symmetric. When such a septum is employed for example in an infusion set, leakage between the septum and the housing often occurs. Thus, multi-layered septa may be suited for decreasing the occurrence of leakages between the cannula and the septum, however, these often lead to leakages between the septum and the housing of an infusion set.

In particular multiple piercing with a cannula still represents a significant source for leakages. This is highly problematic, as firstly, in case of the small dosing units in the nanoliter range typically employed in continuous insulin infusion, any occurring undetected leakage may have a dramatic influence on dosage and thus on the patient's health. Secondly, many automated infusion devices comprise occlusion detection devices which are malfunctioning if operated in an untight system.

Embodiments of the present invention seek to improve the state of the art regarding the design and use of elastic septa in the context of infusion and/or injection of liquid drugs, thereby preferably avoiding disadvantages of the prior art fully or partly. The septum may in particular belong to an infusion set as used, for example, in CSII, or a drug reservoir.

In favorable embodiments, the improved septum provides a tight sealing by the septum even if pierced multiple times and/or if exposed to higher pressures.

Further in favorable embodiments, the septum can be manufactured in a cost efficient way.

Further advantageous and exemplary embodiments follow from the dependent claims, the description and the figures.

According to a first aspect of the present invention, there is provided a pierceable septum for use in drug reservoir and infusion sets. The pierceable septum comprises an elastic core from a

core material and a surrounding from a surrounding material. Additionally, the elastic core is fully embedded in the surrounding and the surrounding material is more rigid than the core material, wherein the elastic core is radially prestressed by the surrounding.

As the elastic core is fully embedded in the surrounding, the core is completely covered by the surrounding and is thus not exposed at the surface of the septum. This provides the advantage that the expansion behavior of the core material is significantly restricted. In contrast to a septum in which the elastic core is not fully embedded in the surrounding, the expansion of the elastic core upon penetration of the septum by a cannula is restricted from all sides of the elastic core. As the surrounding material is more rigid than the core material, a force acts on the core material, which is radially directed towards the penetrating cannula. As a result, any gaps between the cannula and the septum are avoided and the interface between cannula and septum is tightly sealed.

As used herein, the term “septum” is readily understood by those skilled in the art and is typically an engineered element, for example in the form of a membrane or plug, for sealingly separating a first side and second side in a fluid, i.e. gas and/or liquid tight seal, which can be pierced by a needle or a cannula. Typically, a septum does not comprise an opening or a puncture, which passes through the septum from the first side to the second side, before a needle or a cannula has been pierced through the septum. Consequently, a stump needle cannot be easily pierced through the septum without exerting high forces.

The septum may typically be made from elastomeric and/or thermoplastic-elastomeric materials, such as silicon or natural-rubber and rubber derivatives, i.e. isoprene rubber, butyl rubber, FKM, styrene-butadiene rubber, etc.

A pierceable septum according to the present invention for use in drug reservoirs and infusion sets is essentially cylindrical or cuboid. Preferably, the septum has an essentially flat, plate-like shape. In this context, the term “essentially” is understood as to also include septa comprising for example one or more sealing lips and/or a circumferential groove.

The elastic core may preferably have a cuboid shape. However, the core may also be spherical or have any other suitable shape. Typically, the elastic core is flat and elongated in the lateral direction of the septum. The lateral direction of the septum is normal to the puncturing path of a cannula.

A pierceable septum according to the present invention may typically have a diameter or width of 2 to 20 mm, preferably 2 to 6 mm, more preferably 3 to 4 mm.

Typically, the thickness of the septum, i.e. the distance a cannula needs to pierce in an operative state, may be 1 to 10 mm, preferably 1 to 5 mm, ,more preferably 1 to 2 mm.

Furthermore, the skilled person understands how to determine whether a first material is more rigid than a second material. For example, this may be achieved by measuring and comparing the shore hardness of the materials. Typically, a shore durometer is commonly used in the art for this purpose. The higher the shore hardness of a material, the greater is the resistance to indentation and thus the harder the material. Thus, a more rigid material is also a harder material. This difference in rigidity of the core and surrounding material offers the advantage that upon retraction of the cannula an offset may be generated in the channel-shaped cut, which results from the puncture of the needle. Due to this offset, the sealing of the septum is significantly increased and leakage avoided.

In typical embodiments, the elastic modulus of the core material is smaller than the elastic modulus of the surrounding material.

Preferably, the shear modulus is used herein as the elastic modulus. In an embodiment according to the present invention, the elastic restoring force of the core is smaller than the elastic restoring force of the surrounding. As it is known to the person skilled in the art, the elastic restoring force is directly influenced by the hardness and/or the elastic modulus of the layer. In such embodiments, upon retraction of the cannula an offset may be generated in the channel-shaped cut, which results from the puncture of the needle.

Typically, the pierceable septum is integrally designed, that is the elastic core and the surrounding are fixedly connected to each other.

In preferred embodiments, the surrounding material has a shore hardness, which is chosen such that the expansion of the core material upon penetration of the septum with a cannula is confined.

In other embodiments, the surrounding material has a shore hardness of 0 to 100 Shore A, preferably 50 to 80 Shore A, and/or the core material has a shore hardness of 0 to 50 Shore A, preferably 10 to 40 Shore A. Such a hardness is particularly advantageous, as the outer material is rigid enough for providing efficient confinement of the expansion of the core material, which is concomitantly tightly sealed upon removal of the cannula.

In preferred embodiments, the elastic core of the pierceable septum is overmoled by the surrounding. This has the advantage that the elastic core and the surrounding are fixedly connected without the use of any additional adhesives.

In further embodiments, the core material is an elastomer and/or the surrounding material is an elastomer and/or a thermoplastic elastomer. For example in certain embodiments, a mixture of an elastomer and a thermoplastic elastomer may be used. A particular example includes a mixture of silicone and a thermoplastic elastomer.

be surrounded by at least two different materials. In these embodiments, the elastic core material is the least rigid material and the surrounding material aside from the piercing path of the cannula is the most rigid material, while the rigidity of the surrounding material within the piercing path lies in between. The piercing path may be indicated by optical or haptic means.

According to a second aspect of the present invention, there is provided a method for producing a pierceable septum. The method comprises the steps of providing an elastic core from a core material and fully overmolding the elastic core with a surrounding material to produce a pierceable septum with an elastic core, wherein the elastic core if fully embedded in a surrounding, wherein the elastic core is radially prestressed by the surrounding (10).

In a preferred embodiment, the overmolding is performed by injection molding, preferably by 2k molding.

According to a third aspect of the present invention, there is provided an infusion set comprising a pierceable septum defined in the first aspect.

Typically, the septum in an infusion set is radially prestressed by radial compression.

According to a fourth aspect of the present invention, there is provided a reservoir for liquid drugs comprising a pierceable septum defined in the first aspect.

Typically, the septum in a drug reservoir is radially prestressed by radial compression.

Brief description of the figures

Figure 1 shows a cross-sectional view of a pierceable septum in accordance to one embodiment of the invention.

Claims

1. A pierceable septum for use in drug reservoirs and infusion sets, wherein the pierceable septum comprises an elastic core from a core material and a surrounding from a surrounding material, wherein the elastic core is fully embedded in the surrounding, and wherein the surrounding material is more rigid than the core material, wherein the elastic core is radially prestressed by the surrounding.

2. The pierceable septum according to claim 1, wherein the surrounding material has a shore hardness chosen such that the expansion of the core material upon penetration of the septum with a cannula is confined.

3. The pierceable septum according to any of the preceding claims, wherein the surrounding material has a shore hardness of 0 to 100 Shore A, preferably 50 to 80 Shore A and/or wherein the core material has a shore hardness of 0 to 50 Shore A, preferably 10 to 40 Shore A.

4. The pierceable septum according to any of the previous claims, wherein the elastic core is overmolded by the surrounding.

5. The pierceable septum according to any of the previous claims, wherein the core material is an elastomer and/or wherein the surrounding material is an elastomer or thermoplastic elastomer.

6. The pierceable septum according to any of the previous claims, wherein the septum comprises a sealing lip or a circumferential groove.

7. The pierceable septum according to any of the previous claims, wherein the surrounding comprises two different surrounding materials, wherein a first surrounding material along a piercing path of a cannula is less rigid than a second material aside from the piercing path of the cannula.

8. Method for producing a pierceable septum comprising the steps:

- Providing an elastic core from a core material;
- Fully overmolding the elastic core with a surrounding material to produce a pierceable septum with an elastic core, wherein the elastic core is fully embedded in a surrounding, wherein the elastic core is radially prestressed by the surrounding.

9. Method according to claim 8, wherein the overmolding is performed by injection molding, preferably 2k molding.

10. An infusion set comprising a pierceable septum according to any of claims 1 to 7.

11. An infusion set according to claim 10, wherein the septum is radially prestressed by radial compression.

12. A reservoir for a liquid drug comprising a pierceable septum according to any of claims 1 to 7.

13. A reservoir according to claim 12, wherein the septum is radially prestressed by radial compression.