Biofine®
The innovative material for PD
Economic growth and industrial development are causing an increasing burden to the environment. At Fresenius Medical Care we are sensitive to the problem. Today, we value safety and protection of the environment just as highly as competing on the international market.

Fresenius Medical Care is thinking ahead

For a long time experts have been discussing the possible risks of PVC especially where disposal problems could have important unknown consequences. Many medical products consist of different plastic materials, some of which are inseparably bonded. In order to minimize the potential environmental and health hazards, alternatives must be seriously considered.

Biofine® - The new material from Fresenius Medical Care Research

Biofine®, a new material developed by Fresenius Medical Care Research is a substance from the group of polyolefines. Polyolefines are polymers, constructed exclusively from hydrogen and carbon atoms. The various properties of the material such as flexibility are defined by the different three-dimensional configurations of the carbon atoms. This permits to refrain from the use of plasticizers such as di-2 ethylhexyl phthalate (DEHP) that are commonly used to vary properties of materials made of polyvinylchloride (PVC).

Bibliography: 1, 2, 3, 4, 5.

Biofine® excels by its versatility

The new Fresenius Medical Care CAPD system generation stay•safe® is the first product manufactured from Biofine® material. All system components that come into contact with the dialysate provide higher biocompatibility, from the solution/drainage bag, lines and connector to the DISC.
Biofine® protects

During the storage of CAPD solution bags, water evaporates through the film. Biofine® has been tested under stress conditions and proved to be a far superior barrier to water vapour. Therefore we can guarantee an excellent consistency of the solution during the entire storage period.

Bibliography: 7, 8, 9, 13.

Sterilisation process

A good example of the sterilisation process is given by the stay•safe® system. After complete assembly and sealing with the outer wrapping the entire system consisting of Biofine® material undergoes steam sterilisation at 121°C. Thus all parts contained within the outer wrapping foil are sterile.

Bibliography: 6.

Biofine® minimises adsorption and absorption of medication

The adsorption of therapeutic substances is the attachment of particles of one substance to the surface of another. Adsorption occurs in the material of bags and tubes made of PVC. In the case of absorption the substances are not only adsorbed to the surface, but are also taken up into the matrix of the PVC-containing object. Absorption is the even distribution of one substance in another.

The consequence: the medication loses part of its effect. Example: if insulin is added into a PVC bag, a substantial amount will be adsorbed onto the wall of the bag.

This strong adsorption can be attributed to the polar nature of PVC. Polyolefines however are absolutely non-polar and the adsorption is much lower.

Bibliography: 10, 11, 12.
Biofine® is more ecological

During the product life cycle – production, usage and disposal – the Biofine® material is not harmful to the environment. Biofine® will degrade to carbon dioxide, carbon monoxide and water upon complete incineration without release of hydrochloric acid and the formation of its reaction products.

Bibliography: 5, 14, 15, 16.

Biofine® does not contain plasticizers

Although health risks could never be directly attributed to the use of plasticizers in PVC, several studies have reported that di-2-ethyl-hexylphthalate (DEHP), one of the most frequently used plasticizers, is not firmly integrated into the PVC matrix. Whether or not plasticizers are harmful in the field of peritoneal dialysis is no longer a point of discussion – Biofine® does not contain any.

Bibliography: 1, 2, 3, 4, 5.

Biofine® – a high-tech material

Biofine® has a different molecular structure to that of PVC. In producing the bags for the stay•safe® CAPD system, the Biofine® foil is 60% thinner, thus saving valuable raw materials and reducing waste. The multi layer foil contains no glue and the foil structure is optimized to meet the requirements for CAPD bags.

Biofine® allows recycling

In the new CAPD system generation stay•safe®, all system components are manufactured from Biofine®, making them easier to recycle.
Our development work will not cease

We want to continue to make innovative contributions for the benefit of the dialysis patient. Biofine® is a milestone opening up far reaching possibilities for us in many different fields of application.

Less material = lower environmental burden

Bibliography


6. Fresenius Medical Care: Own investigations, not published. 1995.


8. Fresenius Medical Care: Own investigations, not published. 1995.


13. Fresenius Medical Care: Own investigations, not published. 1995.


15. Fresenius Medical Care: Own investigations, not published. 1995.


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