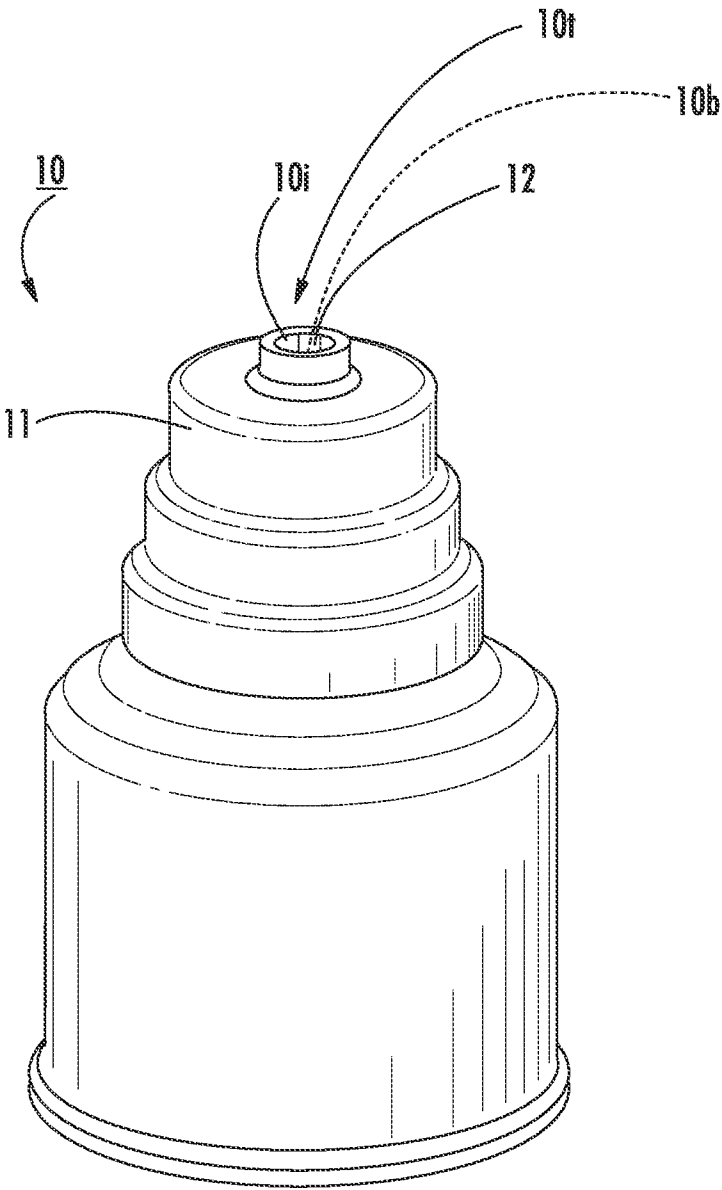
20. The injection mold assembly of any of Claims 15-19, wherein the core pin flat surfaces extend a distance between about 0.10 mm -0.11 mm.

21. The injection mold assembly of any of Claims 15-20, wherein the core pin flat surfaces define an outer surface with a nominal diameter that is less than a nominal diameter of adjacent outer surface segments by between about 5% to about 10%.

22. A method of fabricating an adaptor cap, comprising:  
providing an injection mold cavity;  
placing a core pin in the mold cavity, wherein the core pin has an end portion with a plurality of longitudinally extending spaced apart flat surfaces and a thread configuration;  
introducing a moldable polymer material into the injection mold cavity having the core pin;  
injection molding a monolithic adapter cap with a needle bore having threads and longitudinally extending flat surfaces; and  
using a straight pull to remove the core pin thereby exposing the injection molded adapter cap with the needle bore without requiring spinning to form the threads.

23. The method of Claim 22, further comprising placing a cavity pin in the mold cavity aligned with the core pin, wherein the cavity pin has a plurality of longitudinally extending spaced apart flat surfaces and a thread configuration.

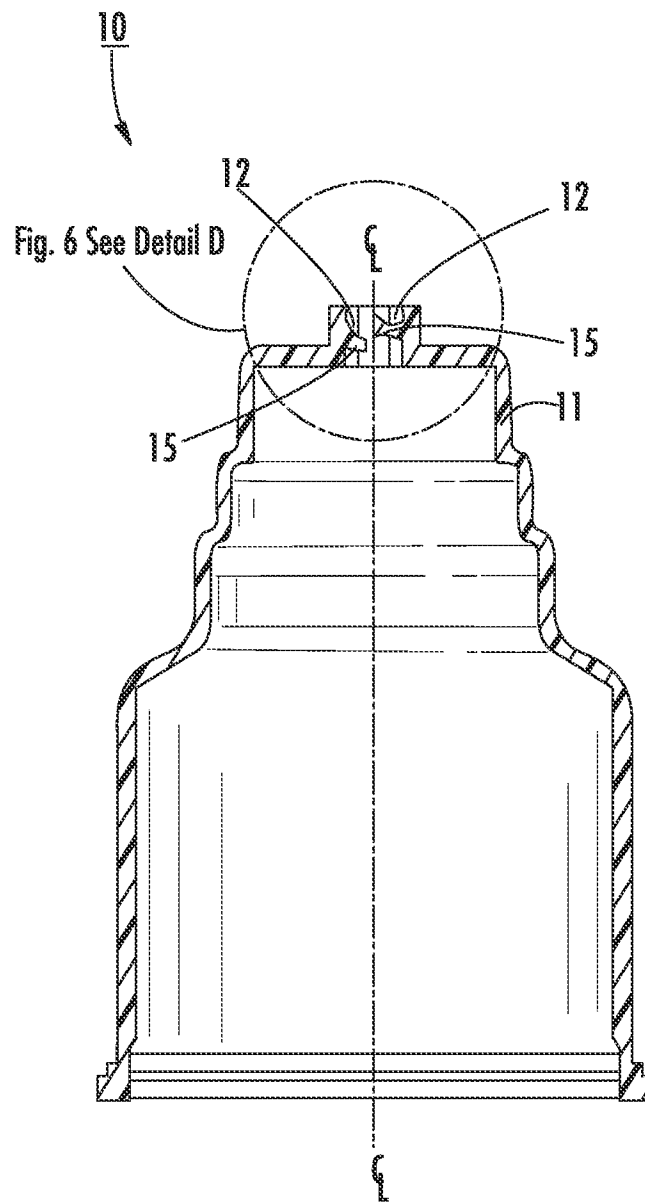
24. The method of Claim 22 or 23, wherein the injection molding is carried out to form a needle bore having longitudinally extending flat surfaces that extend above and below the threads.



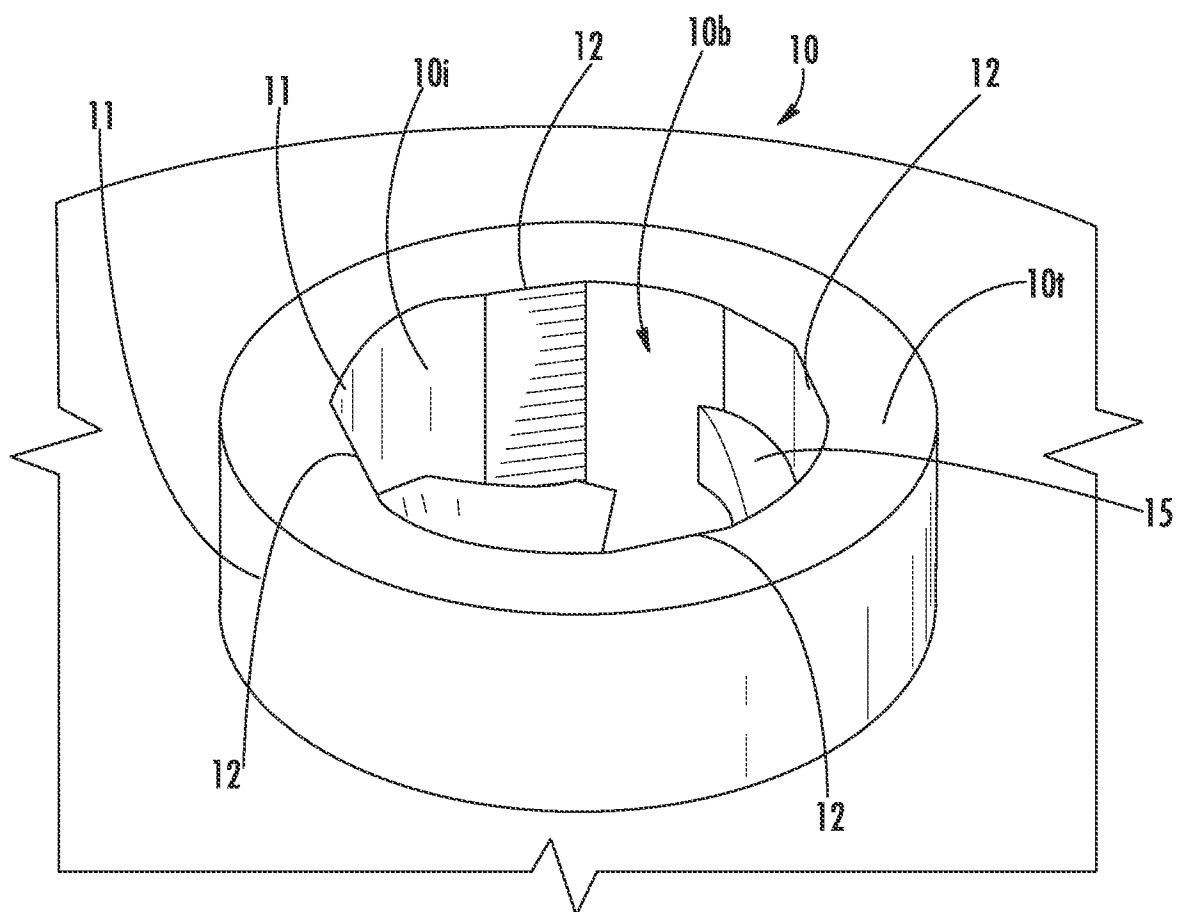
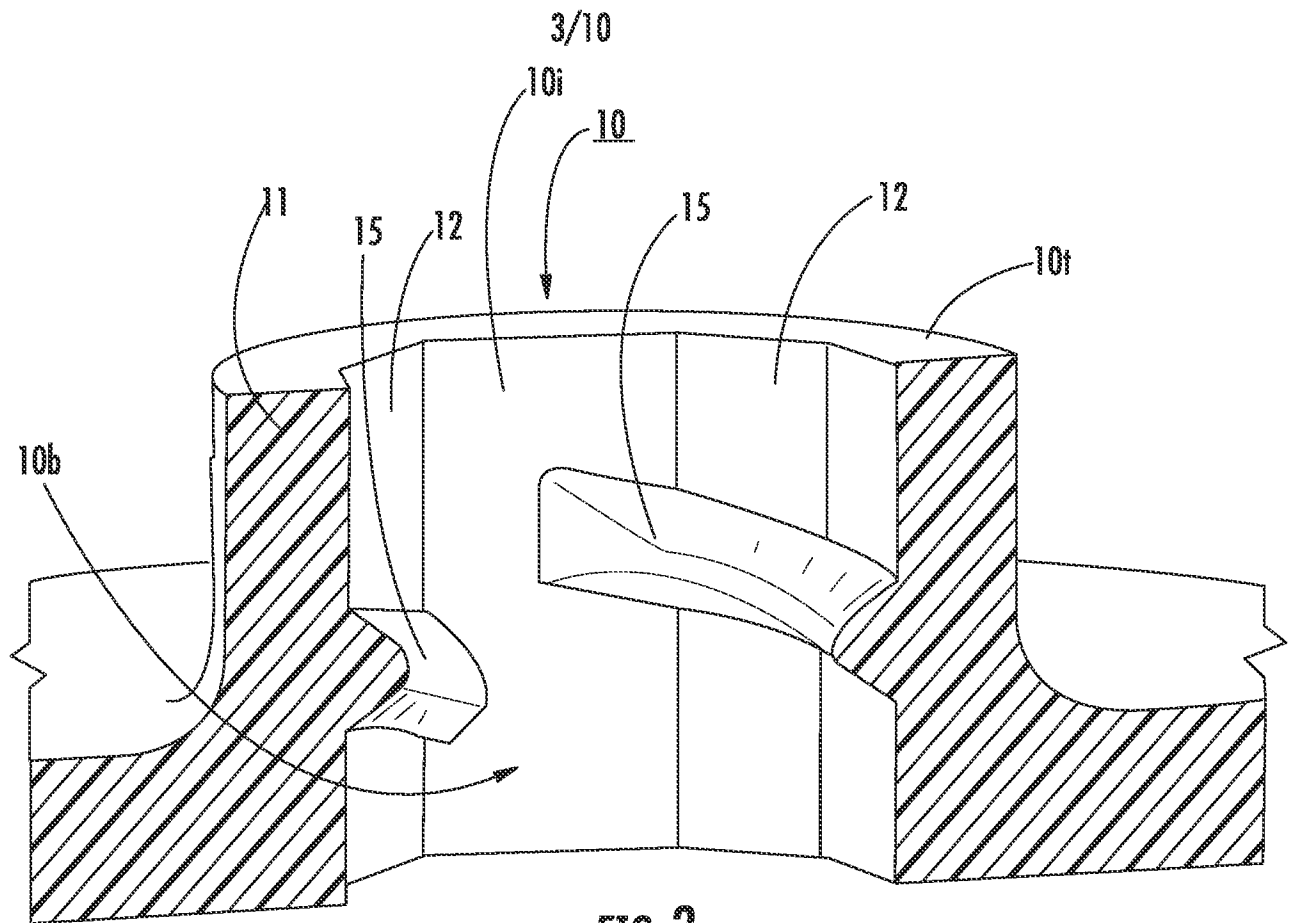
**FIG. 1**



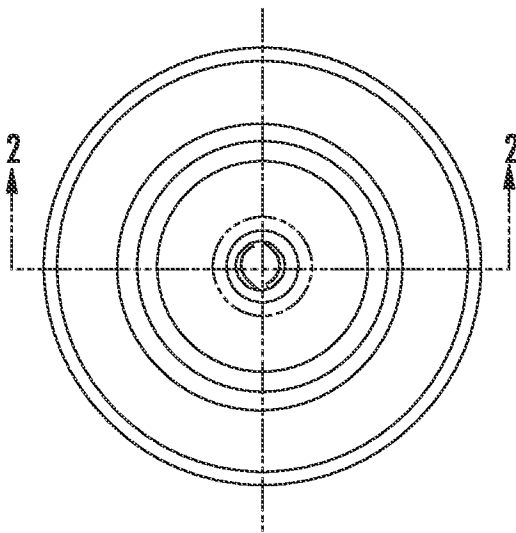
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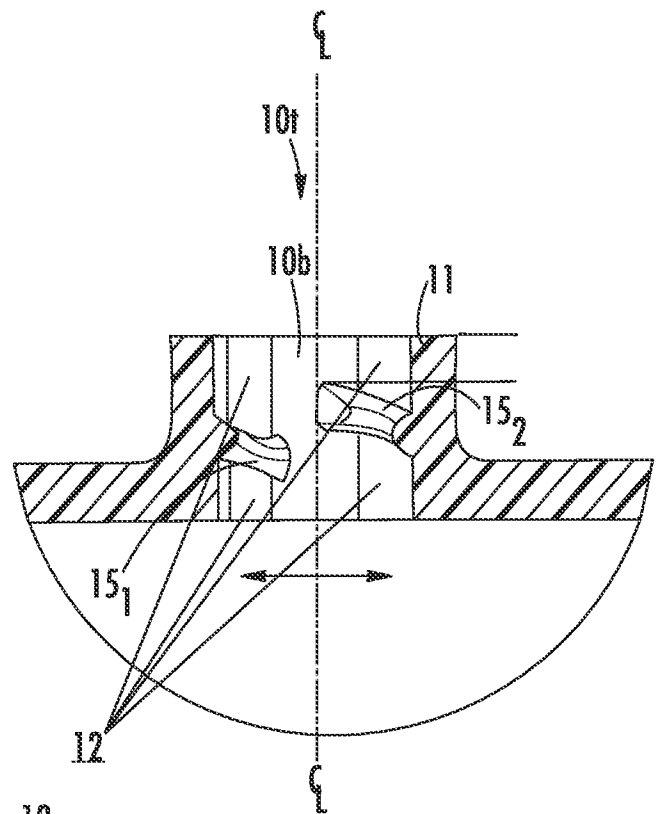
**FIG. 2**



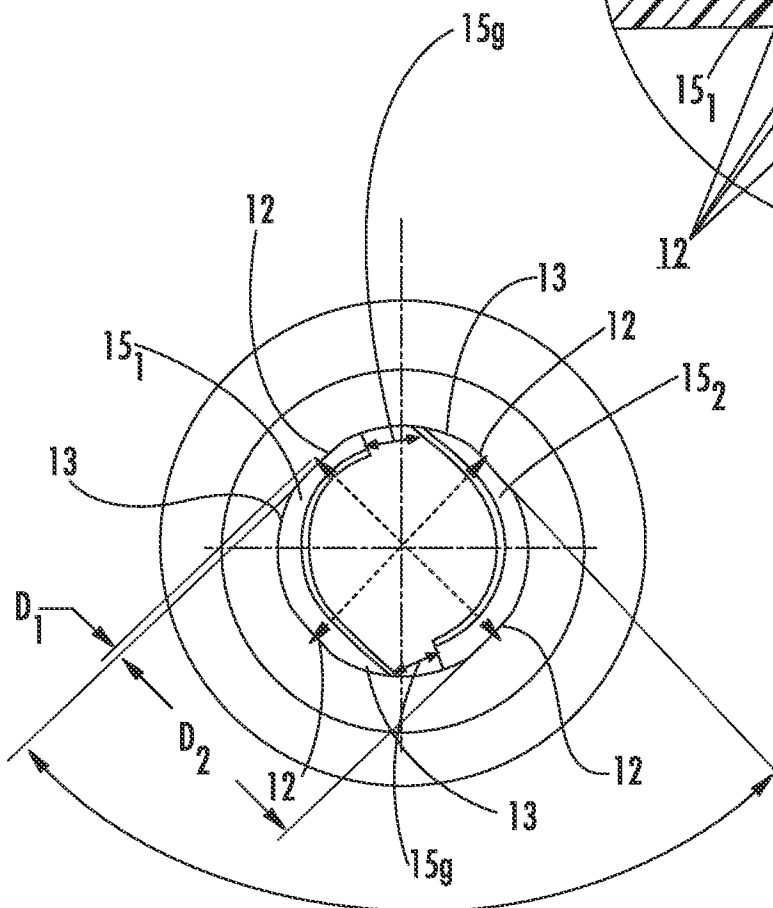
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**FIG. 5**



**FIG. 6**



**FIG. 7**

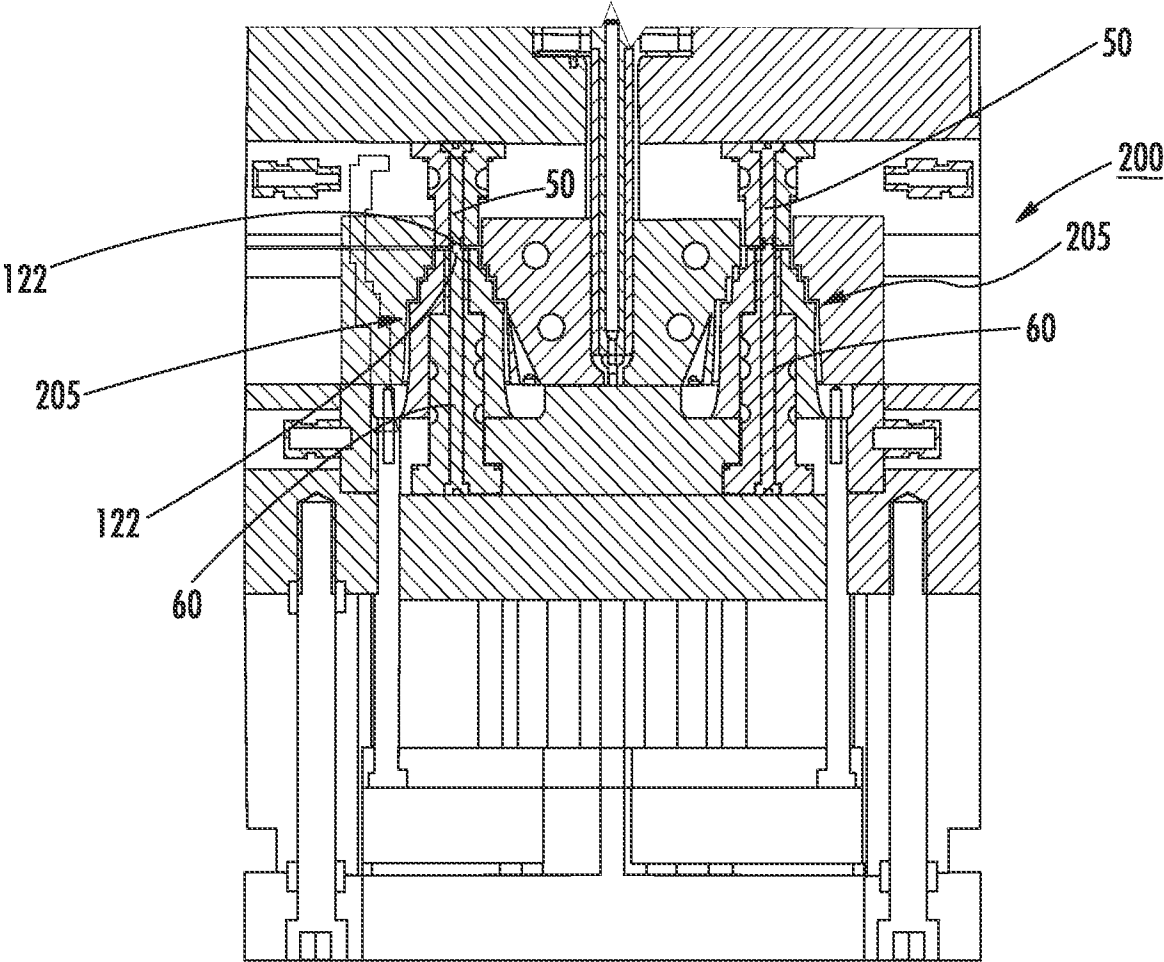
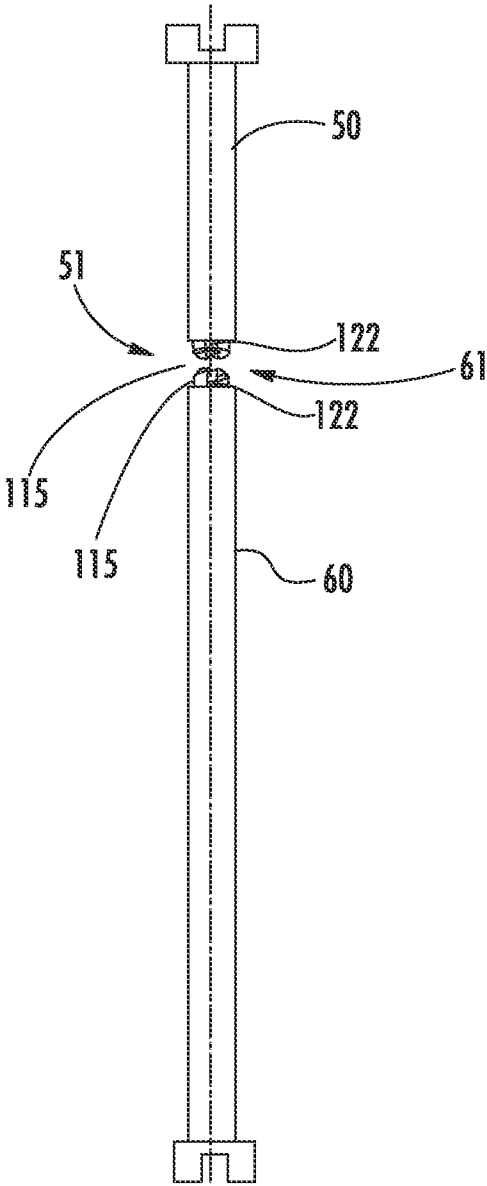


FIG. 8



**FIG. 9**

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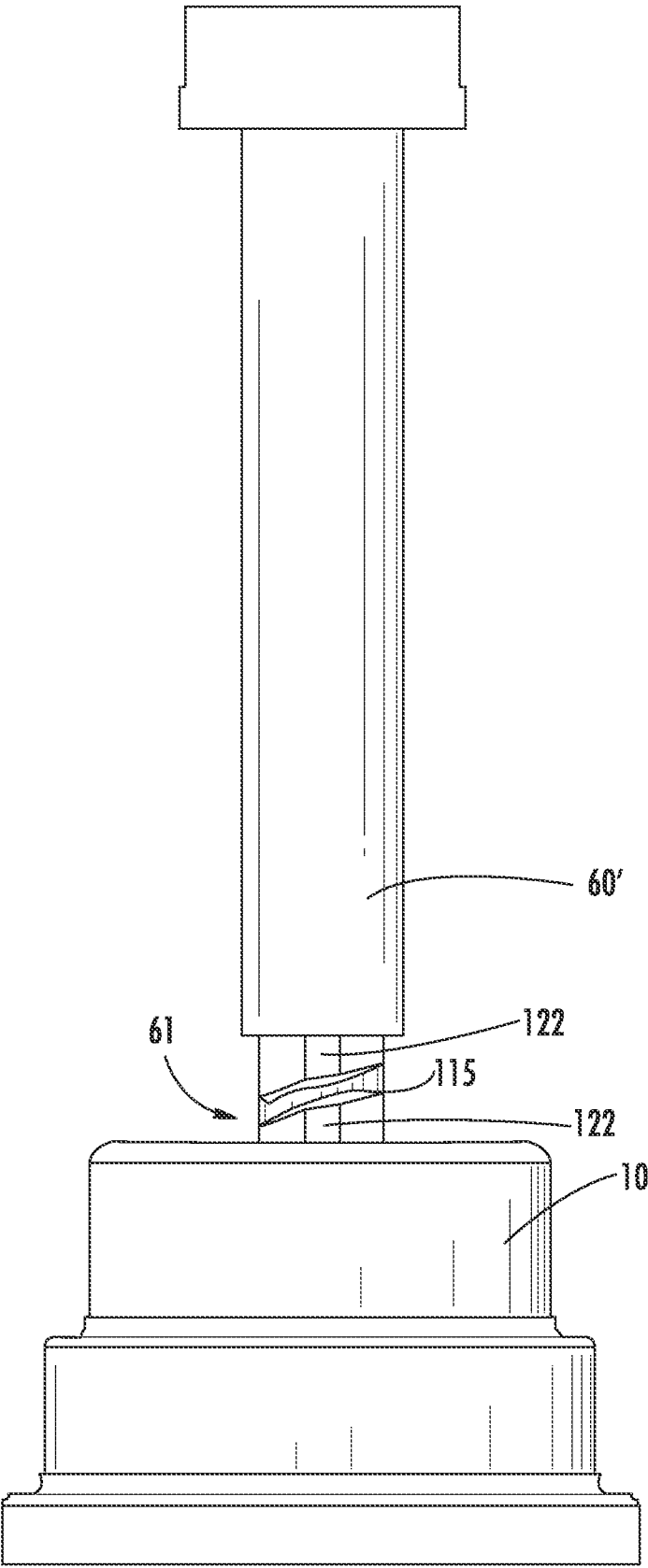


FIG. 10

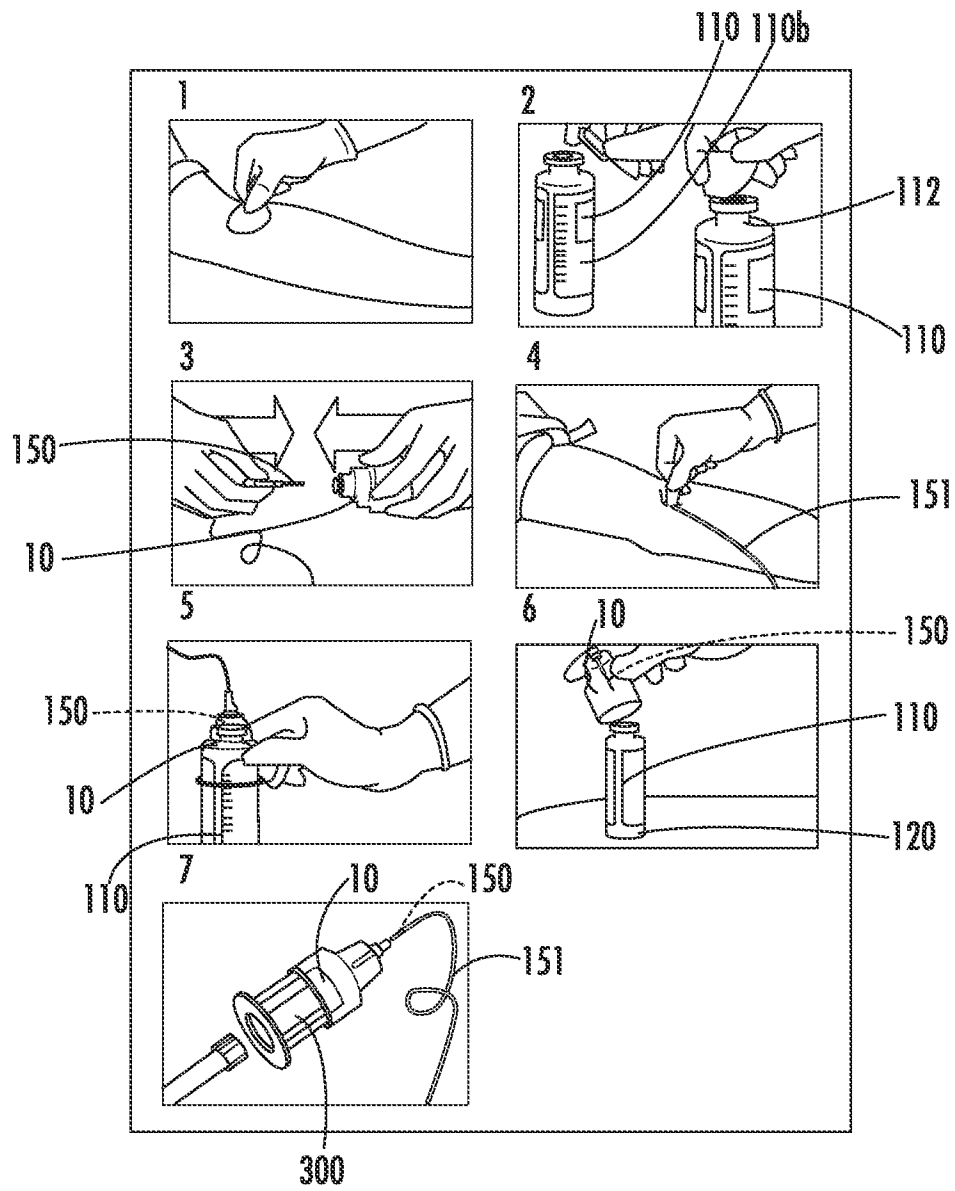


FIG. 11

ADAPTER CAP INSERT NEEDLE (OLD AND NEW) THREAD COMPARISONS

OLD DRAW NEEDLE #1			OLD DRAW NEEDLE #2			NEW DRAW NEEDLE		
EXTERNAL THREADS READINGS			EXTERNAL THREADS READINGS			EXTERNAL THREAD READINGS		
INCHES	mm		INCHES	mm	AVERAGE	INCHES	mm	AVERAGE
0.1831	4.651		0.1835	4.661	4.663	0.1755	4.458	4.425
0.1839	4.671		0.1843	4.681		0.1735	4.407	
0.1850	4.699		0.1818	4.618		0.1736	4.409	
INTERNAL THREADS READINGS			INTERNAL THREADS READINGS			INTERNAL THREADS READINGS		
INCHES	mm		INCHES	mm	AVERAGE	INCHES	mm	AVERAGE
0.1344	3.414		0.1350	3.429	3.392	0.1288	3.272	3.250
0.1330	3.378		0.1322	3.358		0.1276	3.241	
0.1328	3.373		0.1338	3.399		0.1274	3.236	
PITCH			PITCH			PITCH		
INCHES	mm		INCHES	mm		INCHES	mm	
0.0618	1.570		0.0622	1.580		0.0549	1.394	
0.0617	1.567		0.0615	1.562		0.0554	1.407	

LOT# UNKNOWN	LOT# UNKNOWN	LOT# 1H0891
EXPIRATION DATE UNKNOWN	EXPIRATION DATE UNKNOWN	EXPIRATION DATE 2014-08

FIG. 12A



## 2ND MEASUREMENTS

OLD DRAW NEEDLE #1				OLD DRAW NEEDLE #2				NEW DRAW NEEDLE #1				NEW DRAW NEEDLE #2			
EXTERNAL THREADS READINGS				EXTERNAL THREADS READINGS				EXTERNAL THREADS READINGS				EXTERNAL THREADS READINGS			
INCHES	mm			INCHES	mm	AVERAGE		INCHES	mm			INCHES	mm	AVERAGE	
0.1845	4.686			0.1860	4.724	4.696		0.1776	4.511			0.18	4.514	4.511	
0.1852	4.704			0.1852	4.704			0.1781	4.524			0.18	4.491		
0.1837	4.666			0.1847	4.691			0.1783	4.529			####	4.496		
INTERNAL THREADS READINGS				INTERNAL THREADS READINGS				INTERNAL THREADS READINGS				INTERNAL THREADS READINGS			
INCHES	mm			INCHES	mm	AVERAGE		INCHES	mm			INCHES	mm	AVERAGE	
0.1353	3.437			0.1341	3.406	3.424		0.1316	3.343			####	3.381	3.353	
0.1341	3.406			0.1341	3.406			0.1323	3.360			####	3.317		
0.1366	3.470			0.1346	3.419			0.1328	3.373			####	3.345		
PITCH				PITCH				PITCH				PITCH			
INCHES	mm			INCHES	mm			INCHES	mm			INCHES	mm		
0.0610	1.549			0.0623	1.582			0.0538	1.367			####	1.422		
0.0609	1.547			0.0629	1.598			0.0542	1.377			####	1.415		
LOT# UNKNOWN EXPIRATION DATE UNKNOWN				LOT# UNKNOWN EXPIRATION DATE UNKNOWN				LOT# 1H0891 EXPIRATION DATE 2014-08				LOT# 1H0891 EXPIRATION DATE 2014-08			

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FIG. 12B

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2014/034766

A. CLASSIFICATION OF SUBJECT MATTER  
 INV. A61J1/20 A61B5/145 A61B5/15  
 ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61J A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 7 261 698 B2 (SAMPSON ERIC [US] ET AL) 28 August 2007 (2007-08-28) cited in the application column 5, line 49 - line 56 column 6, line 15 - line 27 figures 1-11 -----	1-24
A	US 3 610 297 A (RAAF HELMUT W ET AL) 5 October 1971 (1971-10-05) column 2, line 20 - line 25; figure 7 -----	1-24
A	US 4 784 657 A (SHIMP LAWRENCE A [US] ET AL) 15 November 1988 (1988-11-15) column 2, line 38 - line 38; figure 1 -----	1-24
A	US 6 358 236 B1 (DEFOGGI JOHN MARK [US] ET AL) 19 March 2002 (2002-03-19) column 4, line 27 - line 29; figure 1 -----	1-24



Further documents are listed in the continuation of Box C.



See patent family annex.

\* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

31 July 2014

Date of mailing of the international search report

11/08/2014

Name and mailing address of the ISA/

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Authorized officer

Sommer, Jean

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2014/034766

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			WO 0007539 A1 17-02-2000
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