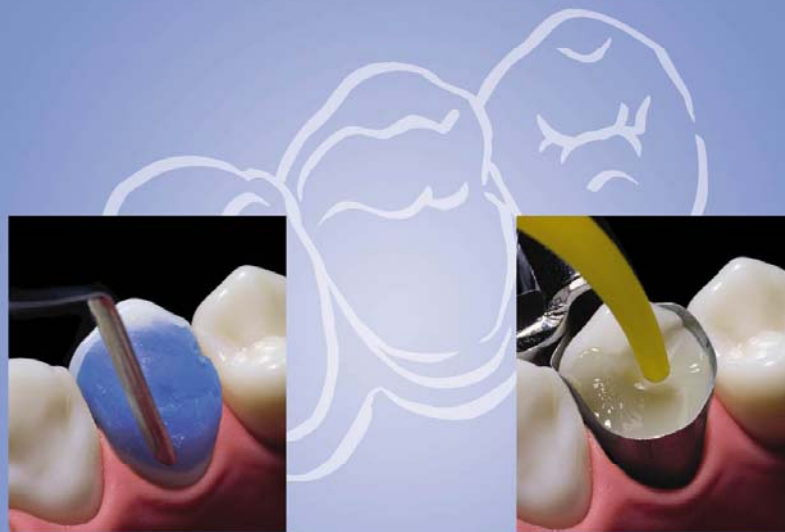


MultiCore®



Scientific Documentation

Contents

1. Introduction.....	3
1.1 Core build-up – A short review	3
1.2 Adhesive build-ups – The state of the art	3
1.3 Objectives of the MultiCore development.....	3
2. Technical data.....	4
3. Materials science investigations on MultiCore.....	5
3.1 Vickers hardness	5
3.2 Flexural strength.....	5
3.3 Flexural modulus	6
3.4 The curing of MultiCore as function of time	6
3.5 Tolerance of MultiCore HB towards hand-mixing	7
3.6 Dentin bonding of MultiCore	7
3.7 Filler particles of MultiCore	8
4. Biocompatibility of MultiCore.....	9
4.1 Composition of MultiCore.....	9
4.2 Toxicity of fillers	9
4.3 Toxicity of dimethacrylates used in MultiCore.....	9
4.4 Mutagenicity data of dimethacrylates used in MultiCore.....	10
4.5 Irritation and sensitization	10
4.6 Conclusions	10
4.7 Literature on toxicology.....	11
5. References and publications.....	11

1. Introduction

1.1 Core build-up – A short review

Materials such as amalgam or glass ionomer cements were formerly used for fabricating core build-ups on vital and non-vital teeth. As these materials had to be anchored primarily in a mechanical way to the remaining tooth structure, it was generally necessary to retain the core build-up by means of an endodontic post.

These therapies, however, had several disadvantages. Core build-ups made of amalgam and the use of metal endodontic posts limited the aesthetics of the restoration due to their lack of translucency. Furthermore, scientific investigations have shown that a post does not reinforce the built-up tooth (Guzy and Nicholls, 1979; Sidoli *et al.*, 1997). On the contrary, while endodontic treatment alone hardly weakens a tooth, the preparation of the root canal for the post in which natural dentin has to be removed significantly reduces the fracture strength of a tooth (Sidoli *et al.*, 1997). Restored teeth become weaker the more natural tooth structure is lost. Particularly MOD defects in which the marginal ridges had to be removed severely weaken the teeth (Reeh *et al.*, 1989).

1.2 Adhesive build-ups – The state of the art

Based on such conclusions, the German Society of Dental Oral and Craniomandibular Sciences published a scientific statement in 2003 (Edelhoff *et al.*, 2003). The following objective was formulated in the statement:

“The build-up of endodontically treated teeth should ensure reliable retention of a permanent restoration by preserving as much as possible of the healthy tooth structure. “

It is specifically mentioned that thanks to the adhesive technique, build-up possibilities are available for numerous clinical situations. These possibilities should be preferred due to minimal invasive procedures as well as the minimization of the risk of a iatrogenic root perforation (Edelhoff *et al.*, 2003).

With their scientifically consolidated statement, the experts from the GSDOM put on record that an adhesive build-up fillings or an adhesive core build-up is the procedure of choice in many clinical situations.

1.3 Objectives of the MultiCore development

The objective in the development of MultiCore was to offer a material with which dentists can efficiently fabricate build-up fillings and core build-ups with their preferred processing techniques. MultiCore is characterized by the following features:

- **Dual-curing:** MultiCore achieves excellent mechanical strength by chemical self-curing alone. By additional light polymerization, the dentist can immediately start with the preparation.
- **Two consistencies:** With the highly viscous MultiCore HB the build-up filling or core build-up can be individually shaped and modelled. MultiCore Flow in a flowable consistency allows core build-ups to be fabricated by placing the material in bulk using matrices.

The present documentation addresses the technical properties of and investigations on MultiCore.

2. Technical data

Composition

	MultiCore HB		MultiCore Flow	
	Base	Catalyst	Base	Catalyst
Dimethacrylates	13.5	13.3	28.1	28.4
Barium glass fillers, Ba-Al-fluoro-silicate glass, Highly dispersed silicon dioxide	75	75	54.9	54.4
Ytterbium trifluoride	11.1	11.1	16.4	16.2
Catalysts, stabilizers and pigments	0.4	0.6	0.6	1

Specifications are in wt %

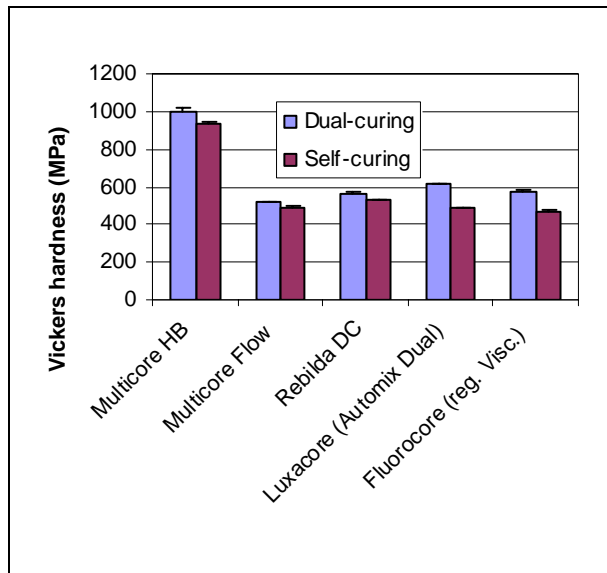
Physical data

	MultiCore HB		MultiCore Flow	
	dual-curing	self-curing	dual-curing	self-curing
Flexural strength (MPa)	140	125	135	120
Modulus of elasticity (MPa)	18'000	14'000	9'000	7'500
Compressive strength (MPa)	250		250	
Vickers hardness (MPa)	1000		510	
Radiopacity (% Al)	300		300	
Water absorption 7 days ($\mu\text{g}/\text{mm}^3$)	14.5		25	
Water solubility 7 days ($\mu\text{g}/\text{mm}^3$)	3		2.5	
Working time at 37°C (s)	90-120		90-120	

In accordance with ISO 4049 – Polymer-based filling, restorative and luting materials

3. Materials science investigations on MultiCore

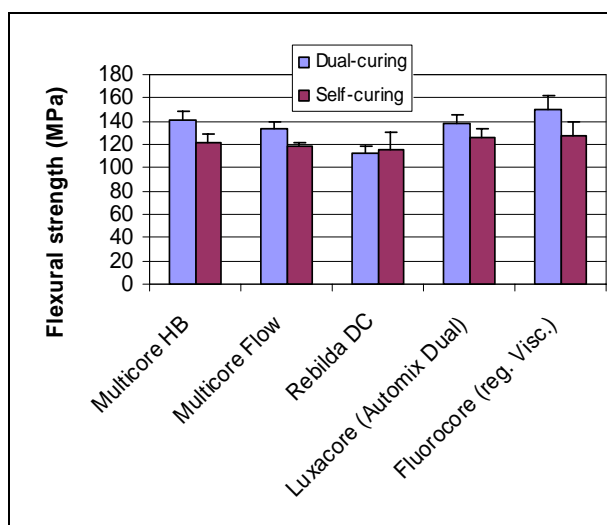
3.1 Vickers hardness



The materials were processed according to the instructions of the manufacturer. All the materials were tested using both the self-curing as well as the dual-curing method. The samples were stored in the dry box for 24 hours at 37°C. Subsequently, the Vickers hardness was measured in compliance with EN ISO 4049. For this purpose, the sample was subjected to a specified load by a pyramid indenter for a defined period of time. The two diagonals of the indentation left in the surface of the material after removal were measured and the hardness calculated.

Investigation: R&D, Ivoclar Vivadent, Schaan

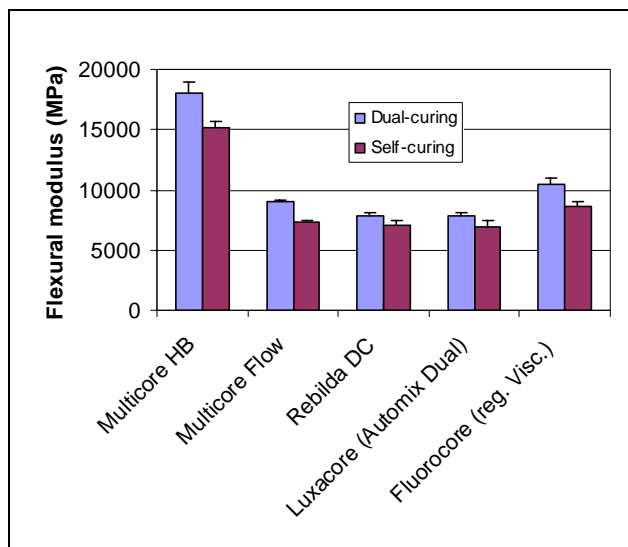
3.2 Flexural strength



The materials were processed according to the manufacturer's instructions using the self- and dual-curing methods. For dual-curing purposes, the material was additionally polymerized with a Heliolux light for 40 s with a light intensity of 500 mW/cm². After 24 hours, the flexural strength was measured by means of a Zwick universal testing machine in compliance with EN ISO 4049.

Investigation: R&D, Ivoclar Vivadent, Schaan

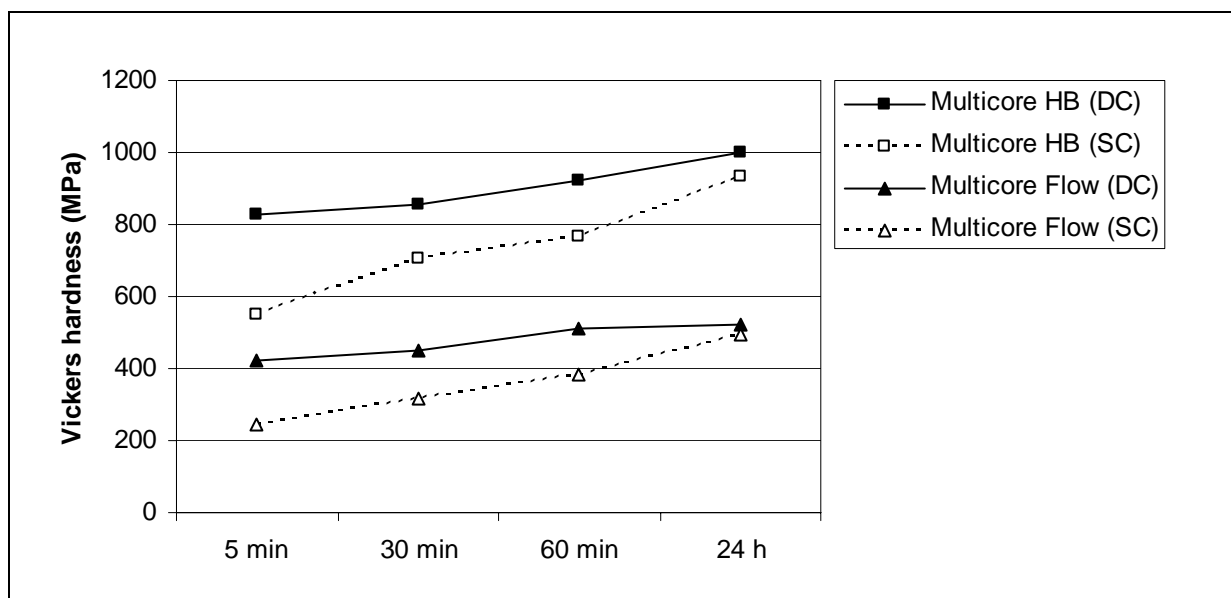
3.3 Flexural modulus



The materials were processed according to the instructions of the manufacturer using the self-curing as well as the dual-curing method. After 24 h, the flexural modulus was measured with a Zwick universal testing machine in compliance with EN ISO 4049.

Investigation: R&D, Ivoclar Vivadent, Schaan

3.4 The curing of MultiCore as function of time



When processing a self- or dual-curing composite material for core build-ups, the time needed for curing plays a decisive role. The material has to set sufficiently in order to be processed with rotating instruments. Therefore, the Vickers hardness of MultiCore HB and MultiCore Flow was measured as a function of time both for self-curing as well as for dual-curing applications with light.

If curing is additionally initiated by light, MultiCore Flow and MultiCore HB can be processed without delay. What is noteworthy is that both materials achieve the same Vickers hardness after 24 hours of self-curing as they do if they are additionally light-cured.

Investigation: R&D, Ivoclar Vivadent, Schaan

3.5 Tolerance of MultiCore HB towards hand-mixing

The mixing ratio of the base and catalyst paste may vary for all hand-mixed self-curing or dual-curing materials, as the quantity of the material used depends on the operator's visual judgement. Therefore, the material has to cure reliably while offering manageable working times even if slight deviations of the mixing ratio occur. MultiCore HB was tested with these properties in mind.

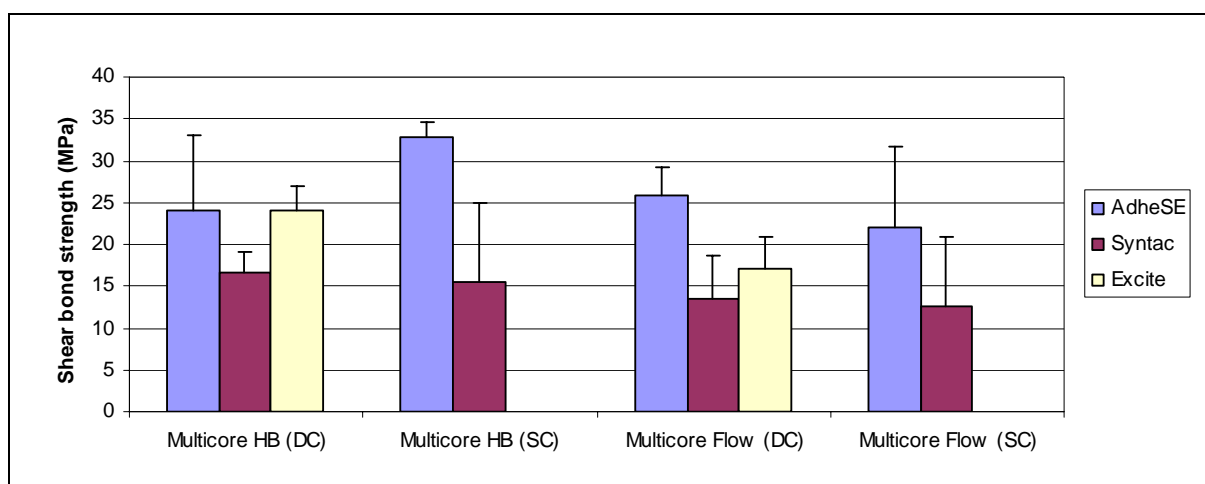
Mixing ratio (Base : Catalyst)	2 : 1	1 : 1	1 : 2
Working time (s)	120 – 150	120 – 132	120 – 126
Flexural strength self-curing (MPa)	117 ± 6	122 ± 7	123 ± 10
Flexural strength dual-curing (MPa)		141 ± 7	143 ± 7
Flexural modulus self-curing (MPa)	12,400 ± 1,200	15,100 ± 600	13,400 ± 1,500
Flexural modulus dual-curing (MPa)		18,100 ± 900	16,700 ± 800

Investigation: R&D, Ivoclar Vivadent, Schaan

Result: The data show that large deviations from the stipulated mixing ratio of 1:1 neither significantly influence the working time nor the physical strength of MultiCore HB.

3.6 Dentin bonding of MultiCore

The bond of MultiCore to dentin was tested with Syntac, AdheSE and Excite. First, the adhesive was applied to dentin according to the Instructions for Use and light cured in all cases. Subsequently, MultiCore was either light cured (DC) or self-cured (SC) if Syntac or AdheSE were used. In contrast, a dualcuring composite has to be light cured if Excite is used (see Instructions for Use). The following figure shows the shear bond strength on bovine dentin, which was measured in compliance with ISO/TS 11405



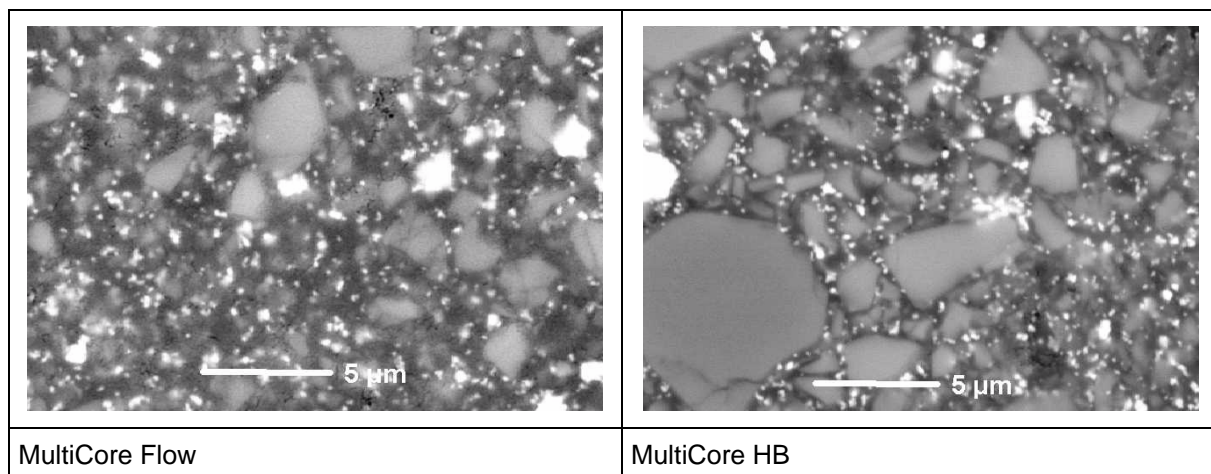
Investigation: R&D, Ivoclar Vivadent, Schaan

3.7 Filler particles of MultiCore

The development of core build-up composites implies other priorities than those for the development of restoratives. Composites for Class I and II fillings should primarily feature minimum wear. However, for composites for the anterior region, aesthetics and polishability and the surface lustre in particular are decisive properties. Minimum wear and good polishability are achieved with microfillers. These features, however, are irrelevant for core build-up materials. The focus here is set on high strength and good handling properties. For this purpose, especially the viscosity has to be accurately adjusted.

MultiCore HB is highly viscous and can be conveniently modelled and shaped. Nevertheless, the material should allow hand-mixing. MultiCore Flow has to feature a low viscosity so that the material can be dispensed from the double-barrel cartridge and the mixing tip. However, it should not be too flowable to prevent the material from flowing away from the application field.

The mixing properties, physical strength, viscosity and the handling characteristics depend to a large extent on the filler particles used. The following figures show the fillers of MultiCore.



Samples made with MultiCore were polished and examined under the scanning electron microscope (SEM). The bright white particles are ytterbium trifluoride, which is responsible for the radiopacity of the material. Therefore, ytterbium trifluoride reflects most of the electrons under the SEM and thus appears white. The polymer matrix and silicon dioxide fillers are dark. Fillers of barium glass and Ba-Al-fluorosilicate glass appear grey. They have diameters of up to several micrometers. Big filler particles result in high physical strength and allow high filler contents to be achieved.

Images: R&D, Ivoclar Vivadent, Schaan

4. Biocompatibility of MultiCore

4.1 Composition of MultiCore

MultiCore HB and MultiCore Flow are composed of dimethacrylates and fillers. The monomer matrix consists of Bis-GMA, urethane dimethacrylate and triethylene glycol dimethacrylate. The inorganic fillers are barium glass, Ba-Al-fluorosilicate glass, silicon dioxide and ytterbium trifluoride. The present documentation first deals with the toxicity of the fillers and then addresses that of the monomers.

4.2 Toxicity of fillers

Glass and silicon dioxide fillers are considered to be chemically inert. During the polymerization process, the fillers are additionally embedded in a resin matrix. Therefore, these fillers do not pose a toxicological risk. According to the materials safety data sheet, the LD₅₀-value for the acute oral toxicity of silicon dioxide in rats is greater than 10,000 mg/kg [1]. The toxicity of the ytterbium trifluoride filler, which is responsible for the excellent radiopacity of Ivoclar Vivadent composites, was tested in rats. At the maximum dose of 5000 mg/kg tested, none of the rats died and no pathologic organ changes were observed in any rat [2]. A test also revealed that ytterbium trifluoride shows no radioactivity beyond natural background [3].

This information shows that the filler particles used in MultiCore *per se* pose no toxicological risk. Therefore, the toxic properties of composite materials are essentially determined by their monomer matrix.

4.3 Toxicity of dimethacrylates used in MultiCore

Cytotoxicity data

Compound	XTT ₅₀	Cell line	Ref.
Urethane dimethacrylate	600 µg/ml	L929	4
Bis-GMA	25 µg/ml	L929	4
Triethylene glycol dimethacrylate	25 µg/ml	L929	4

Acute oral toxicity data

Compound	LD ₅₀	Species	Ref.
Urethane dimethacrylate	> 5000 mg/kg	Rats	5
Bis-GMA	> 5000 mg/kg	Rats	5
Triethylene glycol dimethacrylate	10'837 mg/kg	Rats	5

Evaluation of toxicological data on the MultiCore monomer:

Cytotoxicity data of all dimethacrylates used in MultiCore materials is available. The high LD₅₀-value of Bis-GMA and triethylene glycol dimethacrylate demonstrates that these dimethacrylates do not exhibit relevant oral toxicity. These results are confirmed by clinical experience with dental composite materials of more than 20 years.

The catalysts, stabilizers and pigments employed in the base and catalyst pastes of MultiCore have already been employed in other dental materials for many years without problems. Hence, it can be assumed that they do not pose an unknown toxicological risk for the patient.

4.4 Mutagenicity data of dimethacrylates used in MultiCore

Ames test

	Result w/o S9	Test conc.	Result w S9	Test conc.	Ref.
Urethane dimethacrylate	neg.	5000 µg/plate	neg.	5000 µg/plate	6
Bis-GMA	neg.	5000 µg/plate	neg.	5000 µg/plate	6
Triethylene glycol dimethacrylate	neg.	5000 µg/plate	neg.	5000 µg/plate	6

To assess the carcinogenic risk of a medical device, mutagenicity tests are carried out, as cellular mutation is the initial step in the development of cancer. Today, such tests are carried out *in vitro* with bacterial or cell cultures. The advantage of *in vitro* tests is that they are usually more sensitive than *in vivo* carcinogenicity studies. A disadvantage of *in vitro* tests with cell cultures is that they may not show up components which only become mutagenic after they have been metabolized in tissues such as the liver. To simulate such 'metabolic activation' components are incubated with extracts of liver tissues (S9 mix). Under such conditions, metabolic products are formed, which also can occur *in vivo* upon exposure to the test material. Therefore, mutagenicity results are presented without metabolic (w/o S9) and with metabolic activation (w S9) in the table above. The most commonly employed test for mutagenicity is the *Salmonella typhimurium* reverse mutation test (Ames test).

4.5 Irritation and sensitization

Like all dental composite materials MultiCore contains dimethacrylates. Such materials may have an irritating effect on predisposed persons and may cause sensitization to methacrylates. This can lead to allergic contact dermatitis. These reactions can be minimized by clean working conditions and avoiding contact of the unpolymerized material with the skin. Commonly employed gloves, e.g. latex or vinyl gloves, do not provide effective protection against sensitization to methacrylates. Allergic reactions are extremely rare in patients but are increasingly observed in dental personnel, who handles uncured composite materials on a daily basis [7, 8].

4.6 Conclusions

The toxicological evaluation shows that according to the current knowledge MultiCore

- is no more toxic than dental composite materials in general.
- is not mutagenic.
- contains methacrylates. Therefore, the material can lead to sensitization towards methacrylates. This risk which is intrinsic to all methacrylate-based dental materials is particularly important for dental technicians who handle uncured material.

In summary, the information currently available shows that MultiCore provides the same level of safety as other composite materials presently used in dentistry with respect to toxicity, mutagenicity, irritation and sensitization.

4.7 Literature on toxicology

- [1] Sicherheitsdatenblatt (93/112/EG). April 2000.
- [2] Acute Oral Toxicity (LD₅₀) Study with Ytterbiumtrifluoride, anhydrous in Rats. RCC Project 048881. July 1985.
- [3] Certificate – Determination of radioactivity. RCC Project 045224. February 1985.
- [4] In vitro cytotoxicity assay: evaluation of materials for medical devices (XTT-test) with five monomers. RCC Project 652768, May 1997.
- [5] Schmalz G (1998) The biocompatibility of non-amalgam dental filling materials. *Eur. J. Oral. Sci.* 106:696-706.
- [6] Schweikel H, Schmalz G, Rackebrandt K (1998). The mutagenic activity of unpolymerized resin monomers in *Salmonella typhimurium* and V79 cells. *Mut. Res.* 415:119-130.
- [7] Biocompatibility of resin-modified filling materials. Geurtsen W. *Crit. Rev. Oral Biol. Med.* 11:333-355, 2000.
- [8] Self-reported occupational dermatological reactions among Danish dentists. Munksgaard EC, Hansen EK, Engen T, Holm U. *Eur. J. Oral Sci.* 104:396-402, 1996.

5. References and publications

Edelhoff D, Heidemann D, Kern M, Weigl P (2003). Gemeinsame Stellungnahme der DGZMK, der DGZPW und der DGZ - Aufbau endodontisch behandelter Zähne. *Zahnärztliche Mitteilungen* 93:42-44.

Guzy GE, Nicholls JI (1979). In vitro comparison of intact endodontically treated teeth with and without endo-post reinforcement. *J Prosthet Dent* 42:39-44.

Reeh ES, Messer HH, Douglas WH (1989). Reduction in tooth stiffness as a result of endodontic and restorative procedures. *J Endod* 15:512-516.

Sidoli GE, King PA, Setchell DJ (1997). An in vitro evaluation of a carbon fiber-based post and core system. *J Prosthet Dent* 78:5-9.

This documentation contains a survey of internal and external scientific data ("Information"). The documentation and Information have been prepared exclusively for use in-house by Ivoclar Vivadent and for external Ivoclar Vivadent partners. They are not intended to be used for any other purpose. While we believe the Information is current, we have not reviewed all of the Information, and we cannot and do not guarantee its accuracy, truthfulness, or reliability. We will not be liable for use of or reliance on any of the Information, even if we have been advised to the contrary. In particular, use of the information is at your sole risk. It is provided "as-is", "as available" and without any warranty express or implied, including (without limitation) of merchantability or fitness for a particular purpose.

The Information has been provided without cost to you and in no event will we or anyone associated with us be liable to you or any other person for any incidental, direct, indirect, consequential, special, or punitive damages (including, but not limited to, damages for lost data, loss of use, or any cost to procure substitute information) arising out of your or another's use of or inability to use the Information even if we or our agents know of the possibility of such damages.

Ivoclar Vivadent AG
Research and Development
Scientific Services
Bendererstrasse 2
FL - 9494 Schaan
Liechtenstein

Contents: Dr Urs Lendenmann
Issued: February 2004
