Title: NEEDLE PROTECTION DEVICE WITH GAUGE SPECIFIC COLOR CODING AND METHOD FOR MANUFACTURING THEREOF

Abstract: To enable a user to readily determine the gauge of the needle of a needle assembly (2) that has a base (4) and a needle protective housing (6) pivotally attached thereto, the needle assembly (2) is injection molded from a color coded molding material which color was preassigned to correspond to the gauge of the needle (12). As a result, both the base (4) and the protective housing (6) of the needle assembly (2) have the same specific color, and reflect or provide an indication of the given gauge of the needle (12). The needle sheath (26) that covers the needle (12) prior to use may be made of a plastics material that may be clear, or have the same or a different color than that of the needle assembly. The gauge of the needle (12) of a fixed needle syringe (48) could also be ascertained by its color coded needle protective housing. Color coded markings that correspond to the gauge of the needle (12) may also be printed onto the syringe barrel of the fixed needle syringe (48).
Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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NEEDLE PROTECTION DEVICE WITH
GAUGE SPECIFIC COLOR CODING AND
METHOD FOR MANUFACTURING THEREOF

[001] This application is a continuation-in-part of application No. 10/751,982 filed on January 7, 2004.

Field of the Invention

[002] The present invention relates to needle assemblies and specifically needle assemblies that have a protective housing connected to a base, with a color scheme for the needle assembly that relates to the gauge of the needle of the needle assembly.

Background of the Invention

[003] In a medical environment, to draw blood from or inject fluid to a patient, in the case of a syringe being used, conventionally a needle is mated to the syringe by way of a hub to which the needle is attached or integrated. Depending on the procedure, the gauge of the needle tends to vary. It is well established that the gauge of the needle may be determined by the color of the hub. Yet the needle hub, or at least a portion thereof, is often hidden by the needle sheath that covers the needle when the needle is mated to the luer of the syringe.

[004] With current technological and safety advances, a needle protective housing may be attached to the needle hub, with the needle hub, or base, and the needle protective housing being joined and either acting as an adapter as taught by U.S. patent 4,982,842, or as a single unit with the needle integrated to the base and the needle protective housing connected to the base as disclosed in U.S. patent 5,993,426 and U.S. patent RE37,110. There are also instances where a needle protective housing may be connected to a syringe, as disclosed by U.S. patents 5,232,455, 6,582,397, and application Nos. 10/657,171 and 29/189,589, both filed on September 9, 2003. The respective disclosures of the ‘842, ‘426, ‘110, ‘455, and ‘397 patents and the ‘171 and ‘589 applications are incorporated by reference herein.
[005] In the devices disclosed by the aforesaid patents as well as in the prior art, there has not been any established scheme that allows a user to readily determine the gauge of the needle she is using. And given that the use of a needle with a particular gauge may well be of import in an emergency situation, there is a need to provide a scheme whereby a user can readily ascertain the gauge of the needle she would like to use without having to directly look at the needle, which oftentimes is difficult since the needle is usually covered by a sheath prior to use.

**Summary of the Invention**

[006] To enable a user to readily determine the needle gauge of a needle assembly that has a housing attached to a base or a needle hub to which the needle is attached, during the manufacturing process, color pigmentation that is specific to the gauge of the needle is added to the mold material, which most likely would be a plastics material such as polypropylene. With the mold material having the color that corresponds to the gauge of the needle in accordance with the ISO (International Standard Organization) standard, a user could readily pick out from among a plurality of needle assemblies the particular gauge of needle she wants to use. For example, a needle assembly with both the base and the housing being black would signify to the user that it is a 22 gauge (22G) needle, while a blue needle assembly would indicate to the user a 23G needle is in that blue needle assembly.

[007] To provide a redundant or back up check for the user to determine the gauge of the needle for the needle assembly, the needle sheath that covers the needle prior to use may be made of clear plastic, so that the user can ascertain the gauge the needle visually, and confirm it with the color scheme of the needle assembly, or vis versa. Alternatively, the needle sheath may be manufactured to have the same color as the needle protection housing.

[008] The needle device or needle assembly of the instant invention has a needle of a particular gauge and a base having attached thereto a needle protection housing that is pivotable relative to the base. Both the base and the needle protection housing are formed from a molding material that has added thereto a specific color pigmentation
preassigned, pursuant to ISO standard, to a particular gauge of needle. With the needle of the particular gauge attached or integrated to the base or needle hub of the needle assembly, and given that both the base and the needle protection housing are of the same specific color, a user can readily ascertain the gauge of the needle by merely looking at the color of the needle assembly, i.e. either the base or the housing, or both. The needle protective housing is used to cover the needle once it is used, by being pivoted to a position in alignment substantially along the longitudinal axis of the needle assembly.

[0009] The instant invention also relates to the method of manufacturing the needle device that includes the steps of selecting a needle having a particular gauge, adding a specific color to a molding material, forming a needle assembly having a base and a needle protection housing pivotable relative to the base from the molding material so that the base and the housing have the same specific color, attaching the needle to the base, with the needle being coverable by the housing when the housing is pivoted to a position in alignment along the longitudinal axis of the base, and corresponding the specific color to the particular gauge of the needle so the user can ascertain the gauge of the needle by looking at the color of the needle assembly.

[0010] The instant invention also relates to the manufacture of a plurality of needle devices in which the respective colors are assigned to needles of different gauges. Moreover, different colored molding materials are provided and a color molding material with the color assigned to a given needle gauge is used for forming a plurality of needle assemblies each having a base and a needle protection housing pivotable relative to the base being the same specific color. Needles of the gauge that correspond to the specific color are attached to the base of the needle assemblies. When the job batch involving all of the needles of the same gauge have been attached to needle assemblies that have the color specific to the needle gauge, another job batch may begin whereby needles of a different gauge are attached to needle assemblies whose bases and needle protective housings have the same color that has been assigned to the needles with the different gauge. With the needle assemblies each being color coded to correspond to a particular needle gauge, a user can readily determine the
gauge of the needle that she wants to use by merely looking at the color of the needle assembly.

[0011] The instant invention further is related to syringes to which a needle protective housing is connected, either directly or by way of a collar to the neck of the syringe. For the inventive syringes, a needle is fixedly fitted to the syringe, and it is usually covered by a needle sheath prior to its use. As is the case with non-syringe needle protection devices, different syringes have different needle sizes. For the syringe invention, the needle protective housing of the syringe is manufactured to have a color that corresponds to the gauge of the needle that is fitted to the syringe. Alternative embodiments of the syringe invention entail the manufacturer of the needle sheath to have the same color as the needle housing, so that prior to use, a syringe with a fixed needle would have both its housing and the needle sheath that covers the needle prior to use being color coded to represent the gauge of the needle of the syringe. Yet a further variation of the syringe of the instant invention entails the manufacturer of the syringe to also have the same color as the protective housing so that everything on the syringe may have the same color that corresponds to the gauge of the needle. It may well be that the needle sheath is made of clear plastic material so that the user can view the needle prior to its use.

**Brief Description of the Figures**

[0012] The present invention will become apparent and the invention itself will be best understood by reference to the following description of the present invention taken in conjunction with the accompanying drawings wherein:

[0013] Fig. 1 is a perspective view of a needle assembly of the instant invention in which the base has attached thereto a needle protective housing;

[0014] Fig. 2 is a needle assembly of the instant invention that has attached to its base or needle hub a needle of a gauge that corresponds to the color scheme of the needle assembly;
[0015] Fig. 3 is a flow chart illustrating an exemplar method of manufacturing the instant invention;

[0016] Fig. 4 is a side view of a fixed needle syringe modified to receive the collar of a needle protective housing;

[0017] Fig. 5 is a section view of the needle housing shown in Fig. 4;

[0018] Fig. 6 is a front view of the needle housing of Fig. 4;

[0019] Fig. 7 is a perspective view of the syringe of Fig. 4 with the needle sheath removed showing an exposed needle;

[0020] Fig. 8 is a perspective view of the syringe of Fig. 7 with the exposed needle covered by the needle housing;

[0021] Fig. 9 is cross-sectional view of syringe having attached thereto a needle protective housing and markings with a color that corresponds to the gauge of the needle; and

[0022] Fig. 10 illustrates a fixed needle syringe that has a marking in the form of a ring, or lines, at the barrel of the syringe and a decal that may be added to, or replaces the ring, at the syringe barrel.

**Detailed Description of the Invention**

[0023] The present invention safety needle device comprises a needle assembly 2 that has a base 4 and a protective housing 6. Base 4 is connected to protective housing 6 by a living hinge 8. Base 4 has a needle hub 10 to which a needle 12 is attached at an opening 14. Once attached, needle 12 is sealed. Needle 12 could also be integrated to needle hub 10. Base 4 further has a luer end 16 which mates with a luer end of a syringe, as is well known in the art. Protective needle housing 6, for the embodiment shown, comprises a housing that has a longitudinal slot 18 through which needle 12
passes, when housing 6 is pivoted in the direction as shown by directional arrow 20 toward the longitudinal axis 22 of base 4 for enveloping or covering needle 12. A needle retention mechanism such as a hook 24 is provided in needle protective housing 6 for grasping needle 12, once housing 6 is pivoted to be in substantial alignment along the longitudinal axis 12. Once grasped by hook 24, needle 12 and housing 6 are retained relative to each other so that needle 12 is prevented from being further exposed. Note that instead of a hook, other needle retention mechanism such as the SIDE SNAP locking mechanism as disclosed in the afore-mentioned incorporated by reference RE 37,110 may also be used.

[0024] As best shown in Fig. 1, needle assembly 2 is a single unit that may well be injection molded from a medical plastics material such as for example polypropylene. In some instances, instead of being a single unitary unit, housing 6 and base 4 may be molded as separate units with means provided at housing 6, such as for example a ring or a collar, that allows housing 6 to be attached to base 4. In any event, housing 6 and base 4 for the embodiment shown in the drawings are parts of the same needle assembly and are injection molded from a given conventional medical plastics molding material such as for example polypropylene.

[0025] Because there are a number of different medical procedures, needle 12 may be manufactured with different dimensions, or different gauges, for example from 18 gauge to 30 gauge in conventional practice. Prior to the instant invention, a needle of a particular gauge is attached to a needle hub of a specific color. To use, the needle is mated to a luer end of a syringe. But the needle, whatever its gauge, is covered by a needle sheath such as component 26 shown in Fig. 2. Needle sheath 26 most likely is mated to needle hub 10 by frictional contact with the fins 10a that extend along the length of needle hub 10. Needle sheath 26 may well be made from an opaque plastics material so that once needle sheath 26 is fitted to needle hub 10 to cover needle 12, needle hub 10 is not readily viewable. Indeed, insofar as the major portion of needle hub 10 is covered by the base of needle sheath 26, there is but a small portion of needle hub 10 that may be viewed by the user for determining the color of the needle hub. Accordingly, the gauge of needle 12 is not readily ascertained.
[0026] The International Standard Organization (ISO) has assigned to the different gauged needles specific corresponding colors. Relying on the ISO standard, the inventors of the instant invention envision the color coding of the different gauged needles by making the complete needle assembly to which a needle is attached the specific color that is assigned to the particular gauge of the needle. In other words, assuming that a 22 gauge needle has been assigned the color “black”, that 22 gauge needle would be fitted or attached to a completely black needle assembly such as for example needle assembly 2 as shown in Fig. 1. The needle assembly may be injection molded from a molding material that has added thereto a black color pigmentation. Thus, the 22 gauge needle assembly is black at both its base 4 and its protective housing 6, as well as hinge 8. Similarly, for a 23 gauge needle, the needle assembly 2 to which the 23 gauge needle is attached would be blue, insofar as it is assumed that a 23 gauge needle has been assigned the color “blue”. For a 25 gauge needle, the needle assembly for that needle would be orange, pursuant to the “orange” color that has been assigned to a 25 gauge needle, etc.

[0027] With both the base 4 and the needle protective housing 6 being of the same specific color that corresponds to the gauge of the needle, a user can therefore readily determine from a glance of the needle assembly the gauge of its needle, even were the needle covered by a needle sheath 26 that is opaque. To provide a redundant means for a user to determine the gauge of the needle, needle sheath 26 may be made of a clear plastic material.

[0028] The method by which the gauge of a needle is color coded per the instant invention is discussed herein with the flow chart in Fig. 3. Assume that a plurality of needles of different gauges are to be manufactured. Further assume that there are a number of batches of needles to be manufactured, with the needles of each batch being of a particular gauge.

[0029] Starting at step 30, the process of the instant invention begins by determining the gauge, or gauges, of the needles to be manufactured. At step 32, different colors are assigned to the different gauged needles. At step 34, molding materials of different
colors are obtained. Assume that for the manufacturing process, a batch of needles each having the same particular gauge are to be manufactured. That being the case, at step 36, the gauge of the batch of needles that are to be manufactured is determined. Thereafter, the molding material that has the color that corresponds to the determined gauge of the needle is selected, per step 38. With the appropriately colored molding material now selected, the process proceeds with the injection molding of the needle assembly, for the embodiment comprising both the base and the housing as a single unit, from the chosen colored molding material, per step 48. This injection molding process may be performed by a number of conventional injection molding machines such as for example the injection molding machines manufactured by the Nissei Company of Japan. With the molded needle assemblies on hand, the needles of the same particular gauge each are attached to the base, or the needle hub of the base, of one of the color coded needle assemblies, as shown in Fig. 2, per step 42. At the end of the manufacturing process after step 42, a needle assembly that has a needle of a particular gauge with a base and a housing both having the same specific color that corresponds to the gauge of the needle, such as that shown in Fig. 2, is produced. Thereafter, a determination is made per step 44 to see whether all of the needles of the same particular gauge have been assembled to corresponding needle assemblies for that job batch. And if it is determined that the job batch is finished, the process proceeds to step 46 where it is further determined whether there are other needles of other particular gauges that need to be manufactured. If there are, then the process once again proceeds as outlined above starting at step 36. On the other hand, if there are no other color coded needle assemblies to be produced, then the manufacturing process is stopped.

[0030] It should be appreciated that even though the needle sheath as disclosed above is made of either an opaque material or a clear plastics material, it may well be that the needle sheath may also be made of a material that may have the same color as, or a different color than, that of the base and protective housing of the needle assembly. Furthermore, even though the needle assembly as shown in Figs. 1 and 2 is formed as a unitary unit, it may well be that the base and the protective needle housing may be formed as separate units from different molds and be connected later during the
manufacturing process. If the needle sheath were also molded from the same colored molding material as the base and the needle protection housing, the needle sheath that covers the needle prior to its use may therefore also be color specific to the particular gauge of the needle.

[0031] With reference to Figs. 4-6, a fixed needle syringe 48 is shown to include a syringe barrel body 50 that includes a distal portion 52. A needle hub 54 at the distal portion 52 of the syringe has fixedly extending therefrom a needle 56. A finger flange 58 is provided at the proximal portion of the syringe, with a plunger 60 movably mated to the syringe barrel 50, as is well known in the art.

[0032] At the distal portion 52 of the syringe 58 there is formed a groove 62. Prior to use, needle 56 is covered by a needle sheath 64 that is frictionally held to hub 54 of syringe 48.

[0033] A needle protection housing 66 that has a base or collar 68 connected thereto by a flexible hinge 70 is fitted about syringe 48 at groove 62. Collar 68, as best shown in Figs. 5 and 6, has a number of flanges 72 formed at its inner circumferential surface. A number of protrusions are also formed at the inner surface of collar 68. Two extensions or fingers 76 are formed at the opposite sides of the outer surface of collar 68. These fingers 76 coact with corresponding catches 78 formed at the base of housing 66, when housing 66 is pivoted in the direction as indicated by directional arrow 80, to align along the longitudinal axis 82 of collar 68 and syringe 48, as shown in Fig. 4.

[0034] When collar 68 is fitted to syringe 48, flanges 72 are matingly fitted to groove 62. The dimension of the inside diameter and more particularly the circumference formed by flanges 72 is such that it is slightly larger than the diameter of groove 62, so that collar 68 is rotatable about groove 24 after being press fitted thereto. Protrusions or bumps 74 are designed to be in contact with the syringe barrel 50 so as to provide additional friction between collar 68 and syringe 48, so that collar 68 is rotatable relative
to syringe barrel 48 only if a predetermined torque is applied against collar 68, or housing 66, for rotating collar 68 relative to syringe 48.

[0035] After needle sheath 64 is removed from syringe 48, to cover the now exposed needle 56, housing 66 is pivoted in the direction of arrow 80 so that it becomes substantially aligned along the longitudinal axis 82 for covering needle 56, when needle 56 passes through slot 84 of housing 66. A hook 86 in housing 66 grasps needle 56 at this time so to prevent needle 56 from being further exposed. At the same time, housing 66 is retained to collar 68 by the interaction between catches 78 and fingers 76.

[0036] To ensure that a user can readily ascertain the gauge of needle 56 of the fixed needle syringe, housing 66, as well as collar 68 are molded from a plastics material such as that discussed earlier so that the color of the housing 66 and collar 68 would have the same color as that given in the common ISO standard that corresponds to the gauge of needle 56, as noted earlier. For example, a 22 gauge needle would have a housing that is black, a 23 gauge needle would have a housing that is blue, and a 25 gauge needle would be orange, etc.

[0037] For the Fig. 4 embodiment, instead of being clear, needle sheath 64 may also be molded or formed from a plastics material that has a color that corresponds to the gauge of the needle. Such needle sheath therefore enables a user to readily ascertain the gauge of the needle, even before the user removes the needle sheath from the syringe. Alternatively, as was noted before, needle sheath may be made from a clear plastics material or a translucent material. Figs. 7 and 8 provide perspective views of the fixed needle syringe of the instant invention, with Fig. 7 showing the exposed needle 54 and Fig. 8 illustrating needle 54 being covered by housing 66.

[0038] Although the embodiment illustrated in Figs. 4-8 shows a fixed needle syringe that has attached thereto a housing via a rotatable collar, a fixed needle syringe could have a housing integrally or directly formed with the syringe, so that the housing is not rotatable relative to the syringe. For that embodiment, both the syringe barrel and the
housing would be manufactured from a plastics material that has added thereto the color pigmentation that corresponds to the gauge of the needle to be fixed to the syringe. In other words, aside from possibly plunger 60, the body of the syringe barrel, as well as the needle housing, would be color coded to correspond to the gauge of the needle to which the particular syringe is fitted. It should be appreciated however that plunger 60 may also be color coded to the needle gauge. For this embodiment, needle sheath 64 may be made of the same color coded molding material so that it too is color coded to correspond to the gauge of the needle of the syringe.

[0039] The manufacturing of a fixed needle syringe of the instant invention begins with a determination of the gauge of the needle that is to be fitted to the syringe, either individually or for the batch of the same needle gauge syringes that are to be manufactured. The specific color that corresponds to the gauge of the needle is then determined according to a given standard, such as the ISO Standard. Appropriate color pigmentation is next added to the material to be used for forming the mold. In the case of the syringe as shown in Figs. 4-8, the housing is formed with a base, or a collar, that is to be fitted to the syringe. In this case, the syringe barrel itself may be formed from a different plastics material, or be formed from the same color coded material so as to have the same color as the housing and the base. Once the housing is formed, it is fitted to the syringe barrel via the collar, so that it is rotatable relative to the syringe barrel. With the housing thus color coded, a user can readily ascertain the gauge of the needle, even when the needle sheath that covers the needle prior to use is made of a clear or translucent material. To further enhance the determination of the gauge of the needle of the syringe, the needle sheath that covers the syringe prior to use may also be manufactured to have the same color as the housing.

[0040] For the case where the needle housing is integrally formed with the syringe from a mold, both the housing and syringe would naturally have the same color that corresponds to the gauge of the needle. Of course, the needle sheath that covers the needle prior to use may likewise have the same color as the housing.
[0041] Fig. 9 is an illustration of an alternative embodiment of the instant invention in which markings 86 are provided on syringe barrel 50 in a color that corresponds to the gauge of the needle 56. For this embodiment, housing 66 may be directly attached to the syringe 48 by way of living hinge 70, or as was the case for the Fig. 4 embodiment, attached by way of a collar 68 shown in dotted line. In the case were housing 66 is an integral part of syringe 48, as for example by being manufactured from the same mold during the same operation, housing 66 may have the same color as syringe barrel 50, or may in fact be clear. Yet by using a color coded marking such as the scales 86 printed directly on syringe barrel 50, a user can readily ascertain the gauge of the needle 56 by the color of the markings. Markings 86 in fact provide multiple functions in that, in addition to informing the user at a glance the gauge of the needle, they, being in the form of scales that are printed onto the body of the syringe, also enable a user to ascertain the volume of fluid in the syringe.

[0042] For the case where housing 66 is coupled to syringe 48 by way of a collar 68, housing 66 as well as collar 68 are color coded to reflect the gauge of needle 56 that is fixed to syringe 48. Needle sheath 64 could either be clear, translucent, or color coded to correspond to the gauge of the needle 56. Thus, for the Fig. 9 embodiment, the syringe, prior to use, may have a conventional syringe barrel, but with markings and its needle protective housing being color coded to indicate the gauge of the needle that is covered by the needle sheath. The needle sheath may also be color coded. Alternatively, the syringe barrel as well as the needle protective housing may be non-color coded, while the markings are color coded to indicate the gauge of the needle. In this alternative embodiment, the needle sheath may or may not be color-coded. Markings 86 may be added to syringe barrel 50 by a conventional printing process.

[0043] Fig. 10 shows a fixed needle syringe that, instead of markings, has a color coded ring or band, or lines 88 printed on the syringe barrel 50. The band or lines may be in addition to the markings or scales that are printed onto syringe barrel 50, and may be located on the syringe barrel in such a way so as not to interfere with the scale markings that indicate the amount of fluid in syringe 48. The number of the gauge that corresponds to the thickness of needle 56 may be printed onto the band, as indicated
by XX. The color coded band 88 may be printed on barrel 50, using a process that is used to conventionally print the markings or scales onto syringe barrel 50.

[0044] In place of, or in addition to, a color coded band or ring(s), a decal 90 may be adhesively attached to, or printed on, syringe barrel 50 at a location that does not interfere with the graduating scale markings that are ordinarily printed onto a syringe barrel. Decal 90 is color coded to indicate the gauge of needle 56. In addition, the number of the gauge of the needle may be printed onto decal 90, as indicated by "XX". For the Fig. 10 fixed needle syringe, only a color coded decal or lines or band(s) may be used to indicate the gauge of the needle. Alternatively, housing 66 attached to syringe 48 may also be color coded. Likewise, sheath 64 may also be color coded to reflect the gauge of needle 56.
Claims

1. A method of manufacturing a needle device, comprising the steps of:
   a) selecting a needle having a particular gauge;
   b) adding a specific color to a molding material;
   c) forming a needle assembly having a base and a needle protection housing
      pivotable relative to said base from said molding material, said base and housing
      having the same specific color;
   d) attaching said needle to said base, said needle adapted to be covered by said
      housing when said housing to pivoted to a position in alignment along the longitudinal
      axis of said base; and
   e) corresponding said specific color to said particular gauge of said needle so that
      the gauge of said needle can be determined by looking at the color of said needle
      assembly.

2. Method of claim 1, further comprising the steps of:
   assigning respective colors to needles of different gauges; and
   corresponding each particular gauged needle with a specific color so that the
   gauge of a needle can be determined by looking at the color of said needle assembly.

3. Method of claim 1, wherein said molding material is plastic; and
   wherein said step c comprises the step of injection molding said base and said
   housing as a single piece needle assembly.

4. Method of claim 1, further comprising the step of:
   covering said needle with a needle sheath to prevent contamination of said needle
   before use.

5. Method of claim 4, further comprising the step of:
   forming said needle sheath to have a different color than said base and housing.

6. Method of claim 4, further comprising the step of:
forming said needle sheath from clear plastic so that the gauge of said needle is viewable without removing said needle sheath.

7. Method of claim 1, further comprising the step of:
   forming a needle retaining mechanism in said housing for preventing relative movement between said needle and said housing after said housing has been pivoted to said alignment position to cover said needle.

8. Method of claim 1, wherein said step c comprising the steps of:
   molding said base and said housing as separate parts from the same molding material; and
   providing said housing with means for attaching to said base;
   wherein said housing and said base have the same specific color.

9. A method of color coding a needle device, comprising the steps of:
   a) determining the particular gauge of a needle;
   b) assigning a specific color to needles having said particular gauge;
   c) adding pigmentation of said specific color to a molding material;
   d) forming from the specific colored molding material a needle assembly having a base and a needle protection housing pivotable relative to said base; and
   e) attaching said needle to said base, said needle adapted to be covered by said housing when said housing to pivoted to a position in alignment along the longitudinal axis of said base.

10. Method of claim 9, further comprising the steps of:
    assigning respective colors to needles of different gauges; and
    corresponding each particular gauged needle with a specific color so that the gauge of a needle can be determined by looking at the color of said needle assembly.

11. Method of claim 9, wherein said step d comprises the step of:
    molding said base and said housing as a single piece needle assembly.
12. Method of claim 9, further comprising the steps of:
   forming a needle sheath having a different color than said base and housing; and
   covering said needle with said needle sheath to prevent contamination of said
   needle before use.

13. Method of claim 9, wherein said step d comprising the step of:
   molding said base and said housing as separate parts from the same molding
   material, said housing molded with means for attaching to said base, said housing and
   said base being the same specific color.

14. A method of manufacturing needle devices, comprising the steps of:
   a) assigning respective colors to needles of different gauges;
   b) providing different colored molding materials;
   c) forming from a colored molding material with the color assigned to a given
      needle gauge a plurality of needle assemblies each having a base and a needle
      protection housing pivotable relative to the base, the base and the needle protective
      housing of each of said needle assemblies having the same specific color;
   d) attaching needles of said given needle gauge to the respective bases of said
      plurality of needle assemblies that have the specific color assigned to said given needle
      gauge, the needle of each of said plurality of needle assemblies adapted to be covered
      by the housing of said each needle assembly when said housing is pivoted to a position
      in alignment along the longitudinal axis of the base of said each needle assembly;
   e) selecting needles of an other needle gauge and an other colored molding
      material that has the color that corresponds to said other needle gauge;
   f) repeating steps c and e until all needles of different gauges are assembled to
      corresponding needle assemblies with the color of each needle assembly matching the
      gauge of the needle attached to said each needle assembly;
   wherein a user can readily determine the gauge of the needle for a needle
   assembly from among multiple needle assemblies with needles of different gauges by
   looking at the color of the base and/or housing of said needle assembly.
15. A needle device, comprising: a needle having a particular gauge, a needle assembly having a base and a needle protection housing pivotable relative to said base formed from a molding material, said molding material having added thereto a specific color pigmentation preassigned to correspond to said particular gauge, said base and said housing each having said specific color, said needle being attached to said base, said needle adapted to be covered by said housing when said housing is pivoted to a position in alignment along the longitudinal axis of said base, wherein the gauge of said needle can be ascertained by looking at the color of said needle assembly.

16. Needle device of claim 15, further comprising a needle sheath covering said needle to prevent contamination of said needle before use.

17. Needle device of claim 16, wherein said needle sheath has a different color than said base and housing.

18. Needle device of claim 16, wherein said needle sheath is formed from clear plastic so that a user can further ascertain the gauge of said needle without removing said needle sheath.

19. Needle device of claim 15, further comprising a needle retaining mechanism in said housing for preventing relative movement between said needle and said housing after said housing has been pivoted to said alignment position to cover said needle.

20. A method of manufacturing a syringe having a needle, comprising the steps of:
   a) determining the gauge of the needle of said syringe;
   b) selecting a specific color that corresponds to the gauge of the needle of said syringe according to a standard;
   c) adding color pigmentation of the selected specific color to a molding material;
   d) forming a base and a needle protection housing pivotable relative to said base from said molding material, said base and housing having the same specific color; and
e) attaching said base to said syringe, said housing adapted to cover said needle when said housing is pivoted to a position in alignment along the longitudinal axis of said syringe;

wherein the gauge of said needle is determinable by looking at the color of said base and/or housing.

21. Method of claim 20, wherein said base comprises a collar that is rotatably mounted about said syringe.

22. Method of claim 20, further comprising the step of:
molding said syringe from said molding material so that said syringe has the same color as said base and housing.

23. Method of claim 20, further comprising the step of:
covering said needle prior to its use with a needle sheath.

24. Method of claim 23, wherein said sheath is molded from said molding material so as to have the same color as said housing.

25. Method of claim 23, wherein said sheath is made from a clear or translucent material.

26. A method of manufacturing a syringe, comprising the steps of:
a) determining the gauge of the needle to be fitted to said syringe;
b) selecting a specific color that corresponds to the gauge of the needle of said syringe according to a standard;
c) adding color pigmentation of the selected specific color to a molding material;
and
d) forming said syringe and a needle protection housing attached to and pivotable from said syringe from said molding material, said syringe and said housing having the same specific color;
wherein the gauge of the needle of said syringe is determinable by looking at the color of said syringe and housing.

27. Method of claim 26, further comprising the step of:
   covering said needle prior to its use with a needle sheath.

28. Method of claim 27, wherein said sheath is molded from said molding material so as to have the same color as said housing.

29. Method of claim 27, wherein said sheath is made from a clear or translucent material.

30. A method of manufacturing a syringe with the gauge of a needle attached thereto readily ascertainable, comprising the steps of:
   a) determining the gauge of the needle to be fitted to said syringe;
   b) selecting a specific color that corresponds to the gauge of the needle of said syringe according to a standard;
   c) adding color pigmentation of the selected specific color to a molding material;
   d) forming a needle protection housing attachable to said syringe from said molding material, said housing having the specific color; and
   e) attaching said housing to said syringe;
   wherein the gauge of the needle of said syringe corresponds to the color of said housing.

31. Method of claim 30, wherein said housing comprises a collar pivotably connected to said housing, said collar rotatably mounted about said syringe.

32. Method of claim 30, further comprising the step of:
   molding said syringe from said molding material so that said syringe has the same color as said housing.

33. Method of claim 30, further comprising the step of:
covering said needle prior to its use with a needle sheath.

34. Method of claim 33, wherein said sheath is molded from said molding material so as to have the same color as said housing.

35. A syringe, comprising a needle protection housing pivotable relative to said syringe, a needle having a particular gauge fitted to said syringe, said needle being covered by a sheath prior to use, said needle adapted to be covered by said housing when said housing is pivoted to a position in alignment along the longitudinal axis of said needle, said housing formed from a plastics material having a specific color preassigned to correspond to said particular gauge of said needle according to a standard so that the gauge of the needle of said syringe is ascertainable prior to use by the color of said housing.

36. Syringe of claim 35, wherein said housing is connected to a base that is rotatably mounted about said syringe.

37. Syringe of claim 35, wherein said housing is integrally connected to said syringe.

38. Syringe of claim 36, wherein said syringe has the same color as said housing, the gauge of said needle being ascertainable by the color of said housing and/or said syringe.

39. Syringe of claim 35, wherein said sheath has the same color as said housing, the gauge of said needle being ascertainable by the color of said sheath and/or said housing.

40. A method of color coding a syringe with the gauge of the needle of the syringe, comprising the steps of:
   a) determining the gauge of the needle of the syringe;
   b) determining the color that corresponds to the gauge of the needle in accordance with a predetermined standard;
c) forming a marking having the determined color on at least a portion of the syringe;

d) attaching a housing pivotable relative to the syringe for covering the needle after use;

wherein the gauge of the needle is determinable by looking at the color of the marking on the syringe.

41. Method of claim 40, further comprising the steps of:

forming said housing from a molding material that has the same color as the determined gauge of the needle so that said marking and said housing have the same color that corresponds to the gauge of the needle.

42. Method of claim 40, wherein said marking comprises scales on said syringe to indicate the amount of fluid in said syringe.

43. Method of claim 40, wherein said step c comprises the step of:

providing a decal having the determined color on the syringe barrel.

44. Method of claim 40, wherein said step c comprises printing a band of a given width having the determined color about said syringe barrel.

45. Method of claim 40, further comprising the steps of:

covering said needle prior to use with a sheath; and

forming said sheath to have the determined color.

46. A syringe having a needle of a given gauge fixed thereto, comprising a marking of a color determined to correspond to the given gauge of the needle in accordance with a predetermined standard provided on at least a portion of the syringe, a housing pivotable relative to the syringe for covering the needle after use attached to said syringe, the gauge of the needle being determinable by looking at the color of the marking on the syringe.
47. Syringe of claim 46, wherein said housing has the same color as said marking.

48. Syringe of claim 46, further comprising a sheath for covering said needle prior to said needle being used, said sheath having the same color as said marking.

49. Syringe of claim 46, wherein said marking comprises volume amount indications of said syringe printed on the barrel of said syringe.

50. Syringe of claim 46, wherein said marking comprises a decal attached to said syringe that has the color determined to correspond to the gauge of said syringe.
Determine gauges of needles

Assign different colors to the different gauged needles

Obtain mold materials with different color

Determine the gauge of the needle to be manufactured

Select the plastics mold material that has the color that corresponds to the determined needle gauge

Injection molded base/housing needle assemblies from the chosen colored mold material

Attach needle of the given gauge to base of the corresponding colored needle assembly

Finish job batch of needles of the given gauge

Needles of another gauge to be manufactured?
INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/00178

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : B29C 45/00
US CL : 264/328.1
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)
U.S. : 264/328.1

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 6,192,568 (KAFRAWY et al.) 27 February 2001 (27.02.2001), column 3, lines 55-57; column 4, lines 60-64; column 5, lines 1-30; column 7, lines 36-63; figure 4, table 1.</td>
<td>1-3, 7-11, 13-15, 19-20, 22, 26, 30, 32, 40-41, 46-47</td>
</tr>
<tr>
<td>Y</td>
<td>US 6,096,065 (CROWLEY) 1 August 2000 (01.08.2000), column 2, lines 55-63; column 3, lines 16-32.</td>
<td>4-6, 12, 16-18, 21, 23-25, 27-29, 31, 33-35, 36-39, 42-45, 48-50</td>
</tr>
<tr>
<td>Y</td>
<td>US 4,034,755 (SCHULTZ) 12 July 1977 (12.07.1977), column 1, lines 51-61.</td>
<td>42, 49</td>
</tr>
<tr>
<td>Y</td>
<td>US 6,663,601 (HETZLER et al.) 16 December 2003 (16.12.2003), column 7, lines 36-43; figure 5, element 142.</td>
<td>43-44, 50</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:
  "A" document defining the general state of the art which is not considered to be of particular relevance
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Date of the actual completion of the international search
20 May 2005 (20.05.2005)

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Date of mailing of the international search report
10 JUN 2005

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Form PCT/ISA/210 (second sheet) (January 2004)