Description

Title of Invention: AN IMPROVED NEEDLE TIP GUARD

[1] The invention relates to a needle guard for use in a medical device, in particular for use in a catheter apparatus. The needle guard includes a base portionhaving a needle passage extending in an axial direction from a proximal side of the base portion through the base portion to a distal side of the base portion. The needle guard further includes first and second arms extending substantially in the axial direction from the distal side of the base portion and a distal wall which is transversely arranged at a distal region of the first arm.

[2] Such needle guards are generally known and are used to cover the tip of a needle of a medical device after use of the medical device. Typically, needle guards are devised to automatically cover the needle tip after withdrawal of the needle, for example, from a patient. The needle guard thereby serves to prevent accidental pricking of, for example, a medical practitioner by the needle tip after removal of the needle from the medical device.Thereby the needle can be safely disposed of after use, without the danger of transmitting possibly highly infectious and/or deadly diseases to the medical practitioner from the patient.

[3] Generally speaking, the term proximal refers to a region of the device or a location on the device which is closest to, for example, a clinician using the device. In contrast to this, the term distal refers to a region of the device which is farthest from the clinician, for example, the distal region of a needle will be the region of a needle containing the needle tip which is to be inserted e.g. into a patient's vein.

[4] It is an object of the invention to provide an improved needle guard.

[5] This object is satisfied by a needle guard in accordance with the independent claims.

[6] According to claim 1, the needle guard of the present invention includes a base portion made of a first material and having a needle passage which extends in an axial direction from a proximal side of the base portion through the base portion to a distal side of the base portion, such that a needle having a principal outer profile can be movably arranged in the needle passage. The needle guard further includes first and second arms extending substantially in the axial direction from the distal side of the base portion, with the first arm having a distal region and a proximal region. A distal wall is transversely arranged in the distal region of the first arm.

[7] The needle guard also includes a stopping element which is arranged in the needle guard. The stopping element is made of a second material different from the first material and has a through-bore with a profile which is adapted to the principal outer profile of the needle shaft. In the case of e.g. circular cross-sections, a diameter of the through-bore can be slightly larger than a principal outer diameter of the needle.

[8] In order to allow a trouble free movement of the needle relative to the needle guard when the needle is withdrawn from the catheter tube, the stopping element is preferably arranged such that its through-bore is in general alignment with the needle passage of the needle guard.

[9] The stopping element can be a circular disk, a ring, or a washer. However, it need not necessarily be circular and can have any other geometric shape such as a rectangular, square or triangular shape.

[10] Preferably, the second material is of greater hardness and/or stiffness than the first material. For example, the first material could be a plastic material and the second material could consist of a metal, a ceramic or a rubber material, or any other type of material which is stiff and not as easily distorted as the first material.

[11] Needle guards of the above kind are used, for example, in catheter apparatuses. The invention therefore also provides a catheter apparatus including a needle guard in accordance with the present invention, with the catheter apparatus further including a catheter tube, a catheter hub and a needle having a needle shaft, a needle tip and a needle hub, wherein the needle shaft has a distal section and a proximal section, with at least the proximal section having a principal outer profile.

[12] The needle also has an enlargement provided between the distal section and the proximal section of the needle shaft. The enlargement has an outer profile one dimension of which is larger than a maximum dimension of the profile of the through-bore of the stopping element. In a preferred embodiment, the enlargement is made by a crimping of the needle shaft. However, other ways of forming the enlargement are possible, such as applying additional material to the needle shaft, e.g. by soldering, welding or gluing etc.

[13] The inner profile of the needle can either be reduced in the region of the enlargement, for example, if the enlargement is formed by crimping, or it can be substantially constant throughout the length of the needle, for example, if the enlargement is formed by applying additional material to the needle shaft.

[14] Prior to the use of the catheter apparatus, the needle guard is arranged in the catheter hub near a proximal end of the needle shaft. In this situation, the needle extends completely through the needle guard, thereby deflecting the first arm of the needle guard outwards, i.e. at an angle to the axial direction, such that the distal wall of the first arm is supported on the needle shaft. Following the insertion of the catheter into a patient, the needle is withdrawn from the catheter tube and the needle shaft moves through the needle guard while the needle guard is retained in the catheter hub. Once the needle tip passes the transverse distal wall of the needle guard, i.e. such that the needle shaft no longer supports the distal wall, a restoring force ensures that the first arm of the needle guard is moved back into alignment with the axial direction of the

needle guard, so that the needle tip is blocked by the distal wall of the needle guard, i.e. the needle tip is prevented from axially projecting out of the needle guard.

[15] Once the needle tip is blocked by the distal wall, the enlargement of the needle shaft engages with the stopping element to prevent the needle guard from being removed from the needle shaft. The fact that the stopping element is made from a second material which is harder and less easily distorted than the first material of the base portion, has the effect that the needle guard is secured more effectively on the needle shaft and can be retained even if excessive external force is applied when pulling on the needle, as the enlargement is prevented from being pulled through the base portion of the needle guard due to the stopping element. Hence, it is less likely that the needle guard is removed from the needle tip accidentally and, as a result, the needle guard provides a better protection against accidental pricking and thus increased safety for the person handling the catheter apparatus.

[16] In a further embodiment of the needle guard, a tension element surrounds the first and second arms of the needle guard. In the deflected state of the first arm, the tension element is expanded against a restoring force of the tension element. Once the needle shaft no longer supports the distal wall, the tension element aids the repositioning of the first arm back into axial alignment with the axial direction. This repositioning is necessary so that the distal wall can block the needle tip from axially sliding out of the needle guard. In addition, the tension element helps to enclose a space between the first and second arms and thus helps to prevent the needle tip from projecting sideways out of the needle guard. In other words, the tension element adds to the protective effect of the needle guard.

[17] In a further embodiment of the needle guard, a recess is provided in the proximal region of the first arm of the needle guard. This recess increases the deflectability of the first arm in the region it is provided and thereby reduces the restoring force acting on the distal wall while this is being supported by the needle shaft. This allows the needle shaft to be moved more easily relative to the distal wall, as the frictional force acting on the needle shaft is reduced.

[18] In a further embodiment of the needle guard, a groove is provided in a side of the distal wall, with the groove extending substantially in the axial direction. The groove acts as a guide groove for the needle shaft and aids the axial movement of the needle shaft relative to the needle guard. Moreover, the needle shaft is prevented from sliding sideways off the distal wall. Such a sideways movement would significantly increase the force required to move the needle shaft relative to the needle guard, which would prevent a correct functioning of the needle guard.

[19] Further subject matter of the present invention satisfying the above mentioned object includes a needle guard according to claim 4 and a needle guard according to claim 7.

In particular, such needle guards do not include stopping elements. Thus, the needle guard of the present invention can also be adapted such that it includes a recess and/or a groove as discussed above, but without including the stopping element. In this case, the outer profile of the enlargement of the needle shaft must be greater than the profile of the through-bore in the base portion of the needle guard, in order to prevent the needle guard from sliding off the needle in a distal direction.

[20] Further advantageous embodiments of the invention and preferred apparatuses for carrying out the invention are set forth in the subordinate claims and are described in connection with the accompanying drawings.

[21] The present invention will now be explained in more detail in the following with reference to preferred embodiments and to the accompanying drawings in which are shown:

[22] Fig. 1 a catheter apparatus in accordance with the present invention;

[23] Fig. 2 a needle, needle hub and needle guard removed from the catheter apparatus of Fig. 1;

[24] Fig. 3A - 3D the needle guard of Fig. 2;

[25] Fig. 4A - 4C further illustrations of the needle guard of Fig. 2 without a tension element;

[26] Fig. 5A - 5B sectional illustrations of the needle guard of Fig. 4; and

[27] Fig. 6 a partially sectional and partially perspective illustration of the needle guard of Fig. 4.

[28] Fig. 1 shows a catheter apparatus 10 in accordance with the invention. The catheter apparatus 10 includes a catheter hub 12, a catheter tube 14, wings 16, a port 18 and a needle 20. The catheter hub 12 has a distal end 22 and a proximal end 24, the catheter tube 14 is arranged adjacent to the distal end 22 of the catheter hub 12.

[29] The needle 20, shown in Fig. 2, has a needle shaft 28, a needle tip 30 at a distal section 34 of the needle shaft and a needle hub 36 attached to a proximal end 36 of the needle shaft 28. Both, the distal section 34 and the proximal section 36 generally have the same outer profile. In the present embodiment, the distal and proximal sections 34, 36 have circular cross-sections with generally identical outer diameters.

[30] An enlargement 32 of the needle 20 is provided between the distal section 34 and the proximal section 36 of the needle shaft 28. The enlargement 32 has a maximum dimension in a direction transverse to the needle shaft 28, which is greater than the outer diameter of the distal and proximal sections 34, 36. The enlargement 32 can be made, for example, by crimping the needle shaft 28.

[31] Prior to use of the catheter apparatus 10, the needle 20 is received in the catheter hub 12 and catheter tube 14, such that the needle shaft 28 extends through the length of the catheter tube 14.

Description

Title of Invention: AN IMPROVED NEEDLE TIP GUARD

[1] The invention relates to a needle guard for use in a medical device, in particular for use in a catheter apparatus. The needle guard includes a base portion having a needle passage extending in an axial direction from a proximal side of the base portion through the base portion to a distal side of the base portion. The needle guard further includes first and second arms extending substantially in the axial direction from the distal side of the base portion and a distal wall which is transversely arranged at a distal region of the first arm.

[2] Such needle guards are generally known and are used to cover the tip of a needle of a medical device after use of the medical device. Typically, needle guards are devised to automatically cover the needle tip after withdrawal of the needle, for example, from a patient. The needle guard thereby serves to prevent accidental pricking of, for example, a medical practitioner by the needle tip after removal of the needle from the medical device. Thereby the needle can be safely disposed of after use, without the danger of transmitting possibly highly infectious and/or deadly diseases to the medical practitioner from the patient.

[3] Generally speaking, the term proximal refers to a region of the device or a location on the device which is closest to, for example, a clinician using the device. In contrast to this, the term distal refers to a region of the device which is farthest from the clinician, for example, the distal region of a needle will be the region of a needle containing the needle tip which is to be inserted e.g. into a patient's vein.

[4] It is an object of the invention to provide an improved needle guard in a catheter apparatus.

[5] The invention is defined in the independent claims. Some optional features of the invention are defined in the dependent claims.

[6] In one example, the needle guard includes a base portion made of a first material and having a needle passage which extends in an axial direction from a proximal side of the base portion through the base portion to a distal side of the base portion, such that a needle having a principal outer profile can be movably arranged in the needle passage. The needle guard further includes first and second arms extending substantially in the axial direction from the distal side of the base portion, with the first arm having a distal region and a proximal region. A distal wall is transversely arranged in the distal region of the first arm.

[7] The needle guard also includes a stopping element which is arranged in the needle guard. The stopping element is made of a second material different from the first material and has a through-bore with a profile which is adapted to the principal outer profile of the needle shaft. In the case of e.g. circular cross-sections, a diameter of the through-bore can be slightly larger than a principal outer diameter of the needle.

[8] In order to allow a trouble free movement of the needle relative to the needle guard when the needle is withdrawn from the catheter tube, the stopping element is preferably arranged such that its through-bore is in general alignment with the needle passage of the needle guard.

[9] The stopping element can be a circular disk, a ring, or a washer. However, it need not necessarily be circular and can have any other geometric shape such as a rectangular, square or triangular shape.

[10] Preferably, the second material is of greater hardness and/or stiffness than the first material. For example, the first material could be a plastic material and the second material could consist of a metal, a ceramic or a rubber material, or any other type of material which is stiff and not as easily distorted as the first material.

[11] Needle guards of the above kind are used, for example, in catheter apparatuses. In another exemplary technique, there is provided a catheter apparatus including a needle guard, with the catheter apparatus further including a catheter tube, a catheter hub and a needle having a needle shaft, a needle tip and a needle hub, wherein the needle shaft has a distal section and a proximal section, with at least the proximal section having a principal outer profile.

[12] The needle also has an enlargement provided between the distal section and the proximal section of the needle shaft. The enlargement has an outer profile one dimension of which is larger than a maximum dimension of the profile of the through-bore of the stopping element. In a preferred embodiment, the enlargement is made by a crimping of the needle shaft. However, other ways of forming the enlargement are possible, such as applying additional material to the needle shaft, e.g. by soldering, welding or gluing etc.

[13] The inner profile of the needle can either be reduced in the region of the enlargement, for example, if the enlargement is formed by crimping, or it can be substantially constant throughout the length of the needle, for example, if the enlargement is formed by applying additional material to the needle shaft.

[14] Prior to the use of the catheter apparatus, the needle guard is arranged in the catheter hub near a proximal end of the needle shaft. In this situation, the needle extends completely through the needle guard, thereby deflecting the first arm of the needle guard outwards, i.e. at an angle to the axial direction, such that the distal wall of the first arm is supported on the needle shaft. Following the insertion of the catheter into a patient, the needle is withdrawn from the catheter tube and the needle shaft moves through the needle guard while the needle guard is retained in the catheter hub. Once the needle tip passes the transverse distal wall of the needle guard, i.e. such that the needle shaft no longer supports the distal wall, a restoring force ensures that the first arm of the needle guard is moved back into alignment with the axial direction of the

needle guard, so that the needle tip is blocked by the distal wall of the needle guard, i.e. the needle tip is prevented from axially projecting out of the needle guard.

[15] Once the needle tip is blocked by the distal wall, the enlargement of the needle shaft engages with the stopping element to prevent the needle guard from being removed from the needle shaft. The fact that the stopping element is made from a second material which is harder and less easily distorted than the first material of the base portion, has the effect that the needle guard is secured more effectively on the needle shaft and can be retained even if excessive external force is applied when pulling on the needle, as the enlargement is prevented from being pulled through the base portion of the needle guard due to the stopping element. Hence, it is less likely that the needle guard is removed from the needle tip accidentally and, as a result, the needle guard provides a better protection against accidental pricking and thus increased safety for the person handling the catheter apparatus.

[16] In a further embodiment of the needle guard, a tension element surrounds the first and second arms of the needle guard. In the deflected state of the first arm, the tension element is expanded against a restoring force of the tension element. Once the needle shaft no longer supports the distal wall, the tension element aids the repositioning of the first arm back into axial alignment with the axial direction. This repositioning is necessary so that the distal wall can block the needle tip from axially sliding out of the needle guard. In addition, the tension element helps to enclose a space between the first and second arms and thus helps to prevent the needle tip from projecting sideways out of the needle guard. In other words, the tension element adds to the protective effect of the needle guard.

[17] In a further embodiment of the needle guard, a recess is provided in the proximal region of the first arm of the needle guard. This recess increases the deflectability of the first arm in the region it is provided and thereby reduces the restoring force acting on the distal wall while this is being supported by the needle shaft. This allows the needle shaft to be moved more easily relative to the distal wall, as the frictional force acting on the needle shaft is reduced.

[18] In a further embodiment of the needle guard, a groove is provided in a side of the distal wall, with the groove extending substantially in the axial direction. The groove acts as a guide groove for the needle shaft and aids the axial movement of the needle shaft relative to the needle guard. Moreover, the needle shaft is prevented from sliding sideways off the distal wall. Such a sideways movement would significantly increase the force required to move the needle shaft relative to the needle guard, which would prevent a correct functioning of the needle guard.

[19] In other examples, the needle guards do not include stopping elements. Thus, the needle guard can also be adapted such that it includes a recess and/or a groove as discussed above, but without including the stopping element. In this case, the outer profile of the enlargement of the needle shaft must be greater than the profile of the

through-bore in the base portion of the needle guard, in order to prevent the needle guard from sliding off the needle in a distal direction.

[20] Further advantageous embodiments and preferred apparatuses for carrying out the invention are set forth in the subordinate claims and are described in connection with the accompanying drawings.

[21] The present invention will now be explained in more detail in the following with reference to preferred embodiments and to the accompanying drawings in which are shown:

[22] Fig. 1 a catheter apparatus in accordance with the present invention;

[23] Fig. 2 a needle, needle hub and needle guard removed from the catheter apparatus of Fig. 1;

[24] Fig. 3A - 3D the needle guard of Fig. 2;

[25] Fig. 4A - 4C further illustrations of the needle guard of Fig. 2 without a tension element;

[26] Fig. 5A - 5B sectional illustrations of the needle guard of Fig. 4; and

[27] Fig. 6 a partially sectional and partially perspective illustration of the needle guard of Fig. 4.

[28] Fig. 1 shows a catheter apparatus 10 in accordance with the invention. The catheter apparatus 10 includes a catheter hub 12, a catheter tube 14, wings 16, a port 18 and a needle 20. The catheter hub 12 has a distal end 22 and a proximal end 24, the catheter tube 14 is arranged adjacent to the distal end 22 of the catheter hub 12.

[29] The needle 20, shown in Fig. 2, has a needle shaft 28, a needle tip 30 at a distal section 34 of the needle shaft and a needle hub 36 attached to a proximal end 36 of the needle shaft 28. Both, the distal section 34 and the proximal section 36 generally have the same outer profile. In the present embodiment, the distal and proximal sections 34, 36 have circular cross-sections with generally identical outer diameters.

[30] An enlargement 32 of the needle 20 is provided between the distal section 34 and the proximal section 36 of the needle shaft 28. The enlargement 32 has a maximum dimension in a direction transverse to the needle shaft 28, which is greater than the outer diameter of the distal and proximal sections 34, 36. The enlargement 32 can be made, for example, by crimping the needle shaft 28.

[31] Prior to use of the catheter apparatus 10, the needle 20 is received in the catheter hub 12 and catheter tube 14, such that the needle shaft 28 extends through the length of the catheter tube 14.