## GapSeal® Questionnaire for Dr. Dr. W. Schmüdderich and Dr. D. Horch:

08.04.2022



#### Dr. Dr. Wolfgang Schmüdderich

- 1988 1994 Study of dentistry, Heinrich Heine University, Düsseldorf, Germany
- 1997 Doctorate in medicine (Dr. med.)
- 1994 1998 Study of dentistry, Heinrich-Heine-University, Düsseldorf, Germany
- 1998 1999 Further training in maxillofacial surgery at Bethesda Hospital, Mönchengladbach, Germany
- 1999 2004 Advance training in maxillofacial surgery, Westdeutsche Kieferklinik, University of Düsseldorf, Germany
- 2001 Doctorate (Dr. med. dent.)
- 2003 Recognition as specialist for oral and maxillofacial surgery
- 2005 Certification Plastic and Aesthetic Surgery
- 2005 Certification in implantology
- Since 2005 Establishment in own practice for maxillofacial surgery in Meerbusch, Germany

Now that the multifactorial causes of peri-implantitis and their treatment concepts have been widely discussed in the literature, re-infection or microleakage from the gaps and hollow spaces in assembled implants is increasingly being recognized as another cause of peri-implantitis. "pip" was able to enlist Dr. Dr. Schmüdderich as co developer of GapSeal for an interview and, as a user of GapSeal, spoke with implantologist Dr. Horch, who shared her experiences and recommendations with us.

### pip: Dr. Schmüdderich, how did you come up with the development of GapSeal?

Schmüdderich: When re-opening assembled dental implants, we noticed material in the gaps and hollows that had a putrid odor. We had this material microbiologically examined and found out that bacteria, fungi and even viruses were present. This proved that composite implants leak and showed that the hollow spaces in the implants are in direct, unhindered connection with the germ-laden oral cavity. It is a fact that multi-part implants have gaps and hollows that can be minimized but not completely prevented - not even with the most meticulous production. Common gap sizes between implant body and abutment range from 10 µm to 120 µm, whereas germs are only about 1.2 µm in size (figs. 1 and 3).

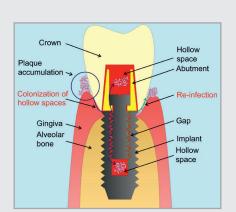


Fig 1: Design drawing showing an assembled implant. Hollow spaces inside implant marked with arrows.

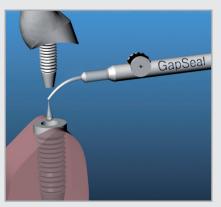


Fig. 2: Schematic illustration of the Gap Seal application

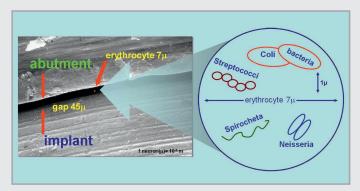


Fig. 3: Gap situation between implant and abutment with an erythrocyte and common germs shown true to scale compared to an erythrocyte



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#### pip: Why are there no gap-free, assembled implants?

<u>Schmüdderich:</u> "It is impossible to achieve 100 percent accuracy in manufacturing." Unfortunately, this mechanical principle also applies to multipart implants. However, in order to meet higher prosthetic demands, implant systems must consist of several components and be assembled. We have, therefore developed the sealing material GapSeal.

#### pip: Where do you see the main problem in re-infection/microleakage from the implant?

<u>Schmüdderich</u>: In peri-implantitis therapy, the implant surfaces and the peri-implant tissues are treated, but the germs inside the implants, which can neither be reached by antibiotic treatment nor by the host's immune system, continue growing undisturbed under ideal conditions.

#### pip: Which qualities must a sealing material have?

<u>Schmüdderich</u>: The material must be hydrophobic to make sure it cannot be dissolved out or washed out by water and saliva. It needs a high viscosity so that it is stable and a hermetic seal is ensured. In order to avoid renewed gap formation due to shrinkage during setting, the sealing material must not set. To prevent germ colonization of the sealing material, it is essential that the material is bactericidal, fungicidal and virucidal. Last but not least, it can have neither sensitizing nor allergenic properties in order to be used safely in all patients. Furthermore, the material must not be toxic in order to avoid possible additional damage, and, finally, must pose absolutely no risk to the adjacent tissues or the organism.

#### pip: What is GapSeal made of?

<u>Schmüdderich</u>: Schmüdderich: A high-viscosity silicone matrix, which has been used successfully in industry and medicine for many years, provides a reliable seal as the base material, and in doing so, prevents the penetration of germs.

#### pip: Why is peri-implantitis also found in one-part implants?

<u>Schmüdderich</u>: Re-infection is only one cause of this disease. The classic reasons for peri-implantitis, such as overload situations, poor gingival conditions and excessive plaque formation, are naturally also present with one-piece implants.

#### pip: What long-term experience can you look back on?

<u>Schmüdderich</u>: Cavity sealing offers effective prophylaxis against peri-implantitis, reducing this disease by at least one third. There is over twenty years of clinical experience. It will certainly not be possible to prevent all cases of peri-implantitis. However, under these conditions it is a great advantage if at least those peri-implantitis cases can be prevented that are caused and supported by reinfection or microleakage inside of the implant.





#### pip: Dr. Horch, what is your experience with GapSeal in everyday clinical practice?

<u>Horch</u>: We were pleasantly surprised by the success of the treatment, as inflammation decreased considerably and recurrences became less frequent. Interestingly, implants sealed with GapSeal do not have any unpleasant odors when reopened.

#### pip: Could you give some advice to users?

<u>Horch</u>: Each implant should be sealed because of the aforementioned, unfortunately unavoidable gaps and hollows in assembled implants. In case of screw-retained prosthetics, the gaps of the superstructure should also be filled. The sealing material should likewise be used for cemented superstructures, since the implant-abutment connection is identical, germs can get into the implant and thus the risk of reinfection is also present here.

#### pip: How is GapSeal applied?

<u>Horch</u>: GapSeal is provided sterile in blister packs to ensure sterility even during operations. The applicator can be re-sterilized for reuse. It is advisable to seal the implant interiors with GapSeal from the beginning, directly after insertion and before screwing in the cover screw. Cases have been documented in which the germ-laden contents of an implant have resulted in early losses during the covered healing process. The implant is filled from the bottom so that air pockets are avoided as far as possible. When the cap is screwed in, excess material swells out, confirming that the filling is good. This excess can be safely left in place, or easily removed with a swab (figs. 2 and 4).

#### pip: When does the material need to be renewed or replaced?

<u>Horch</u>: In case of screw-retained superstructures, it is advisable to renew the material at every recall appointment. In cement-retained restorations, it can be left in place for many years without any problems and retains its qualities. We were able to prove that the germicidal properties are still present even after fifteen years.

#### pip: Why is hardly any attention paid to the problem of gaps and hollow spaces?

<u>Horch</u>: In practice, it is assumed that the implant and abutment are a firmly joined unit. The presence of microbiologically large gaps and hollows is not considered, and least of all the fact that there is also movement between the two components, as demonstrated by Zipprich.

### pip: Is peri-implantitis treatment with GapSeal including conventional therapy more successful?

<u>Horch:</u> Patients should not be deprived of this additional option for implant retention. It is easy to use, involves only low costs and significantly increases the chance of successful treatment.



Fig. 4: Insertion of GapSeal into the screw channel in clinical use



#### Dr. med. dent. Deborah Horch

- 2006 2011 Study of dentistry at Münster University, Germany
- 2012 2014 Dental Practice, Korschenbroich, Germany
- 2014 2016 Education as oral surgeon, OMFS Clinic Essen, Germany
- 2015 Completion Curriculum Implantology
- 2016 2018 Oral surgeon, MKG am Wasserturm, Dr. med. Dr. med. dent. Schmüdderich, Meerbusch, Germany
- 2018 Oral and maxillofacial surgeon

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Applicator separately	REF 152 042
GapSeal Set (applicator with 10 Tips)	REF 152 04
GapSeal Refill Pack (10 Tips à 0,06 ml)	REF 152 040



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