Scientific Documentation

Systemp®.inlay
Systemp®.onlay

Ivoclar Vivadent AG
R&D / Scientific Service
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1 Introduction

The temporary restoration of prepared teeth is an integral part of the restorative treatment provided by dentists. Temporary materials fulfil the following tasks:

- Replace missing tooth structure
- Restore teeth for a limited time

Fermit and Fermit N from Ivoclar Vivadent AG are two light-curing single-component materials designed for the temporary restoration of Class I and II cavities without the application of a temporary cement. They have been commercially available as temporary inlay and onlay materials for a number of years. They are clinical accepted and have proved to be comparable to competitive products (1, 2). In the course of further development activities, the materials have been optimized with regard to the following features:

- Active ingredient
- Shade
- Delivery form

The improvement of Fermit and Fermit N has culminated in the development of the new products Systemp.inlay and Systemp.onlay. Triclosan has been added to these materials to reduce bacterial growth on the temporary restoration. As a result, the development of odours should also be reduced.

Both Systemp.inlay and Systemp.onlay are available in two different shades (universal and transparent). The materials are supplied in composite syringes and in Cavifils.

Systemp.inlay is particularly suitable for deep inlay preparations with parallel walls. It can also be used if small undercuts are present. In addition, the material is suitable for relining prefabricated temporary crowns and bridges made of polycarbonate or methacrylates. Moreover, implant screw access canals can be sealed with Systemp.inlay. The special monomer mixture renders the material highly elastic. Therefore, restorations are easy to remove.

Systemp.onlay is particularly suitable for large preparations such as onlays because of its special consistency. Because of its specific physical properties, Systemp.onlay is more suitable for shallow and less retentive cavities than Systemp.inlay. The material, however, is more difficult to remove from undercut and deep parallel-walled preparations. The higher strength of the material compared with that of Systemp.inlay, which is produced by the higher filler content, provides certain advantages with regard to retention and occlusal and sagittal bracing.

The adhesive and retentive properties of Systemp.inlay and Systemp.onlay are not significantly affected if the prepared dentin is conditioned with Systemp.desensitizer (1).

1.1 Material

Systemp.inlay and Systemp.onlay are light-curing single-component materials for the temporary restoration of Class I and II cavities. The products are based on a monofunctional ethyl triglycol methacrylate and on a polyester urethane dimethacrylate. Prepolymerized dimethacrylates and pyrogenic silicic acid are used as the fillers. The materials also contain catalysts, stabilizers and triclosan.

Systemp.inlay and Systemp.onlay differ from Fermit and Fermit N and competitive products such as Voco Clip, Cosmedent EZ-Temp and Kulzer Precision Fill in that they contain triclosan.

Triclosan is a broad-spectrum antimicrobial 2,4,4'-trichloro-2'-hydroxydiphenylether that is effective against a wide-range of gram-positive and gram-negative bacteria as well as dermatophytes, moulds and yeast (2).

2 Technical data sheet

Standard composition (in wt%)

	Systemp.inlay	Systemp.onlay
Polyester urethane dimethacrylate	49.4	29.4
Ethyl triglycol methacrylate	---	7.5
Highly dispersed silicon dioxide, silanized	16.4	19.4
Copolymers	33.0	42.7
Catalysts, stabilizers and triclosan	1.2	1.0
Pigments	< 0.1	< 0.1

Physical properties

			Systemp.inlay	Systemp.onlay
			transparent / universal	transparent / universal
Shore D hardness	(2x5 min. Spectramat)		44 ± 2 / 46 ± 2	70 ± 2 / 66 ± 2
Curing depth	(20 sec. Astralis 7)	mm	≥ 5	≥ 5
Water absorption	(after 7d / 37 °C)	µg/mm³	21 ± 1	10 ± 1
Water solubility	(after 7d / 37 °C)	µg/mm³	17.5 ± 0.5	14.5 ± 0.5

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3 Clinical procedure

3.1 Preparation

The clinical procedures of Systemp.inlay and Systemp.onlay are comparable. The materials are usually applied without a matrix. If Class II cavities are restored, however, a wedge must be placed to prevent gingival excess. The material is generally applied in bulk. That is, an adequate amount of Systemp.inlay or Systemp.onlay is placed in the cavity using a spatula or a suitable instrument. The contents of Cavifils are directly applied in the cavity with the help of the Cavifil Injector.

Layers of 4-5 mm can be cured with a high-performance curing light (eg Astralis 7 with an intensity of > 700 mW/cm^2) in 20 seconds. Layers of 5 mm thickness should be cured with a standard halogen light (intensity of < 700 mW/cm^2; eg Astralis 5) for 40 seconds.

3.2 Placement

The temporary Systemp.inlay and Systemp.onlay restorations are pulled from the cavity with a suitable instrument (eg probe, scaler). Next, the cavity is cleaned using a rubber cup and cleaning paste. Subsequently, the restoration is tried in and placed.

3.3 Notes

In standard preparations, Systemp.inlay and Systemp.onlay adhere well to the cavity walls. If very little mechanical retention is available, the temporary can be cemented with a eugenol-free cement (eg Provilink, Reocap Temp IC). The retention of the temporary can be improved by modelling Systemp.inlay and Systemp.onlay in the undercuts of the proximal region. In this case, a wooden interdental wedge rather than a matrix should be placed prior to the application.

As Systemp.inlay and Systemp.onlay can bond with light-curing bases and liners (eg glass ionomer cements) because of their similar compositions, the bases and liners should be isolated with glycerine gel (Liquid Strip) to prevent them from being removed from the cavity together with Systemp.inlay or Systemp.onlay.

Excess material is removed with a scalpel or with silicone rubber (Politip F or Astropol F) or tungsten carbide finishers.

To increase the stability of temporaries in large cavities, a composite (eg Heliomolar RO or Tetric Ceram) can be used in the occlusal part of the temporary. Systemp.inlay and Systemp.onlay can be polymerzied separately or together with the restorative material.

Systemp.inlay and Systemp.onlay are easier to contour, if the instrument is wetted with Systemp.desensitizer or an unfilled bonding agent (eg Heliobond).

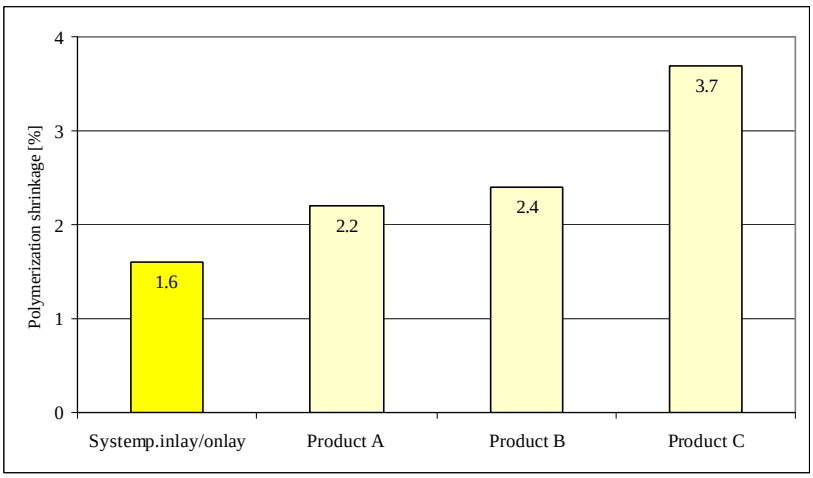
4 Physico-chemical properties

The following graphs show the results of investigations conducted by Ivoclar Vivadent AG R&D in which the most important physical properties of Systemp.inlay and Systemp.onlay were compared with those of competitive products.

4.1 Volume shrinkage

Shrinkage during the polymerization procedure is an important characteristic that has to be taken into consideration in temporary materials. Marginal gaps should be as small as possible to reduce water absorption, discolouration, the development of odours, and sensitivity.

Because of the prepolymers contained in Systemp.inlay and Systemp.onlay, less volume shrinkage occurs during light-curing than in competitive materials. As a result, marginal gap formation, discolouration of the material and the growth of bacteria is reduced. The shown values were determined by means of HG dilatometry.



Polymerization shrinkage of temporary restorative materials (light-curing)

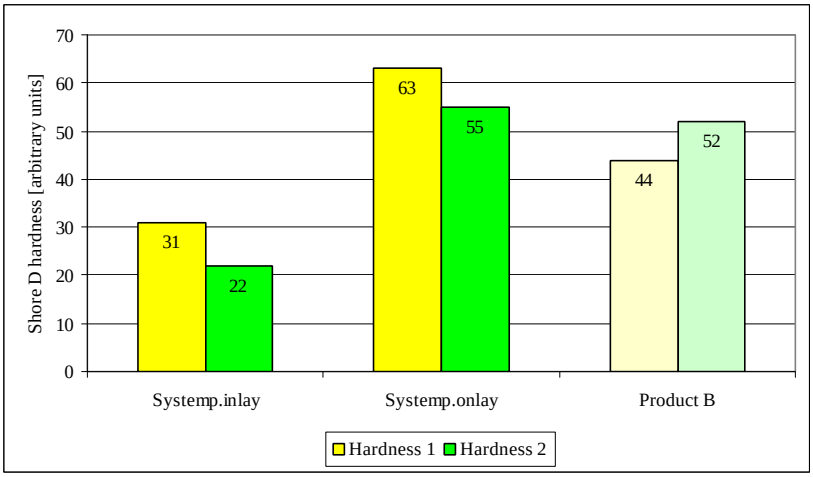
Internal investigation Ivoclar Vivadent AG, Schaan, Liechtenstein

4.2 Shore D hardness

The Shore D hardness according to DIN 53505 is defined as the resistance of an object against another object of a specific shape and the defined penetration depth. The scale of values ranges from 0 to 100.

Hardness 1 was determined after 2x60 s curing with the Heliomat and 24-hour immersion in water at 37 °C, while Hardness 2 was measured after 2x60 s curing with the Heliomat without immersion in water.

The following graph shows that the elastic behaviour of Systemp.inlay and Systemp.onlay corresponds to their indication.



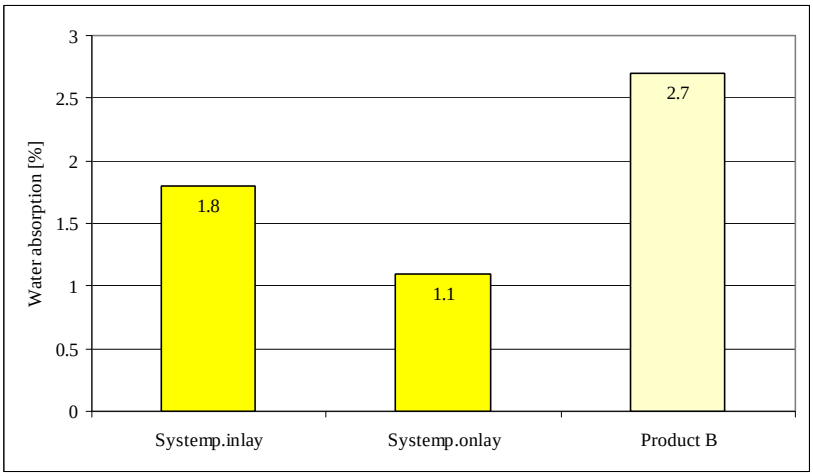
Shore D hardness of temporary restorative materials according to DIN 53505

Hardness 1 2x60 s Heliomat (24h H_2O, 37 °C)
Hardness 2 2x60 s Heliomat

Internal Investigation Ivoclar Vivadent AG, Schaan, Liechtenstein

4.3 Water absorption

The water absorption of temporary materials is determined in connection with discolouration and odour development according to ISO 62-1980 (E) "Plastics determination of water absorption". Lower values are predestined for the mentioned indications. The absorption of water was determined after 7 days of immersion in water at 37 °C.



Water absorption of temporary restorative materials according to ISO 62-1980 (E); Immersion (7d H_2O 37°C)

Internal investigation Ivoclar Vivadent AG, Schaan, Liechtenstein

4.4 Depth of cure

In contrast to competitive materials, Systemp.inlay and Systemp.onlay can be applied in increments of ≥ 5 mm and cured with a halogen light (Intensity > 700 mW/cm^2; z.B. Astralis 7) in 20 seconds.

	Systemp.inlay / Systemp.onlay	Product A	Product B	Product C
Increment thickness	≥ 5	2.0 - 2.5	4.0 - 5.0	4.0 - 5.0
Curing time	20 s	40 s	40 s	40 s

Curing depths of temporary restorative materials

5 Scientific investigations

5.1 Clinical investigations

Temporary materials are designed to replace missing tooth structure and manage teeth for a limited time, while the indirect restoration is being fabricated in the laboratory. The compatibility and effectiveness of Systemp.inlay and Systemp.onlay were tested in the following clinical investigations.

5.1.1 "Clinical evaluation of Systemp.desensitizer and Systemp.onlay"

Dr. C. Prati, University of Bologna, Italy

An investigation was conducted on the topic of desensitization during the temporary restoration phase. The temporary cement System.onlay was used in conjunction with Systemp.desensitizer. Side effects of Systemp.onlay were not found during the investigation. Postoperative sensitivity was significantly reduced if Systemp.desensitizer was used. None of the 44 temporary Systemp.onlay restorations placed were lost during the 2 to 3 weeks between the first appointment and the placement of the restorations, which indicates that the retention of these temporary restorative materials in the cavity is excellent.

5.1.2 Microbiological investigation

Qualitative and quantitative microbiological examinations were conducted (R&D Ivoclar Vivadent AG) on Fermit and Systemp.inlay and Systemp.onlay restorations, which were removed from the cavities of patients. The goal of this investigation was to determine the effectiveness of the antimicrobial agent triclosan with regard to discolouration, odour development and bacterial growth.

The investigation showed that the addition of triclosan does not completely suppress the growth of bacteria. Nevertheless, the bacterial flora was shown to have undergone a change, as cariogenic and odour-forming microorganisms could no longer be identified.

5.2 In vitro investigation

5.2.1 Inhibiting zone assay

The discolouration and/or odours that are often associated with in-situ temporary restoratives may be of bacterial origin. Therefore, they may be influenced by incorporating an antimicrobial agent.

In order to compare the antibacterial potential of the new restorative materials Systemp.inlay and Systemp.onlay with that of competitive materials, an inhibiting zone assay according to the European Pharmacopeia,, Chapter 2.7.2 (Agar Diffusion), was conducted at the Institut Confarma France S.A.R.L. For this purpose, test specimens (diameter 10 mm, height 2 mm) were placed on the surface of inoculated agar. The specimens were incubated at 35 °C to 37 °C for 18 to 24 hours. While the inhibiting zones (results are in mm diameter including specimen diameter) for Systemp.inlay with *Streptococcus mutans* and *Klebsiella pneumoniae* measured 12.7 mm, no inhibiting zones were detected for Product A for example (Figure 1 and 2).

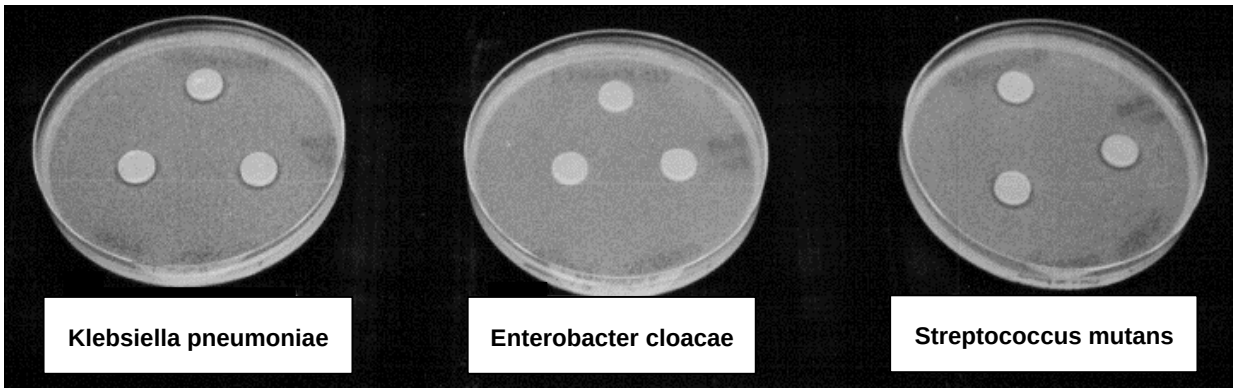


Figure 1: Systemp.inlay after an incubation period of 18 to 24 hours at 35 °C to 37 °C (Institut Confarma France S.A.R.L.)

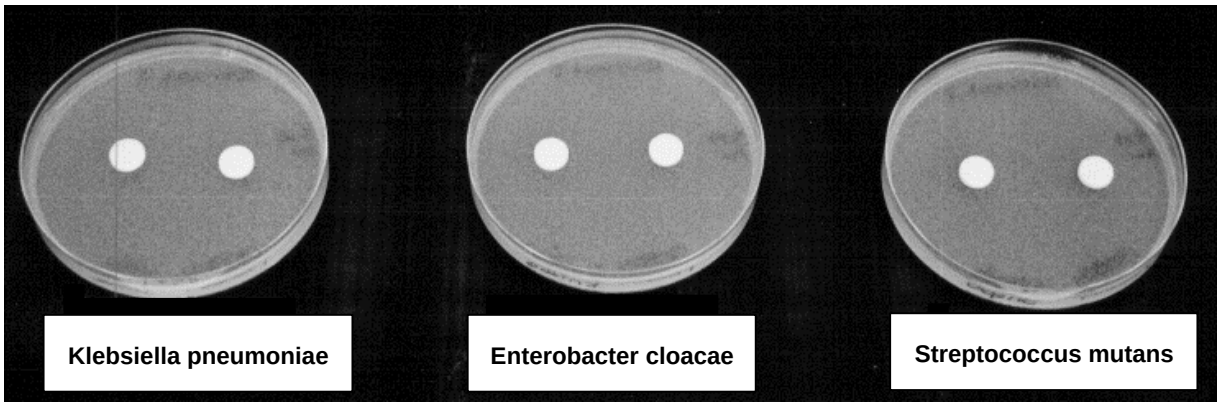


Figure 2: Product A after an incubation period of 18 to 24 hours at 35 °C to 37 °C (Institut Confarma France S.A.R.L.)

6 Toxicological data

On the basis of the existing toxicogical data and tests on Fermit and Fermit N [1-3], it can be concluded that Systemp.inlay and Systemp.onlay do not present a health risk, as the materials are the same with the exception of triclosan, which is contained in Systemp.inlay and Systemp.onlay.

Triclosan is contained in a number of consumer products such as deodorants, tooth pastes (0.6 %) and mouth rinses (0.15 %). On the basis of the published toxicological data, it can be assumed that triclosan does not present a health risk in concentrations of up to 0.6 %.

6.1 Acute oral toxicity (LD-50)

With the data of the individual components [3], the LD-50 of uncured Systemp.inlay and Systemp.onlay can be calculated as > 5000 mg/kg. The acute oral toxicity of the cured material, therefore, is considered to be practically non-toxic. It is a well-known fact that these materials in the cured state are chemically and therefore biologically inert with regard to acute toxicity and do not present a health risk.

6.2 Sensitization

A contact hypersensitivity test was conducted with Fermit N on guinea pigs [1]. Under the given test conditions, no allergic reactions or sensitivity were found.

6.3 Cytotoxicity

A cytotoxicity test was conducted with Fermit N (Agar Overlay) [2]. In this test, Fermit N was shown to be non-cytotoxic.

6.4 Conclusion

On the basis of the available data, a health risk for users and patients can be excluded, if Systemp.inlay and Systemp.onlay are correctly used according to the Instructions for Use.

6.5 Literature

[1] RCC Projekt 351303; Contact Hypersensitivity to Fermit N in Albino Guinea Pigs; Internal Report

[2] RCC Projekt 351314; Cytotixiticy test in vitro: Agar diffusion test with Fermit N, Internal Report

[3] Sicherheitsdatenblätter der Lieferanten

7 Literature

(1) R. Frankenberger, Universität Erlangen-Nürnberg, Kompatibilität von Systemp.Desensitizer mit temporären und permanenten Restaurations-materialien; In-vitro Studie

(2) Niedner, R., Ziegenmeyer, J. (Hrsg.), Dermatika, Wissenschaftliche Verlagsgesellschaft, Stuttgart (1992)

(3) P. Hildelbert et al
A bacterial and dye microleakage study of temporary endo restorative materials
J Dent Res 71 (1992), IADR Abstract 674, p 600

(4) J.M. Espinoza
Materiales de sellapo provosorio; valoracion de hermeticidad
Practica odontologica, Vol 11 (3) (1990) p 11-14

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