3M ESPE Imprint[™] II

Impression Material

Technical Product Profile

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Introduction

A History of 3M[™] ESPE[™] Vinyl Polysiloxane (VPS) Impression Materials

The history of 3M ESPE Vinyl Polysiloxane (VPS) impression material began in 1982 with the introduction of Express[™] Bite Registration Putty. In 1983, the Express brand was expanded to include standard (STD) putty and wash materials. While putty remained hand-mixed, Express wash was introduced in a new auto-mix system which was developed by 3M ESPE. This auto-mix system quickly became the industry standard for VPS delivery.

When compared to hand spatulated or hand mix impression materials, auto-mix systems offer many recognized benefits including:

- ease of use, less mess, less waste (Craig, 1985)
- a consistent, bubble-free mix (Chong et al., 1991)
- no degloving is necessary
- intraoral delivery directly from the auto-mix tip

In 1996 Imprint[™] II Heavy Body/Light Body Impression Material system was introduced as an ideal universal system for your dental practice. The system was comprised of the 3M[™] ESPE[™] Garant[™] Heavy Body Impression Material and your choice of 3M[™] ESPE[™] Garant[™] Light Body Impression Material and 3M[™] ESPE[™] Garant[™] Regular Body Impression Material. The system is easy to use and offers ample working time and an optimal setting time. It's great for impressions involving one or multiple units and for using quadrant, double-bite and full arch trays.

The Imprint II Garant heavy body impression material is now available for use in the Pentamix[™] Mixing Unit. The 3M[™] ESPE[™] Imprint[™] II Penta[™] Heavy Body Impression Material is available in foil bags which are sealed with the 3M[™] ESPE[™] PentaMatic[™] AutoOpen System feature. The PentaMatic AutoOpen System feature automatically opens the foil bags by the push of a button on the Pentamix mixing unit. Both the Imprint II Penta heavy body impression material and the Imprint II Garant heavy body impression material are formulated for use with the Imprint II Garant light body impression material and Imprint II Garant regular body impression material to meet the demands of the one-step/two-viscosity technique. It is great for impressions involving one or multiple units.

Whatever delivery system is used, the Imprint II Penta heavy body impression material or the Imprint II Garant heavy body impression material offers a homogenous and void-free mix.

Imprint[™] II Impression Material

The Imprint II Impression Material System Includes:

Imprint[™] II Penta[™] Heavy Body (mauve) — An auto-mixed heavy body impression material designed for use with the Pentamix[™] Mixing Unit. It is to be used in combination with Imprint II Garant[™] Regular Body or Imprint II Garant[™] Light Body impression material. Imprint II Penta heavy body impression material has 2 minutes of room temperature working time for tray filling and a 4-minute oral setting time. The mixing ratio is 5 volume base paste: 1 volume catalyst paste.

Imprint II Garant[™] Heavy Body (purple) — An auto-mixed heavy body impression material specifically designed to be used in combination with Imprint II Garant regular body or light body. Imprint II Garant heavy body provides 2 minutes of room temperature working time for tray filling and a 4-minute oral setting time. The mixing ratio is 1 volume base paste:1 volume catalyst paste.

Imprint II Garant[™] Regular Body (green) — A controlled-flow, drip-resistant wash for use with Imprint II Penta heavy body or Imprint II Garant heavy body material. Imprint II regular body impression material provides 1 minute of oral working time and a 4-minute oral setting time.

Imprint II Garant[™] Light Body (yellow) — A high-flow, drip-resistant light body impression material for use with Imprint II Penta heavy body or Imprint II Garant heavy body. Imprint II Garant light body also provides 1 minute of oral working time and a 4-minute oral setting time.

3M^{\square} **ESPE**^{\square} **Garant**^{\square} **Dispenser** — The Garant dispenser was specifically designed to be used with Imprint II Garant heavy, regular and light body impression materials.

Accessory Items — Garant Mixing Tip, green; Garant Mixing Tips, yellow; Garant Intraoral Tips, yellow; and VPS Tray Adhesive.

Recommended Techniques for Imprint II Impression Materials

	Heavy Body Impression Materials			
	Imprint II Penta HB Imprint II Garant HB	Imprint II Monophase	Express Putty	
Techniques				
Single Phase	NR	*		
One Step /Two Viscosity Techn (1-4 Preparations)	ique •		*	
Two-Step /Two Viscosity Techn (1-2 Preparations)	ique		■▲*	
	Light Body Impression Material Key	/		
 Imprint II Garant Regular Body Imprint II Garant Light Body 	 Imprint II Monophase** Express Light Body, Regular Se 		ght Body, Fast Set** mmended	
* The stone cast may not be poured imm impression material. A 2-hour wait is rec **Impression material cartridge not curr	quired before pouring.		nprint II light body	

The PentaMatic[™]AutoOpen System

With the aim of developing the best possible handling for the Pentamix[™] Mixing Unit, a self-opening mechanism was developed that makes it unnecessary to cut the foil bags open by hand in the preparation phase and automatically makes the bag's contents available as soon as the plunger disc exerts pressure on the bag.

The main modifications to this system were made to the foil bags. The Pentamix mixing units 1 and 2 and the body of the cartridge are unchanged and can thus still be used. The cartridge caps are now attached directly to the foil bags (Figure 1). After the Pentamix mixing unit is loaded, the pressure in the foil bag increases and the foil stretches in the prepared space of the cartridge cap. Spikes fitted into this area now pierce the overextended foil and cause it to burst over the entire area it occupies (Figure 2). The user is alerted to bag's bursting by a clicking sound when the material is released.

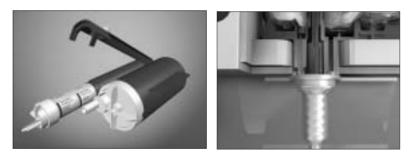
The time before the foil bag opens is about 20 - 25 seconds with the original Pentamix mixing unit and about 10 - 15 seconds with the newer Pentamix mixing unit.

With the PentaMatic AutoOpen System it is no longer necessary to cut the foil bags open by hand. Because of the PentaMatic AutoOpen system, the cartridge cover is incorporated into the foil bag. User errors during opening are eliminated. The PentaMatic AutoOpen system thus promotes hygiene, efficiency, and conserving of resources in the dental practice.

Figure 1. The foil bags with the PentaMatic AutoOpen system are inserted into the cartridge.

Figure 2.

After the first loading the PentaMatic AutoOpen system will automatically open the foil bag with the spikes fitted in the cavity.



Chemistry

The reaction chemistry that drives modern addition-cured silicone impression materials is known as hydrosilation and was first described in the 1950's by Speier at Dow Corning (Speier, 1957). This reaction involves the addition of a silicon-hydrogen bond across a carbon-carbon double bond and is catalyzed by a platinum (Pt) acid, H_2PtCl_6 (Figure 3). A key feature of this chemistry is two molecules reacting to form a third with the lack of any by-products which could cause dimensional stability problems. The utility of Speier's catalyst for high performance specialty applications was limited by a long induction period and solubility problems. These problems were overcome in the early 1970's when Karstedt at GE invented a fast-acting, soluble platinum catalyst (US Patent 3,715,334; 3,775,452; 3,814,730).

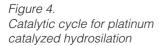
Figure 3. The Addition-Cured (Hydrosilation) Reaction

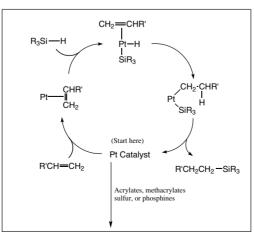
 $R'CH = CH_2 + R_3Si - H \xrightarrow{Pt Catalyst} R'CH_2 - CHSiR_3$

There are several reactive ingredients in addition-cured impression materials including polymers, a crosslinker, and a platinum catalyst. The main component by weight is a carbon-carbon double bond (vinyl) terminated polydimethylsiloxane (vinyl polysiloxane, VPS).

A number of different compounds can be used as setting time inhibitors to help pinpoint the working and setting times, however, they all have a divinyl disiloxane structural feature in common. These inhibitors are also part of the Karstedt catalyst which has three vinyl siloxane groups bound to a neutral platinum atom. The cycle by which the Pt complex catalyzes the reaction between a silicon-hydrogen bond and a carbon-carbon double bond is shown in Figure 4.

These catalysts are very active and under the proper conditions each Pt atom can catalyze several thousand cycles per minute. This high reactivity also means the Pt catalyst is susceptible to a variety of contaminating agents including other carboncarbon double bond containing compounds, especially acrylates and methyacrylates, phosphines, and a variety of sulfur-containing compounds including some latex gloves. These compounds act as contaminants by binding strongly to the Pt atom to form catalytically inactive Pt species. The inactive species is no longer able to catalyze the silicone-hydrogen and carbon-carbon bonds and the material remains unset.





One Step/Two Viscosity Technique

Please note:

Figure 5.

The higher the room temperature, the shorter the working time for both heavy body and light body materials. Conversely, lower room temperatures provide longer working time (Hamilton, 1995).

Figure 5. Working and setting time	Working Times	
recommendations for Imprint II Impression Material	Light Body Impression Materials	
	Heavy Body Impression Material	Tray Filling (73 °F / 23 °C) 2:00 Minutes
	Set Time Heavy Body/Light Body Impression Materials (From tray seating)	Oral Set (92°F / 33.3°C) 4:00 Minutes

Technique Guides

ONE-STEP/TWO VISCOSITY TECHNIQUE

3M[™] ESPE[™] Imprint[™] II Impression Material

Figure 6. Technique Guide for Imprint

I Penta Heavy Body/Garant Light Body



• Apply VPS Tray Adhesive: dry a minimum of 5 minutes.



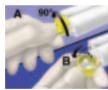
• Insert the loaded Penta[™] cartridge into the Pentamix[™] Mixing Unit.

2

• For initial use extrude a small amount of material and discard it. Wait for a uniform mix.



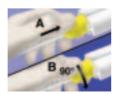
• Locate the V-Notch on the cartridge flange. The V-Notch must be facing down as the cartridge is loaded into the Garant[™] Dispenser.



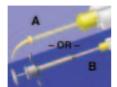
- To remove the cartridge cap, rotate it 90° in a counter-clockwise direction (A).
- With firm pressure, tilt the cap downward and peel it away from the cartridge (B).
- Bleed the cartridge.



• Locate and align the V-Notch on the mix tip with the V-Notch between the cartridge barrels.



- To attach the mix tip, hold the mix tip collar and push firmly to ensure that it is flush with the cartridge (A).
- Rotate the collar 90° in a clockwise direction to its locked position (B).



• Attach an intraoral tip to the light body material mix tip (A) or load an intraoral syringe (B).



- Syringe light body material around the clean, dry tooth preparation(s) using either Imprint[™] II Garant[™] Light Body (A) or Imprint[™] II Garant[™] Regular Body (B).
- Begin filling the tray.



• Slowly seat the tray in the mouth.

Oral Set Time: 4 minutes.



• Immobilize the tray using passive pressure.



- Remove the impression, rinse, dry and disinfect. Wait 30 minutes to pour the stone model.
- 3M ESPE recommends horizontal storage of the ready-for-use cartridges.

Important Information:

Imprint II cartridges are specifically designed for use with the 3M ESPE Garant[™] Dispenser.

- Avoid contact with chemicals known to inhibit the set of vinyl polysiloxane materials such as latex rubber, acrylic and methacrylate residues.
- To avoid inhibition caused by temporary materials, the final impression should be made before fabricating the provisional crown or bridge.

3M ESPE Customer Hotline 1-800-634-2249 Please refer to instructions for more detailed information as well as precautionary and warranty information.

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ONE-STEP/TWO VISCOSITY TECHNIQUE

3M[™] ESPE[™] Imprint[™] II Impression Material

Figure 7. Technique Guide for Imprint II Garant Heavy Body/Garant Light Body



• Apply VPS Tray Adhesive: dry a minimum of 5 minutes.



• Locate the V-Notch on the cartridge flange. The V-Notch must be facing down as the cartridge is loaded into the dispenser.



• Insert the cartridge flange directly behind the retainers on the dispenser and close the cartridge lock.



• To remove the cartridge cap, rotate it 90° in a counterclockwise direction (A). With firm pressure, tilt the cap downward and peel it away from the cartridge (B).



- Bleed the cartridge.
- Locate and align the V-Notch on the mix tip with the V-Notch between the cartridge barrels.
- To attach the mix tip, hold the mix tip collar and push firmly to ensure that it is flush with
- the cartridge (Å). Next, rotate the collar 90° in a clockwise direction to its locked position (B).
- Attach an intraoral tip to the light body material mix tip (A) or load an intraoral syringe (B).







- Syringe light body impression material around the clean, dry tooth preparation(s) using either Imprint II Garant Light Body (A) or Regular (B) Body impression material. Intraoral Work Time: 1 minute.
- Fill the tray with Imprint II Garant Heavy Body impression material while the light body impression material is being syringed on the preparation.
- Slowly seat the tray in the mouth.



- F.
- Immobilize the tray using passive pressure. Oral Set Time: 4 minutes.



• Remove the impression, rinse, dry and disinfect. The stone model may now be poured.

Important Information:

Imprint^M II impression material cartridges are specifically designed for use with the 3M ESPE Garant^M Dispenser.

Avoid contact with chemicals known to inhibit the set of VPS materials such as latex rubber, acrylic and methacrylate residues.

To avoid inhibition caused by temporary materials, the final impression should be made before fabricating the provisional crown or bridge.

Please refer to instructions for more detailed information as well as precautionary and warranty information.

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Imprint[™] II impression material may also be used in a two-step/two viscosity technique, please refer to page 34 for detailed instructions.

Additional Technique Recommendations

- 1. **Tray Selection:** A rigid custom or stock tray is recommended to offer stability and support for the final impression.
- 2. **Tray Adhesive:** Tray adhesive should be placed on all surfaces of the tray coming in contact with impression material. It is recommended regardless of tray type (including the gauze inserts of double bite trays). Tray adhesive helps bond the impression material to the tray, minimizing the potential for distortion of the final impression. Tray adhesive is critical, especially when second or third stone model pours are required.
- 3. **Tray Filling/Intraoral Syringing:** To avoid air incorporation during tray filling, the mix tip should remain submerged in Imprint[™] II Garant[™] Heavy Body impression material. The intraoral tip should also remain submerged while syringing around the prepared tooth.
- 4. **Intraoral Syringe Filling:** When possible, fill intraoral syringes from the front while forcing the plunger backwards (see Technique Guides, Figure 7, page 12). "Front loading" helps to reduce the incidence of air incorporation during syringe filling.
- 5. **Tray Seating/Passive Pressure:** Seat the impression tray slowly. Trays should not come in contact with the preparation(s) or surrounding dentition. Once the tray has been seated, maintain passive pressure for the full recommended setting time.

Properties

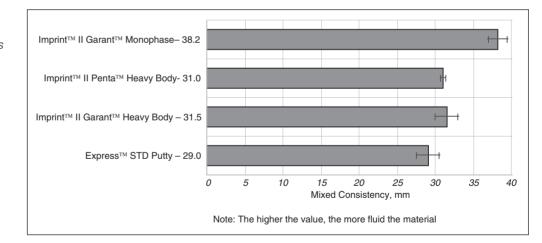
Imprint[™] II Heavy Body Impression Material

The unique handling properties of Imprint II heavy body impression materials are due to the combination of several different fillers. The tray material exhibits the property of shear thinning taken to the extreme, high flow under pressure and zero flow under gravity. The high flow under pressure makes extruding the material less difficult, while the zero flow under gravity gives a no drip, no slump, high viscosity feel during tray seating.

3M ESPE tests all impression materials in accordance with ISO Standard 4823:2000-12-15 for Dental Elastomeric Impression Materials. ISO (International Organization for Standardization) is a worldwide federation of national standards bodies.

Mixed Consistency (ISO 4823:9.2)

Mixed consistency refers to a material's ability to flow. The higher the measurement in millimeters, the more fluid the material. The mixed consistency test is performed by dispensing 0.5 milliliters of impression material onto the center of a glass plate. A second glass plate is then placed on top of the first, followed by the addition of a 1,500 gram weight. The weight is placed on the glass 30 seconds from the start of impression material mix. After a period of 5 seconds the weight is removed, and the impression material is allowed to polymerize fully. The diameter of the polymerized disc is then measured in millimeters. Imprint II heavy body impression material has a no drip, no slump mixed consistency.





Detail Reproduction (ISO 4823:9.4)

A number of impression material chemistries are currently available to the dental industry including alginate, rubber base, hydrocolloid, polyether, condensation and addition cured silicones. Of all of the chemistries mentioned, addition silicones (otherwise known as VPS impression materials) are widely recognized as the most accurate in reproducing fine detail (Chee & Donovan, 1992).

Detail reproduction is measured using a stainless steel mold and ruled test block. The test block is tooled with lines 20, 50 and 75 microns in width. First, the impression material is mixed (through its auto-mix tip) and placed into the mold 30 seconds from the start of mix at room temperature. The mold is then covered with a sheet of polyethelyene followed by a rigid, flat, metal plate. Force is applied to seat the plate firmly against the mold. The assembly is then transferred to a water bath at $32 \pm 2^{\circ}$ C. The assembly remains in the water bath for the full recommended impression material set time plus an additional three minutes. The mold and test block are then separated. The impression is inspected under low-angle illumination using 6× magnification. The detail reproduction of a 50 micron line is considered satisfactory for heavy body materials if the line is reproduced in the impression for a distance of 25mm in three (of three) specimens.

Three different standards exist for detail reproduction as outlined in ISO 4823. At a minimum, heavy body tray materials are required to reproduce a line 50 microns in width. As a point of reference, 40 microns corresponds to the average width of a human hair. The ISO specification for light body materials is more rigorous, requiring that at a minimum they must have the ability to reproduce a 20 micron line. Imprint[™] II heavy body impression materials, while only required by ISO to reproduce a 50 micron line, passed the 20 micron test for detail reproduction.

While providing excellent detail reproduction, Imprint II heavy body impression materials are not suitable for use as a single phase or syringeable light body material because of its high consistency.

Strain in Compression (ISO 4823:9.8)

Strain in compression is a measure of the rigidity of an impression material, expressed in percent. The lower the value, the more rigid the final set. A rigid material by definition is less flexible, and therefore more difficult to deform once polymerized.

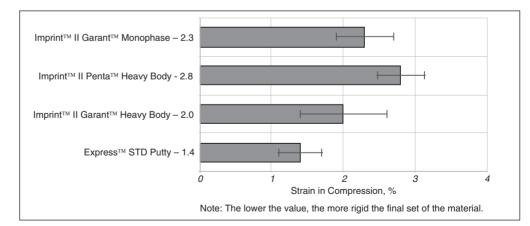


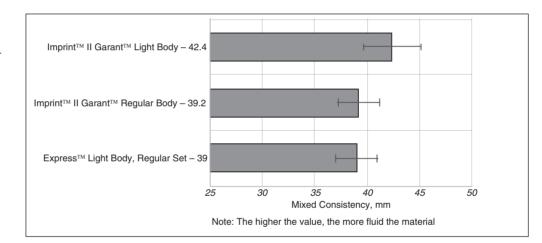
Figure 9. Strain in Compression, 3M ESPE Impression Materials

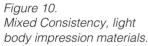
Imprint[™] II Garant[™] Regular and Light Body Impression Materials

The high flow, drip resistant characteristics of Imprint II Garant light body impression materials derive from a special combination of mineral and synthetic fillers. Because they are drip resistant, Imprint II Garant light body impression materials are often described as thixotropic. Thixotropic materials have high flow under pressure, but low flow under gravity.

Mixed Consistency (ISO 4823:9.2)

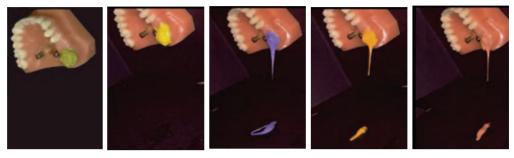
While both are considered thixotropic, Imprint II Garant regular and light body impression materials have distinct mixed consistencies. Imprint II Garant regular body impression material is a controlled-flow, drip resistant light body impression material with a mixed consistency identical to that of Express[™] Light Body, Regular Set impression material. Imprint II Garant light body impression material is a highflow, drip-resistant light body impression material with a mixed consistency determined through clinical and simulated operatory evaluations involving literally hundreds of dentists. Imprint II Garant light body impression material represents the most fluid light body material manufactured by 3M ESPE.





Drip Resistance

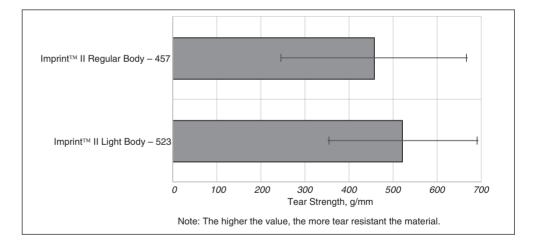
A "drip test" was created by 3M ESPE and used to determine the predisposition of a variety of low viscosity light body materials to running or dripping off tooth preparation(s). First, a typodont was mounted on a 55° angle. Next, 0.5 ml of impression material was dispensed into an intraoral syringe and syringed around a prepared maxillary second molar. Photographs were taken 1 minute after the start of syringe filling.



I to r: Imprint™ II Garant™ Regular Body, Imprint™ II Garant™ Light Body, Kerr Extrude™ Light Body, Caulk Reprosil® Light Body, GC America Examix® Injection

Tear Strength

Tear strength is the measure of the resistance of an impression material to tearing in grams/mm. The higher the value, the more tear resistant the material. This test is performed on an Instron (Model 1123), and is used as an indicator of the structural integrity of an impression material.





Detail Reproduction (ISO 4823:9.4)

Light body impression materials must provide excellent detail reproduction because they are intended to replicate, in fine detail, the margin of the prepared tooth. Both Imprint II Garant regular and light body impression materials passed the ISO:4823 test for detail reproduction and are able, at a minimum, to reproduce a 20 micron line.

System Information

Applications Per Foil Bag

Imprint[™] II Penta[™] Heavy Body Impression Material provides 10 medium size full arch trays depending on user.

Applications Per Cartridge

Applications per cartridge will vary depending on tray type, tray size, loading volume and impression technique. The following chart estimates applications per cartridge for full arch, quadrant and double-bite trays.

	milliliters/ application	applications/ cartridge
Imprint [™] II Garant [™] Heavy Body Impression Materials		
Full Arch (Master Tray™ Teledyne #3)	19	2
Double-Bite (Coe Check-Bite-GC America)	18	2
Quadrant (Coe Tray #30D)	15	3
Imprint [™] II Garant [™] Regular and Light Body Impression	n Materials	
Single Preparation	4	12

Disinfection

Impressions made using Imprint II impression material may be disinfected using any liquid disinfectant. VPS impression materials have been shown to be dimensionally stable after 60 minutes in 2% acidic glutaraldehyde (Davis & Powers, 1994).

Recommendations for Cast/Model Pouring

Impressions made using Imprint II Garant heavy body impression material may be poured immediately following disinfection. Because the heavy body and light body materials are hydrophilic, surfactants are not required. If surfactants are used, it is important to blow dry the impression thoroughly to ensure that no puddles or pools of liquid are present when the dye stone is poured.

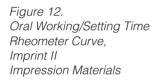
NOTE: Impressions made using Imprint II Penta heavy body impression material may be poured 30 minutes following disinfection.

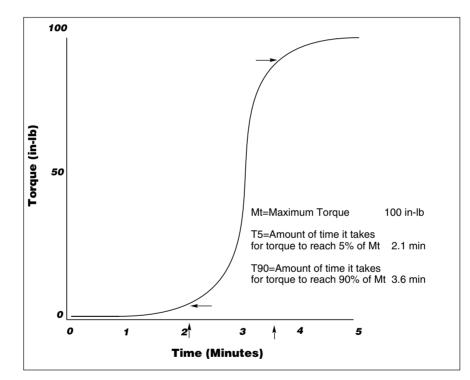
Determining the Working/Setting Times

An oscillating disc rheometer measures changes in the rheology of an impression material and is used by 3M ESPE to determine clinical timing recommendations for impression materials. Freshly mixed impression material is placed between two discs, one fixed and one which rotates back and forth. The rotating disc is attached to a transducer which measures the amount of force required to rotate the disc. As the material cures more force is required for rotation. The force required to displace

the material is plotted as a function of time. The displacement rheometer gives three very important pieces of information. First is the maximum torque, which is a measure of the final set rigidity. Second is a value called T5, the amount of time it takes to reach 5% of the maximum torque. T5 is correlated to the impression material working time. And finally, a value called T90, the amount of time it takes for the torque to reach 90% of the maximum. T90 is correlated to the impression material setting time.

Another important consideration in determining work and setting times is the fact that the heat of the mouth catalyzes the VPS polymerization reaction. In order to generate an accurate estimate of oral working and setting times, rheometer tests are run at 92°F (33.3°C) which simulates the temperature found in the mouth. Rheometer testing is reported to offer "a means of monitoring the working time and setting time of elastomeric impression materials which is based upon readily identifiable and clinically relevant changes in the elastic properties of the setting material (Abuasi, 1993)." Room temperature working times are listed at 73°F (23°C) and are an important reference for tray and syringe filling.





Imprint[™] II Impression Material Features

Features	Benefits
Garant [™] Heavy Body/Garant [™] Light Body System	Faster and easier Fully auto-mixed, eliminates contamination concerns of hand-mixing
Unique Heavy Body Material	No drip Patient comfort
Regular Body	Controlled flow Drip resistant
Light Body	High flow Drip resistant
Immediate Pour Following Disinfection with Imprint II Garant heavy body	Saves time Less technique sensitive
Hydrophilic Heavy and Light Body Materials	Better stone cast (Chai et al., 1991)
No Taste or Odor	Patient comfort

Garant[™] Dispenser

This impression material dispenser was engineered specifically for use with Imprint II impression material and offers two important features:

Features	Benefits
More Extrusion Power	Less hand fatigue
100% Steam Autoclaveable	Simplified and improved infection control

Disinfection and Sterilization

The Imprint II Garant dispenser is 100% autoclaveable. It is no longer necessary to remove the plunger before disinfecting the dispenser. The dispenser is detergent safe and requires no lubrication. It may be disinfected using liquid sterilants or may be sterilized using a steam autoclave.

Caution:

Do not sterilize using dry heat or chemical vapor as damage to the dispenser may result.

Cartridge Design

Designed in conjunction with the Garant[™] Dispenser, Imprint[™] II Garant[™] Heavy Body and Light Body Impression Materials have a unique cartridge which offers:

Features	Benefits
Dual Port Mix Tip	Virtually eliminates plugging
Reuseable Cartridge Cap	Improved infection control Compact storage
Intraoral Tip	Increased length and a smaller orifice for better intraoral access
Improved Cartridge Labels	Working/setting times, expiration date and lot number communicated more clearly

Please note:

Imprint II impression material cartridges are specifically designed for use with the Garant dispenser

Cartridge Labels

Imprint[™] II Garant[™] Impression Material cartridge labels were designed to clearly convey critical product information including:

- Working times for oral syringing and tray filling
- Oral setting time
- Expiration date
- Lot number
- Color coding by product:
 - Heavy Body impression material Purple
 - Regular Body impression material Green
 - Light Body impression material Yellow

The labels underwent several design phases which utilized feedback from dozens of practicing dentists and dental assistants.



Competitive Comparison

Comparison Table - Heavy Body Impression Materials Hand Dispensed

	Imprint™ II	Caulk Aquasil™	Kerr Take One	Kulzer Flexitime®	Discus Splash!™
	Garant™ HB	Rigid Tray	Tray	Tray	HB
Mixed Consistency, mm**	31.5	33	26	33	33
Strain in Compression, %*	2.5	1 to 2	4.4	1.8**	2.4
Vorking Time at 73° F, minutes*	2:00	2:00 - 2:30	2:00	2:30	2:15
Setting Time, minutes*	4:00 ^{92°F}	5:00	5:00	3:30 - 5:00	4:30
/lix Tip Waste, ml	2.1	2.1	2.1	2.1	2.1
laterial Extrusion Force**, kg	45	43	48	47	80
hore A hardness after 15 mins.	67	73	54	69	65
– After 1 hour	68	74	54	69	67
– After 24 hours	72	77	55	72	68

Comparison Table - Heavy Body Impression Materials Automatic Dispensing Units

	Imprint™ II Penta™ HB	Caulk Aquasil DECA Heavy	DMG Honigum® Heavy	Kulzer Flexitime Magum 360 H
Mixed Consistency, mm**	31.5	33	30	30
Strain in Compression, %*	2.9	2.0-2.5	1.4	1.3**
Working Time at 73° F, minutes*	2:00	2:15***	2:15	2:30
Setting Time, minutes*	4:00 ^{92°F}	5:00***	3:15	3:30-5:00
Mix Tip Waste, ml	6.4	4.5	4.5	6.4
Shore A hardness after 15 mins.	57	65	72	76
—After 1 hour	57	66	72	76
—After 24 hours	62	69	72	79

* Recorded from manufacturer's instructions

** Measured value 3M ESPE internal laboratory test

*** From start of mix

Comparison Table - Light Body Impression Materials

			DMG	Kulzer
	Imprint™ II	Caulk	Honigum®	Flexitime®
	Garant™ RB	Aquasil™ LV	Automix Light	Correct Flow
Mixed Consistency, mm**	39.2	39	44	41
Oral Working Time, seconds*	60 ^{92°F}	2:3073°F	2:1573°F	2:3073°F
Setting Time, minutes*	4:00	5:00***	3:15	3:30 - 5:00
Mix Tip Waste, ml**	0.9	2.2	0.9	0.9
Tear Strength, g/mm**	457	581	286	487
 * Recorded from manufacturer's instructions ** Measured value 3M ESPE internal laboratory test 	st			

*** From start of mix

	Imprint™ II	Discus	Kerr
	Garant™ LB	Splash!™	Take One Wash
Mixed Consistency, mm**	42	41	43
Oral Working Time, seconds*	6092°F	2:1573°F	2:00 ^{73°F}
Setting Time, minutes*	4:00	4:30	5:00
Mix Tip Waste, ml**	0.9	0.9	0.9
Tear Strength, g/mm**	523	460	537
 Recorded from manufacturer's instructions ** Measured value 3M ESPE internal laboratory 	tast		

** Measured value 3M ESPE internal laboratory test

Questions and Answers

How does Imprint[™] II Penta[™] Heavy Body Impression Material compare with Imprint[™] II Garant[™] Impression Material?

- The Pentamix[™] Mixing Unit delivers a homogeneous and void free mix.
- The material is thicker to create a putty-like resistance when seating the impression.
- The colors will not match exactly between Imprint II Garant heavy body impression material and Imprint II Penta heavy body impression material in order to differentiate between 3M ESPE's Impregum[™] Impression Materials and Position[™] Penta[™] Quick Impression Material colors.
- When put to the test by field evaluators*, 90% stated that they were satisfied or very satisfied with the Imprint II Penta Heavy Body impression material. 85% of the evaluators* ranked Imprint II Penta impression material as the same or better than their current impression material. 60% of Imprint II Garant impression material users in the survey* thought Imprint II Penta impression material was better than their current impression material.
- Depending on the user, some may notice minimal handling differences compared to their current heavy body impression material.

How does Imprint II Penta impression material compare with Dimension^m Penta^m H Impression Material?

- The color difference is noticeable: Dimension Penta H impression material has a green hue while Imprint II Penta impression material is mauve in color.
- Imprint II Penta impression material is manufactured to Imprint II impression material working and setting time specifications and is designed to work with the Imprint II Garant Light Body and Garant Regular Body impression materials.
- When put to the test by field evaluators*, 90% stated that they were satisfied or very satisfied with the Imprint II Penta impression material. 85% of the evaluators* ranked Imprint II Penta impression material as the same or better than their current impression material. 57% of the Dimension users in the survey* thought Imprint II Penta impression material was better than their current impression material.
- Depending upon the user, some may notice minimal handling differences compared to their current heavy body impression material.
- * 38% Imprint II users, 36% Dimension Penta H users and 26% competitive VPS users. April 2002 VPS Impression Material Field Evaluation, The Marketing Solutions Group, Inc.

How does $Imprint^{TM}$ II PentaTM impression material compare with competitive VPS materials?

- 80% of the evaluators* that use competitive VPS materials thought that Imprint II Penta impression material was better than what they currently use.
- The Pentamix[™] mixing unit delivers a homogeneous and void free mix.
- The PentaMatic[™] AutoOpen foil bags offer safe, fast and clean loading and dispensing.
- A complete system that offers the benefits of the Pentamix mixing unit combined with the comfort and awareness of the Imprint II brand
- * 38% Imprint II users, 36% Dimension Penta H users and 26% competitive VPS users. April 2002 VPS Impression Material Field Evaluation, The Marketing Solutions Group, Inc.

What causes a non-homogeneous mixing of the material?

The Penta[™] Mix Tip might not be securely fastened onto the drive shaft. If the mixing shaft is not properly engaged, then the rotor inside the mix tip is not turning. A non-homogeneous mix will result.

To solve this problem, push the Penta mix tip onto the drive shaft and then into the corresponding holes in the cartridges. It might be necessary to rotate the mixing tip slightly on the drive shaft for correct seating. A mix tip can only be used as long as the rotor in the mixing tip turns easily. Make sure the drive shaft channel is not clogged with dirt.

Can the Penta mix tip be attached to the cartridge before it is placed inside the Pentamix mixing unit?

No. Attach the new Penta mix tip to the cartridge after placing the cartridge inside the Pentamix mixing unit. For opened PentaMatic foil bags, it is recommended to keep the used Penta mix tip on the cartridge for storage.

The drive shaft might not be properly engaged and the rotor inside the mix tip might not turn if the new mixing tip is attached before placing the cartridge into the Pentamix mixing unit. A non-homogeneous mix could result.

To solve this problem, insert the loaded cartridge into the Pentamix mixing unit and then attach the new mix tip.

I am experiencing cartridges that are cracked. Why?

There are three potential causes for cracked cartridges:

• If you own the original Pentamix mixing unit, you might have a cartridge with a "V" notch. This style of cartridge was available when the Pentamix system was first introduced and has, therefore, exceeded its usable life. The V-notch cartridge has been replaced by a "semi-circular" notch cartridge. To solve this problem, replace the V-notch cartridge with a new-style cartridge that has a semi-circular notch.

- Cartridges manufactured by 3M ESPE are accessory items and are made of plastic. The cartridges are subject to damage when exposed to catalyst from the original Penta[™] Foil Bags when not opened properly. The result could be a cracked cartridge which cannot open the PentaMatic[™] AutoOpen Foil Bags properly. To solve this problem, conduct periodic inspections of the cartridge and replace it when contaminated with catalyst.
- The condition of the cartridge is dependent upon the frequency of use. A cartridge could crack when the shelf life has been exceeded. To solve this problem, replace a cartridge approximately every 1-2 years, depending upon usage.

Can the PentaMatic AutoOpen foil bags be refrigerated?

Yes. However, the PentaMatic foil bags must be at room temperature (at least 18 degrees C/64°F) for 8-10 hours prior to use. Due to the increase in material viscosity that occurs with refrigeration, the foil bag could burst if used immediately after refrigeration.

What causes the plunger discs to loosen or crack?

The plunger discs are functioning parts and could wear with time. Plunger discs are used to apply force to the foil bags gliding inside the Penta cartridge. The high forces applied could cause fatigue of the plastic disc over time. How fast these parts wear depends on the frequency of use. To solve this problem, 3M ESPE recommends checking the plunger discs periodically and replacing as necessary.

Is Express[™] compatible with Imprint[™] II Impression Material?

While the chemistry of Imprint II impression material is compatible with other 3M ESPE VPS impression materials, the technique is not. Imprint II heavy body and light body impression materials were formulated to provide a coordinated 4 minute oral set. The working/setting times of other 3M ESPE products may not correspond to those of Imprint II impression material. Lastly, Express cartridges are not currently compatible with the Garant[™] Dispenser.

Are other brands of VPS impression material compatible with Imprint II impression material?

Due to differences in requirements for work, set and pour times, 3M ESPE does not recommend the use of Imprint II impression material with other brands of impression material.

What is the shelf life of Imprint II impression material?

Shelf life is 36 months at room temperature (70-75°F or 21-24°C) for Imprint II Garant heavy body impression material. The expiration date of the product may be found on the outer box or on the cartridge label. Imprint II Penta heavy body impression material has a shelf life of 24 months. The expiration date of the product may be found on the outer box or on the foil bag.

Will latex gloves inhibit the set of Imprint II impression material?

Avoid contact with chemicals known to inhibit the set of vinyl polysiloxane impression materials such as latex rubber, acrylic and methacrylate residues. If contamination from latex gloves is suspected, scrub the area with an aqueous solution of hydrogen peroxide before making the impression (Browning et al., 1994). Vinyl gloves are recommended for use with VPS impression materials. If acrylic and methacrylate residues are present, clean the affected tooth surface with isopropyl alcohol before making the impression. To avoid inhibition caused by custom temporary materials, the final impression should be made before fabricating the provisional crown or bridge.

How does heat affect the working time of Imprint II impression material?

Heat is known to catalyze the polymerization reaction of VPS impression materials. The amount of working time will decrease as the room temperature increases. Also, if the impression material has been stored in a warm environment (temperatures above 73°F or 23°C) working time may be decreased.

Will hemostatic agents inhibit the set of Imprint II impression material?

Hemostatic agents are not believed to inhibit the set of VPS impression material. However, when wearing latex gloves it is possible to transfer sulfur from the gloves to either the retraction cord, teeth or soft tissues, causing site specific inhibition (de Camargo et al, 1993).

Is it possible to prepare adhesive coated trays in advance? How long in advance is considered acceptable?

Adhesive should be applied to an impression tray not more than 24 hours in advance of making the impression (Cho et al, 1995).

Occasionally, when I am trying to attach a Garant mix tip, I cannot push the tip flush with the impression material cartridge. What's wrong?

It is not possible to attach a mix tip to the cartridge if the ports which separate the catalyst and base are not in alignment. If the mix tip cannot be pushed, flush with the cartridge, rotate the collar of the tip 90° . This rotation will ensure that the separated mix tip ports are in alignment with the ports on the impression material cartridge.

Introductory Kit Contents

Item #9370P Imprint[™] II Penta[™] Impression Material

Qty.	Product	Item #
1	Imprint II Penta Base paste, 300ml	
1	Imprint II Penta Catalyst, 60ml	
1	Imprint II Penta cartridge	77804
10	Penta Mixing Tips	
1	Imprint II Garant Light Body Cartridge, 50ml	9372
1	Imprint II Garant Regular Body Cartridge, 50ml	9373
10	Garant Mixing Tips (yellow)	71461
10	Garant Intraoral Tips (yellow)	71462
1	Garant Dispenser 1:1/2:1	77580
1	VPS Tray Adhesive, bottle	7307
1	Technique Guide	
1	Instructions	

Item #9370 Imprint[™] II Garant[™] Impression Material

Qty.	Product	Item #	
2	Cartridges, Heavy Body	9371	
1	Cartridge, Light Body	9372	
1	Cartridge, Regular Body	9373	
10	Garant Mixing Tips, green	71450	
10	Garant Mixing Tips, yellow	71461	
10	Garant Intraoral Tips, yellow	71462	
2	Garant Dispenser	77580	
1	VPS Tray Adhesive, bottle	7307	
1	Technique Guide		
1	Instructions		

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Instructions for Use

Product Description

Imprint[™] II Impression Material, manufactured by 3M ESPE, is composed of hydrophilic vinyl polysiloxane impression materials designed for making precise inlay, onlay, veneer, crown or bridge impressions. The Imprint[™] II Penta[™] Heavy Body Impression Material, manufactured by 3M ESPE, is to be used with the Pentamix[™] Mixing Unit, manufactured by 3M ESPE. The foil bags are sealed with the PentaMatic[™] Sealing Cap, manufactured by 3M ESPE. The PentaMatic sealing cap automatically opens the foil bags by the push of a button once sufficient pressure is established by the plunger of the Pentamix mixing unit. The Imprint[™] II Penta heavy body impression material as well as the Imprint[™] II Garant[™] Heavy Body Impression Material, manufactured by 3M ESPE, are formulated for use with the Imprint[™] II Garant[™] Light Body Impression Material and Imprint[™] II Garant[™] Regular Body Impression Material, manufactured by 3M ESPE to meet the demands of the two viscosity technique.

Areas of Application

• Impression of inlay, onlay, veneer, crown, and bridge preparations.

Preparation

Impression trays:

- 1. Particularly suitable are rigid trays or custom plastic trays. Blocking of the distal edge of the tray with a silicone or thermoplastic material provides for controlled flow properties affording beneficial effects especially in the distal molar area.
- 2. For sufficient adhesion, apply a thin layer of 3M[™] ESPE[™] VPS Tray Adhesive, manufactured by 3M ESPE, to the tray and allow to dry a minimum of 5 minutes.

Penta cartridge/foil bag:

- 1. Place Imprint II Penta heavy body impression material in the designated cartridge only.
- 2. Insert the loaded Penta cartridge into the Pentamix mixing unit.
- 3. Install a Penta mixing tip and check to ensure the drive shaft is engaged.
- 4. Prior to first use, push the button and discard the first 3 cm of paste from the newly filled cartridge. The color of the dispensed paste must be uniform.

Garant dispenser/cartridge:

- 1. Place the Imprint II Garant heavy body impression material, Imprint II Garant light body or Imprint II Garant regular body impression material into the Garant dispenser, manufactured for 3M ESPE.
- Dispense a small amount of impression material until both the base and catalyst emerge uniformly, then attach a green mix tip for the Imprint[™] II Garant[™] heavy body impression material, a yellow mix tip for the Imprint[™] II Garant[™] light body and Imprint II Garant regular body impression materials.
- 3. For intraoral use of Imprint II Garant light body, or Imprint II Garant regular body, attach a yellow intraoral tip to the yellow mix tip. (Note: Use moderate pressure and push the blunt end of the intraoral tip into the mix tip. A click will be heard when the intraoral tip is locked into positon). Alternatively, dispense the Imprint II Garant light body or Imprint II Garant regular body material into an intraoral syringe.

Retraction

Areas from which impressions are to be taken should be kept dry but not dessicated. In subgingival preparations, hemostatic threads or rings may be used. Prior to taking the impression, completely remove any residue of the retraction agent by rinsing and drying.

Dosing and Mixing

Dosing and mixing are performed automatically in the Pentamix mixing unit for the Imprint II Penta heavy body impression material and in the Garant dispenser for the Imprint II Garant heavy body, Imprint II Garant light body, or Imprint II Garant regular body impression materials.

The mixing ratio is 5 volume base paste: 1 volume catalyst for the Penta system and 1 volume base paste: 1 volume catalyst for the Garant system, respectively.

	Room Temperature Working Time	Intraoral Setting Time	
Imprint II Penta heavy body	2:00	4:00	
Imprint II Garant heavy body	2:00	4:00	
	Intraoral Working Time	Intraoral Setting Time	
Imprint II Garant light or Imprint II Garant regular body	1:00	4:00	

Times in Minutes

Note: Once the tray is seated in the mouth, it is not necessary to add any unused work time to the 4 minute oral set time.

Impression Taking

One-Step/Two Viscosity technique - Penta[™] System:

- 1. Insert the Imprint[™] II Penta[™] Heavy Body cartridge into the Pentamix[™] Mixing Unit and install a new Penta mixing tip. Use the hand-wheel to turn the plungers down to the stop.
- 2. While the assistant loads the tray, the dentist may begin to syringe light body or regular body impression material around the preparation. Depending on the number of teeth, initiate application such that tray loading and application of the wash material around the preparation are completed at the same time. During application, the mix tip should be immersed in the material at all times to avoid trapping air bubbles.
- 3. Slowly place the loaded tray in the mouth parallel to the vertical axes of the prepared teeth. Once the tray is seated, hold in place without applying pressure for 4 minutes. Avoid contact of the teeth with the tray.
- 4. After 4 minutes apply pressure along the periphery of the impression tray to break the seal of the impression. The impression can then be removed from the mouth.
- 5. Thoroughly examine and explore the margins of the prepared teeth and surrounding dentition. Remove any residual cured impression material from the mouth.

One-Step/Two Viscosity technique - Garant[™] System:

- 1. Place Imprint[™] II Garant[™] heavy body impression material into the Garant dispenser.
- 2. While the assistant loads the tray, the dentist may begin to syringe light body or regular body impression material around the preparation. Depending on the number of teeth, initiate application such that tray loading and application of the wash material around the preparations are completed at the same time. During application, the mix tip should be immersed in the material at all times to avoid trapping air bubbles.
- 3. Slowly place the loaded tray in the mouth parallel to the vertical axes of the prepared teeth. Once the tray is seated, hold in place without applying pressure for 4 minutes. Avoid contact of the teeth with the tray.
- 4. After 4 minutes apply pressure along the periphery of the impression tray to break the seal of the impression. The impression can then be removed from the mouth.
- 5. Thoroughly examine and explore the margins of the prepared teeth and surrounding dentition. Remove any residual cured impression material from the mouth.

Two-Step/Two Viscosity Technique

1. Fill the impression tray with Imprint II Penta heavy body or Imprint II Garant heavy body impression material.

- 2. Place a plastic spacer over the mixed heavy body material and seat the tray in the mouth. Maneuver the tray in the mouth to create a 2-3 mm space between the teeth and impression material.
- 3. Remove the tray after 4 minutes and discard the spacer.
- 4. Trim out any undercuts and interdental appendages for a distortion free seating.
- 5. Syringe the Imprint[™] II Garant[™] light body, or Imprint II Garant regular body material into the spaces of the preliminary impression and around the prepared teeth.
- 6. Re-seat the tray being careful to avoid contact of the teeth with the pre-set heavy body impresson material. Note: The tray must be seated within one minute from the start of oral syringing.
- 7. Once the tray is seated, hold in place without applying pressure for 4 minutes.
- 8. After 4 minutes apply pressure along the periphery of the impression tray to break the seal of the impression.
- 9. Thoroughly examine and explore the margins of the prepared teeth and surrounding dentition. Remove any residual cured impression material from the mouth.

Caution

- 1. At the onset of mixing, closely monitor the entry of paste into the mixing tip and ensure that both base paste and catalyst paste flow into the mixing tip.
- 2. Avoid surface contact or contamination with chemicals known to inhibit the set (e.g. acrylate and methacrylate residues, latex rubber, and sulfur compounds). If acrylic and methacrylate residues are present, clean the affected tooth surface with isopropyl alcohol before making the impression. To avoid inhibition caused by custom temporary materials, the final impression should be made before fabricating the provisional restoration. If contamination from latex rubber or sulfur is suspected, rinse the area with an aqueous solution of hydrogen peroxide before making the impression.
- 3. The oxygen inhibition layer of composite materials, e.g. in fillings or core buildups, may impair the setting of silicone materials, and should therefore be removed completely.
- 4. Premature exposure of the syringe material to the higher temperature of the mouth causes this material to set more rapidly than the tray material. This may distort the impression.
- 5. Load the impression tray, and then insert into the mouth proceeding slowly and along the vertical axes.
- 6. As with any rigid setting impression material, if undercuts or gingival recession are noted, blocking out may be required to prevent the material from "locking" onto tooth structure. Failure to do so may make tray removal difficult, or cause extraction of natural teeth or prosthesis.

7. Imprint[™] II Penta[™] heavy body, Imprint[™] II Garant[™] heavy body are not suitable for use as a monophase or syringeable wash material.

Hygiene

Place the impression in a standard ADA-accepted liquid disinfectant and disinfect according to standard procedures. Immediately after disinfecting, rinse the impression in water and blow dry.

Model Preparation

When using Imprint II Penta heavy body impression material the stone model may be poured 30 minutes after the impression has been made. When using Imprint II Garant heavy body impression material the stone model may be poured immediately after disinfection. The impressions can be silver or copper-plated. Impressions made using Imprint II are very stable and may be poured up to two weeks post polymerization.

Cleaning

- 1. Disassemble the Garant dispenser, and sterilize the dispenser handle and plunger separately at up to 135°C/275°F or with commercial cleaning agents containing no strong organic solvents, such as alcohols. Do not use disinfectants.
- 2. Pastes that have not set may be removed with ethanol. The adhesive can be removed from metal trays with acetone.
- 3. Clean all components of the Pentamix mixing unit with a soft cloth and, if necessary, a mild detergent.
- 4. For disinfection of the Pentamix mixing unit use commonly available disinfection sprays. Under no circumstances use solvents or scouring agents as they will permanently damage the plastic.
- 5. Do not allow detergent or water to enter the mixing unit.

NOTE: CAREFULLY READ AND FOLLOW THE CLEANING SOLVENT MANUFACTURER'S PRECAUTIONS AND DIRECTIONS FOR USE.

Notes

- 1. The oxygen inhibition layer of composite materials, e.g. in fillings or core buildups, may impair the setting of silicone materials, and should therefore be removed completely.
- 2. Keep the filled mixing tip on the cartridge to serve as a closure until the next use. Storage with a new Penta or Garant mixing tip may lead to carry-over of paste and cause a plug to form in the cartridge.
- 3. Disposable latex gloves impair the setting of impression materials. Hence, vinyl or nitrile gloves are more suitable.

Technical Data

The impression materials comply with ISO 4823.

Imprint™ II Penta™ HB	Imprint II Garant™ HB	Imprint II Garant RB	Imprint Garant II LB		
Strain in compression (%):					
2.9	2.5	2.7	3.0		
Recovery from deformation (%):					
> 99.0	> 99.0	> 99.0	>99.0		
Linear dimensional change (after 24 h) (%):					
0.20	0.3	0.20	0.20		

Storage and Stability

The system is designed to be used at room temperature of approximately 21-24 °C (70-75° F). Do not store the product above 25° C/77° F. Do not use after the expiration date. Store impressions below 30° C/86°F.

No Person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

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3M ESPE

Dental Products

3M Center, Building 275-2SE-03 St. Paul, MN 55144-1000 Dental Products 3M Canada Post Office Box 5757 London, Ontario, Canada N6A4T1



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