

Contents

1	Basic Aspects	1	2.2.4.2	Implantation Tests	19
	<i>G. Schmalz and D. Arenholt-Bindslev</i>		2.2.4.3	Pulp Damage and the Pulp/ Dentin Test	20
1.1	Introduction	1	2.2.4.4	Mucosal Damage and Mucosa Usage Tests	23
1.2	Health Effects	2	2.2.4.5	Periapical Tissue Damage and Endodontic Usage Test	23
1.2.1	Systemic Toxicity	3	2.2.4.6	Intraosseous Implant Test	24
1.2.2	Local Reactions	3	2.2.5	Allergenic Properties	24
1.2.3	Allergies	3	2.2.6	Other Reactions	25
1.2.4	Other Effects	4	2.2.6.1	Mutagenicity	25
1.3	Risk	5	2.2.6.2	Teratogenic Effects and Influence on Reproduction	26
1.3.1	Risk Analysis	6	2.2.7	Clinical Studies	26
1.3.2	Risk Evaluation/Risk Perception	6	2.3	Diagnostic Tests on Patients	27
1.3.3	Risk Management	7	2.3.1	Allergy Tests	28
1.3.4	Threshold Values	7	2.3.1.1	Patch Test	28
1.4	Effective Dose/Concentration	7	2.3.1.2	Prick Test	30
1.4.1	Principle of Dose	7	2.3.1.3	Radioallergosorbent Test (RAST)	32
1.4.2	Effective Versus Applied Dose	8	2.3.1.4	Immunotoxicological Test Methods	32
1.4.3	Low-Level Dose Range	8	2.3.2	Measurement of Intraoral Voltage	32
1.4.4	Placebo/Nocebo Effect	9	2.3.3	Evaluation of Pulp Sensitivity	33
1.5	Interdisciplinary Collaboration	10	2.3.4	Analysis of Intraoral Alloys	34
	Conclusions for the Dental Practitioner	10	2.3.5	Analysis of Metals in Saliva and Biopsies	34
	Appendix	10	2.3.6	Test Methods of “Alternative Medicine”	36
	References	11		Appendix	39
				Conclusions for the Dental Practitioner	39
				References	40
2	Determination of Biocompatibility	13	3	Regulations and Standards	45
	<i>G. Schmalz</i>			<i>G. Schmalz and P.L. Fan</i>	
2.1	Introduction	13	3.1	Introduction	45
2.2	Evaluation of Materials	13	3.2	Legal Regulations in the European Union	45
2.2.1	Principles of Biocompatibility Testing	13	3.2.1	Medical Device Directive	45
2.2.1.1	Overview of Test Methods	13	3.2.1.1	Area of Jurisdiction and Definitions	46
2.2.1.2	Phenomena and Mechanisms	14			
2.2.1.3	Strategies for Evaluating Biocompatibility	14			
2.2.2	Test Materials	15			
2.2.3	Systemic Toxicity	16			
2.2.4	Local Toxicity and Tissue Compatibility	16			
2.2.4.1	Cell Cultures	17			

3.2.1.2	Essential Requirements	46	4.3.1.4	Mercury Concentrations in Blood, Feces, and Urine	67
3.2.1.3	Classification of Medical Devices	46	4.3.1.5	Mercury in Saliva	69
3.2.1.4	Conformity Assessment	46	4.3.1.6	Mercury in Scalp Hair	70
3.2.1.5	Responsibilities and Liability	48	4.3.1.7	Transplacental Distribution of Mercury from Dental Amalgam	70
3.2.2	European Chemical Legislation (REACH)	48	4.3.1.8	Mercury in Breast Milk	71
3.3	Legal Regulations in the United States	49	4.3.2	Immunotoxicity	72
3.3.1	Food, Drug, and Cosmetic Act and Medical Device Amendments	49	4.3.3	Neurotoxicity	73
3.3.2	Classification of Devices	49	4.3.4	Fertility Dysfunction and Teratogenicity	74
3.3.3	Premarket Notification and FDA Review	50	4.4	Local Toxic Reactions	76
3.3.4	Records and Reports on Devices	50	4.4.1	Cytotoxicity and Implantation Studies	76
3.4	Legal Regulations in Australia	50	4.4.2	Pulp Reactions	76
3.5	Legal Regulations in Japan	51	4.4.3	Reactions of the Oral Mucosa	77
3.5.1	Classification and Marketing Authorization	51	4.4.3.1	Mercury	77
3.5.2	Marketing and Manufacturing Licenses	52	4.4.3.2	Amalgam	78
3.5.3	Marketing Authorization	52	4.5	Allergies	80
3.6	Labeling	52	4.6	Carcinogenicity	85
3.7	Standards	54	4.7	Clinical Studies	85
3.7.1	Harmonized Standards	54	4.7.1	Relationships Among Symptoms, General Diseases, and Amalgam Fillings	85
3.7.2	OECD Guidelines	54	4.7.2	Removal of Amalgam Restorations	88
3.7.3	Relevant Standards	55	4.7.2.1	Effect on Health Improvement	88
3.8	Surveillance and Reporting Systems	56	4.7.2.2	Mercury Burden in Relation to Removal of Amalgam Fillings	88
	Conclusions for the Dental Practitioner	57	4.8	Public Discussion	89
	References	57		Conclusions for the Dental Practitioner	90
4	Dental Amalgam	59		References	91
	<i>D. Arenholt-Bindslev and P. Hørsted-Bindslev</i>		5	Resin-Based Composites	99
4.1	Introduction	59		<i>G. Schmalz</i>	
4.2	Composition and Setting Reaction	60	5.1	Introduction	99
4.2.1	Mercury-Based Amalgams	60	5.2	Basic Material Properties	99
4.2.1.1	Setting Reaction	60	5.2.1	Composition	99
4.2.1.2	Mercury Emission and Corrosion Products	60	5.2.2	Setting Reaction	104
4.2.1.3	New Alloys	63	5.2.3	Release of Substances	105
4.2.2	Mercury-Free Amalgams	63	5.2.4	Biodegradation of Monomers	107
4.3	Systemic Toxicity	64	5.3	Systemic Toxicity	108
4.3.1	Metabolism, Distribution, and Excretion of Mercury	64	5.3.1	Preclinical Studies	108
4.3.1.1	Release and Uptake	64	5.3.2	Estrogenicity	108
4.3.1.2	Proposed Threshold Values	65	5.3.3	Clinical Symptoms and Complaints	109
4.3.1.3	Deposition in Organs	66	5.4	Local Toxicity and Tissue Compatibility	110
			5.4.1	Cytotoxicity	110
			5.4.2	Influence on Cell Metabolism	112

5.4.3	Antimicrobial Properties	112	6.2.3.6	Gingival Reactions	146
5.4.4	Implantation Tests	114	6.2.4	Mutagenicity and Carcinogenicity	147
5.4.5	Pulp Reactions	114	Conclusions for the Dental Practitioner		147
5.4.5.1	Diffusion Through Dentin	114	References		147
5.4.5.2	Usage Tests	115	6.3	Glass Ionomer Cements	149
5.4.5.3	Bacteria at the Cavity Floor	117	<i>G. Schmalz</i>		
5.4.5.4	Direct Pulp Capping with Dentin Adhesives	117	6.3.1	Basic Material Properties	149
5.4.5.5	Thermal Effects of Light-Curing Units	119	6.3.1.1	Composition	149
5.4.5.6	Postoperative Sensitivity and Clinical Studies	119	6.3.1.2	Setting Reaction	149
5.4.6	Hazards for Eyes	120	6.3.1.3	Release and Degradation	150
5.4.7	Inhalation of Resin-Based Composite Particles	121	6.3.2	Systemic Toxicity and Allergies	151
5.4.8	Reactions of Gingiva and Oral Mucosa	121	6.3.3	Local Toxicity and Tissue Compatibility	151
5.5	Allergies	121	6.3.3.1	Cytotoxicity	151
5.5.1	Prevalence	122	6.3.3.2	Antimicrobial Properties	152
5.5.2	Preclinical Studies	123	6.3.3.3	Implantation Studies	153
5.5.3	Allergic Reactions in Patients	124	6.3.3.4	Pulp Reactions	154
5.5.4	Allergic Reactions in Dental Personnel	125	6.3.3.5	Reactions of Gingiva and Oral Mucosa	155
5.6	Mutagenicity and Carcinogenicity	127	6.3.4	Mutagenicity and Carcinogenicity	156
5.7	Public Discussion	127	Conclusions for the Dental Practitioner		156
Conclusions for the Dental Practitioner		128	References		156
Appendix		129	6.4	Zinc Oxide and Eugenol Cements	160
References		130	<i>G. Schmalz and B. Thonemann</i>		
6	Cements and Ceramics	139	6.4.1	Basic Material Properties	160
6.1	Introduction	139	6.4.1.1	Composition and Setting Reaction	160
<i>G. Schmalz</i>			6.4.1.2	Release and Degradation	160
References		140	6.4.2	Systemic Toxicity and Allergies	160
6.2	Zinc Phosphate Cements	141	6.4.2.1	Preclinical Allergy Studies	160
<i>H. Stanley †</i>			6.4.2.2	Allergic Reactions of Patients	160
6.2.1	Basic Material Properties	141	6.4.2.3	Allergic Reactions of Dental Personnel	161
6.2.1.1	Composition and Setting Reaction	141	6.4.3	Local Toxicity and Tissue Compatibility	162
6.2.1.2	Release and Degradation	142	6.4.3.1	Cytotoxicity	162
6.2.2	Systemic Toxicity and Allergies	142	6.4.3.2	Antimicrobial Properties	162
6.2.3	Local Toxicity and Tissue Compatibility	143	6.4.3.3	Implantation Studies	162
6.2.3.1	Cytotoxicity	143	6.4.3.4	Pulp Reactions	162
6.2.3.2	Implantation Studies	143	6.4.4	Mutagenicity and Carcinogenicity	163
6.2.3.3	Pulp Reactions – Histopathology	143	Conclusions for the Dental Practitioner		163
6.2.3.4	Pulp Reactions – Clinical Observations	145	References		164
6.2.3.5	Microgaps (“Microleakage”)	146	6.5	Calcium Hydroxide Cements	166
			<i>H. Stanley (†) and B. Thonemann</i>		
			6.5.1	Basic Material Properties	166

6.5.1.1	Composition and Setting Reaction	166	7.2.5	Antimicrobial Properties	194
6.5.1.2	Release and Degradation	167	7.2.6	Clinical Data and Mandibular Nerve Injuries	194
6.5.2	Systemic Toxicity and Allergies	168	7.3	Root Canal Sealers	195
6.5.2.1	Calcium Hydroxide	168	7.3.1	Overview	195
6.5.2.2	Alternatives to Calcium Hydroxide	168	7.3.2	Zinc Oxide Eugenol Sealers	195
6.5.3	Local Toxicity and Tissue Compatibility	169	7.3.2.1	Composition	195
6.5.3.1	Cell Cultures	169	7.3.2.2	Setting Reaction and Release of Substances	196
6.5.3.2	Antimicrobial Properties	169	7.3.2.3	Systemic Toxicity and Allergies	196
6.5.3.3	Pulp Reactions	169	7.3.2.4	Local Toxicity and Tissue Compatibility	196
6.5.4	Mutagenicity and Carcinogenicity	173	7.3.2.5	Aspergillosis	198
Conclusions for the Dental Practitioner		173	7.3.2.6	Antimicrobial Properties	199
References		174	7.3.2.7	Clinical Data and Mandibular Nerve Injuries	199
6.6	Dental Ceramics	177	7.3.3	Polyketone-Based Sealers	200
	<i>G. Schmalz</i>		7.3.3.1	Composition, Setting Reaction, and Release of Substances	200
6.6.1	Basic Material Properties	177	7.3.3.2	Systemic Toxicity and Allergies	200
6.6.1.1	Composition	177	7.3.3.3	Local Toxicity	200
6.6.1.2	Release and Degradation	179	7.3.4	Epoxy-Based Sealers	201
6.6.2	Systemic Toxicity and Allergies	180	7.3.4.1	Setting Reaction and Release of Substances	201
6.6.3	Local Toxicity and Tissue Compatibility	180	7.3.4.2	Systemic Toxicity and Allergies	201
6.6.3.1	Cell Cultures	180	7.3.4.3	Local Toxicity	202
6.6.3.2	Implantation Studies	181	7.3.4.4	Mutagenicity	202
6.6.3.3	Pulp Reactions	182	7.3.4.5	Antimicrobial Properties	203
6.6.3.4	Gingival Reactions	182	7.3.4.6	Clinical Studies and Mandibular Nerve Injuries	203
6.6.3.5	Periapical Area	183	7.3.5	Calcium-Hydroxide-Based Sealers	203
6.6.3.6	Implants	183	7.3.5.1	Composition	203
6.6.4	Mutagenicity and Carcinogenicity	183	7.3.5.2	Setting Reaction and Release of Substances	203
Conclusions for the Dental Practitioner		184	7.3.5.3	Systemic Toxicity and Allergies	203
References		185	7.3.5.4	Local Toxicity and Tissue Compatibility	204
7	Root Canal Filling Materials	187	7.3.5.5	Antimicrobial Properties	205
	<i>G. Schmalz</i>		7.3.5.6	Clinical Data and Mandibular Nerve Injury	205
7.1	Introduction	187	7.3.6	Mineral Trioxide Aggregate	205
7.1.1	Classification	187	7.3.6.1	Composition and Setting Reaction	206
7.1.2	Requirements	188	7.3.6.2	Release of Substances	206
7.1.3	Clinical Data and Biocompatibility	189	7.3.6.3	Systemic Toxicity and Allergy	206
7.1.4	Mandibular Nerve Injuries	189	7.3.6.4	Local Toxicity and Tissue Compatibility	206
7.1.5	Rubber Dam	190	7.3.6.5	Antimicrobial Properties	207
7.2	Gutta-Percha	191	7.3.6.6	Mutagenicity	207
7.2.1	Composition	191	7.3.7	Calcium Phosphate Cement	207
7.2.2	Release and Degradation	191	7.3.8	Silicones	208
7.2.3	Systemic Toxicity and Allergies	191			
7.2.4	Local Toxicity and Tissue Compatibility	192			

7.3.8.1	Composition	208	8.4.2	Implanted Dental Alloys	233
7.3.8.2	Systemic Toxicity and Allergy	208	8.4.3	Nonimplanted Dental Alloys	234
7.3.8.3	Local Toxicity and Tissue Compatibility	208	8.4.3.1	Cell Cultures	234
7.3.8.4	Antimicrobial Properties	208	8.4.3.2	Adhesion of Bacteria	236
7.3.9	Resin-Based Sealers	208	8.4.3.3	Implantation Tests	237
7.3.9.1	Composition and Setting Reactions	208	8.4.4	Local Clinical Symptoms and Complaints	237
7.3.9.2	Degradation and Release of Substances	208	8.4.4.1	Subjective Complaints	237
7.3.9.3	Local Toxicity and Tissue Compatibility	208	8.4.4.2	Gingival Inflammation	238
7.3.9.4	Antimicrobial Properties	210	8.4.4.3	Alterations of the Tongue	239
7.3.9.5	Clinical Data	210	8.4.4.4	Palatal Erythema	239
7.4	Materials for Retrograde Root Canal Fillings	210	8.4.4.5	Lichenoid Reactions	239
7.4.1	Composition and Setting Reaction	211	8.5	Allergies	240
7.4.2	Systemic Toxicity and Allergies	211	8.5.1	Mechanisms	240
7.4.3	Local Toxicity and Tissue Compatibility	211	8.5.2	Diagnosis and Frequency of Allergies to Metal Ions	241
7.4.4	Clinical Data	212	8.5.3	Clinical Symptoms	242
Conclusions for the Dental Practitioner		213	8.6	Mutagenicity, Carcinogenicity, and Teratogenicity	242
References		213	8.7	Public Concerns and Controversies	244
8	Dental Alloys	221	8.7.1	Palladium in Dental Alloys	246
	<i>J. C. Wataha and G. Schmalz</i>		8.7.2	Nickel in Dental Alloys	246
8.1	Introduction	221	Conclusions for the Dental Practitioner		248
8.2	Basic Material Properties	221	Appendix		249
8.2.1	Composition	221	References		250
8.2.1.1	Elements	221	9	Polymethylmethacrylate Resins	255
8.2.1.2	Weight Percentage vs. Atomic Percentage	222		<i>W. Geurtsen</i>	
8.2.1.3	Phases	223	9.1	Introduction	255
8.2.1.4	Analysis of Dental Alloys	223	9.2	Basic Material Properties	255
8.2.2	Corrosion and Release of Elements	224	9.2.1	Composition and Setting Reaction	255
8.2.2.1	Fundamentals	224	9.2.2	Release of Substances and Degradation	256
8.2.2.2	Implanted Dental Alloys	227	9.3	Systemic Toxicity	258
8.2.2.3	Nonimplanted Dental Alloys	227	9.4	Local Toxicity and Tissue Compatibility	259
8.3	Systemic Toxicity	228	9.4.1	Cytotoxicity	259
8.3.1	Absorption, Distribution, and Excretion	229	9.4.2	Microbial Effects	261
8.3.2	Implanted Dental Alloys	230	9.4.3	Implantation Studies	262
8.3.3	Nonimplanted Dental Alloys	231	9.4.4	Pulp Reactions	262
8.3.4	Clinical Symptoms and Complaints	232	9.4.5	Reactions of the Gingiva and Oral Mucosa	262
8.4	Local Toxicity and Tissue Compatibility	232	9.4.6	Burning Mouth Syndrome	263
8.4.1	Corrosion and Local Toxicity	232	9.5	Allergies	264
			9.6	Mutagenicity and Carcinogenicity	265
			Conclusions for the Dental Practitioner		266
			References		267

10	Oral Hygiene Products	271	11.2.5	Mutagenicity	299
	<i>A. Richards</i>		11.3	Periodontal Dressings	299
10.1	Introduction	271	11.3.1	Basic Material Properties	300
10.2	Toothpastes and Mouthwashes	271	11.3.1.1	Composition	300
10.2.1	Systemic Toxicity	272	11.3.1.2	Setting Reaction and Release of Substances	300
10.2.1.1	Acute Systemic Toxicity	272	11.3.2	Systemic Toxicity	300
10.2.1.2	Chronic Systemic Toxicity	274	11.3.3	Local Toxicity and Tissue Compatibility	301
10.2.2	Local Toxicity and Biocompatibility	276	11.3.3.1	Cytotoxicity	301
10.2.2.1	Mechanical Abrasion	276	11.3.3.2	Implantation Tests	301
10.2.2.2	Hard Tissue Erosion	277	11.3.3.3	Local Reactions in the Oral Cavity	301
10.2.2.3	Soft Tissue Reaction	277	11.3.3.4	Antimicrobial Properties	302
10.2.2.4	Detergents	278	11.3.4	Allergies	302
10.2.2.5	Alcohol	279	11.3.5	Mutagenicity	302
10.2.2.6	Chlorhexidine	279	11.4	Suture Materials	303
10.2.3	Allergies	279	11.4.1	Basic Material Properties	303
10.2.3.1	Prevalence	279	11.4.1.1	Composition	303
10.2.3.2	Allergy Testing	280	11.4.1.2	Degradation	303
10.2.3.3	Allergens	280	11.4.2	Systemic Toxicity	303
10.2.4	Mutagenicity, Carcinogenicity, and Teratogenicity	282	11.4.3	Local Toxicity and Tissue Compatibility	303
10.3	Tooth Bleaching Agents	284	11.4.3.1	Reactions at the Suture Site	304
10.3.1	Carbamide Peroxide	284	11.4.3.2	Bacterial Colonization	304
10.3.2	Systemic Toxicity	284	11.4.4	Allergies	305
10.3.3	Local Toxicity and Tissue Compatibility	285	11.4.5	Mutagenicity	306
10.4	Fluoride Varnishes and Gels	286	Conclusions for the Dental Practitioner	306	
10.4.1	Gels	286	Appendix	307	
10.4.2	Varnishes	287	References	307	
10.4.3	Vehicle Substances	287			
Conclusions for the Dental Practitioner	288				
References	289				
11	Materials for Short-Term Application in the Oral Cavity	293	12	Occupational Exposures	311
	<i>G. Schmalz</i>			<i>A. Hensten and N. Jacobsen</i>	
11.1	Introduction	293	12.1	General Aspects	311
11.2	Impression Materials	294	12.1.1	Introduction	311
11.2.1	Basic Material Properties	294	12.1.2	Exposure Modalities	312
11.2.1.1	Composition	294	12.1.3	Absorption Routes	312
11.2.1.2	Setting Reaction, Release, and Degradation	295	12.1.4	Nature of Reactions	312
11.2.2	Systemic Toxicity	295	12.2	Clinical Symptoms and Related Materials	313
11.2.3	Local Toxicity and Tissue Compatibility	295	12.2.1	Historic Aspects	313
11.2.3.1	Cytotoxicity	295	12.2.2	Nondermal Reactions	313
11.2.3.2	Implantation Tests	296	12.2.2.1	Amalgam-Related and Mercury- Related Hazards	313
11.2.3.3	Periodontal and Pulpal Damage	297	12.2.2.2	Methylmethacrylate-Related Reactions	314
11.2.4	Allergies	299	12.2.2.3	Reactions Related to Grinding Dusts and Fumes	314
			12.2.2.4	Other Nondermal Reactions	315
			12.2.3	Dermal Reactions	315

12.2.4	Relevant Substances and Materials	316	14.2	Delayed Allergic Reactions (Cell Mediated)	338
12.2.4.1	Metals	316	14.2.1	Clinical Picture	338
12.2.4.2	Polymer-Associated Substances	317	14.2.2	Verified Contact Allergic Reactions to Dental Materials and Substances Released by Dental Materials	340
12.2.4.3	Miscellaneous	317	14.2.2.1	Dental Metals	340
12.2.4.4	Rubber Chemicals	317	14.2.2.2	Rare Metals	345
12.3	Prophylactic Measures and Safety Precautions	318	14.2.2.3	Acrylate-Based Materials	345
12.3.1	General Considerations	318	14.2.2.4	Activators and Inhibitors	349
12.3.2	Handling of Dental Materials	319	14.2.2.5	Epoxy Compounds	349
12.3.2.1	“No-Touch” Technique for Resin-Based Materials	319	14.2.2.6	UV Absorbers	350
12.3.2.2	Amalgam and Mercury Precautions	319	14.2.2.7	Root Canal Sealers and Cavity Liners	350
12.3.2.3	Barrier Equipment	320	14.2.2.8	Antimicrobials	351
Appendix		321	14.2.2.9	Other Disinfectants	352
Conclusions for the Dental Practitioner		321	14.2.2.10	Fragrances and Colophony	352
References		322	14.2.3	Epicutaneous Test (Patch Test)	353
13	Environmental Aspects	325	14.3	Immediate Allergic Reactions (IgE Mediated)	353
	<i>D. Arenholt-Bindslev</i>		14.3.1	Clinical Picture	353
13.1	Introduction	325	14.3.2	Verified Immediate Allergic Reactions to Dental Materials	354
13.2	Environmental Aspects of Dental Amalgam	325	14.3.3	Chemicals with Low Molecular Weight	356
13.2.1	Mercury in the External Environment	325	14.3.3.1	Metals	356
13.2.2	Environmental Mercury Burden Related to the Use of Amalgam in Dentistry	327	14.3.3.2	Antimicrobials	356
13.2.3	Amalgam Separating Devices – Regulations and Recommendations	330	14.3.3.3	Fragrances and Flavorings	356
13.2.4	Interment and Cremation	331	14.3.3.4	Medicaments	356
13.3	Environmental Aspects of Composite Dental Filling Materials	332	14.3.4	Skin Test with Low Molecular Weight Compounds	357
Conclusions for the Dental Practitioner		332	14.3.5	Management of Acute Allergic Reactions	357
References		332	14.4	Diagnosis of Side Effects Caused by Dental Materials	357
14	Diagnosis of Side Effects of Dental Materials, with Special Emphasis on Delayed and Immediate Allergic Reactions	335	14.4.1	Anamnesis	357
	<i>D. Arenholt-Bindslev, R. Jolanki and L. Kanerva</i>		14.4.2	Local Irritative Reactions	358
14.1	General Diagnostic Aspects and Irritant/Allergic Stomatitis	335	14.4.3	General Symptoms	358
			14.4.4	Allergy	359
			14.4.4.1	Delayed Allergic Reactions (Type IV)	359
			14.4.4.2	Evaluation of Patch Test Results	360
			14.4.4.3	Immediate Allergic Reactions	361
			14.4.5	Defining the Causative Agent(s)	361
			14.4.6	The Importance of Communication	361
			References		361
			Subject Index		367



<http://www.springer.com/978-3-540-77781-6>

Biocompatibility of Dental Materials

Schmalz, G.; Arenholt Bindslev, D.

2009, XVI, 379 p., Hardcover

ISBN: 978-3-540-77781-6