3M ESPE

Impregum™ Penta™ Soft MB
Impregum™ Penta™ Soft HB
Impregum™ Garant™ Soft LB
Impregum™ Penta™ Soft Quick Step MB
Impregum™ Penta™ Soft Quick Step HB
Impregum™ Garant™ Soft Quick Step LB

Polyether Impression Material

technical product profile

Impregum™

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Introduction

When polyethers were introduced by 3M ESPE in 1965 hardly anybody would have imagined that almost 40 years later precision impressions would have become unthinkable without them. The accuracy of this class of materials has set a standard that is well respected. Polyethers are characterized by their initial and intrinsic hydrophilicity, structural viscosity, snap set behavior, and their high tolerance to moisture.

Continuous innovation has substantially simplified polyether handling. Automatic mixing in the Pentamix™ Mixing Unit ensures precise dosing of the base and catalyst paste, resulting in a void free impression material of highly homogeneous mixing quality.

The Impregum™ Penta™ Soft polyether impression material product range launched in 2000 was designed to facilitate impression removal, even in difficult clinical settings such as severe undercuts, and provided fresh tasting peppermint flavorings.

The Impregum™ Penta™ Soft Quick Step polyether impression material product range also answers the need of many dentists for a faster setting polyether, especially when dealing with just 1 or 2 prepared teeth.

Overview over the New Generation of Soft Polyether Impression Materials

	Regular setting	Fast setting
Monophase Impression	Impregum Penta Soft	Impregum Penta Soft Quick Step
One-step/two-viscosity technique	Impregum Penta Soft HB + Impregum Garant™ Soft LB	Impregum Penta Soft Quick Step HB + Impregum Garant Soft Quick Step LB

History of Precision Impressions

After the first impression techniques employing wax, plaster, and zinc oxide eugenol paste, true precision impressions using hydrocolloids were initially taken in 1925. To this day, hydrocolloids still have their definite place, albeit a small one, in precision impressions. By contrast, the polysulphides introduced somewhat later for precision impressions are rarely used nowadays.

In the fifties a new class of materials entered the dental market that had not originally been intended for intraoral use - condensation cured or C-type silicones. The major drawback of these products has been and is intrinsic shrinkage, since condensation curing entails hydrophobicity and the release of a byproduct.

In 1965, just 10 years later, 3M ESPE introduced polyether (see Figure 1). This addition–cured hydrophilic impression material, polymerized by ring opening, was a vast improvement over hydrocolloids and C-type silicones in its mechanical properties, such as tensile strength, and it is associated with less shrinkage, since this addition curing does not lead to by-product release.

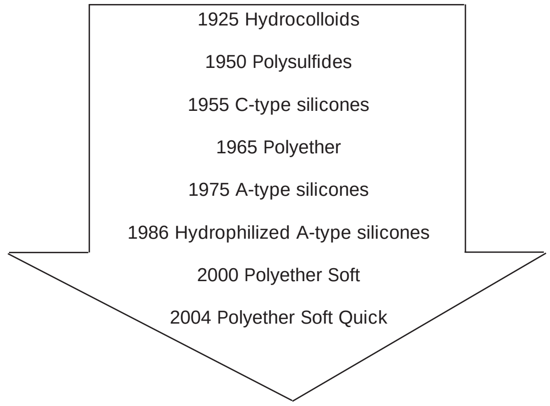


Figure 1. Timeline of introduction of different impression materials classes

It took another 10 years until 1975 when the next generation of silicone impression materials came into general use. These addition cured A-type silicones were, however, still hydrophobic. Not until 1986 were efforts successful to reduce the hydrophobicity that is intrinsic to the material's molecular structure. The hydrophilicity of the mixed material could be increased over time by adding surfactants, or soap-like agents.

With the launch of the Polyether Soft product range and their new technological base the foundation has been laid for future developments in polyether impression materials.

Development of 3M ESPE Polyether Products

3M ESPE introduced Impregum™, its first polyether impressions material for monophase impressions, in 1965. Permadyne™, a combined product for the one-step/two-viscosity technique, followed it in 1980.

Until 1993 polyethers were only available for mixing by hand. When the Pentamix™ Mixing Unit came to market in 1993 Impregum™ Penta™ became the first polyether ready for fully automatic mixing. Two years later Permadyne and Ramitec™ complemented the Pentamix product line.

With the introduction of the Soft technology line of impression materials in 2000, polyether material development advanced to yet another landmark. This latest development combined all the positive characteristics of polyether with easier removability, a large improvement in handling compared to previous versions not only for the clinical practice but also for the dental laboratory.

After the Impregum™ Penta™ Soft Quick Step polyether impression material product range entered the market in 2004, dentists, for the first time, could use fast setting modified polyether impression material for the monophase and one-step/two-viscosity technique. This met the need of many dentists for a polyether impression material with a faster setting time.

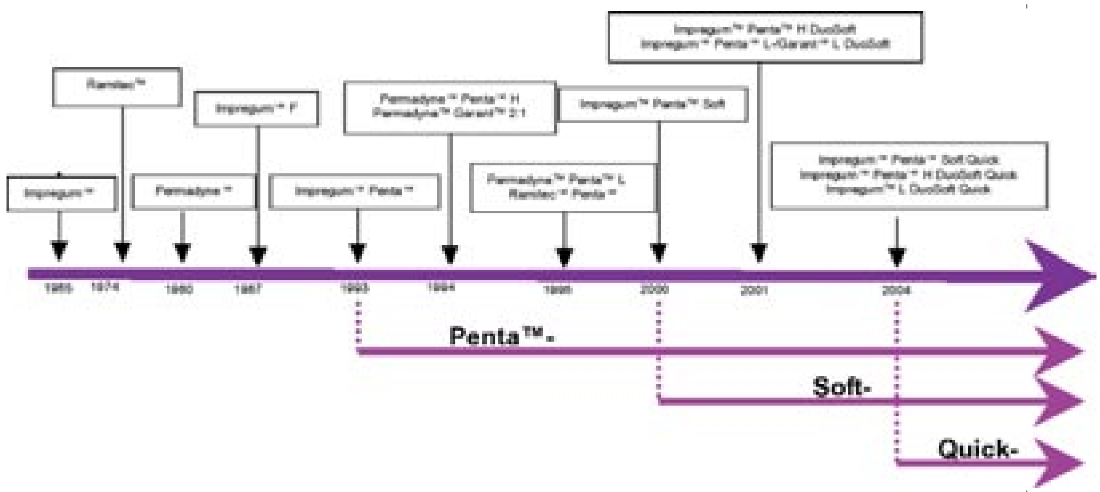


Figure 2. Development of the 3M ESPE Polyether Product Range

Objective

Polyether impression materials feature high-level accuracy of detail and dimensional stability. However, the most important feature of polyethers is the reliability of their impressions – even under difficult clinical conditions – and the high-precision fit of the finished work.

The superb detail reproduction of polyether is primarily a result of its initial hydrophilicity, which is in turn due to the polyether's chemical makeup. Hydrophilicity allows the material to precisely reproduce surfaces moist with saliva or even blood. Besides being hydrophilic, the structural makeup of polyether makes it also thixotropic, a characteristic imbuing the material with a very high degree of reliability.

The objective in developing Impregum™ Penta™ Soft polyether impression materials was to make real the easier removability of the set impression both from the mouth as well as from the die model, and an improved taste, while at the same time retaining all the positive characteristics of polyether material. The development of Impregum™ Penta™ Soft Quick Step polyether impression material has made it possible to tackle smaller cases with a fast setting polyether.

The following chapters will show that the newly developed polyether impression materials, Impregum Penta Soft and Impregum Penta Soft Quick Step, meet all the requirements for modern impression materials while, at the same time, allowing clinicians to treat patients successfully.

Indications

Impregum Penta Soft and Impregum Penta Soft Quick Step are well suited for precision impressions, in particular for the following applications:

Indications	Impregum Penta Soft	Impregum Penta/Garant™ Soft H/L	Impregum Penta Soft Quick Step	Impregum Penta Soft H/L Quick Step
Impressions of inlay, onlay, crown, and bridge preparations	X	X	X*	X*
Functional impressions	X	X		
Implant impressions	X	X	X*	X*
Fixation impressions	X	X	X*	X*

*particularly well suited for impressions of 1 or 2 preparations/units

Newly defined setting times for Impregum™ Penta™ Soft Quick Step and Impregum™ Penta™ Quick Step HB/LB

A new time protocol has been developed for the Soft Quick Step product line. Figures 3 and 4 compare both protocols in order to illustrate their differences.

Figure 3 demonstrates the new polyether time protocol for the Quick Step product line. The working time* may vary and ends at 1:00 minute after mixing has been started. Oral residence time is fixed at 3:00 minutes. The time at which the tray is removed from the mouth may vary. It depends on the sum of the actual working time ** plus the fixed setting time, and will be at most 4:00 minutes after mixing has been initiated***.

- Example 1: working time 0:30 seconds + oral residence time 3:00 minutes = removal from mouth 3:30 minutes
- Example 2: working time 1:00 minutes + oral residence time 3:00 minutes = removal from mouth 4:00 minutes

Figure 3. Setting times for the fast setting Soft Quick Step polyether product line

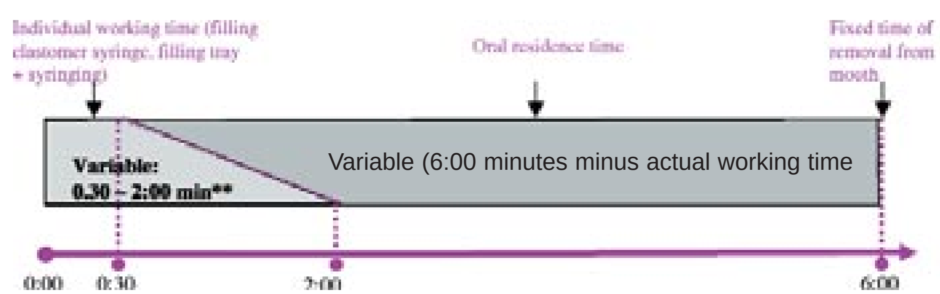


Figure 4. Setting times for the regular setting polyether soft product line

Figure 4 demonstrates the polyether time protocol for Impregum Penta Soft impression material with its regular setting time. Here, working time* as well as oral residence time may vary but must always add up to 6:00 minutes. According to the Instructions for Use the working time is at most 2:45 minutes after mixing has been initiated (at 23°C/73°F). Typical clinical working time for Impregum Penta Soft, Impregum Penta HB/Impregum Garant Soft LB are between 0:30 and 2:00 minutes (depending on the indication, speed of the dentist etc.). Therefore, oral residence time is that time until the 6:00 minute period has elapsed.

* The working time starts as soon as the paste enters the mixing tip. It includes tray filling time (for the monophase technique also the initial time required for filling the elastomer syringe) as well as the time for intraoral syringing. It ends as soon as the tray has been placed within the mouth.
** depending on the number of prepared teeth, indication, impression technique, type of tray used, speed of the dentist...).
*** Start of mixing = when paste enters mixing tip

- Example 1: working time 0:30 seconds + oral residence time 5:30 minutes = removal from mouth 6:00 minutes
- Example 2: working time 2:00 minutes + oral residence time 4:00 minutes = removal from mouth 6:00 minutes

The previous and present definition of the setting time differ mainly by the shorter total impression time for the Quick Step product line, where this total time may vary depending on the actual working time needed (see Table 1). This will enable the dentist to save a considerable amount of time, compared to existing 3M ESPE polyether materials, especially when working on 1 - 2 unit cases. Polyethers impression materials of the Quick Step product line set at least 1/3 faster than regular set polyethers.

Assumed working time (minutes)		Time in mouth (minutes)		Total time for impression (minutes)		Time saved with Polyether Quick (minutes)	
Quick	Normal	Quick	Normal	Quick	Normal	Oral residence time	Total time
0:30	0:30	3:00	5:30	3:30	6:00	2:30 (45%)	2:30 (42%)
1:00	1:00	3:00	5:00	4:00	6:00	2:00 (40%)	2:00 (33%)

Table 1. Minutes saved in oral residence time and total time for impression with the Polyether Quick Step line of materials as compared to the present polyethers, depending on the actual working time required.

Depending on the working time, the Polyether Quick Step line of materials will save at least 2 minutes compared to the present polyethers, due to the shorter oral residence and total time.

Materials Science Background

General Overview

The Impregum™ Penta™ Soft and Impregum™ Penta™ Soft Quick Step base paste contains the polyether macromonomer. This unique macromonomer was developed by 3M ESPE for dental impression materials. Its structure resembles that of a long chain where oxygen molecules alternate with alkyl groups. The macromonomer is made up of two distinct structural units with statistical distribution across the polyether backbone.

Proper choice of these structural units, their relative percentage, and adjustment of the molecular weight will result in the excellent elastomeric and hydrophilic characteristics of polyether. The highly reactive groups R terminate the polyether monomers. They mediate polymerization crosslinking as shown in Figures 5 and 6.

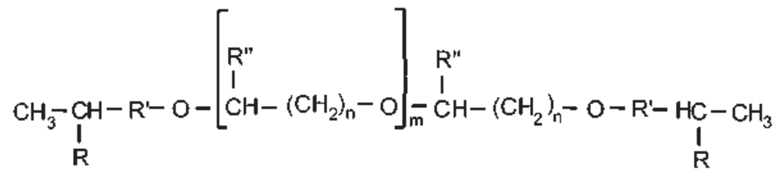


Figure 5. Polyether macromonomer – the chains are terminated by the highly reactive ring groups (marked with an R)

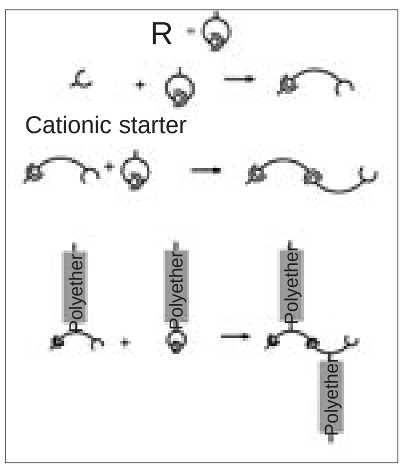


Figure 6. Polymerization process, and cross-linking (setting) of polyether

The setting reaction of the polyethers can be classified as cationic polymerization, opening a highly reactive cation ring group. The setting reaction is initiated by the cationic starter activating a ring group R (Figure 6). The activated ring group now becomes a cation and can attack other rings while it itself will be split open (domino effect). As each ring splits open, the cation that opened it up will terminate the polyether macromonomer. Successive addition of these opened ring groups will result in a cross-linked polymer.[1]

Inorganic fillers induce the high degree of stiffness in the impression and help maintain dimensional stability once the polyether material has set and been removed.

The addition of synthetic triglycerides increases the structural viscosity of the material. They are also responsible for the superb ability to flow under pressure; see page 13 Materials Science Background – Intrinsic Viscosity). Because of their identical chemical origin, polyethers of any consistency may be combined with one another. The material is crosslinked by covalent bonds during the setting reaction.

Compared to polyethers with regular setting times, Impregum Penta Soft Quick Step/Impregum Penta Soft Quick Step HB/LB will set faster because of its additional accelerator. Since the reactive components (cation starter and the highly reactive rings R of the polyether molecule) have not been altered, even the fast setting materials will exhibit the same proven setting characteristics.

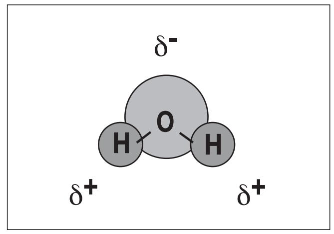
In general, it is the plasticizers that define the degree of viscosity of the material.

Base	Catalyst
Polyether macromonomer	Initiator (cation starter)
Fillers	Fillers
Plasticizers (heavy and light body)	Plasticizers
Pigments	Pigments
Flavors	
Triglycerides	
Accelerator*	

* only in Impregum Penta Soft Quick Step/Penta Soft Quick Step HB/LB

Table 2. Typical compound classes in polyether

Hydrophilicity



The term hydrophilic is generally used to describe materials with a strong affinity for water. From a chemical point of view hydrophilicity derives from the polarity of water. Within a water molecule, there is a strong difference in polarity between the hydrogen and oxygen atoms. If a water molecule encounters another polar group made up of similar chemical structures it will attach there due to its polarity and chemical makeup.

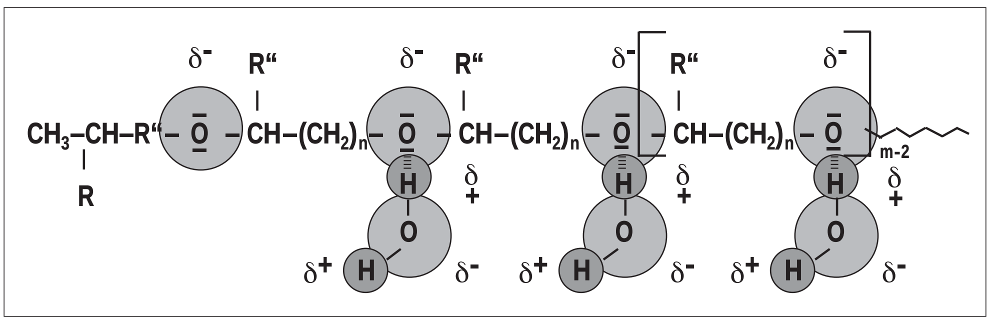


Figure 7. Polar water molecules can attach themselves to the polar groups of the polyethers

Due to their chemistry, addition (A-) and condensation (C-) cured silicones are hydrophobic (lacking affinity for water) since they basically consist of apolar siloxane units.[2] In recent years this structurally induced hydrophobicity of the silicones has been reduced by the addition of hydrophilizers (surfactants); however, it does take a certain amount of time until the surfactants take effect on the surface of the impression material.

Apart from hydrocolloids, polyether material is the only precision impression material where the crosslinking molecules themselves are hydrophilic. Unlike hydrophilized A-type silicones polyether material is intrinsically hydrophilic. In other words upon contact with water the hydrophilic characteristics will become evident immediately. This intrinsic hydrophilicity is induced by the molecular structure of polyether. The molecular structure of polyether itself consists of a long chain of alternating oxygen atoms and alkyl groups as shown in the example of a polyether molecule in Figures 5 and 6. Due to the polarity difference between oxygen and carbon, water – which is also polar – can attach itself to the polar polyether chains (Figure 7).

Because of its intrinsic hydrophilicity polyether material thus exhibits very good flow characteristics even around detailed structures in the moist oral cavity. The intraoral flow of the impression material, e.g. resulting from the pressure when the tray is introduced, will constantly generate a new surface coming into contact with the moist structures of the oral cavity. If the impression material is hydrophilic at the moment of contact it will be able to flow precisely along these moist structures.

The implication for clinical practice is that, due to its hydrophilic nature, polyether shows great penetration ability even into the sulcus. This characteristic of polyether is particularly important for subgingival preparations[3], where its precise flow along delicate structures is vital. This also helps to explain the strong adhesion of the polyether impression initially experienced during removal.

The intrinsic hydrophilic nature of polyether can be demonstrated using the sitting droplet technique. If a drop of water is placed on the surface of Impregum™ Penta™ Soft (-Quick)/Penta Soft (-Quick) HB/LB not yet set it is downright attracted and will spread on the surface (Figure 8). By contrast, contact between A-type silicones and the water droplet typically results in a very obtuse contact angle. A-type silicones are outright hydrophobic at this phase. A-type silicones hydrophilized with surfactants will also exhibit a typical initial contact angle of >100°.

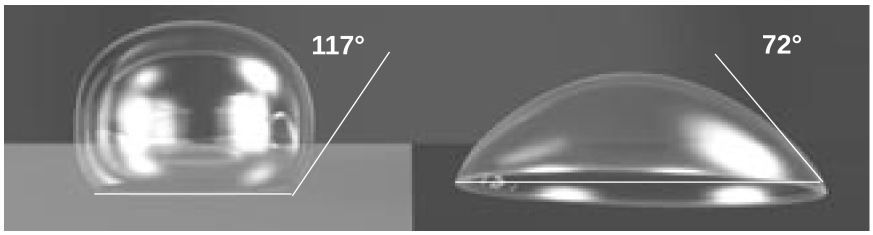


Figure 8. Water droplet on A-type silicone (left) and Impregum Penta Soft (right). In contrast with A-type silicones, a smaller contact angle will form immediately after the first contact of a water droplet with Impregum Penta Soft due to its intrinsic hydrophilic nature.

Although polyether is hydrophilic, by comparing it with A-type silicones various studies have been able to demonstrate that the intrinsic hydrophilicity of polyether has no effect on the dimensional stability (e.g. in case of disinfectant when used as recommended).[4, 5, 6, 7, 8, 9, 10]

Snap Set

In the context of impression materials the term “snap set” refers to the rapid transition from the unset to the set state, as shown in Figure 9. In terms of rheology snap set can best be described as the sudden transition from an extended preservation of plasticity to the manifestation of elasticity.

Plasticity refers to the property of material to remain deformed after having been exposed to an outside force. Elasticity refers to the ability of material to return to its original state after having been deformed.

During the working phase impression material should be completely plastic in order to ensure optimum flow. As soon as it begins to set the material becomes more and more elastic, until after setting is complete it can be said to be almost completely elastic.

If the impression material already demonstrates elastic properties during the working phase, premature elasticity may cause tension in the material and, subsequently, an inaccurate impression. Therefore, the material should transit from plasticity to elasticity as quickly as possible. Polyethers, and Impregum Penta Soft (-Quick Step)/Penta Soft (-QuickStep) HB/LB in particular, display such a behavior. On the other hand, in silicones pre-setting takes place quite early, so that some elastic sections will be found even during the working phase. The snap set seen in polyethers is not observed here[11] (see also page 20 Studies in light body [low viscosity] impression material) and the transition from the plastic to the elastic phase is less abrupt.

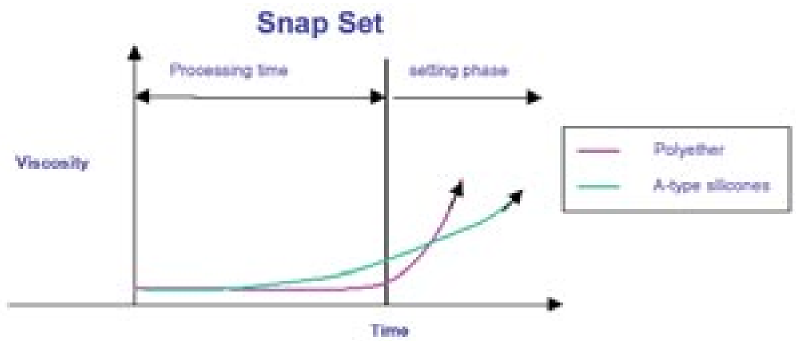


Figure 9. The fast transition from the working phase (plastic) to the set state (elastic), so typical for polyether, is known as "snap set".

Structural Viscosity (thixotropy)

The rheological characteristics of impression materials have a major influence on their behavior in clinical applications. Therefore, the materials should exhibit intrinsic viscosity well matched to their clinical use. The thixotropy of a material is evidenced by a reduction in viscosity with an increasing outside force (shearing speed). Once this outside force has been removed the viscosity will slowly be restored. At increased shearing speed, such as when injecting impression material or applying it to the tray, its viscosity should be reduced. But when the material is under no outside influence, it must quickly become highly viscous again in order to stop the material from oozing away from the tooth stump or out of the tray.

Impregum™ Penta™ Soft (-Quick Step)/Penta™ Soft (-Quick Step) HB/LB exhibit significant structural viscosity. This is partly due to the addition of triglycerides, as is typical for polyethers. Through crystallization, triglycerides form a three-dimensional lattice that harbors the liquid parts of the impression material. This three-dimensional lattice gives polyether the required stability (Figure 10). Once the material comes under outside strain the crystals will align evenly and the ability to flow will increase - or in other words the viscosity will decrease (Figure 11).

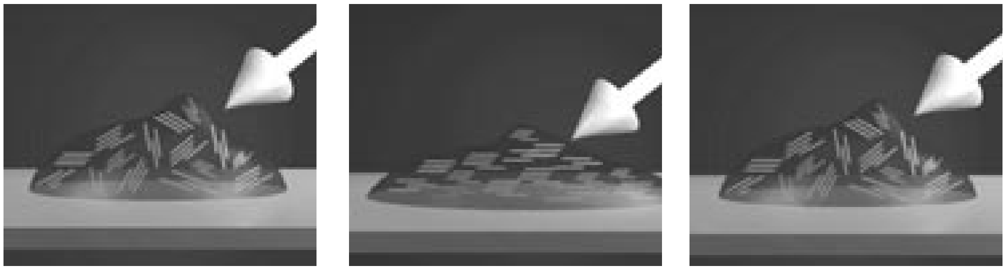


Figure 10. Crystallization of the triglycerides within the polyether will result in a three dimensional lattice that lends the polyether a high level of stability.
Figure 11. Under outside strain the crystals will align themselves and the ability of the polyether to flow will increase.
Figure 12. Once the outside force is no longer applied the three dimensional lattice will be restored and the polyether resumes its high level of stability.

Once there is no more outside force the three-dimensional lattice will be restored, and the material will return to its original viscosity (Figure 12).

This snap setting just described gives Impregum Penta Soft (-Quick Step)/Penta Soft (-Quick Step) HB/LB ideal handling properties. During the working time the network of weak interactions, induced by the trigylicerides, will determine the viscosity and flowability of the material. The special strong point of polyether impression materials, their very high degree of flow becomes manifest even in the case of very small outside forces (Figure 13). After the brief setting time the viscosity is determined by the strong lattice resulting from the polymerization. The material now exhibits ideal elastic behavior.

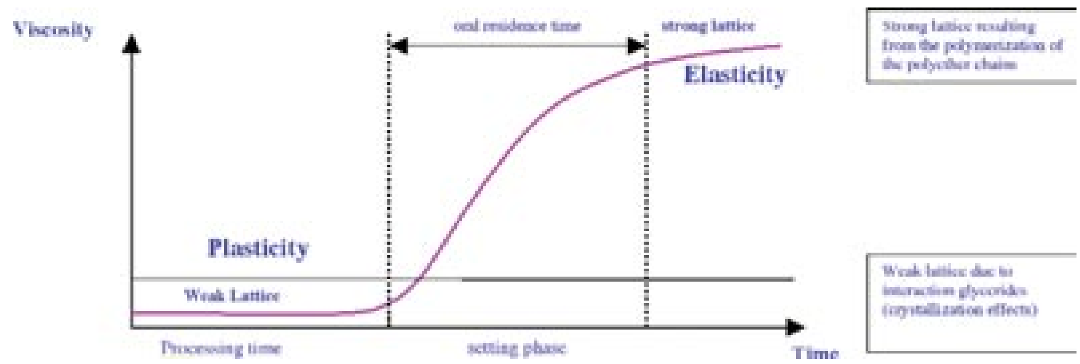


Figure 13: The weak lattice determines the plasticity and the strong lattice the elasticity

Technical Properties

Materials Science Properties at a Glance

Characteristics of all polyethers:

Characteristic	Clinical benefit
Initial hydrophilicity (while unset during the working phase as well as after setting)	Precise even in wet environment
High flowability throughout the working time	Precise reproduction of detail
Structural viscosity (thixotropy)	Flows ideally under low pressure but does not slump
Precise setting behavior (snap set)	Superb accuracy and fit; reliable features during whole working time
Cationic ring opening polymerization	Dimensional stability

Polyether Soft Characteristics:

Characteristic	Clinical benefit
Decreased Shore-A hardness	Easier removal of the impression from mouth and gypsum cast
Improved taste by adding fresh mint flavor	More comfort for the patient

Polyether Soft Quick Step Characteristics:

Characteristic	Clinical benefit
Variable working phase (1 minute max.)	Best suited for 1 and 2 unit impressions Especially suited for the dual arch tray technique
Short total setting and oral residence times (at least 1/3 quicker than regular setting polyether)	Saves time (at least 2 minutes compared to regular setting polyethers) More comfort for the patient

Product Composition

The following table gives an overview of the qualitative composition of Impregum™ Penta™ Soft (-Quick Step)/Impregum™ Penta™ Soft (-Quick Step) HB/LB.

Base	Catalyst
Polyether macromonomer	Initiator (cation starter)
Fillers	Fillers
Plasticizers (heavy and light body)	Plasticizers
Pigments	Pigments
Flavors	
Triglycerides	
Accelerator*	

* only in Impregum Penta Soft Quick Step/Penta Soft Quick Step HB/LB

The composition of the Impregum Penta Soft products is comparable to that of Impregum Penta impression material, but modified to achieve the following improvements:

- easier removal
- fresh tasting peppermint flavorings

These goals have been met by reducing the amount of fillers, thereby decreasing the final hardness of the set material. This makes it easier to remove the impression from the mouth and from the model. However, in order to ensure the characteristic viscosity and flowability of polyether impression material despite the reduced amount of fillers, a highly viscous plasticizer was developed and employed.

Improvement in taste has been achieved by reducing the level of bitter materials and by adding fresh mint flavor.

The composition of the Impregum Penta Soft Quick Step/Impregum Penta Soft Quick Step impression materials is very similar to that of the Impregum Penta Soft product line. Here, the development focused on:

- shorter working and s.etting phases.

Faster setting of the Soft Quick Step materials was realized by adding an accelerator.

Clinical and Materials Science Results

Contact Angle Studies

Contact Angle Studies on Unset Impression Material
– Contact Angle Studies on Unset Monophase Impression Materials

Mondon M, Ziegler Ch., Reusch B., Kaiserslautern University, Germany, AADR, #618, 2001[12]
Hydrophilicity can be demonstrated by the contact angle in the so-called "sitting droplet" test. This test measures the contact angle, which a water droplet assumes on a test specimen of the material under examination, said contact angle being a direct measurement of the material's hydrophilicity - its affinity for water. The more hydrophilic the material, the smaller the angle of contact, and therefore the better the droplet will flow on the material (see Figure 14).

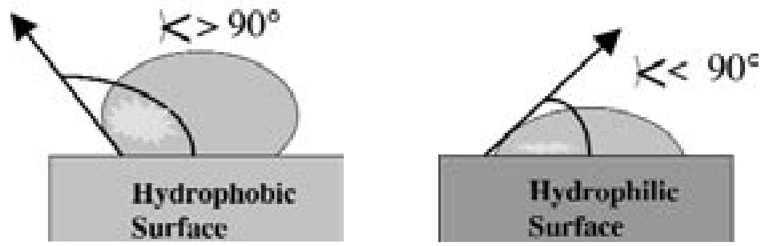


Figure 14. A water droplet on a hydrophobic surface will exhibit a contact angle of more than 90°; on a hydrophilic surface, however, the contact angle will be less than 90°.

So far, contact angle studies based on this method have mainly been done on set material. The objective of this study at Department of Kaiserslautern University[13] was to determine the hydrophilicity and wetting properties of impression materials in the unset state (intrinsic hydrophilicity), in other words as close to the clinically relevant conditions as possible.

A droplet on a thin layer of unset material modelled the flow of the impression material within the patient's mouth. Studied were the A-type silicone Aquasil™ Monophase FS (Dentsply DeTrey GmbH) and the Impregum™ Penta™ Soft polyether impression material.

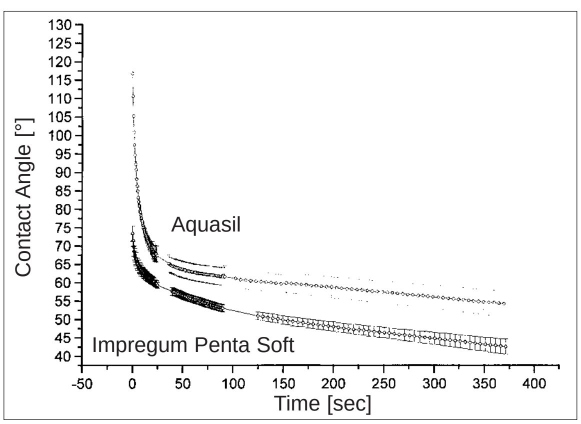


Figure15. Contact angle as a function of time in unset impression materials (measurements with standard deviations)

There were significant differences between the impression materials investigated. Compared with Impregum Penta Soft the A-type silicone Aquasil Monophase FS demonstrates a more obtuse contact angle over the entire range of the graph. The initial contact angles (see Figure 15) of 116.8° ± 5.5° and 73.4° ± 2.1° for Aquasil Monophase FS and Impregum Penta Soft polyether material respectively are especially indicative of the considerably stronger intrinsic hydrophilicity of Impregum Penta Soft.

Contact Angle Studies on Unset Impression Material
– Contact Angle Studies on Unset Light Body Impression Materials

Mondon M, Ziegler Ch., Reusch B., Kaiserslautern University, Germany, AADR, #618, 2001 [12]

Apart from these monophase materials a second study investigated light body impression materials. It compared the A-type silicones Aquasil™ ULV and Provil Novo Light C.D. with the two polyethers impression materials, Impregum™ Soft Garant™ L and Permadyne™ Garant™ 2:1. The picture here was comparable to that of the monophase materials. According to the study, Aquasil ULV has an initial contact angle of 86° and Provil™ Novo Light C.D. one of 91°, while Impregum Soft Garant L (59°) and Permadyne Garant 2:1 (62°) are considerably more hydrophilic. Figure 16 illustrates the initial contact angles as well as their course over time for all materials studied.

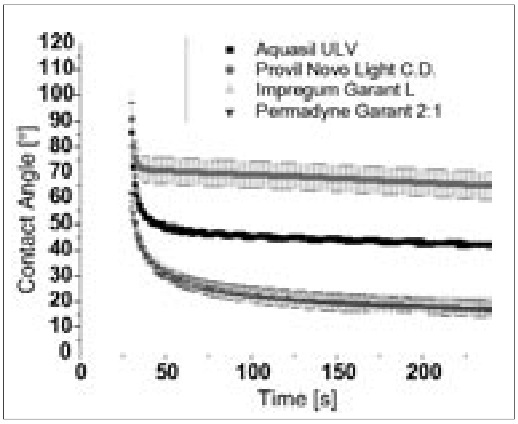


Figure 16. Contact angle as a function of time in unset light body impression materials (measurements with standard deviations)

Klettke Th., Kuppermann B., Führer C., Richter B., "Hydrophilicity of Precision Impression Materials During Working Time", CED/IADR, Istanbul, #141, 2004 [14]

By their chemical nature 3M ESPE polyether impression materials are hydrophilic. This ensures that from mixing to setting the polyether material will exhibit its characteristic of precise flow and exact detail reproduction even on moist surfaces, such as the subgingival areas of the preparation. This is also known as intrinsic or initial hydrophilicity.

Silicone impression materials, on the other hand, are naturally hydrophobic and have to be hydrophilized by the addition of surfactants. This is accompanied by some drawbacks since upon contact with moisture the surfactant first has to "migrate" to the surface. Obviously, this will prohibit complete manifestation of hydrophilicity during the working and setting time.

One common tool to study the hydrophilicity of a material is to determine its contact angle. Usually this study is undertaken for set impression material. But is this methodology of any true clinical importance? Therefore, recent studies [12, 13, 15] have focused on measuring the contact angle in unset impression material, i.e. during its working time. In this new technique the water droplet was placed on to the material 45 seconds after mixing had started and then was "observed" on video for 10 seconds. (Drop Shape Analysis System DSA10, Krüss GmbH, Hamburg). The results are illustrated in Figure 17.

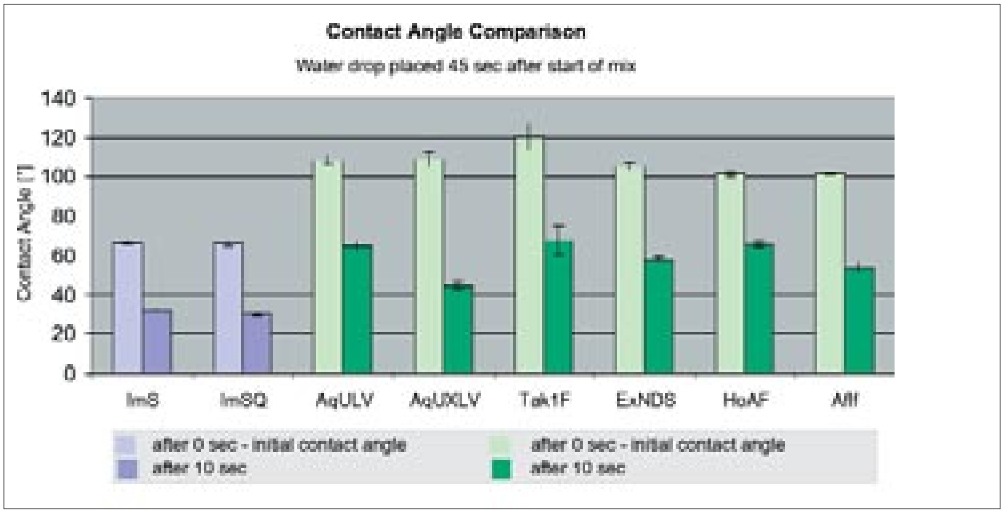


Figure 17. Contact angle studies on unset impression materials: Comparison of various materials. [ImS=Impregum™ Soft; ImSQ = Impregum™ Soft Quick Step Light Body; AqULV = Aquasil Ultra LV Fast Set; AqUXLV = Aquasil Ultra XLV Fast Set; Tak1F = Take 1™ Fast Set Wash; ExNDS = ExaFast™ NDS Injection; HoAF = Honigum® Automix Light Fast; Aflf = Affinix Light Body Fast]

The study clearly demonstrates that in the unset state, i.e. during the working time, the hydrophilicity of polyether impression material is much more distinct than in silicones (significantly smaller contact angle).

Figure 17 also demonstrates that the intrinsic hydrophilicity, i.e. the hydrophilicity at time t = 0, of polyether impression material in the unset state is significantly lower than in A-type silicones (significantly higher contact angle). This becomes even more evident in Figure 18. With 67°±2° the initial contact angle (time t = 0) of Impregum™ Garant™ Soft Quick Step LB is about 30° less than the 109°±4° value for Aquasil Ultra XLV Fast Set vinyl polysiloxane impression material.

This is of great clinical importance, because while the impression material is filled into the tray and injected around the preparation it continues to produce new surfaces, which come into immediate contact with the moist tooth and the mucosa. Therefore, a high degree of intrinsic hydrophilicity is an essential prerequisite for precise reproduction of even the finest details during impression taking.

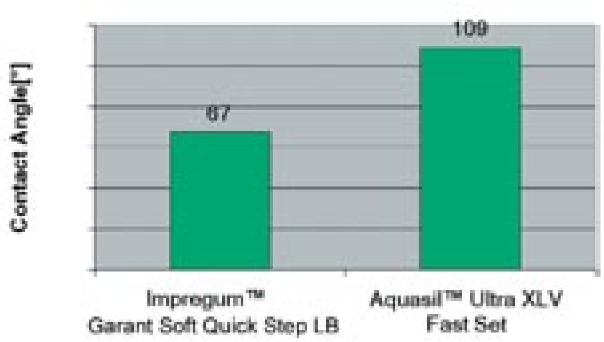


Figure 18. Comparison of the initial contact angles (in unset impression material) of Impregum Garant Soft Quick Step and Aquasil Ultra XLV Fast Set.

Contact Angle Studies on Set Material
– Contact Angle Studies on Set Light Body Impression Material

3M ESPE internal data, 2004.

The hydrophilicity of set impression material is of no particular importance for its performance in the hands of the dentist but rather for making casts in the dental laboratory. The above also holds true here: Intrinsic hydrophilicity is the decisive parameter; in other words, the hydrophilicity of the set impression material upon its initial contact with the wet gypsum.

Even on set impression material (the specimens were measured after 24 hours with the same test set-up as described[14]) the initial hydrophilicity of Impregum™ Garant™ Soft Quick Step LB (initial contact angle 87°±2°) is still higher than that of Aquasil™ Ultra XLV Fast Set (contact angle 106°±2°) (Figure 19).

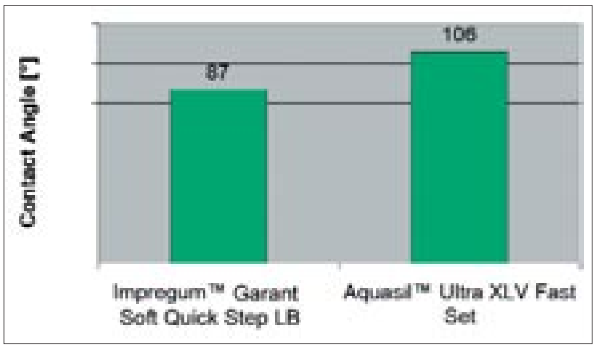


Figure 19. Comparison of the initial contact angles (on set impression material) of Impregum™ Garant™ Soft Quick Step LB and Aquasil™ Ultra XLV Fast Set.

The graph of the contact angle as a function of time differs between polyether material and A-type silicone material (see Figure 20 for Impregum Garant Soft Quick Step LB and Aquasil Ultra XLV Fast Set).

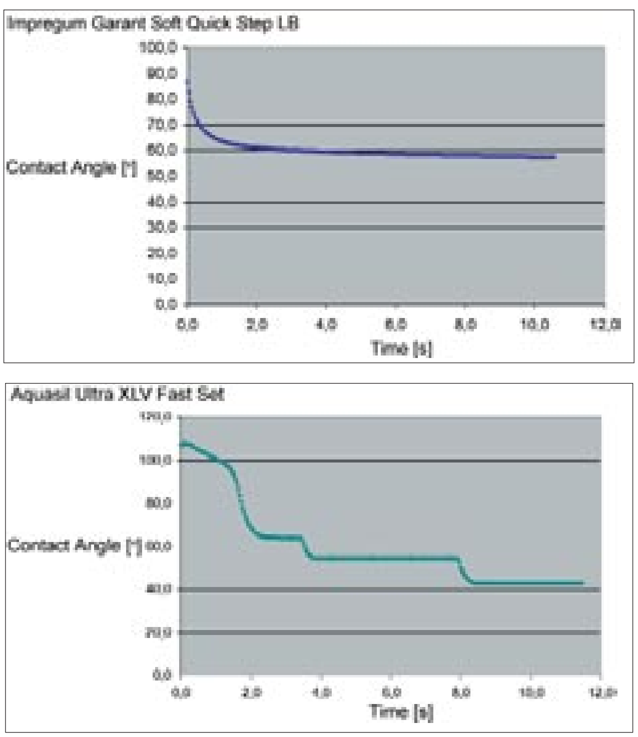


Figure 20. Contact angle of set impression material as a function of time: comparison of Impregum Garant Soft Quick Step LB and Aquasil Ultra XLV Fast Set.

The stepped decrease in the contact angle of Aquasil Ultra XLV Fast Set is typical for hydrophilized A-type silicones. It is due to the successive migration of surfactants to the surface.

Flowability

Flow Under Pressure

Kim M.S., Doherty E. H., Kugel G., School of Dentistry, Tufts University (Boston, Ma), AADR, #624, 200116

This study at the Tufts University School of Dentistry (Boston, MA, USA) examined the flow ability of various medium body impression materials under pressure.

To simulate the intra-oral conditions, a special test known as the Shark Fin test was used (for further details, see V. Vaughn et. al., IADR 1997[17, 18]). The measuring device used in the study has a slot-shaped opening (length 18 mm, maximum width 2mm). The impression material is put into a mold and the measuring device described above is placed on top with a specified force (a total weight of 415grams). After the material has set, the test specimen is removed and the height of the test specimen obtained in this way is measured. The test specimen is shaped like a shark fin, hence the name of the test. The maximum height of this "fin" is measured. The higher the measurement, the better the flow ability of the impression material under pressure.

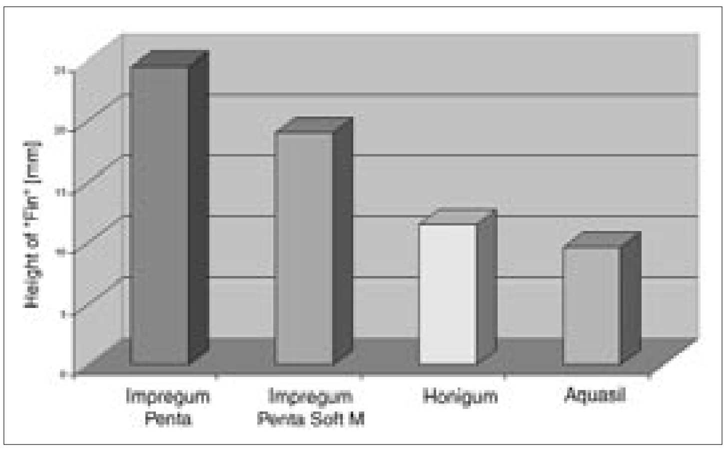


Figure 21. The height in mm of the specimens indicates how well the material flows under pressure.

The results showed that flowability under pressure is most pronounced with Impregum™ Penta™ and Impregum™ Penta™ Soft medium body impression material. Flowability under pressure is a very important clinical characteristic of impression materials. It has a direct effect on how the material flows into the sulcus, and is necessary for obtaining a precisely formed margin of preparation with good detail reproduction.

Flowability Under Reduced Pressure During the Working Time – Studies in Light Body (Low Viscosity) Impression Material

Bettina Richter, Thomas Klettke, Bernd Kuppermann, Cornelia Führer, CED/IADR, Istanbul, #142, 2004 (Title: Flow Properties of Light Bodied Impression Materials During Working Time)

Impressions materials not only have to display hydrophilicity during the working time but also very good flow properties. Only the latter ensures that the surface to be replicated will undergo ideal wetting after injection. The material to be syringed will only be pushed into the vital areas by pressure from the tray material (while it is charged). Apart from the two step putty wash technique the pressure exerted on the material is quite low; this is particularly true for "slipstream" pressure areas such as deep in the sulcus, around areas with voids below, and in case of dual-arch impression trays.

Therefore, in clinically relevant studies it is of vital importance to know the precise time when the flow properties are determined. Light and medium body impression materials will be applied to the preparation at the beginning of the working time, while quite often the precise flowing action will take place toward the end of that time period during tray seating.

The shark fin test is one established method of investigation of the flow ability of impression materials.[16] However, in order to simulate more real conditions the weight was reduced from 415g to 147g, and the slot from 2.0mm to 1.6mm. Each material underwent two test runs: pressure loading 25 seconds after mixing was started (test 1) and at the end of the working time specified by the manufacturer (test 2). Figure 22 is a graphic representation of the study results for eight light body precision impression materials.

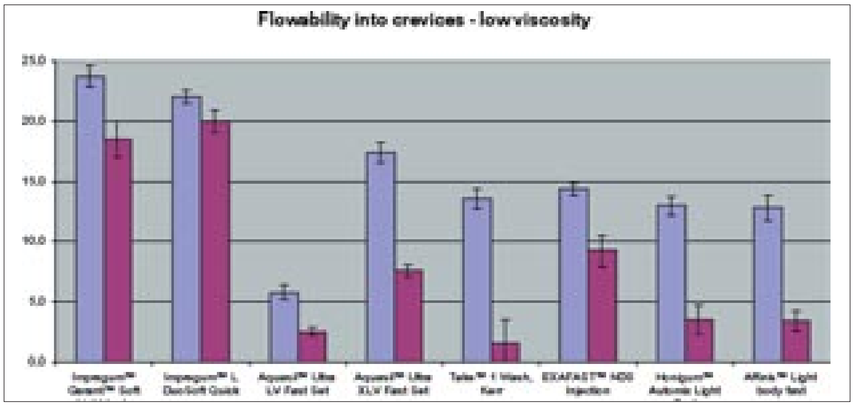


Figure 22. Ability of various light body impression materials to flow into crevices (shark fin test, weight 147g, slot size 1.6mm) at 25 seconds after mixing was started, as well as at the end of the respective working time.

After 25 seconds as well as at the end of the working time both polyether impression materials demonstrated significantly better flow ability than the silicones. Furthermore, the polyether flow characteristics remain almost constant over the entire working time.

Combined with the snap set characteristic so typical of polyether materials these polyether impression materials offer a property profile which is extremely well-suited for clinical applications.

Studies in Medium Body Impression Materials – Monophase Materials

Impregum™ Penta™ Soft Quick Step and Aquasil™ Ultra Monophase Fast Set were studied along the same lines as the light body materials. The results (3M ESPE internal data, 2004) are compared in Figure 23.

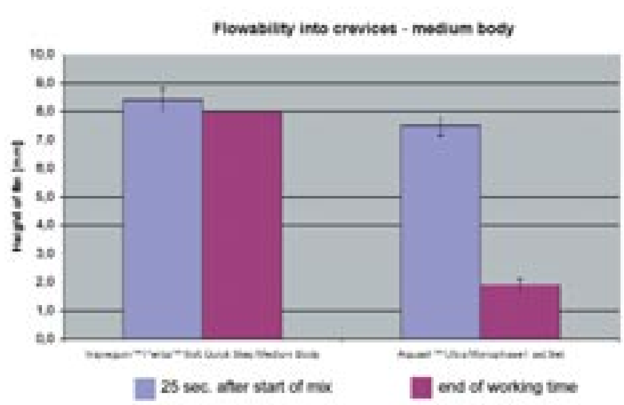


Figure 23. Ability of various impression materials to flow into crevices (shark fin test, weight 147g, slot size 1.6mm) at 25 seconds after mixing was started as well as at the end of the working time. Comparison of Impregum Penta Soft Quick Step and Aquasil Ultra Monophase Fast Set

This demonstrates the very high flow ability of Impregum Penta Soft Quick Step compared with Aquasil Ultra Monophase Fast Set, particularly toward the end of the working time.

Studies in Heavy Body Impression Material – High Consistency of Two-Step Material

The flow ability of the tray material over the entire working time is of essential importance for a clinically successful one-step/two-viscosity technique. Here, too, the study (3M ESPE internal data, 2004) of the ability of various tray materials to flow into crevices was able to show that at the end of the working time polyether impression material flows significantly better than A-type silicones (Figure 24). During the entire working time the flow characteristics of polyether impression materials do not change as much as the measured VPS materials. This behavior ensures a high degree of reliability for the clinical user when working with polyether impression material.

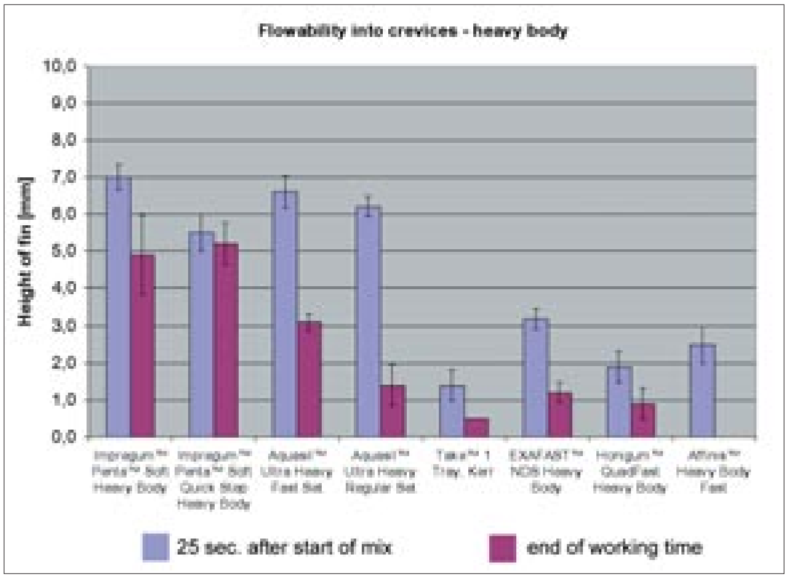


Figure 24. Ability of various heavy body impression materials to flow into crevices (shark fin test, weight 147g, slot size 1.6mm) at 25 seconds after mixing was started as well as at the end of the working time.

Rheology

J. F. McCabe, "Evaluation of the rheological properties of Impregum™ Garant Soft and Impregum™ Penta™ Soft H"[19]

The flow characteristics can be examined through rheological studies. Prof. John F. McCabe (Department of Restorative Dentistry, Newcastle upon Tyne) already undertook such studies in 1998 (1. McCabe J. F., Carrick T. E., Rheological Properties of Elastomers during Setting, J Dent Res 68(8), 1218-1222, 1998; 2. McCabe J. F., Arikawa H., Rheological properties of elastomeric impression materials before and during setting, J Dent Res 77(11), 1874-1880, 1998).[20,21] These investigations were able to demonstrate the very high flow characteristics of polyether during the working time when compared with other elastomeric impression materials. To test whether these properties are also apparent with the new polyether "Soft" chemistry, the rheological tests with the impression materials Impregum™ Penta™, Impregum™ Penta™ Soft, and the A-type silicone Aquasil™ Monophase FS were repeated.

As already discussed in the previous chapters, impression materials should exhibit plastic or flowable behavior during the working time. In general the plasticity of an impression material allows for optimum flow free of material stress. In the studies presented here, a first approximation would see this mirrored in a large tan δ.

In the set state, the material should be elastic, corresponding to a small tan δ. Elasticity in the set state is necessary so that after deformation the impression material can return to its original state.

Plastic and elastic behavior was examined in these tests by means of a cone-plate rheometer.

Figure 25 shows the tan δ curve as a function of time for Impregum™ Penta™ Soft and Aquasil™ Monophase FS. Both materials exhibit high initial tan d values, which is characteristic for a high degree of plasticity at the beginning of the working time. The plateau-like shape of the tan δ curve of Impregum Penta Soft shows that the plastic properties are maintained throughout the working time. This results in very good flow until insertion of the tray. If Impregum Penta Soft impression material were to display elastic properties during the working time, this could produce tension and inaccuracies in the impression. At the end of the working time, Impregum Penta Soft impression material displays a rapid transition from the plastic (large tan δ) to the elastic (small tan δ) state (also see the Chapter on Snap Set).

In contrast to the tan δ curve for Impregum Penta Soft impression material, the tan δ curve for Aquasil Monophase FS continuously drops after the measurement has started. The fact that the elastic components gain in significance at an earlier stage indicates a material with early crosslinking.

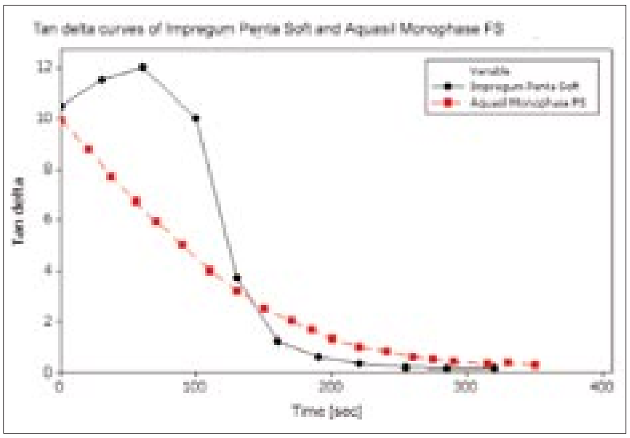


Figure 25.
tan δ curves of Impregum Penta Soft and Aquasil Monophase FS.

Accuracy

Transverse Accuracy and Sulcus Fluid Flow Model

Lammert U., Nave S., Wöstmann B., Gießen University, Germany, AADR, #972, 200122

For the successful fitting of a prosthesis, two criteria are critical from the dentist's and dental technician's point of view: the dimensional accuracy and marginal integrity of a restoration. For this reason the clinical situation must be recorded with utmost precision by the impression material and subsequently transferred to the cast with equal precision. The effect of moisture, which can never be entirely excluded under clinical conditions, should influence the impression as little as possible.

Two models were used to study the accuracy. A master model for recording the transverse accuracy (Figure 26) and a sulcus fluid flow model (Figure 27) for the accuracy of marginal adaptation.

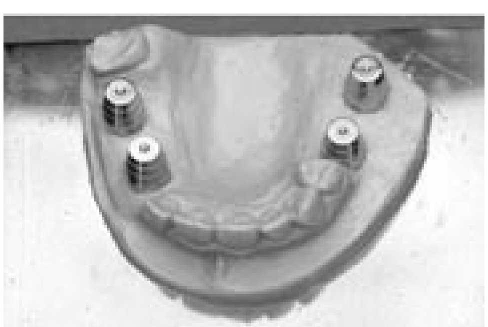


Figure 26. The master model for recording the accuracy. The transverse distances are measured on the cast and then compared with those of the master.

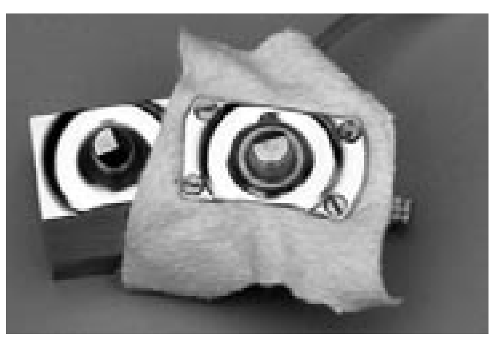


Figure 27. Sulcus fluid flow model for determining the accuracy of marginal adaptation. The idealized tooth stump on the right is used to simulate a moist sulcus.

The tests were carried out under the auspices of Professor Wöstmann, Dept. of Dental Prosthetics, Justus Liebig University, Giessen, Germany.

The master model (Figure 26) has four surface-ground metal abutments. Each of these has a central occlusal hole, which is used to determine the transverse abutment distances. The master model was adapted to the clinical situation by integrating a palate as well as anterior and posterior teeth made from epoxy resin. An impression is taken of the master model with the materials and processes to be tested, and the cast is made after one hour using Type IV gypsum stone. The six transverse distances are determined with a measuring microscope and then compared with those of the master. In Figure 28, the transverse distances measured on the master and on the cast have been drawn in. A comparison between the distances measured on the casts and the original distances of the master shows that the transverse distances are reproduced with extreme precision in impressions taken with Impregum™ Penta™, Impregum™ Penta™ Soft, Impregum™ Penta™ H and L Soft impression material (see Table 4 and Figure 29).

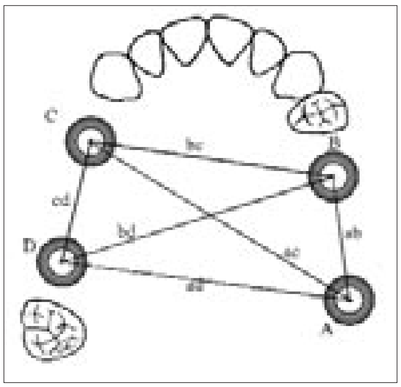


Figure 28. The distances have been drawn the way they are measured on the cast and the master.

	distance ab [mm] Δ[mm]	distance ac [mm] Δ[mm]	distance bc [mm] Δ[mm]	distance bd [mm] Δ[mm]	distance cd [mm] Δ[mm]	distance da [mm] Δ[mm]
Master	*14.551*	*47.579*	*37.986*	*43.674*	*13.519*	*45.844*
Impregum Penta	14.549 (+0.002)	47.583 (-0.004)	38.028 (-0.042)	43.702 (-0.028)	13.529 (-0.010)	45.866 (-0.022)
Impregum Penta Soft	14.564 (-0.013)	47.55 (+0.029)	38.016 (-0.030)	43.654 (+0.020)	13.476 (+0.043)	45.861 (-0.017)
Impregum Penta Soft H and L Soft	14.563 (-0.012)	47.577 (+0.002)	38.018 (-0.032)	43.681 (-0.007)	13.485 (+0.034)	45.863 (-0.019)

Table 4. Results and comparison of the distances measured

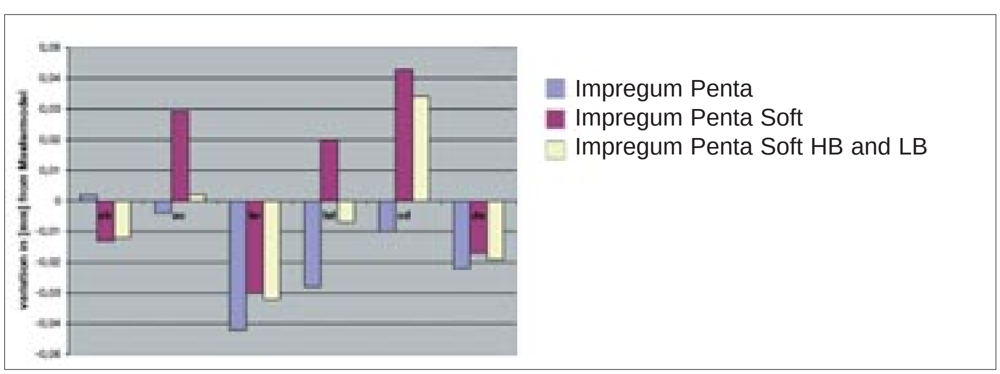


Figure 29. Difference in [mm] of the distances measured from the master

The sulcus fluid flow model (Figure 27) consists of two idealized tooth stumps, which are precisely fitted into a brass block representing the model base. One such idealized stump simulates a moist sulcus, while the second preparation represents a tooth in a dry sulcus. A feed system delivers a defined quantity of liquid to the moist stump. The gingiva is simulated by semi-permeable leather fleece. An impression is taken of the sulcus fluid flow model using the material under study, and a cast is made from the impression using type IV gypsum stone. Metal copings are made on the model. These copings are used as measuring copings on the master stump. The accuracy of marginal adaptation of the copings is measured with a measuring microscope at six reference points.

Figure 30 depicts the mean values of the crown margin gap measured between the coping and the master stump. For each of the impression materials examined, the crown margin gap at the coping was measured on the stump in both the dry state and covered by moisture.

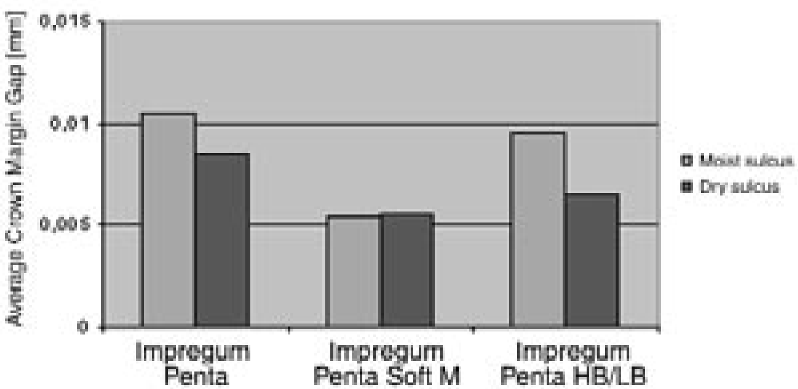


Figure 30. Crown margin gaps at the copings on both the dry stump and covered by moisture.

With Impregum™ Penta™ Soft Impression Material the mean values for dry and moist stump are at similar levels, i.e. in this test the moist stump did not influence the accuracy. For Impregum Penta and Impregum Penta Soft H/L the mean value of the crown margin gap on the moist stump increased somewhat, but based on the standard deviation of the means this increase was not statistically significant. Thus, both Impregum Penta Soft and Impregum Penta Soft H/L meet the high standard of accuracy for polyether so well known from clinical experience.

Accuracy of Detail Under Moist Conditions

Jia W., Sorensen J. A., Oregon Health Sciences University (Portland, OR), AADR, #1679, 2001[23]

Accuracy of detail is an important characteristic of impression materials. According to the most widely used specification (ADA specification No. 19), it is measured using a stainless steel standard, which has three lines of a specific width (75, 50, and 20 micrometers).

To obtain data that are more relevant to dental practice, the Department of Prosthodontics at Oregon Health Sciences University (Portland, OR) carried out a study, in which a moist plaster block with line structure (width 75, 50, and 25 micometers) was used instead of the stainless-steel standard described above.

Ten test specimens were prepared for each of the impression materials studied. Then the number of test specimens, which fully reproduced all the lines at 75, 50, and 25 micrometers, was recorded. The results of this study are shown in Figure 31.

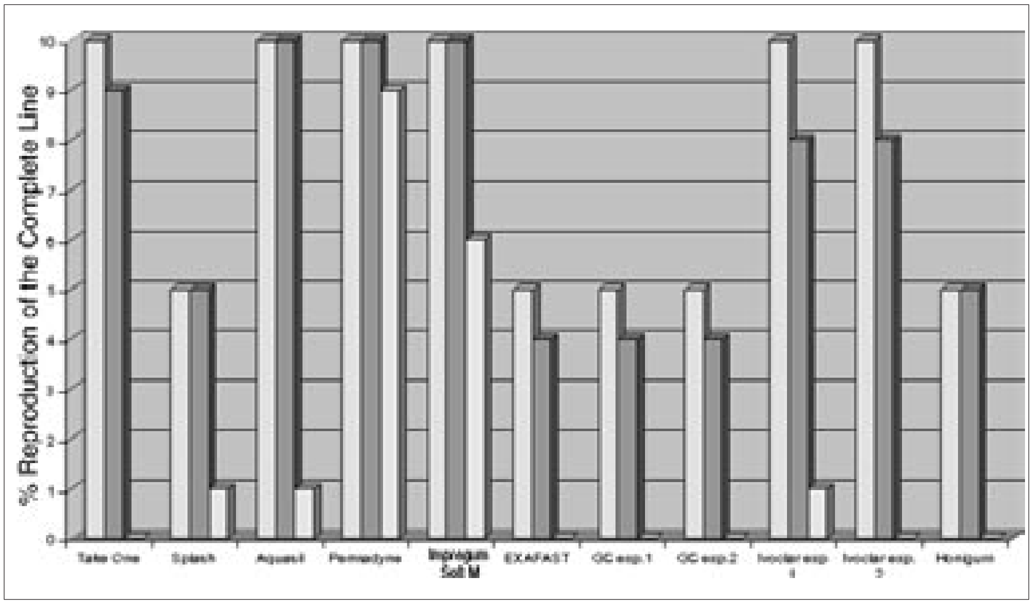


Figure 31. Accuracy of line details under moist conditions for various impression materials. Width of line from left to right: 75, 50, 25 micrometers.

According to this study, the light body polyether impression material Permadyne™ Garant™ 2:1 by 3M ESPE reproduces detail most accurately, followed closely by Impregum™ Penta™ Soft. Most silicone impression materials could not reproduce the 25-micrometer line.

Similar results were seen in a study by Johnson et al. (2003)[24] at the University of Washington School of Dentistry, Seattle, WA. One of the objectives was to demonstrate for various impression materials the influence of moisture on the accuracy of detail reproduction. The materials tested were polyether and A-type silicones. Under moist conditions here, too, polyether offered the best reproduction of details of all materials tested.

Reproduction of Detail

Numerous studies were able to demonstrate that polyether materials achieve a particularly good reproduction of details, especially under clinically relevant moist conditions.[13,23,25]

Not only in clinical dentistry, but also in scientific research inside and outside the dental field, polyether is usually preferred over silicone to produce models with optimal reproduction of detail. For instance, polyether materials are most often used for the replica technique.[26,27,28,29] Alternatively, SEM evaluations can be done by investigating polyether impressions directly.[24]

Disinfection – 3D Dimensional Accuracy

Stoll R., Segschneider F., Stachniss V., Jürgensen R., Marburg University, Dtsch Zahnärztl Z 46, 718-721, 1991[6]

The objective of this study under the auspices of Dr. R. Stoll, Department of Conservative Dentistry, Marburg University, Germany, was to investigate the influence of disinfectants on the stability of polyether impression materials.

This included taking 10 cylindrical impression specimens with Impregum™ Penta™, Impregum™ Penta™ Soft, Impregum Penta Soft L , and Impregum Penta Soft H from a stylized model of the upper jaw. After a recovery time of 60 minutes the impressions were immersed in water or Impresept™ (glutaraldehyde) for 10 and 60 minutes respectively. Casts were then taken from the impressions with gypsum stone. The specimens were measured with a 3D coordinate measuring machine. These results were compared with measurements taken from specimens, where the impressions were not disinfected but casts were made after a 60- minute recovery time; a control measurement was also undertaken, these values being listed in the figures as control group.

The results were then checked for Gaussian distribution and compared with nonparametric tests

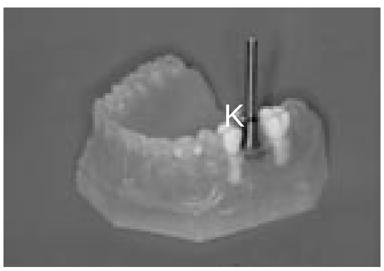


Figure 32. Master specimen fitted into the model of the upper jaw. Orientation of the post is in the occlusal direction, and the notch (K) marks the mesial position.

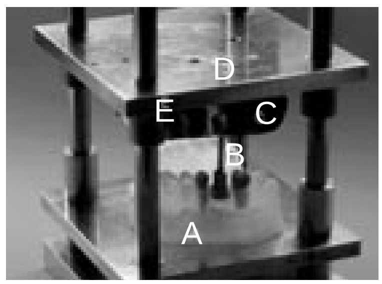
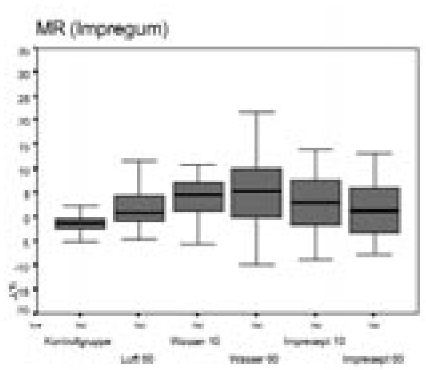


Figure 33. Model (A) in the impression rig. The suitable rim-lock tray (C) is mounted to the base plate (E) and can be lowered to the correct position. Post (B) will then jutt out of hole (D).

Figures 34-37 illustrate the results for the various materials and different pretreatments. For Impregum Penta no difference was noted between water and disinfectant after an immersion time of 10 minutes. However, if the time was exceeded (60 minutes) a slight swelling was noted in the Impresept group (decreased mean radius, MR). Impregum Penta Soft did not exhibit any changes in the mean radius when immersed in water or Impresept.

For regular immersion times Impregum Penta Soft L was characterized by slight shrinking (increased mean radius MR) which was compensated by the swelling induced by a longer immersion time. The opposite effect was seen in Impregum Penta Soft H . However, both trends were not statistically significant.

In summary, it may be said that the dimensional changes found in this study[6] and in the literature are of no clinical consequence. [Langenwalter, E.M., Aquilino, S.A., Turner, K.A., The dimensional stability of elastomeric impression materials following disinfection., J Prosth Dent 63, 270-276, 1990] [30]. Therefore, it can be assumed that immersion disinfection will not have any negative consequences on the dimensional stability of the impression, as long as the recommended immersion times are kept. It is even of no consequence if the disinfection time is exceeded several times over, something which is quite common in clinical practice. However, if the disinfection time has been extended to several hours this could create problems in polyether materials, and also in silicone impression materials. Even under the conditions of regular clinical practice, simple countermeasures in the work flow would ensure that the disinfection time is not exceeded by 8-16 hours.



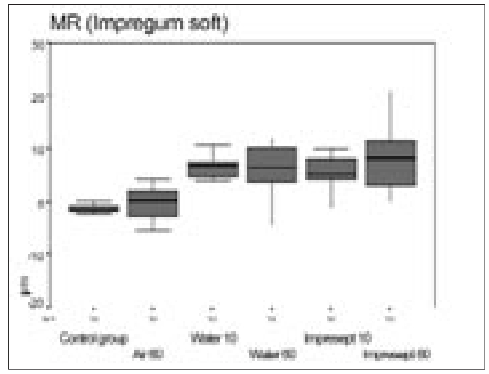
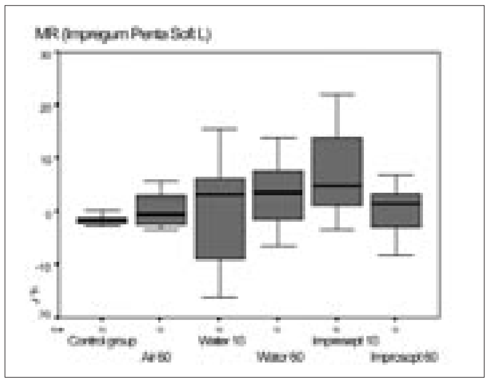


Figure 34. MR (mean change in radius in µm) boxplots (mean plus inner 50% quartile range) for group 1 (Impregum™ Penta)™

Figure 35. MR (mean change in radius in µm) boxplots (mean plus inner 50% quartile range) for group 2 (Impregum Penta Soft)



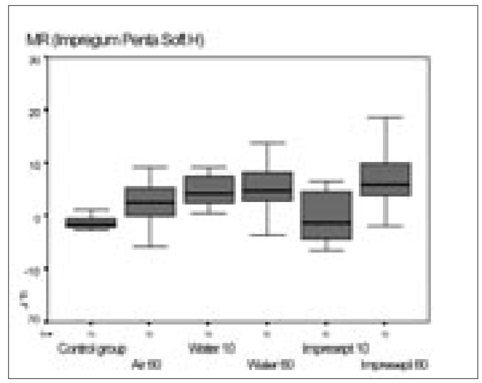


Figure 36. MR (mean change in radius in µm) boxplots (mean plus inner 50% quartile range) for group 3 (Impregum Penta Soft L)

Figure 37. MR (mean change in radius in µm) boxplots (mean plus inner 50% quartile range) for group 4 (Impregum Penta Soft H)

Ease of Removal

Dunne J. T., Zech J., University of Iowa, IA, IADR, #2436, 2000.

An in vitro study at the University of Iowa[31] has shown that the force necessary to remove an impression could be considerably reduced by decreasing the final rigidity of the set material (Shore-A hardness). The development of Impregum™ Penta™ Soft medium body impression material was founded on these test results. Both dentists (corresponds to Shore-A hardness after 15 minutes) and dental technicians (Shore-A hardness after 1 and 24 hours) benefit from the decreased hardness of Impregum Penta Soft impression material, since it can be removed with less effort than Impregum Penta medium body impression material .

Clinical Case Report – PFM Crown

Case report by Andre v. Ritter, University of North Carolina, Chapel Hill, USA)

The patient initially presented with a broken anterior buccal cusp of tooth #5 (FDI 14). A large MOD (mesial-occlusal-distal) amalgam restoration was already present (Figures 38, 39). First, all treatment options and possible end results were discussed with the patient. He decided on a PFM crown with complete frontal porcelain veneer.

The patient was anesthetized, the old restoration isolated and removed and the stump built up (Figure 40). Once the preparation had been completed (Figure 41), the impression was taken with Impregum™ Penta™ Soft impression material in the syringe and tray (Figure 42). The impression is very homogeneous with easy to recognize detail. The preparation margins are precisely reproduced.

After checking the final crown on the master cast, the restoration was permanently cemented. Figures 43 and 44 demonstrate the postoperative buccal view of the final crown.

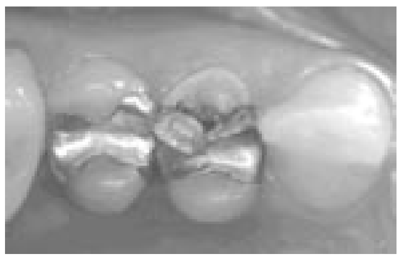



Figure 38: Buccal view of fractured tooth 14.
Figure 39: Occlusal view of fractured tooth 14.


Figure 40: Situation after removal of the amalgam restoration.
Figure 41: Occlusal view of the completed preparation.

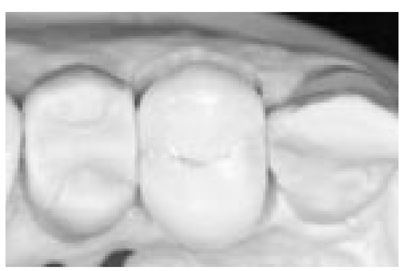



Figure 42: Impression with Impregum Penta Soft; precise delineation of the preparation margins and superb reproduction of detail
Figure 43: Crown on master cast.

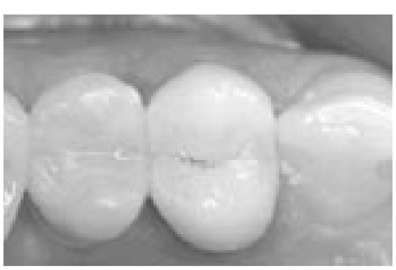



Figure 44: Permanently cemented crown (14). Composite treatment of tooth 15.
Figure 45: Buccal view of finished crown.

Clinical Case Report –
Precious Metal Post and Crown

Clinical images by Dr. Volker Bonatz, Landau, Germany

After post preparation at tooth 15, an impression is taken with Impregum™ Penta™ Soft H/L (Figures 46, 47). Based on this first impression, a cast is made and a precious metal post produced (Figure 48). After final positioning of the metal post, another impression is taken with Impregum Penta Soft H/L. The partially subgingival preparation has been precisely reproduced in the impression (Figure 50). A precision impression is the foundation for an exact fitting crown with aesthetic crown, as can be seen in the intraoral setting after final cementation (Figures 53).

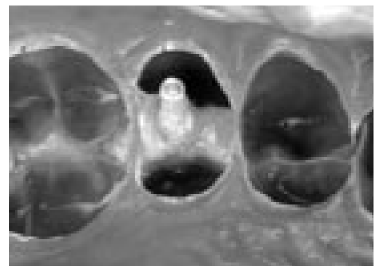



Figure 46. Post preparation
Figure 47. In the Impregum Penta Soft H/L impression material

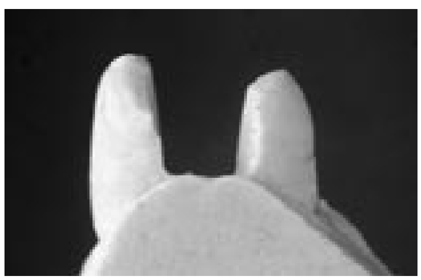



Figure 48. Excellent edge stability of the stumpdue to easier removal of Impregum Penta Soft H/L impression material
Figure 49. Inserted gold alloy

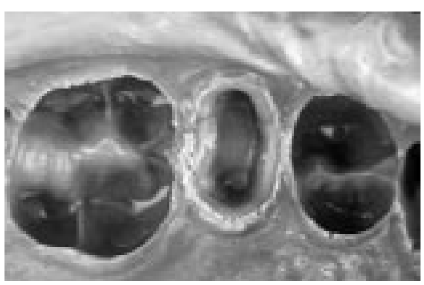
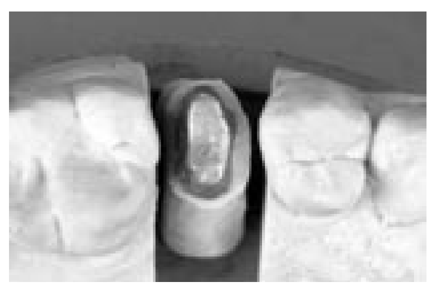



Figure 50. Impression of the partially subgingival preparation
Figure 51. Master cast

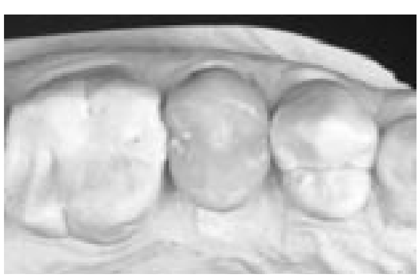
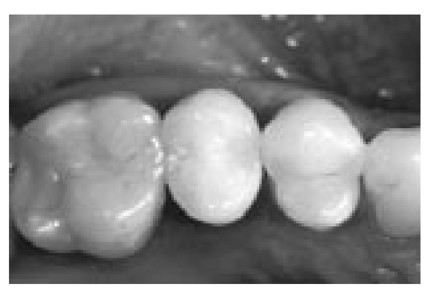



Figure 52. Finished crown on master cast
Figure 53. Crown after permanent cementation.

Clinical Case – Anterior Crowns

Clinical images by Dr. Volker Bonatz, Landau, Germany

After preparation of anterior teeth 12 to 21, an impression is taken with Impregum™ Penta™ Soft H/L (Figures 54, 55). The impression shows excellent detail reproduction and very good definition of the preparation margins are clearly visible. The prepared stumps are fitted with temporary crowns fabricated chairside crowns (Figure 56). A control model and master cast with accurate detail reproduction are essential for producing the restorations (Figures 59, 60, 61).

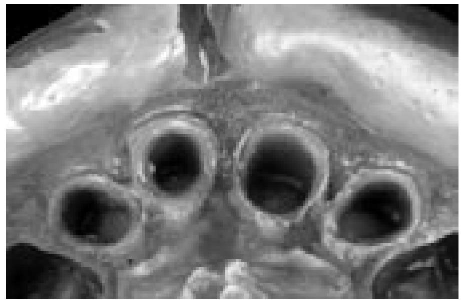



Figure 54. Crown preparations of 4 anterior teeth
Figure 55. Impregum Penta Soft H/L impression

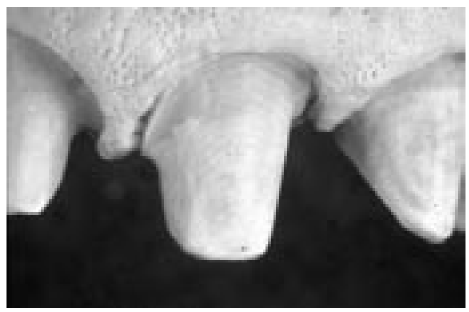



Figure 56. Chairside-made temporary
Figure 57. High-detail reproduction of the control model

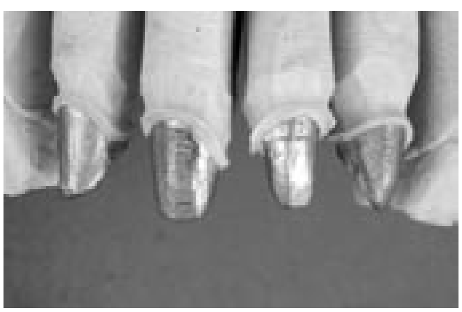



Figure 58. Master cast
Figure 59. Finished PFM crowns


Figure 60. Intraoral placement
Figure 61. Anterior crowns after permanent cementation

User Handling Guide

Practical Processing

Working with the Pentamix™ Mixing Unit 2 offers decisive benefits for handling. Dynamic mixing will yield standardized, consistently reproducible mixing quality and thus leads to improvement in the quality of the impression (void free and homogeneous). Mixing in the Pentamix 2 mixing unit will ensure reproducible results, simplify the work flow, and is the decisive factor for better hygiene and cleanliness in the clinical workplace.

Pentamatic™ Technology

With the objective of developing the best possible handling for the Penta™ mixing system, a self-opening mechanism was developed that automatically dispenses the contents of the foil bag as soon as the plunger disc exerts pressure on the bag.

When the Pentamix mixing unit is started the pressure within the foil bag increases and the foil stretches, lining the preformed cavity of the cartridge top (Figure 62). The spikes located there now pierce the hyper-stretched foil, and this results in complete rupture of the foil within the cavity. Release of the material is signalled by a clearly audible click.

With the Pentamix™ 1 Mixing Unit it takes about 20 - 25 seconds for the foil bag to open, and about 10 - 15 seconds with the Pentamix 2 mixing unit.

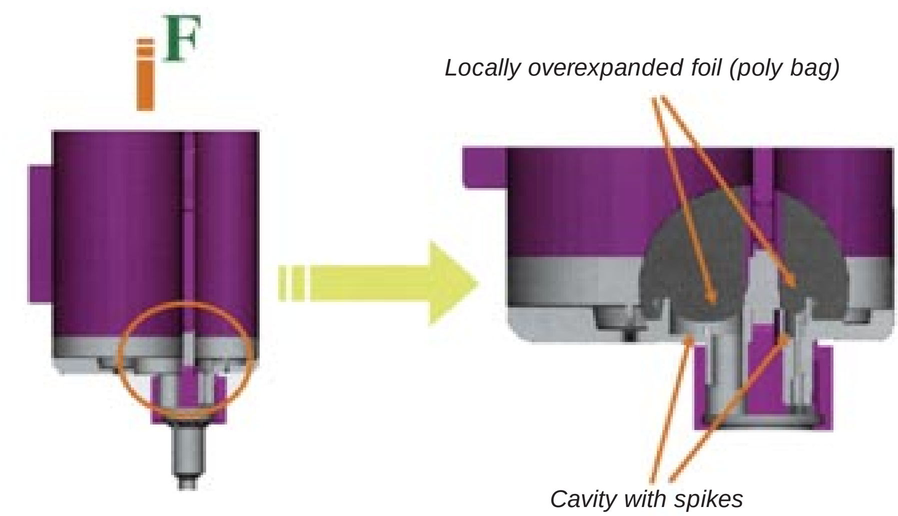


Figure 62. The basic Pentamatic automatic bag opening mechanism

New Pentamix™ System Components

Impregum™ Penta™ Soft Quick Step medum body and Impregum™ Penta™ Soft Quick Step heavy body/light body are introduced along with 3 new components of the Pentamix™ 2 mixing unit. These are:

- new Penta mixing tip - red
- stronger product-specific colored caps for the foil bags
- steel reinforced grey cartridge with product-specific color lever

The new components of the system were developed in order to offer the Pentamix system user an even more rugged design with increased reliability and ease of handling.

The new red Penta mixing tip (Figure 63) decreases the dispensing ejection force, in the range of 30-50% less force, of the paste depending on the impression material used (Figure 64, for further information see technical product profile for Pentamix 2). This results in much less stress on the Pentamix unit, the cartridges, and the caps of the foil bags. The new system components thus offer higher reliability compared to the former components. Because of decreased wear the working life of the Pentamix unit will be improved as well.

Figure 63. The new Penta mixing tip (red)

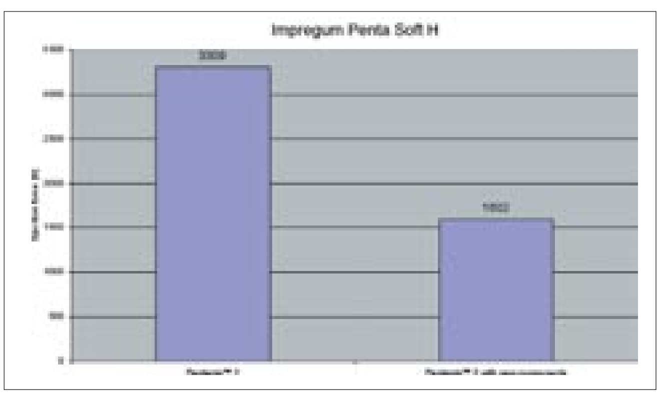


Figure 64: Dispensing force for present Pentamix 2 system compared to the new Pentamix 2 with new components Impregum Penta Soft H. The force required is reduced by 51.6% (3M ESPE internal data, 2004).

The front caps of the foil bags were reinforced (Figure. 65). The outlet side of the catalyst paste front cap was reinforced with plastic ribs. Two additional plastic wedges reinforced the base cap. This significantly increases the stability and thus reliability of the foil bag caps.

Figure 65: The new improved foil bag caps in product specific color for Impregum™ Penta™ Soft Quick Step

The new cartridge is made of inner steel tubing encased in plastic (Figure 66). This leads to higher stability and increased reliability resulting in less cartridge breakage. It is offered in the standard color - grey - with a product-specific colored lever. In addition, this new combination of materials makes it significantly more acid- and solvent-proof (e.g. against aggressive detergents).

Now the products delivered through the Pentamix™ 2 device are even more reliable and again improved for uncompromising clinical handling.

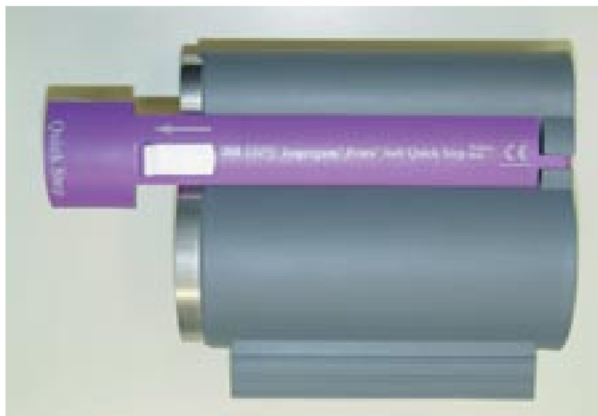
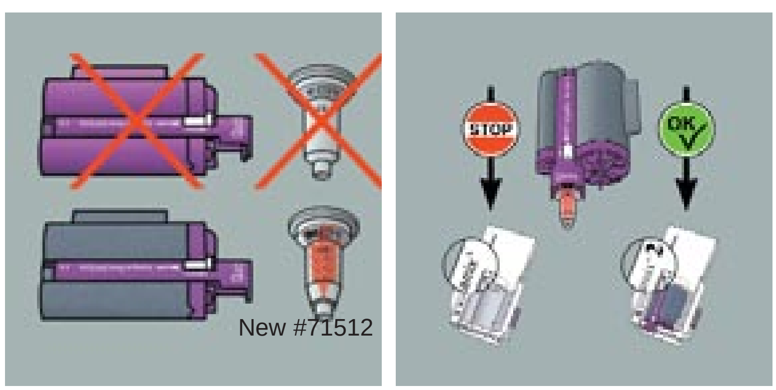


Figure 66. The new steel reinforced cartridge in standard grey with product-specific colored lever.

The new Impregum Penta Soft Quick Step products may only be used together with the 3 new Pentamix system components.



Use **only** the red color Penta Mixing tips with **color**-capped Penta foil bags.
Use **only** the steel-reinforced Penta cartridges.
Use **only** the Pentamix 2 mixing unit.

Instructions for Use

Impregum™ Penta™ Soft Medium Quick Step Body

Product Description

Impregum™ Penta™ Soft Quick Step Medium Body is a fast-setting polyether impression material with a medium-bodied consistency for use in the Pentamix™ 2 mixing unit, both products manufactured by 3M ESPE. The mixing ratio, based on volume, is 5 parts base paste :1 part catalyst.

Due to the lower Shore hardness, the impression material is highly suitable for impressions with slight undercuts, even without additional blocking out.

Each of the foil bags is sealed with a PentaMatic™ cap, manufactured by 3M ESPE. This PentaMatic cap opens the foil bag automatically in the Pentamix 2 as soon as enough pressure is built up by the plunger.

See the pertinent instructions for use for details on the Pentamix 2 and accessories, Polyether Adhesive, Penta™ Elastomer Syringe, Penta™ Mixing Tips Red, and Impresept™, all products manufactured by or for 3M ESPE.

- These instructions for use must be kept for reference for the duration of product use.

Range of Indications

- Impressions of inlay, onlay, veneer, crown, and bridge preparations
- Fixation and implant impressions

Impregum Penta Soft Quick Step Medium Body is especially suitable for taking impressions of single-unit and two-unit preparations.

Preparatory Steps

Impression tray:

Any impression trays generally used for precision impressions are suitable.

- For sufficient adhesion to metal and plastic, apply a thin layer of Polyether Adhesive to the impression tray and allow it to dry completely (at least 30-60 sec,15 min is ideal).

Pentamix 2/Penta Cartridge/Foil Bag:

Only the Pentamix 2 mixing unit must be used to mix Impregum Penta Soft Quick Step Medium Body.

- Use the Impregum Penta Soft Quick Step Medium Body foil bag only in combination with the designated Penta cartridge and with Penta Mixing Tips Red.
- Prepare new foil bags before taking the first impression by extruding about 3 cm of paste. The paste must emerge in a uniform color.
- If a new mixing tip has already been mounted when the cartridge is inserted, make sure that the drive shaft engages the mixing tip prior to start of mixing.

Retraction

Solutions based on aluminum hydroxide chloride or aluminum sulfate are suitable retraction agents. The use of hemostatic threads containing epinephrine (adrenaline), 8-hydroxyquinoline sulfate, and iron (III) sulfate for retraction may impair the setting of polyether impression materials.

- Keep the area dry where the impression is being taken.
- If necessary, use hemostatic threads for subgingival preparations.
- Before taking the impression, remove completely any residue of the retraction agent by rinsing and drying.

Dosing and Mixing

Dosing and mixing are done automatically in the Pentamix 2.

Times

The processing time (max.1:00 min) begins with the entry of the paste into the Penta Mixing Tip Red (= start of mixing). It includes the filling of the Elastomer Syringe, application around the preparation, loading of the impression tray, and the positioning of the tray in the mouth.

The residence time in the mouth must always be 3 minutes, regardless the previously needed processing time.

Impression Taking

Mono-phase technique

- To apply around the preparation, attach the Penta Elastomer Syringe to the Penta Mixing Tip Red of the Pentamix 2 and fill it.
- Then load the impression tray which has been prepared with adhesive. Keep the mixing tip immersed in the impression material at all times.
- Apply around the dried preparation from the bottom up. Keep the tip of the intra-oral tip immersed in the impression material and in contact with the tooth surface at all times during application.

  - Application around the preparation and loading of the impression tray must be coordinated so that the loaded impression tray can be placed in the mouth immediately after the application. The processing times shown for the materials used must not be exceeded. Otherwise, the two materials will not set together. The consequence would be deformations or a poor bond in the impression.

- Position the loaded impression tray in the mouth immediately after the application and hold it in place, without applying pressure, until setting is complete.
- When the setting time has lapsed, remove the impression from the mouth.

  - To remedy initial adhesion ("setting the valve"), especially with upper jaw impressions, remove the tray from the gingiva on one side in a posterior position. If this proves difficult it may be necessary to carefully blow some air or water between the impression and the gingiva.

After Impression Taking

- Thoroughly examine and explore the sulcus of the prepared teeth and surrounding dentition. Remove any residual cured impression material from the mouth.

Hygiene

- Place the impression in a standard disinfectant solution, e. g. Impresept*, for the period of time recommended by the manufacturer, i. e.,10 min in the case of Impresept. Excessive disinfection may damage the impression.
- After disinfection, rinse the impression under running water for approx. 15 sec, then dry.

  * Impresept is not available in all countries.

Model Preparation

- Prepare a cast from the impression with a commercial specialized stone plaster no earlier than 30 min and no later than 14 days after taking the impression. Processing time Residence time in Setting time from from start of mixing the mouth start of mixing min:sec min:sec min:sec Max.1:00 + 3:00 = Max. 4:00
- To avoid introducing bubbles into the model, briefly pre-rinse with water, and dry. Do not use surfactants as these impair the quality of polyether impressions and are not necessary.
- Polyether impressions may be silver-coated, whereas copper-coating is not feasible.

Cleaning

Paste that has not set may be removed with ethanol or by rinsing with water and soap.

Acetone can be used to remove the adhesive from impression trays.

Notes

Impregum Penta Soft Quick Step Medium Body

- At temperatures below 18°C/64°F, the viscosity of the pastes will increase to an extend that there may be mixing problems in the unit. Store the pastes for 1 day at a minimum temperature of 18°C/64°F; they can then be processed without loss of quality.
- Impregum Penta Soft Quick Step Medium Body must be combined only with 3M ESPE polyethers.

Impression

- Direct exposure to sunlight and moist storage conditions may damage the impression, see Storage.
- Polyether impressions should not be exposed to solvent-containing liquids under any circumstances. Swelling and imprecise modeling may result. Incompatibilities In susceptible individuals, sensitization to the product cannot be excluded. If allergic reactions occur, discontinue the use and remove the product completely.

Incompatibilities

In susceptible individuals, sensitization to the product cannot be excluded. If allergic reactions occur, discontinue the use and remove the product completely.

Storage and Stability

Store the products at 18-25°C/64-77°F. Do not refrigerate! Do not use after the expiration date. Store impressions in a dry place away from light at temperatures below 30°C/86°F.

Customer Information

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.

Limitation of Liability

Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Information valid as of 06/04

Impregum™ Penta™ Soft Quick Step Heavy Body
Impregum™ Soft Quick Step Light Body

Product Description

Impregum™ Penta™ Soft Quick Step Heavy Body is a fast-setting polyether impression material with a heavy-bodied consistency for use in the Pentamix™ 2 mixing unit, both products manufactured by 3M ESPE. The mixing ratio, based on volume, is 5 parts base paste :1 part catalyst.

Each of the foil bags is sealed with a PentaMatic™ cap, manufactured by 3M ESPE. This PentaMatic cap opens the foil bag automatically in the Pentamix 2 as soon as enough pressure is built up by the plunger.

Impregum™ Soft Quick Step Light Body is a fast-setting polyether impression material with a light-bodied consistency in the Garant™ cartridge, both products manufactured by 3M ESPE. The mixing ratio, based on volume, is 2 parts base paste :1 part catalyst.

Due to the low Shore hardness, the impression materials are highly suitable for impressions with slight undercuts, even without additional blocking out.

See the pertinent information for use for details on the Pentamix 2 and accessories, Polyether Adhesive, Penta™ Mixing Tips Red, Garant™ Dispenser, Garant™ Mixing Tips and Intra-oral Tips, and Impresept™, all products manufactured by or for 3M ESPE.

These instructions for use must be kept for the duration of product use.

Range of Indications

- Impressions of inlay, onlay, veneer, crown, and bridge preparations
- Fixation and implant impressions

Impregum Penta Soft Quick Step Heavy Body and Impregum Soft Quick Step Light Body are especially suitable for taking impressions of single-unit and double-unit preparations.

Preparatory Steps Impression tray:

Any impression trays generally used for precision impressions are suitable.

- For sufficient adhesion to metal and plastic, apply a thin layer of Polyether Adhesive to the impression tray and allow it to dry completely (at least 30-60 sec,15 min is ideal).

Pentamix 2/Penta Cartridge/Foil Bag:

Only the Pentamix 2 mixing unit may be used to mix Impregum Penta Soft Quick Step Heavy Body.

- Use the Impregum Penta Soft Quick Step Heavy Body foil bag only in combination with the designated Penta cartridge and with Penta Mixing Tips Red.
- Prepare new foil bags for use before taking the first impression by extruding about 3 cm of paste. The paste must emerge in a uniform color.
- If a new mixing tip has already been mounted when the cartridge is inserted, make sure that the drive shaft engages the mixing tip prior to start of mixing.

Garant™ Dispenser/Cartridge:

- At the start of a new cartridge and before every new mixing process, first extrude a quantity of paste without using a mixing tip until both components emerge evenly; remove any paste plugs that have formed in the cartridge openings.
- Then attach a Garant Mixing Tip White and a Garant Intra-oral Tip White.

Retraction

Solutions based on aluminum hydroxide chloride or aluminum sulfate are suitable retraction agents. The use of hemostatic threads or rings containing epinephrine (adrenaline), 8-hydroxyquinoline sulfate, and iron (III) sulfate for retraction may impair the setting of polyether impression materials.

- Keep the area dry where the impression is being taken.
- If necessary, use hemostatic threads or rings for subgingival preparations.
- Before taking the impression, remove completely any residue of the retraction agent by rinsing and drying.

Dosing and Mixing

- Dosing and mixing is done in the Pentamix 2 mixing unit or in the Garant Dispenser, respectively.

Times

Impression Material	Processing time from start of mixing * min:sec		Residence time in the mouth min:sec		Setting time from start of mixing * min:sec
Impregum Penta Soft Quick Step Heavy Body	Max.1:00 [1]	+	3:00	=	Max. 4:00
Impregum Soft Quick Step Light Body	Max.1:00 [2]	+	3:00	=	Max. 4:00

* Start of mixing = Entry of paste into the Penta Mixing Tip Red or Garant Mixing Tip

1 Time available to load the impression tray and position it in the mouth

2 Time available for application around the preparation and, as necessary, prior filling of the Elastomer Syringe.

The residence time in the mouth must always be 3 minutes, regardless the previously needed processing time.

Impression Taking
One-step Technique

- Load the impression tray which has been prepared with adhesive with Impregum Penta Soft Quick Step Heavy Body. Keep the Penta Mixing Tip Red immersed in the impression material at all times.
- Apply Impregum Soft Quick Step Light Body around the dried preparation from the bottom up. Keep the tip of the intra-oral tip immersed in the impression material and in contact with the tooth surface at all times during application. -

  – Application around the preparation and loading of the impression tray must be coordinated so that the loaded impression tray can be placed in the mouth immediately after the application. The processing times shown for the materials used must not be exceeded. Otherwise, the two materials will not set up together. The consequence would be deformations in the impression or a poor bond of the two materials.
- Position the loaded impression tray in the mouth immediately after the application and hold it in place, without applying pressure, until setting is complete.
- When the setting time has lapsed, remove the impression from the mouth.

  - To remedy initial adhesion (“setting the valve”), especially with upper jaw impressions, remove the tray from the gingiva on one side in a posterior position. If this proves difficult it may be necessary to carefully blow some air or water between the impression and the gingiva.

After Impression Taking

- Thoroughly examine and explore the sulcus of the prepared teeth and surrounding dentition. Remove any residual cured impression material from the mouth.

Hygiene

- Place the impression in a standard disinfectant solution, e. g. Impresept*, for the period of time recommended by the manufacturer, i.e.,10 min in the case of Impresept. Excessive disinfection may damage the impression.
- After disinfection, rinse the impression under running water for approx. 15 sec, then dry.

* Impresept is not available in all countries.

Model Preparation

- Prepare a cast from the impression with a commercial specialized stone plaster no earlier than 30 min and no later than 14 days after taking the impression.
- To avoid introducing bubbles into the model, briefly pre-rinse with water, and dry. Do not use surfactants as these impair the quality of polyether impressions and are not necessary.
- Polyether impressions may be silver-coated, whereas copper-coating is not possible.

Cleaning

- Garant™ Dispenser: Remove paste that has not set using an alcohol-soaked cloth. The dispenser handle and plunger can be autoclaved up to a temperature of 135°C/275°F. Disassemble the dispenser before autoclaving. Glutaraldehyde-based solutions can be used for disinfection.
- Impression Tray: The adhesive can be removed from impression trays using acetone.

Notes

Impregum Penta Soft Quick Step Heavy Body:

- At temperatures below 18°C/64°F, the viscosity of the pastes will increase to an extend that there may be mixing problems in the unit. Store the pastes for 1 day at a minimum temperature of 18°C/64°F; they can then be processed without loss of quality.

Impregum Soft Quick Step Light Body:

- Turning or reattaching a mixing tip without subsequent impression taking may lead to carry-over of paste and clogging. The filled mixing tip should therefore be left as a closure on the Garant cartridge until the next impression is taken.
- If the material is stored at temperatures below 18°C/64°F, precise dosing and mixing can no longer be guaranteed even if subsequently kept at room temperature for a longer period of time.

Impregum Penta Soft Quick Step Heavy Body and Impregum Soft Quick Step Light Body must be combined only with 3M ESPE polyether materials.

Impression Taking

- Direct exposure to sunlight and moist storage conditions may damage the impression, see Storage.
- Polyether impressions should not be exposed to solvent-containing liquids under any circumstances. Swelling and imprecise modeling may result.

Incompatibilities

In susceptible individuals, sensitization to the product cannot be excluded. If allergic reactions occur, discontinue the use and remove the product completely.

Storage and Stability

Store the products at 18-25°C/64-77°F. Do not refrigerate!

Do not use after the expiration date.

Store impressions in a dry place away from light at temperatures below 30°C/86°F.

Customer Information

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.

Limitation of Liability

Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

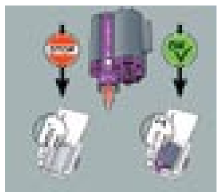
Information valid as of 06/04

Technique Guides

Impregum™ Penta™ Soft Quick Step Medium Body

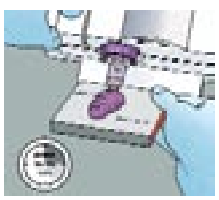
Polyether Impression Material

Only the red Penta™ mixing tip is used with Impregum™ Penta™ Soft Quick Step.



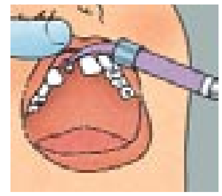
Only usethe Pentamix™ 2 Mixing Unit.

Insert the loaded Penta cartridge into the Pentamix 2 Mixing Unit.

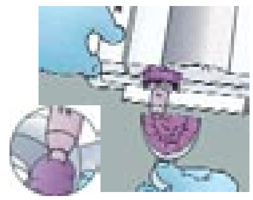


For initial use extrude a small amount of material and discard it. Wait for a uniform mix.

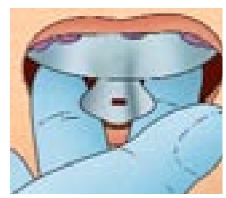
Begin filling the syringe. Working Time up to 1:00.



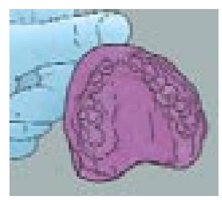
Syringe the impression material around the clean, dry tooth preparation(s). Working Time up to 1:00.



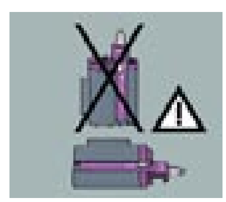
Finish filling the tray. Working Time up to 1:00.



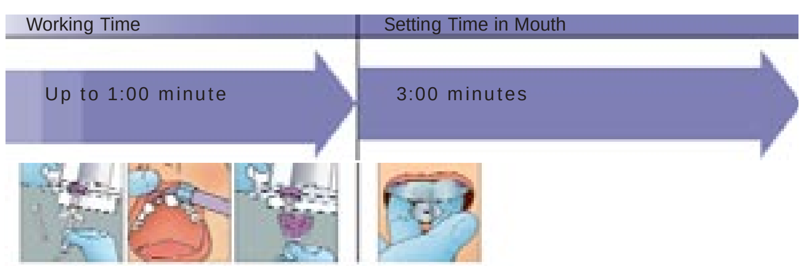
Insert and immobilize the tray using passive pressure. Once the tray is placed in the mouth wait 3:00 minutes.



After removal, rinse, dry and disinfect. Wait 30 minutes to pour the stone model.



3M ESPE recommends horizontal storage of the ready-for-use cartridge.



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Dental Products
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Helpful Hints

Storage	When stored below 18°C/64°F the viscosity of the paste may increase enough to cause mixing problems infor the Pentamix unit. Store cooled foil bags for one day at 18°C/64°F minimum. This will re-establish its usual handling characteristics without compromising quality.
Removing the impression	Slightly lift the edge of the impression with one finger in order to let air creep under the impression thus overcoming the vacuum. Carefully blow air or water with the air syringe between the impression and the teeth underneath.
Void formation at the margin of preparation	Start spiral syringing around the tooth stump in the sulcus without stopping, and while ensuring that the mixing tip is not removed from the material If the preparation has been cleaned with hydrogen peroxide, rinse carefully with water.
Greasy impression surfaces	Thoroughly rinse off retraction solution with water around the preparation If topical anesthetics containing epinephrine are used let the patient rinse out his mouth well before the impression is taken.
Making the cast from the impression	The cast should be prepared from the impression with com mercial gypsum stone no earlier than 30 minutes and no later than 14 days after making the impression. Do not use surfactants!
Impression storage	Carefully dry off impression after disinfection. Do not expose to direct sunlight and do not store when moist (e.g. storing an impression not quite dry yet in a plastic bag or together with alginate) since this may damage the impression.
Removing the impression	Briefly immerse tray in hot water (60-70°C/140-160°F). from the tray.

Summary

Impregum™ Penta™ Soft HB/LB/MB and Impregum™ Penta™ Soft Quick Step HB/LB/MB are polyether materials for precision impressions, fulfilling the requirements demanded of modern impression materials. Impregum Penta Soft (HB and MB) and Impregum Penta Soft Quick Step (HB and MB) products are dispensed from the Pentamix™ 2 automatic mixing unit while the Impregum Soft LB and Impregum Soft Quick Step LB products are dispensed from the Garant™ 2 dispenser system. These impression materials have the following characteristics:

Characteristics of all polyethers

Characteristic	Clinical benefit
Initial hydrophilicity (while unset during the working time as well as after setting)	Precise even in wet environment
High flowability throughout the working time	Precise reproduction of detail
Structural viscosity (thixotropy)	Flows ideally under low pressure but does not slump
Precise setting behavior (snap set)	Superb accuracy and fit; reliable features during whole working time
Cationic ring opening polymerization	Dimensional stability

Polyether Soft Characteristics:

Characteristic	Clinical benefit
Decreased Shore-A hardness	Easier removal of the impression from mouth and gypsum cast
Improved taste by adding fresh mint flavor	More comfort for the patient

Polyether Soft Quick Characteristics:

Characteristic	Clinical benefit
Variable working timephase (1 minute max.)	Best suited for 1 and 2 unit impressions Especially suited for the dual arch tray technique
Short total setting and oral residence times (at least 1/3 quicker than regular setting polyether)	Saves time (at least 2 minutes compared to regular setting polyethers) More comfort for the patient

Impregum Penta Soft (HB/LB/MB) and Impregum Penta Soft Quick Step (HB/LB/MB) (impression material products combine all the good qualities of polyether impression materials and the highest level of comfort for dentists, patients, and dental technicians alike, offering the prerequisites for clinical success.

Technical Data

Technical Properties	Limit	Impregum™ Penta™	Impregum™ Penta™ Soft	Impregum™ Penta™ Soft™ Quick Step
Lot		# 149598/149643	# 149466/150215	# 176018/174222
DIN EN 24823-00 ISO 4823-00) Total working time* [minutes:seconds]	—-	3:30	3:00	2:15
Viscosity [mm]	31-39	36	36	35
Recovery after deformation [%]	96.5 - 100	>98#	>98#	>98
Deformation under pressure [%]	2.0 -20	2.9#	5.2#	2.3
Linear change in size [%]	< - 1.5	- 0.3	- 0.4	-0.3
Compatibility with gypsum line [mm] (visibility of line)	0.050	fulfilled	fulfilled	fulfilled
Accuracy of detail line [mm] (visibility of line)	0.020	fulfilled	fulfilled	fulfilled
DIN 53 505: Shore-A hardness after:				
15 min	—-	45-51	53-58	58-61
1 h	—-	40-44	46-50	47-51
24 h	—-	51-54	52-56	53-57
DIN 53 504 Tensile strength [MPa]		1.9±0.2	1.8±0.2	2.1±0.3
Expansion [%]		235±46	301±56	305±46
In-house tests				
Flowability into crevices**	—-	27	25	21

*= ISO test data for the total working time may differ from actual working time in practice, which helps to explain any possible differences in the instructions for use.

**weight = 415grams, width of slot = 2mm

= typical times in clinical practice: Working time 2:00 minutes, intraoral setting time 4:00 minutes

Note: The data do not represent ranges of values but are individual values, each relating to a specific production batch

Technical Properties	Limit	Impregum™ Penta™ Soft HB	Impregum™ Garant™ Soft LB	Impregum™ Penta™ Soft Quick Step HB	Impregum™ Garant™ Soft Quick Step LB
Lot		# 149013/ 150252	# 152509/ 153151	# 174902/ 174222	# 174999/ 173527
DIN EN 24823-00 ISO 4823-00) Total working time* [minutes:seconds]	—-	3:15	3:15	2:00	2:45
Viscosity [mm]	<35 (Typ 1) >36 (Typ 3)	35	40	34	41
Recovery after deformation [%]	96.5 - 100	>98#	>98#	>98	>98
Deformation under pressure [%]	2.0-20	5.5#	5.3#	2.8	5.6
Linear change in size [%]	< - 1.5	- 0.4	- 0.4	-0.3	-0.4
Compatibility with gypsum line [mm] (visibility of line)	0.050	fulfilled	fulfilled	fulfilled	fulfilled
Accuracy of detail line [mm] (visibility of line)	0.050 0.020	fulfilled	fulfilled	fulfilled	fulfilled
DIN 53 505: Shore-A hardness after:					
15 min	—-	39-44	34-42	49-53	44-47
1 h	—-	46-50	46-52	51-55	49-52
24 h	—-	47-53	47-52	52-56	50-53
DIN 53 504 Tensile strength [MPa]		1.4±0.2	1.3±0.2	2.2±0.2	1.5±0.2
Expansion [%]		268±28	161±33	395±53	199±55
In-house tests					
Flowability into crevices**	—-	20**	19***	16**	19***

*= ISO test data for the total working time may differ from actual working time in practice, which helps to explain any possible differences in the instructions for use.

**weight = 415grams, width of slot = 2mm

***weight = 415grams, width of slot = 1mm

= typical times in clinical practice: Working time 2:00 minutes, intraoral setting time 4:00 minutes

Note: The data do not represent ranges of values but ar individual values, each relating to a specific production batch

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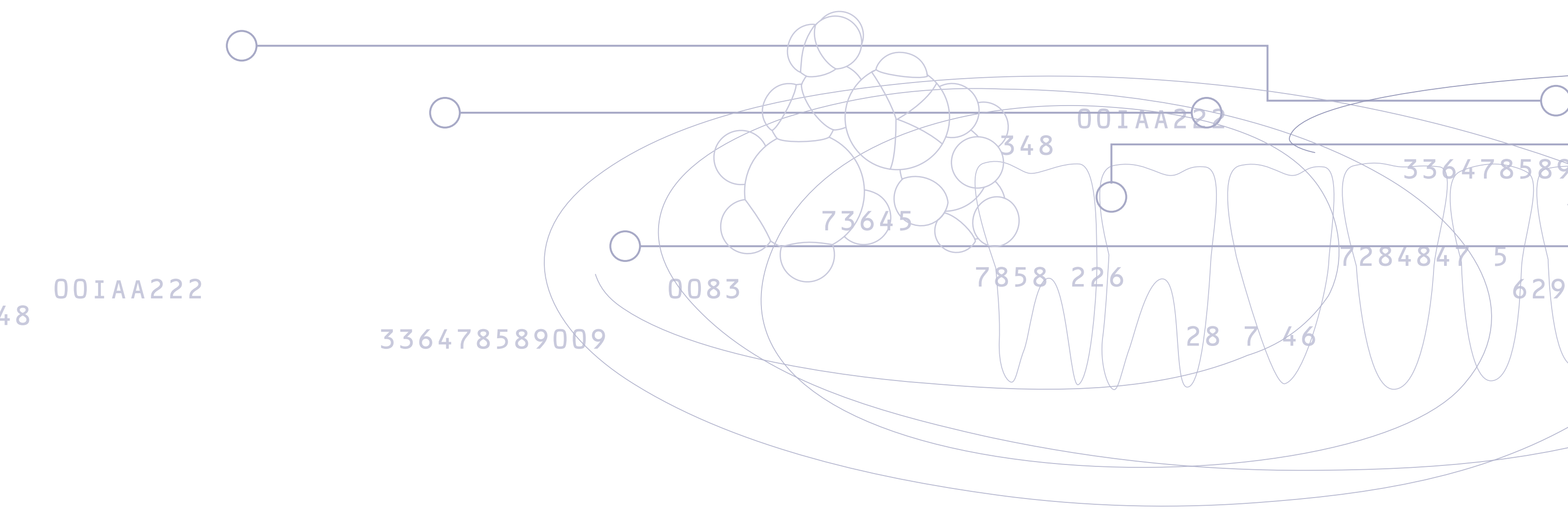

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