by Christian Wolf

ISO 11607 – New Packaging Standards Raise Quality Requirements for Dentists

Like cleaning, disinfection and sterilization, the process of packaging medical devices such as instruments constitutes an essential phase of instrument preparation. Accordingly the new ISO 11607 standard requires the reproducibility and validation of this process. The quality specifications to be fulfilled here entail an in-depth understanding of the process.

For a long time, little attention was paid to the packaging of dental instruments as part of instrument preparation. The psychological assurance afforded by visible packaging was more important than actual requirements or knowledge of the underlying processes. Little consideration was given to correct types of packaging and the consequences of faulty packaging. Today, it is known that sterility until removal of medical devices is guaranteed in large part by correct packaging. National and international standardization committees are therefore dealing ever more intensively with this topic. Of late, industrial standards have also encompassed dentists and clinics because they, too, prepare and produce medical devices.

Selection of a Packaging System

According to the new ISO 11607 packaging standard as well as to most national Medical Device Directives, packaging systems for medical devices shall maintain sterility until the point of use. The safety standards attained depend decisively on the type of packaging selected.

Disposable packaging, like sealable pouches or reels, provides full protection. However, some disposable packaging also poses risks. A use of packaging whose quality fluctuates from one application to another is unthinkable today. This includes, for instance, adhesive coated packaging (e.g. Self Seal pouches), a system which is declining worldwide in view of its inability

> **"A packaging process must constantly achieve the results expected of it: The process shall maintain sterility until the point of use. This requirement can only be fulfilled if the packaging process is reproducible, i.e. if the user does not have any influence on the result."**

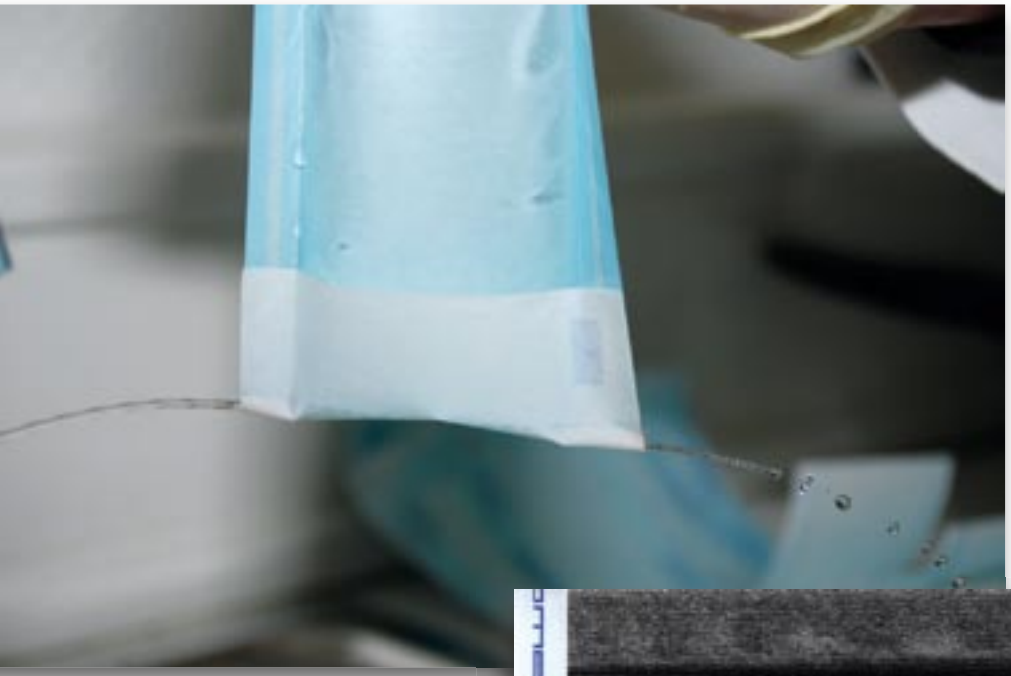
to ensure full packaging integrity. An independent study by the University of Tübingen / Germany revealed a residual risk of more than 30% posed during the use of self-sealable materials. In accordance with that study 'self-seal pouches' shall not be used because they compromise pack integrity. Furthermore the process cannot be validated.

Decision Criterion: Validatable Processes

International standard ISO 11607 "Packaging for terminally sterilized medical devices" explicitly requires reproducible and validatable process for all packaging systems. In any case, this standard is also applicable to dentists. In the scope of the new standard this is clearly described: "This International Standard ISO 11607 is applicable to industry, health care facilities and wherever medical devices are packaged and sterilized" – dentists are considered as 'health care facilities'.

But what exactly does this mean?

A packaging process must constantly achieve the results expected



of it: The process shall maintain sterility until the point of use. This requirement can only be fulfilled if the packaging process is reproducible, i.e. if the user does not have any influence on the result. At present, only automized packaging processes (heat-sealed pouches or reels, for example) are reproducible.

A basic prerequisite for this validatable process is that the sealing machine complies with the specifications of the standard. The packaging parameters (temperature and contact pressure) have to remain constant. Furthermore the process has to be interrupted in case of any parameter deviation. If either of these parameters can be influenced by users, the process is no longer reproducible and therefore not compatible to the standards. Simple devices whose packaging integrity depends solely on the user motivation (for example, simple household appliances) are unthinkable in clinical operations. Furthermore, such products usually fail to attain the specified sealed seam width.

hawo GmbH / Germany developed the first fully validatable dental heat sealing device which fully accomplishes the requirements of the new standard. The hawodent hd 680 DE-V is the perfect tool for every dentist surgery or clinic – not only because of its functionality and its award-winning design but also because of its environmental approach. A uniquely compact construction, the use of wear resistant materials as well as an automatic stand-by function, in which the motor is automatically turned off when not in use, label the product as being “Greentek”.

A further tool to individually monitor the quality of the seal seems is the so called Seal Check dent that was explicitly developed for dentists. It is a simple test of the quality properties of seal seams and shows if the sealing was generally intact, if there were no channels or open seals, no punctures or tears and no material delamination or separation. If deviations occur in the critical parameters, this is made visible on the indicator strip.

In summary, not all common packaging systems are compatible with the new standards. Accordingly, future hygienic strategy should be based on the latest standards. Overall it is important to remember that the number of nosocomial infections resulting from dental treatment worldwide is taking on dramatic proportions and let us not forget that we are talking about the safety of the patient.

About the company...

First founded in 1975 by Hans Wolf, the family-owned company hawo is now a worldwide market leader in medical heat sealing systems. Main focuses of its work are heat sealing systems and testing systems for doctors, hospitals, as well as for medical and cleanroom technology industries. Today hawo’s products are marketed in over 100 countries

For more information, visit www.hawo.de.

Mr Christian Wolf is Managing Director of hawo, Germany and is responsible for product development, innovation management and marketing & sales. Next to developing new products that follow highest demands, he is working actively in the development of international medical standards and has contributed to enhance and harmonize sterilization packaging standards.