



IMPRESIL™
Heatless Liquid Dam and Block-Out resin
Lichthärtend
KIT: 3 x 3 ml Spritze IMPRESIL™

PRODUKTBESCHREIBUNG
IMPRESIL™ wurde speziell entwickelt, um Zähne und Zahnfleisch vor Irritationen zu schützen.
• Keine Erwärmung beim Lichthärten. Geringe exotherme Reaktion verhindert Brennen und Schmerzen und ist angenehm für den Patienten.
• IMPRESIL™ ist geförmig und tropft nicht. Einfach auftragen und nur einmal lichterhärten. Erspart mehrere Arbeitsgänge und wiederholtes Lichthärten.
• Bleibt nach dem Aushärten flexibel. Ein Kofferdam Ersatz - das gummiartig ausgehärtete Material ist leicht zu entfernen und ist reißfest.

INDIKATIONEN
• Power Bleaching: IMPRESIL™ wird verwendet, um das Zahnfleisch während des Bleichvorgangs zu schützen.
• Ausblockmasse: IMPRESIL™ wird verwendet, um Unterschnitte auszublocken und gingivale Unterschnidungen vor der Abdrucknahme von Kronen und Brücken auszukleiden.
• Sandstrahlen: IMPRESIL™ wird verwendet, um die Gingiva abzudecken und beim Sandstrahlen zu schützen. Er kann auch zum Abdecken der Zähne angewendet werden.

KONTRAINDIKATIONEN
Nicht als Ersatz für Kofferdam bei endodontischen Behandlungen geeignet.

VERARBEITUNGSANLEITUNG
1. Eine grüne 18-Gauge oder rosa 20-Gaugen Applikatort Spitze auf die Luer-Lock-Spritze aufschrauben.
2. Eine 1–2 mm dicke Schicht IMPRESIL™ auf die zu schützende Gingiva oder Zahnoberflächen vor dem Bleichen oder Sandstrahlen auftragen. Sandstrahlen und andere Verfahren erfordern intraoralen Schutz. Ebenso kann es vor der Abformung verwendet werden um Unterschnitte auszublocken. IMPRESIL™ ist so ausgelegt, dass dieser vor der Härtung auch über mehrere Zähne aufgetragen werden kann, ohne wegzuzießen. Nach Gebrauch Spritze sofort wieder verschließen.
3. Lichthärtung für ca. 10 Sekunden, je nach Lichthärtegerät.

WARNHINWEIS
Ungehärtetes Material kann bei Kontakt zu Augen- oder Hautreizungen führen. Zahnmedizinische Fachkräfte müssen eine Schutzbrille und OP-Handschuhe tragen. Überschreiten Sie keinesfalls die vom Hersteller für das verwendete Licht empfohlene Härtezeit.

LAGERUNG UND HANDHABUNG
• Gut verschlossen in der Original-Verpackung lagern bei kühler Raumtemperatur.
• Direktes Licht und extreme Temperaturschwankungen vermeiden. Vor Kontamination und Brandquellen schützen.
• Haltbarkeit bei ungeöffneter Packung: 2 Jahre ab Herstellungsdatum.
• Nach Gebrauch sofort verschließen.

Anmerkung: Mehrfachdosier-Spritzen sollten entweder in einer frischen Schutzblille für jedes Patienten verpackt oder nach jedem Patienten angemessen gereinigt und desinfiziert werden.

Nur für den zahnärztlichen Gebrauch.



IMPRESIL™
Diga liquida, atermica, per isolamento della gengiva e sottosquadri. Fotopolimerizzabile
KIT: 3 x 3 ml siringhe IMPRESIL™

DESCRIZIONE DEL PRODOTTO
IMPRESIL™ è stata formulata unicamente per eliminare i problemi associati all'utilizzo delle comuni dighe liquide.
• Non surriscalda durante la polimerizzazione. La bassa reazione esotermica elimina il bruciore ed il dolore assicurando un elevato comfort al paziente.
• Non cola. Il prodotto è applicato e polimerizzato con un'unica operazione. Sono così eliminati i passaggi multipli di applicazione e di polimerizzazione.
• Rimane flessibile dopo la polimerizzazione. Sostituisce interamente la diga di gomma. Il materiale non diventa rigido dopo la polimerizzazione e viene rimosso facilmente in un unico pezzo senza lacerarsi.

INDICAZIONI
• Power Bleaching: IMPRESIL™ protegge i tessuti soffici durante i trattamenti di sbiancamento alla poltrona ed i denti adiacenti alle aree sottoposte ad abrasione con sabbiatrici intraorali.
• Protesi: IMPRESIL™ può essere usato per eliminare sottosquadri e difetti gengivali prima di prendere impronte per corone e ponti.
• Sabbatura: IMPRESIL™ è usato per mascherare e proteggere la gengiva durante la sabbatura. È anche posto sulle aree di denti da mascherare durante il processo di sabbatura.

CONTROINDICAZIONI
Non sostituisce la diga di gomma per le procedure endodontiche.

ISTRUZIONI PER L'USO
1. Fissare l'applicatore verde da 18-gauge oppure rosa da 20-gauge sulla siringa "luer lock".
2. Applicare uno strato di 1-2 mm circa sulle superfici da proteggere prima delle operazioni di sbiancamento, sabbatura, mordenzatura e altre procedure che richiedano una protezione intraorale, o nei sottosquadri da eliminare prima della presa dell'impronta. IMPRESIL™ non cola permettendo l'applicazione simultanea su più denti prima della polimerizzazione. Richiudere immediatamente dopo l'uso.
3. Fotopolimerizzare per 10 secondi, tempo che può variare leggermente in funzione del tipo di lampada utilizzata.

ATTENZIONE
Il materiale non polimerizzato può causare irritazione per contatto con la pelle e gli occhi. Indossare occhiali e guanti chirurgici durante l'utilizzo. Non superare i tempi di polimerizzazione raccomandati dal produttore della lampada che si sta utilizzando.

CONSERVAZIONE E GESTIONE
• Conservare nel contenitore originale ben sigillato a temperatura ambiente fresca. Evitare la luce diretta, temperature estreme, contaminazione e fonti di ignizione.
• Periodo di validità del prodotto non aperto: 2 anni dalla data di produzione.
• Richiudere immediatamente dopo l'uso.

Nota: Le siringhe multidose devono essere rivestite da una copertura monouso prima dell'utilizzo su ogni paziente o pulite e disinfettate tra un paziente e l'altro.

Esclusivamente per uso odontoiatrico.

La Maison Dentaire SA REV. 6 : December, 2024

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EC) No. 1272/2008 (CLP) Trade Name: IMPRESIL™

1.0 Commercial Product Name and Supplier			
1.1	Commercial product name / designation	Impresil Heatless Liquid Dam & Block Out Resin	
1.2	Application / Use	Dental material for use by dental professional only.	
1.2.2	SIC	851 Human health activity	
1.2.3	Use Category	55	
1.3	Manufacturer	LA MAISON DENTAIRE SA Pralawisch 13 FL-9496 BALZERS LIECHTENSTEIN	
1.4	CH-REP / Importer	MEDIREL SA CH-6982 Agno Switzerland Tel. +41 91 604 54 34 info@medirel.ch	
1.4.1	Emergency Telephone Number	+41 91 604 54 34	
2.0 Hazards Identification			
2.1	Classification	Irritant	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	Hazard Class	Hazard Category Hazard Statement
		Eye irritation	2 H319
		STOT SE	3 H335
		Skin irritation	2 H315
		Skin sensitization	1 H317
2.2	GHS Label Elements Hazard Pictograms		

Signal Word: WARNING
Restricted to use by dental professional only.
Hazard Statements
H319: Eye irritation. 2. May cause eye irritation.
H335: STOT SE. 3. May cause respiratory irritation.
H315: Skin irritation. 2. May cause skin irritation.
H317: Sensitization. 1. May cause an allergic skin reaction.

Precautionary Statements
P261: Avoid breathing vapor.
P280: Wear protective gloves and eye protection
P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
P337+P317: If eye irritation persists, get medical advice/attention.
P302+P352: If on skin, wash with plenty of soap and water.
P333+P317: If irritation or rash occurs, get medical advice/attention.
P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.

3.0 Composition			
3.1	Chemical characterization of the preparation	Aliphatic and Polyurethane Dimethacrylate Oligomer / Monomer in a light-cured, glass-filled paste.	
3.2	Hazardous ingredients		
	CAS Number	Name of the Ingredient	Concentration
			Classification according to Regulation (EC) No.1272/2008 (CLP)
	Proprietary	Aliphatic and Polyurethane Dimethacrylate Oligomer / Monomer	55-65%
	112945-52-5	Amorphous silica	5 %
			Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
			Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
4.0 First Aid Measures			

4.1 General Information
Minimal health hazard under normal conditions of use. May be irritating to eyes, respiratory system and skin on contact. Prolonged or repeated contact with Oligomer / Monomer may cause sensitization. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

4.2 Inhalation
Move to fresh air. If necessary, administer oxygen / artificial respiration; seek medical attention.

4.3 Skin Contact
Take off contaminated clothing. Wash skin thoroughly with soap and water for 15 minutes.

4.4 Eye Contact
Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention.

4.5 Ingestion
Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes. Never give anything by mouth to an unconscious person.

4.6 Precautions for first responders
Ventilate the area. Wear eye and skin protection.

4.7 Information for physicians
Symptoms
Irritation or redness in eyes, throat or on skin.

Hazards
May be irritating to eyes, respiratory system and skin. May cause sensitization by skin contact.

Treatment
As above under First Aid.

5.0 Fire Fighting Measures	
5.1	Suitable extinguishing media Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.
5.2	Extinguishing media to avoid Do not use direct water stream
5.3	Special exposure hazards in a fire Heat may cause polymerization with rapid release of energy.
5.4	Special protective equipment for fire-fighters A self-contained breathing apparatus should be worn by fire fighting personnel.

6.0 Accidental Release Measures	
6.1	Personal precautions Ventilate area. Wear safety glasses, gloves, and lab coat.
6.2	Environmental precautions Contain spilled material. Follow all government regulations.
6.3	Method for clean up Absorb or wipe up spill with suitable material (paper towels or cloths). Collect for disposal in a covered container. Wash area of spill with alcohol or soap and water.

7.0 Handling and Storage	
7.1	Handling For use only by dental professionals. Follow good hygiene practices. Remove applicator tip from syringe and recap immediately after use. Keep light-cured materials shaded from intense light sources. Keep light-cured materials shaded from intense light sources.

7.2 Storage
Store tightly capped in original container at cool room temperature (<25°C). Avoid direct light, sources of ignition extremes of temperature (>27°C/80°F, <5°C/40°F). Shelf life for unopened product is two years from date of manufacture, provided that the material has been stored properly.

7.3 Specific uses
Dental material

8.0 Exposure Controls / Personal Protection	
8.1	Exposure limit values PEL: Not established. TLV: Not established.
8.2	Exposure controls
8.2.1	Occupational exposure controls No special equipment required under normal conditions of use.

8.2.1.1 Respiratory protection
Good general ventilation is sufficient to control any airborne vapors.

8.2.1.2 Hand protection
No special requirements other than the usual surgical gloves.

8.2.1.3 Eye protection
No special requirements other than the usual safety glasses.

8.2.1.4 Skin protection
Good personal hygiene and safety practices; lab coat.

8.2.1.5 Other controls
Emergency eye wash fountain should be available. Wash hands after use.

8.2.2 Environmental exposure
Follow all government regulations. Cure material before disposing.

9.0 Physical and Chemical Properties	
9.1	Characteristics
9.1.1	Appearance / Color / Physical state Light blue gel
9.1.2	Odor Faint, characteristic

9.2 Important health, safety and environmental information

9.2.1 pH
Not determined

9.2.2 Boiling point
Not determined

9.2.3 Flash point
Not determined

9.2.4 Flammability (solid, gas)
Not applicable

9.2.5 Explosive properties
Not applicable

9.2.6	Oxidizing properties	Not determined
9.2.7	Vapor pressure	< 1 mm Hg / 133 Pa / Id: B
9.2.8	Specific gravity	1.290
9.2.9	Solubility in water	Nil
9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined
9.2.12	Vapor density	Not determined
9.2.13	Evaporation rate	Not determined

10.0 Stability and reactivity

10.1	Conditions to avoid	Temperature extremes (>80°F / 27°C, <40°F / 5°C), intense light, contamination.
10.2	Materials to avoid	Reducing and oxidizing agents, peroxides, amines.
10.3	Hazardous decomposition products	Under fire conditions and with amounts far greater than that supplied in this product, hazardous polymerization may occur with heat build-up, release of carbon monoxide, carbon dioxide, and oxides of nitrogen.
10.4	Further information	Polymerization will occur when exposed to direct light.

11.0 Toxicological information

11.1	Acute toxicity	Not toxic. Minimal health hazard in the quantities present in this product and under normal conditions of use.
11.2	Irritation and corrosiveness	May be irritating to eyes, mucous membranes or skin on contact or with prolonged exposure.
11.3	Sensitization	May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.
11.4	Sub-acute, sub-chronic and prolonged toxicity	Prolonged and/or frequent skin contact may cause allergic skin reactions in susceptible individuals. Prolonged exposure to large amounts (more than in this product) of this material may cause eye and respiratory irritation.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available

11.7	Clinical experience	Impresil has been used safely on the domestic and international market for more than 10 years. During that time there have been no reports of adverse events.
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12.0 Ecological Information

12.1	Ecotoxicity	To the best of our knowledge, polymerized material is inert. No other information is available. Follow all government regulations.
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13.0 Disposal Considerations

13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.
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14.0 Transport Information

14.1	Restrictions	None. Not regulated.
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15.0 Regulatory Information

15.1	EU Regulations	Class I medical devices under the Medical Devices Regulation (EU) 2017/745
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16.1	Hazard Statements	H319: Eye irritation. Hazard category 2. H335: Specific Target Organ Toxicity - Single exposure; hazard category. 3. Respiratory tract irritation. H315: Skin irritation. Hazard category 2. H317: Skin Sensitization. Hazard category 1.
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16.2	Precautionary Statements	P261: Avoid breathing vapor. P280: Wear protective gloves and eye protection P305 + P351+ P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing. P337 + P317: If eye irritation persists, get medical advice/attention. P302 + P352: If on skin, wash with plenty of soap and water. P333 + P317: If irritation or rash occurs, get medical advice / attention. P410 + P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.
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16.3	Restrictions on use	La Maison Dentaire SA products are to be sold to and used by dental professionals only.
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16.4	Further information	The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which La Maison Dentaire SA bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.
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16.5	Sources of key data	Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP), Regulation (EU) No. 487/2013 and Regulation (EC) No. 1907/2006 (REACH).
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European Chemicals Agency Guidance on the compilation of safety data sheets Version 4.0 April 2020.

16.6	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, Regulation (EC) No. 487/2013 (CLP) and Regulation (EC) No. 1907/2006 (REACH) and ECHA Version 4.0 April 2020. Specifically Sections 1.3,2,2.9.1, 9.1.1, 15.1, 16.2, 16.5 have been modified.
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REV: 12/2024



IMPRESIL™
Heatless Liquid Dam and Block Out Resin Light Cure
KIT: 3 x 3 mL syringes IMPRESIL™

PRODUCT DESCRIPTION
IMPRESIL™ has been uniquely formulated to eliminate the problems associated with paint on dam materials.
• Does not produce heat when cured. Low exothermic reaction eliminates burning and pain assuring patient comfort.
• Does not run. A single application is light cured one time only. Eliminates multiple passes and multiple light curing procedures.
• Remains flexible after curing. Truly a rubber dam substitute, the rubbery cured material is easily removed and is tear resistant.

INDICATIONS
• Power bleaching: IMPRESIL™ is used to protect the gingival during power bleaching procedures.
• Block-out resin: IMPRESIL™ is used to block out undercuts and gingival embrasures prior to taking impressions for crowns and bridges.
• Sandblasting: IMPRESIL™ is used to mask and protect the gingiva during sandblasting. It is also placed on the areas of teeth to be masked during the sandblasting process.

CONTRAINDICATIONS
Does not replace rubber dam for endodontic procedures.

DIRECTIONS FOR USE
1. Place a green 18-gauge or pink 20-gauge applicator tip securely on the luer lock syringe.
2. Apply a coat of IMPRESIL™ 1-2 mm thick on the gingival or tooth surfaces to be protected prior to power bleaching, sandblasting or other procedures requiring intraoral protection, or place in areas to be blocked out prior to taking impressions. IMPRESIL™ does not run and is designed so that it can be placed over multiple teeth before curing. Re-cap immediately after use.
3. Light cure for 10 seconds, depending on the light you are using.

CAUTION
Uncured material may cause eye or skin irritation on contact. Dental professionals should wear safety glasses and surgical gloves. Do not exceed manufacturer's recommended curing time for the light you are using.

STORAGE AND HANDLING
• Store tightly sealed in original container at cool room temperature. Avoid direct light, extremes of temperature, contamination and sources of ignition.
• Shelf life of unopened product: 2 years from date of manufacture.
• Re-cap immediately after use.

Note: Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient. For additional information, refer to: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm>

Restricted to use by dental professionals only.

IMPRESIL™
Digue liquide, athermique, pour isolation de la gencive et Block-Out résine, Photopolymérisable KIT: 3 x 3 mL seringues IMPRESIL™

DESCRIPTION DU PRODUIT
IMPRESIL™ a été formulé de manière unique pour éliminer les problèmes associés aux digues liquides :
• Ne produit de chaleur lors de la photopolymérisation. Une réaction exothermique faible élimine les sensations de brûlures et douleurs assurant le confort du patient.
• Ne coule pas. Une seule application suffit. Pas de besoin de passages multiples et / ou de procédures multiples de photo-polymérisation.
• Reste flexible après séchage. Un réel substitut de digue, le matériau durci est caoutchouteux et se retire facilement. Résiste aux déchirures.

INDICATIONS
• Power Bleaching : IMPRESIL™ est utilisé pour protéger la gencive pendant les procédures de blanchiment.
• Block-Out résine : IMPRESIL™ est utilisé dans les contre-dépouilles et embrasures gingivales avant la prise d'empreintes pour couronnes et ponts.
• Sablage : IMPRESIL™ est utilisé pour masquer et protéger la gencive pendant le sablage / ponçage. Il est également placé sur les zones de dents à masquer au cours du processus de sablage.

CONTRE-INDICATIONS
Ne remplace pas une digue en caoutchouc pour les procédures endodontiques.

MODE D'EMPLOI
1. Placer un embout-applicateur vert à 18-gauge ou rose à 20-gauge sur la seringue «luer lock».
2. Appliquer une couche de IMPRESIL™ de 1 à 2 mm d'épaisseur sur la gencive, dents et/ou surfaces à protéger avant au le blanchiment, le sablage ou autres procédures nécessitant une protection. IMPRESIL™ ne coule pas et est conçu de telle sorte qu'il peut être placé sur plusieurs dents avant le durcissement. Reboucher immédiatement après usage.
3. Photopolymériser pendant 10 secondes, en fonction de la lumière que vous utilisez.

MISE EN GARDE
Le contact des yeux et de la peau avec le matériau non polymérisé peut causer une irritation. Les professionnels dentaires doivent porter des lunettes de sécurité et des gants chirurgicaux. Ne pas excéder le temps de polymérisation recommandé par le fabricant pour la lumière que vous utilisez.

STOCKAGE ET MANIPULATION
• Conserver hermétiquement clos dans le contenant original à température ambiante fraîche. Éviter la lumière directe, les températures extrêmes, la contamination et les sources d'ignition.
• Validité du produit non ouvert : 2 ans à partir de la date de fabrication.
• Reboucher immédiatement après l'usage.

Remarque : seringues multidoses doivent être enfermées dans une nouvelle barrière protectrice pour chaque patient et nettoyées et désinfectées entre les patients, le cas échéant.

Exclusivement pour usage professionnel dentaire.