

## Report to recall

Regarding the product "Compules with Enamel Plus HFO / HRi" it has been noticed for the first time during part of the quality control on May 27, 2016 that some compules burst at certain points during the application and that some parts can also be torn off.

This product is a dental filling material, which is filled in a quantity of 0.3 g in so-called compules (also called fillis or tips). These are inserted in an applicator ("Dispenser") and the material can either be expressed outside of the mouth or applied by the dentist directly into the dental cavity.

For illustration purposes we have included photos of defective compules.

Initially this situation did not appear to be a risk for patients. However, further studies made us arrive to the following conclusion:

In our opinion, the breakage of compule tips can lead to the following possible hazards:

1. Ingestion of plastic parts by the patient
2. Aspiration

So far, this behavior of compules was not reclaimed by any customer nor have any patients come to harm. Furthermore, we consider this probability to be extremely low. However, due to the fact that the risks cannot be completely excluded we have taken the decision to recall the corresponding lots.

In the course of further research it was determined that the dental filling material meets our quality criteria and that this can be excluded as the cause of the error. Instead, a material error of the compules has been determined as the cause. The injection mold for producing the compules is damaged by wear and tear at certain points, so that the plastic shows reduced mechanical stability.

By far not all compules are affected, but only those that derive from two (of eight) certain cavities.

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