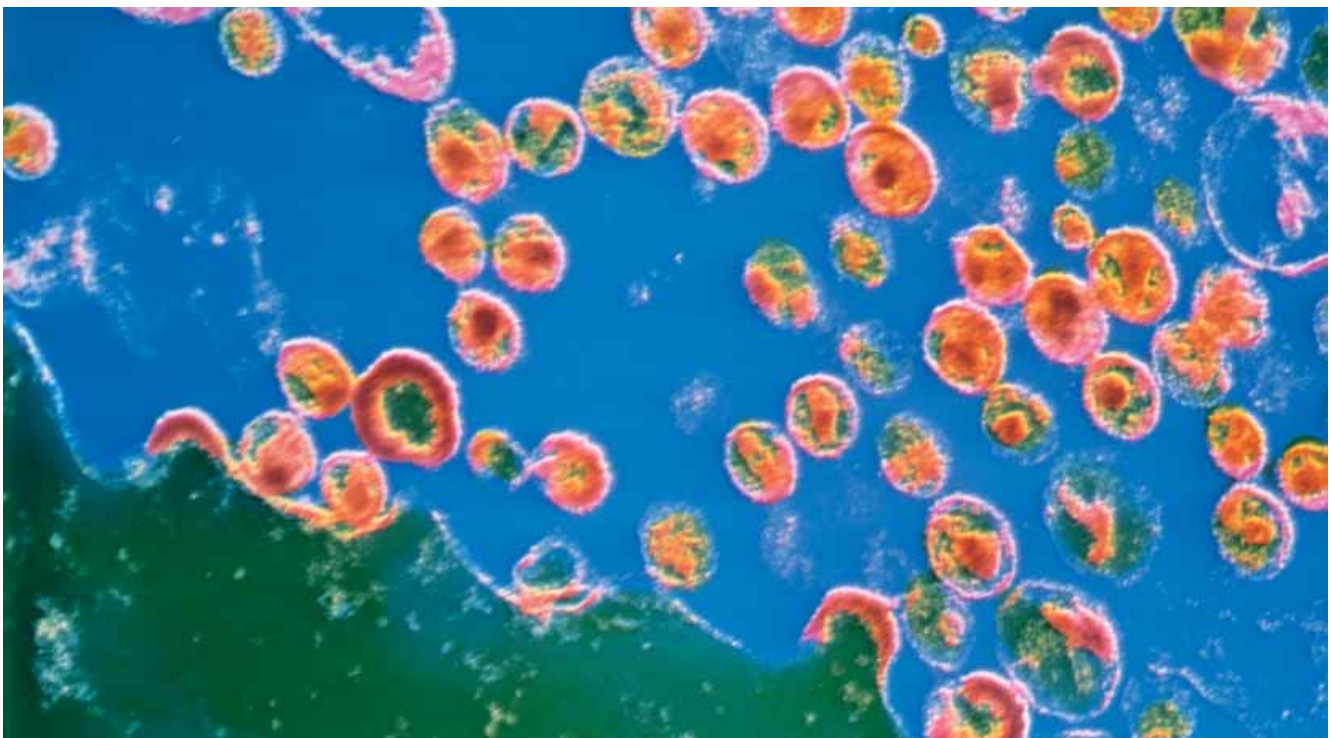


## Fiction and truth – Virus permeability of Latex Gloves.

Are surgical gloves really impermeable to bacteria and viruses? During the last few years various reports were published via the media, which cast doubt on this statement for approximately one third of all gloves. The question is, however, is there any foundation to these doubts?

The well-known "World of Science" published an article on the subject of the permeability of viral agents through medical gloves. The content was hard hitting: Scientists of the Medical College in Milwaukee suspect that more than 30% of all latex gloves are not impermeable against bacteria and viruses. Are micro-organisms really capable of penetrating the

latex film of a glove? The American scientists suspect that with a film-like structure of the latex material some pore-like penetrations could exist, which would form a type of passage for micro-organisms. It is therefore essential to know what a medical glove looks like under the microscope.



Microscope photograph – release of HI-Viruses

### A dense net

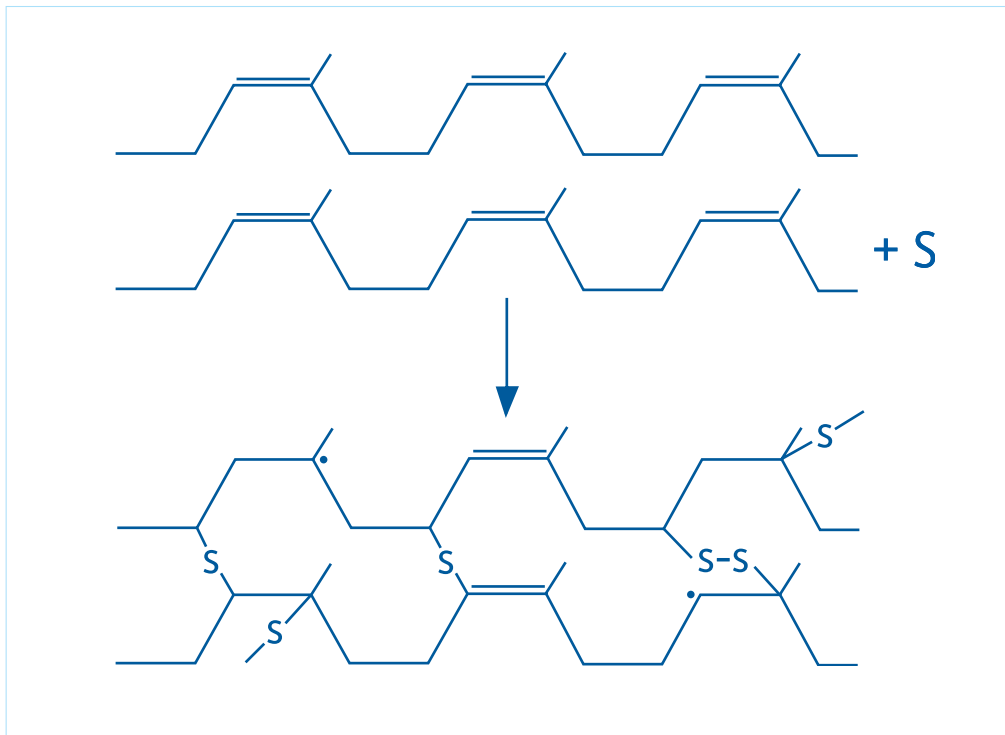
The raw material for latex gloves is the milk juice (latex) of various plants from the Hevea family. The raw natural „caoutchouc" gained in this way consists of unsaturated, unpolymerised polymers, i.e. more appropriately, long chains which form a line of molecules and thereby form a giant molecule.

These individual threads lie closely side-by-side and provide high tensile strength in the direction of the

firmer, the better and more complete this polymerisation is.

### Contradicting requirements

Gloves fulfil many tasks in the everyday medical field. Most of all, they serve as protection against illness-inducing organisms. They need therefore to be impermeable, hard-wearing and resistant. The thicker the glove, the denser its characteristics. At the same time,



Polymerization of rubber with the aid of sulphur (vulcanization)

individual threads, comparable to an expander. In cross-wise direction to the thread, tensile and tear resistance are low. In order to produce a material which is tear-resistant in all directions, these threads or molecule chains must be polymerised with each other. These lateral connections are achieved by vulcanisation of the natural raw caoutchouc.

An inter-molecularly polymerised rubber material is therefore produced from the string-like raw caoutchouc. The gaps between the individual polymer chairs of the rubber must be so small that neither liquids nor particles can pass through the glove film. The glove will be denser, i.e. the more impenetrable and

however, medical gloves must be as thin as possible to ensure optimum sensing. This contradiction between density and thinness of the material becomes even more apparent if the size of particles present in the medical field is considered. Parvo viruses, the cause of rubella, are, for example, only approx. 20 nanometre (nm) in size. Even smaller are prions, being only 4–6 nm, which are responsible for the Creutzfeldt-Jakob-syndrome. The AIDS viruses on the other hand, are true "giants" of more than 100 nm.

### Contradicting research results

Numerous scientific examinations have been dealing with the subject of "virus-impermeability of surgical

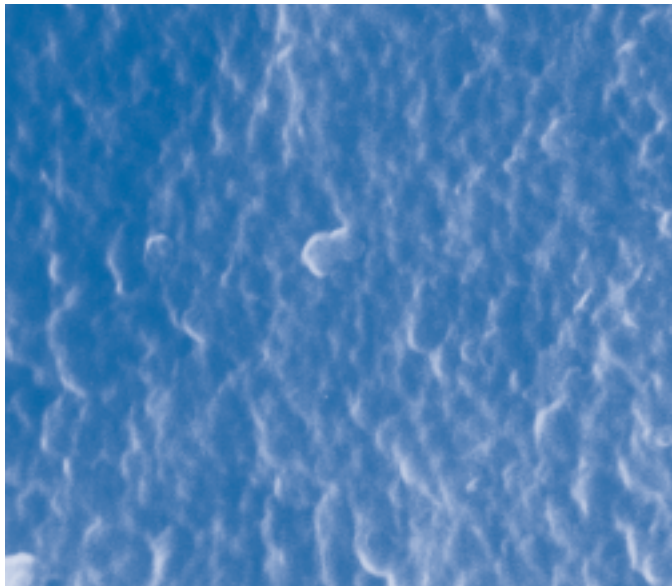
gloves". The results are however contradictory, partly as a result of the lack of safe testing procedures. The examinations by Kampf et al. (1991) and Zbitnev et al. (1989) show, for example, that gloves which are impermeable to water are also impermeable to micro-organisms. Kampf used for this test micro-organisms with a size of 95 nm, Zbitnev those of only 25 nm. Dierich too, who tested with coloured molecules, confirmed this assumption. Examinations by Gerhardt on the other hand, showed high penetration ratios.

### Tested Safety

By reason of the contradiction of the results and the high expenditure for the test procedures used, other testing methods had to be developed for routine quality control of medical gloves. Differing proposals existed for this, such as for example the AC- or phenolphthalein test and furthermore the air and water retention test. Also electrons or ions were proposed as the smallest particles which could penetrate the material. At present, the electronic test is used for testing of condoms. For medical gloves, the water retention test was retained as the most simple and safest testing method, as described in ISO 10282 and EN 455/1.

At SEMPERMED the impermeability of gloves is continuously tested as

per the standard which is valid throughout Europe. The EN 455/1 prescribes as test procedure the water retention test, the glove is filled with 1000 ml water and must remain impermeable for the duration of a defined period. The glove is however destroyed during this test procedure. The air test, which is also used, where the glove is inflated to a defined pressure and tested for the formation of perforations is, a non destructive testing procedure and can therefore be used for the entire quantity produced.



Latex glove material under the electron scan microscope

### Classified world-wide

Under all current requirements and testing procedures and the latest scientific knowledge, medical gloves by SEMPERMED are at present classified as virus-tight.

With all examinations to date it has been proved that they are completely impermeable against viruses and liquids.

When dealing with risk patients, it is however recommended that two pairs of gloves are worn, one on top of the other. This will create a second safety barrier which will make immediately visible any possible damage to the outer glove through needle pricks, bone splinters or sharp objects, by means of the penetration of body fluid between the two glove layers. This will guarantee the highest possible safety.



Air test

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## Sempermed –

### the European experts for medical gloves

SEMPERMED specialists are experts in the art of latex dipping. We have been manufacturing medical gloves for more than 80 years, and are known as the caoutchouc pioneers of Europe. We have more than 175 years of experience in processing this natural raw material. The vast experience and knowledge we have gained over this period, are your constant guarantee for highest product quality. Additionally, our gloves are tested far beyond the legally prescribed AQL value of 1,5. Our continuous quality control in respect of perforations achieves internally an AQL of 0,4. SEMPERMED gloves are regarded as one of the best quality products on the market.

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