



primosplint

Instruction Manual

Light cured composite rods,
MMA- and peroxide free

Especially developed for the production of
function - therapy bite splints and more...

patent no.: 102 24 002

primosplint – the product

primosplint is a patented, light cured composite material, methylmetacrylate and peroxide free, especially developed for function therapy bite splints.

primosplints provide highest stability without any brittleness, as the materials tensile strength and modulus of elasticity (E-Modulus) are adjusted for the application as an ideal splint material. This means that, at the same time, even though primosplints are highly stable, when strained unphysiologically (i.e. distorted impression, bubble in the stone model, etc.) they would rather break, before such wrongly made splints could stress the joint unnecessarily.

primosplint protects the natural dentition as well as the TMJ because the material is "abrasion-optimised". Any premature contacts will wear faster; consequently the TMJ will not be stressed unnecessarily.

primosplint has a much greater working time compared to conventional PMMA materials. Due to the photo initiators used, the polymerisation process mainly starts, when primosplint is exposed to the light in a light curing unit.

primosplint has, being a light cured composite, lowest polymerization-shrinkage, and consequently highest dimension-stability. This means, no "rocking", just precise passive fit after the light curing process.

primosplint can be easily adapted and nicely modelled due to its composite like consistency - similar to modelling clay - combined with the special rod shape. This way, bite splints can be produced very efficiently and complication-free.

In the articulator not only the centric stops but also all movements (disclusion) can be simulated prior to the polymerisation. primosplint keeps the occlusal relations established and does not move back to its original shape. This results in a highly reduced working time for checking and adjusting occlusion after polymerisation.

primosplint can be adapted right onto the stone model. A suck-down matrix as splint base is not necessary. However, if a suck-down base is requested by the dentist, primostick – a light cured bonding material – will be applied to the suck-down matrix first, working as a chemical connector between the base and primosplint.

As an alternative to mechanical polishing, primosplints can be "polished" very efficiently by applying primoglaze – a light cured glaze lacquer.

primosplint has no taste or smell and is in accordance with CE- and Medical Product Law.

Indications

The main indication for primosplint is the production of function therapy bite splints, most of the time as single material, or if requested in combination with suitable suck-down matrices. primosplint is also used for night guards, implant surgical guides, CT scanning guides, implant x-ray guides, implant jigs and verification indexes, transfer and insertion guides, PIB – Procera implant bridges, checking and insertion guides for veneers and as a block-out material.

Light curing

Ideally primosplint is light cured in the Metalight classic light curing unit (primotec), as this Metalight accommodates a complete articulator. Alternatively primosplint can be polymerized in any other light curing unit that is equipped with UV-A bulbs (320 nm to 400 nm), i.e. a conventional unit to polymerize light cured custom impression tray materials.

Warning:

If the polymerisation time is insufficient (too short), or primosplint is polymerized in a defect or unsuitable light curing unit, the material may not be fully cured. This can result in taste irritations for the patient.

Strong stroboscope light curing units with high polymerization temperatures can negatively influence the precision of the bite splint and should not be used.

polishing

mechanical polishing of primosplint with pumice and high shine polishing paste and wheels is, of course possible, but only the second best solution. Due to its chemical composition, primosplint needs to be polished with more pressure (resulting in more heat) compared to conventional PMMA powder/liquid acrylics, in order to reach the desired shine. The resulting heat, especially when doing the high shine polishing might lead to slight distortion.

Safer and much more efficient is the use of primoglaze glaze lacquer. It gives the splint maximum clarity without any danger of distortion.

First the finished splint is lightly sandblasted inside and outside (approx. 110 micron aluminum oxide, 30 PSI), steam cleaned or rinsed under water and dried with compressed air.

Then one thin layer of primoglaze is brushed on the inside of the splint. Any excess of primoglaze inside the splint must be gently blown off with compressed air. For light curing, the splint's inside must face downwards to avoid any primoglaze lacquer to flow into the pits (which would result in mal fitting of the splint).

The outside of the splint gets, in general, two primoglaze coatings. First one thin coating is applied with a fine brush and pre-polymerized for about one minute. Then a second thin coating of primoglaze is brushed on but in cross direction to the first coat. Finally primoglaze is light cured for five minutes. The result is a perfect shine with highest primosplint clarity.

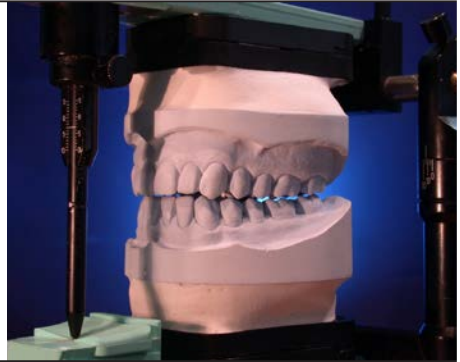
How to use primosplint

Step by Step procedures 1. – 3.

1.

Mount the models in the articulator (removable), and adjust the articulator pin according to the bite.

In principle, primosplints should have a minimum thickness of 1.2 mm. If they need to be thinner (i.e. unfavourable bite situation, bruxer, etc.) use a suck-down matrix as splint base.



2.

To block out the model on which the splint should be produced, use conventional wax or silicon and block out the undercuts as usual.

Wet the model for about one minute. The dental arch, however, should not be under water. Then apply a first layer of primosep...



3.

... separator, let it dry for about three minutes, and apply a second layer. This second layer has to be dry, before primosplint is adapted.

The opposing model is isolated with Metatouch separator. Both separators (primosep and Metatouch) are best applied with a brush.



How to use primosplint

Step by Step procedures 4. – 6.

4.

When primosep is dry it gets firm and slightly sticky, so that during the modelling phase the primosplint rod “sticks” to the model. When re-watering the model after light curing (before lifting the splint off the model) the water re-activates primosep and makes it soft. Thus the light cured splint can be lifted off the model without problems.



5.

Recommended modelling instruments are, next to the fingers, a flexible spatula (as commonly used for indirect composite veneering) and a scalpel.



6.

Fingers and instruments will be lightly covered with Metatouch. This separator allows fast and comfortable working procedures.

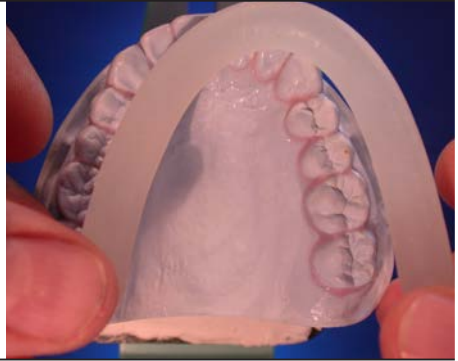


How to use primosplint

Step by Step procedures 7. – 9.

7.

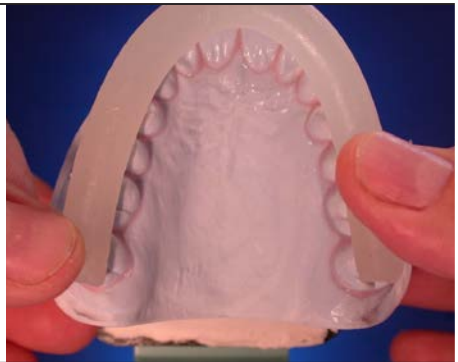
Open a new stick of primosplint and gently bend and knead it for about 10 to 15 seconds. This way you bring energy into this thixotropic material, meaning it becomes softer and more pliable. Use a bit of Metatouch on your fingers to smoothen the side of the stick that is facing towards the dental arch. Thus you achieve the...



8.

... best surface condition on the inside of the splint. Bend the new stick, that has been conditioned as described above, and pre-form it into dental arch shape.

Push the pre-formed rod onto the model...



9.

... with a tapping, pulsating motion (remember: thixotropic material) and lightly pre-adapt it.

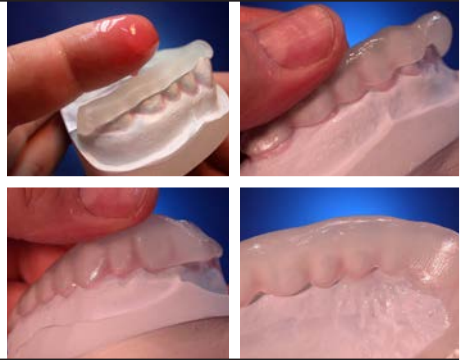


How to use primosplint

Step by Step procedures 10. – 12.

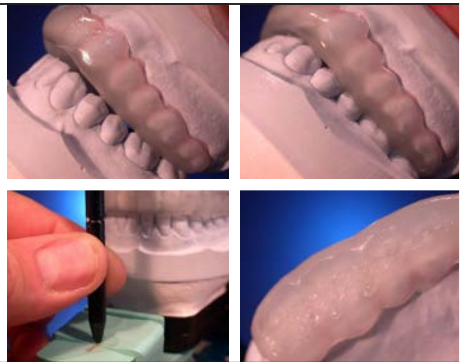
10.

Cover the pre-adapted rod with a thin layer of Metatouch separator, and model it in gingival direction, both labially and lingually. Make sure, that a sufficient amount of primosplint material remains occlusally, depending on the desired thickness of the splint.



11.

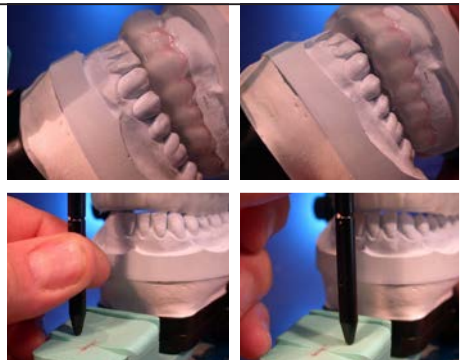
With a tapping movement, slowly close the articulator until the pin touches the incisal plate. Since the opposing model, as well as the primosplint material itself, is slightly covered with Metatouch, primosplint will not stick to the opposing model.



12.

Simulate the disclusion movements (working, non-working, protrusion), always moving from ex-centric to centric.

Beware: on occlusal thin, flat splints make sure to build in sufficient stability, either by thickening or extending the splint further bucal and/or lingual.



How to use primosplint

Step by Step procedures 13. – 15.

13.

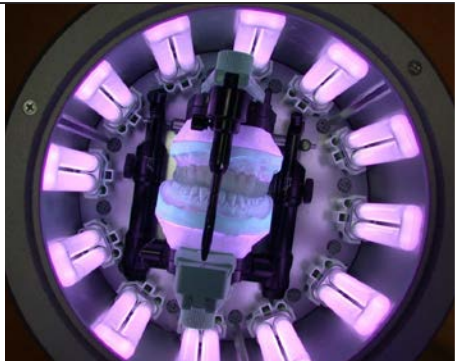
Once all movements are simulated, the occlusal pattern achieved remains exactly in its shape. Consequently, after light curing, only minor occlusal adjustments are necessary.



14.

Light cure the splint for 10 minutes by placing the whole articulator in the Metalight classic (primotec) or any other light cure unit equipped with UV-A bulbs (320-400 nm).

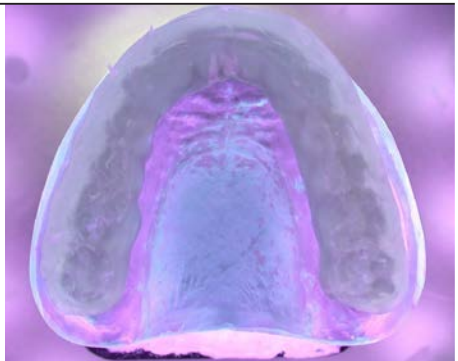
In case no light curing unit that would accommodate an articulator is available...



15.

.... use a conventional light curing unit, commonly used to polymerise custom impression trays. In this case, remove the model from the articulator and place it in the light curing unit.

After light curing, wet the model again for one minute to activate the primosep separator, meaning to soften it.



How to use primosplint

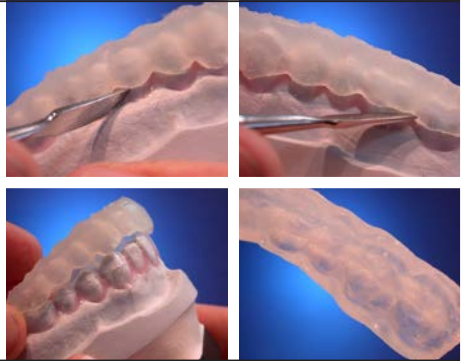
Step by Step procedures 16. – 18.

16.

After the initial polymerization is completed, use a stiff and dull instrument to carefully remove the splint from the model.

Do not lever. Just apply enough pressure to let air come between the splint and the model.

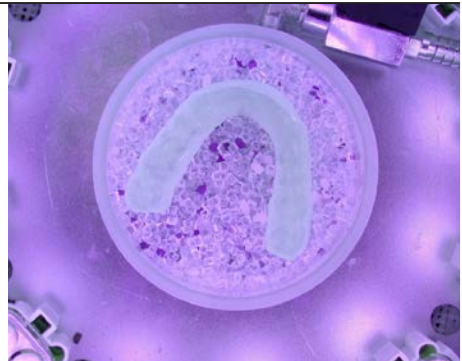
If the block out is done correctly, primosplint can always be used right on the master model (no duplicate model necessary).



17.

To ensure complete polymerization of the primosplint material, especially when the splint has become thick, it needs to be light cured for another 5 to 10 minutes - depending on the light curing unit used - with the occlusal surface face down.

This step does not apply when primoglaze is used later on.



18.

After complete polymerization, a very thin oxygen inhibition layer remains on the surface. This layer can be easily wiped off by utilizing primoclean liquid on i.e. a tissue or a small sponge, prior to further shaping the splint by grinding.

If the shaping is done right away with a sandpaper roll, use primoclean only after the trimming is completed.

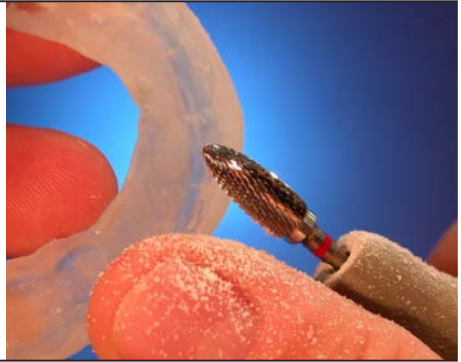


How to use primosplint

Step by Step procedures 19. – 21.

19.

Once the splint is completely cured and cleaned, do necessary shape corrections by grinding, using a coarse, cross-bladed carbide bur or a sandpaper roll. When trimming occlusal, imperatively follow the Wilson and Spee curves, otherwise the transition form occlusal to buccal/lingual might become too thin (risk of fracture).

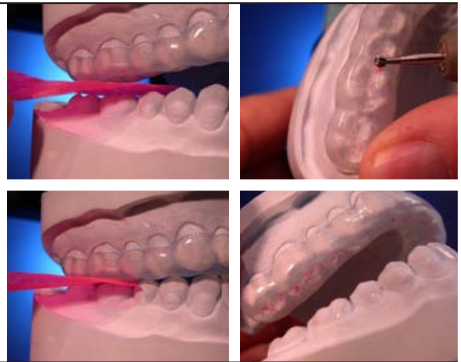


20.

Finally centric and ex-centric will be checked and, if necessary, selectively adjusted using a small round carbide bur.

An even, ideally smooth surface can be achieved, when the splint is lightly sandblasted with aluminum oxide (110 micron, 30 PSI) inside and outside.

Alternatively use sandpaper stripes on a mandrel.



21.

Important: read the chapter regarding polishing on page two carefully!

Finally primosplint will be “polished” with primoglaze. To do so, apply thin layer(s) of the primoglaze lacquer with a brush and light cure the splint for five minutes. Alternatively pre-polish with pumice followed by a high shine polishing procedure.



How to use primosplint

Step by Step procedures 22. – 24.

22.

In case, a suck-down matrix shall be used as the splint base, use primostick light cured bonding material as a connector between the matrix and primosplint.

Important: only use those suck down matrices that can connect to PMMA materials!



23.

The prepared matrix needs to be roughened, prior to applying primostick. To roughen the matrix just sandblast it with aluminium oxide - grain size 50 or 110 micron - at a blasting pressure of 30 – 60 PSI.



24.

After sandblasting, clean the surface of the matrix and apply primostick with a brush.



How to use primosplint

Step by Step procedures 25. – 27.

25.

To polymerize the applied primostick bonder, just light cure the matrix for approx. two minutes. primostick is completely polymerized, when its surface is not sticky anymore after light curing.



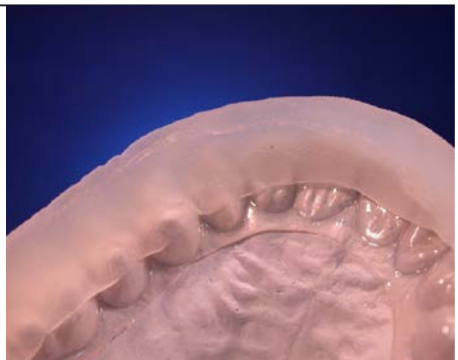
26.

Once primostick bonder is light cured, take a primosplint rod and adapt it to the matrix. Now follow steps 11 to 21 of this manual to achieve the desired result.



27.

Note: To add uncured primosplint to already polymerized primosplint material, or to repair primosplint (or even PMMA-splints), always follow the steps 23 to 26. Roughen the surface, apply primostick, light cure for two minutes, adapt primosplint material and polymerize it.

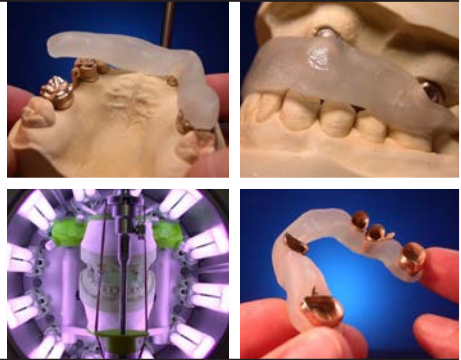


How to use primosplint

Instructions check-bite for try-in

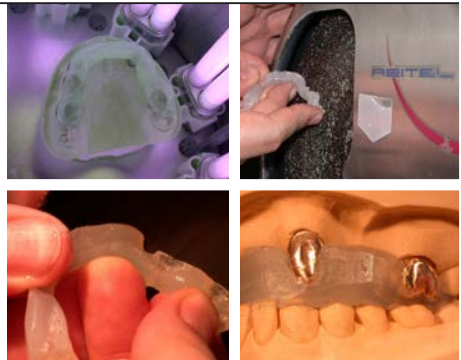
1.

To produce a check-bite for the try-in, first adapt primosplint over the crowns and/or bridges. Raise the bite in the articulator by 5 mm (adjusting the pin), close the articulator, secure the position with a rubber band and polymerize for 10 minutes.



2.

Light cure the check-bite for at least another 5 minutes without the opposing model. After light curing is completed, trim back the buccal surfaces of the check-bite. This way, it becomes easier to check the precise fit of the check-bite, both on the model and in the mouth.



3.

Following this step by step procedure a perfect fit of the check-bite can be achieved.

Assuming that the initial bite registration has been correct, the check-bite will correspond exactly to the intraoral situation.

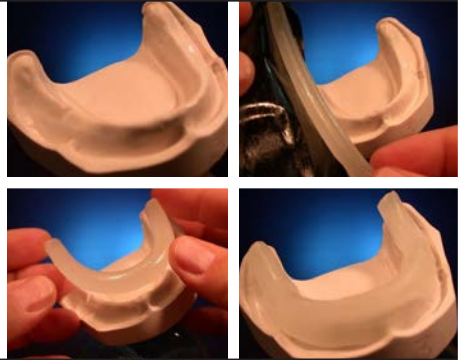


How to use primosplint

Instructions x-ray or drilling splint for implantology

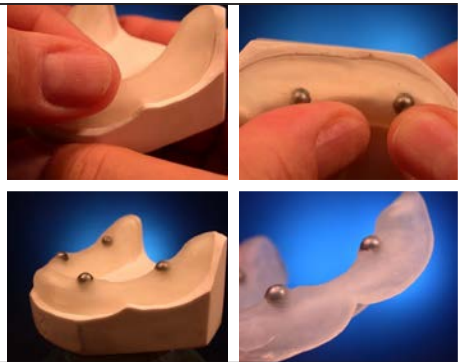
1.

Use the primosep separator on the model and the Metatouch separator for fingers and instruments as instructed. Then adapt primosplint to the model.



2.

Use your fingers to model primosplint to the desired shape. Place the x-ray aids (balls, wires, eventually drilling cylinders) and press them all the way down to the ridge. Light cure the splint, then take it off the model and grind it to shape.

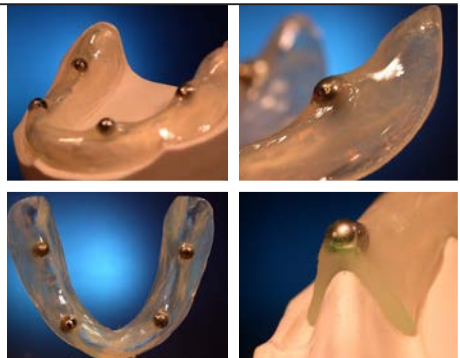


3.

Finally polish the splint with primoglaze lacquer and light cure one more time.

A cross section through the splint shows its superior fit.

As the case progresses, the x-ray splint can also be used as a base for the bite registration or the denture teeth set up.



Description of the periphery products

primostick

is a light cured bonding material which creates chemical bonding between already polymerized and not yet polymerized primosplint material. Furthermore primostick is used to achieve chemical bonding between primosplint and a suck-down matrix, as well as for repairing primosplint and also regular PMMA-splints.

primoglaze

is a light cured glaze lacquer, that is applied and polymerized instead of a mechanical polishing (pumice) to achieve a high shine surface of the splint.

Patent no.: 102 24 002



Composition primosplint

oligomere acrylates, anorganic and organic fillers, photo initiators

Storage notice

primosplint, as well as its periphery products primostick, primoglaze, primosep and primoclean should be stored and used at temperatures between 4°C und 25°C. All materials shall be protected against heat and direct sunlight. Always close the containers right after use. The expiration date is printed on the product label. After the materials are expired they must not be used anymore.

primosplint products warning

primosplint contains acrylate resins and different fillers. In case any irritations occur by using the product, or if the user is aware that he might react allergic to one of the products components, the material should not be used. Avoid direct eye or soft tissue contact with the unpolymerized material, as this might lead to sensitivities. To avoid

primosep

is the separator for the stone model.

primoclean

is a cleaning liquid to wipe off the oxygen inhibition layer that remains on the surface after primosplint is polymerized.

Metatouch

is the separator for fingers and instruments. It is also used in conjunction with the Metacon Light Cured Wax System (by primotec).

any health risks, especially grinding and polishing should only be done at a work bench with an appropriate suction system (for further information check the primosplint safety data sheet).

primostick, primoglaze and primoclean can cause irritations and are flammable. These product contain Methylmetacrylate, PETIA and/or Isopropanol. Avoid skin contact as this might lead to sensitivities (for further information check the relevant safety data sheets).

Regulations for use

All primosplint products were developed for the use in the dental field. They have to be used in accordance with this instruction manual. For any damages caused by the use of the products in any other than the dental field, neither the manufacturer nor the distributor will take any responsibility. In addition, the user is obliged to verify, at his own responsibility, whether the material can be used for the desired purpose, especially if the desired purpose is not described in the instruction manual.

Attention:

Do not use unpolymerized primosplint intraorally!!!



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