Bioctris®

Bio Composants Médicaux

Precautions for use

Bioctris® has been developed solely for use in dentistry.

- Prevent contact of the eyes and skin with uncured material (Bioctris® fibres). Contact of the skin with uncured material may cause slight irritation and sensitization to methacrylate. Always wear gloves to avoid handling uncured Bioctris® fibres with fingers.
- If the material comes into contact with the skin, rinse with copious amounts of water.
- Use suction equipment and a protective mask when grinding the material. Finishing the Bioctris® frameworks creates glass fibre dust, which may cause the skin to itch. Wearing suitable gloves is recommended. Thoroughly clean the skin that has come into contact with glass fibre dust.
- Process of Bioctris® material must be done extra-orally.
- Follow instructions in order to completely cure the Bioctris® fibres.
- Non-cured Bioctris® fibres should not come into contact with mucous tissues.
- Observe the danger signs and notes on the primary packaging and labels of the individual materials.

Working procedure of the Bioctris® framework materials

	Anterior crowns	Posterior crowns	Anterior bridges	Posterior bridges	Inlya-retained bridges
Duplicate die/model	Yes*	Yes*	Yes	Yes*	Yes
Transil matrix	Yes	Yes*	Yes	Yes	Yes
Framework thickness Bioctris abutment	at least 0.3-0.4 mm	at least 0.3-0.4 mm	at least 0.3-0.4 mm	at least 0.3-0.4 mm	at least 0.3-0.4 mm
Joint face of the connector	-	-	at least 3 x3 mm	at least 3 x3 mm	at least 3 x3 mm
Thickness of pontic/abutment contact layer	-	-	at least 0.3 mm	at least 0.3 mm	at least 0.3 mm
Length of the pontic/abutment contact layer	-	-	at least 3 mm	at least 3 mm	at least 3 mm
Long Pontic ribbon	-	-	1 x	1 x	1 x
Medium-sized Pontic ribbon	-	-	1 x	1 x	1 x
Short Pontic ribbon	-	Yes*	2-3 x	3-5 x	3-5 x
Grit size of Al203 jet medium	80-100 µm	80-100 µm	80-100 µm	80-100 µm	80-100 µm
Pressure	1 bar (14.5 psi)	1 bar (14.5 psi)	1 bar (14.5 psi)	1 bar (14.5 psi)	1 bar (14.5 psi)
Cleaning with air or steam	No	No	No	No	No

The indicated numbers of Pontic strips are reference values and may differ depending on the situation in question.
Yes = indicated, Yes* = advisable, no = contraindicated

A. Single crowns

1. Starting situation: Fabricate a master model or a model with detachable segments on the basis of the impression in the usual manner. Expose and mark the preparation margin. It is advisable to apply a sealer to harden the surface and to protect the stone die. The application of the sealer must not cause any changes in the dimension of the stone die. Subsequently, a spacer can be applied, depending on the customary working method. Tip: It is advisable to pour a duplicate die to carry out the vacuum-forming process, as the sharply pointed incisal edges may cause delamination of the stone die.
2. Fabricating the silicone matrix:
   - Silicone matrix made of laboratory silicone (Sil-Tech): Remove the individual dies from the mode! Carefully cover the die with laboratory silicone and adapt the material exactly to the preparation margin. Prepare a shoulder approx. 1 cm down from the preparation margin to facilitate the repositioning of the Transil matrix.
   - Silicone matrix made of Transil: If a deep occlusal preparation is present, prepare a second matrix using Transil (transparent silicone) Separate the laboratory silicone with a thin coat of Vaseline to prevent the two silicone materials from sticking to each other. Insert the Transil cartridge into the dispenser, mount a new mixing tip and apply Transil to the die in a single step. Transil should be applied in a layer thickness of approx. 3 to 6 mm to obtain sufficient stability. The setting reaction may be accelerated by using a hot air dryer. After the material has set, smooth out the exterior surface to enhance the passage of light. Subsequently, remove the Transil matrix from the die. Tip: Smooth out the exterior surface with a Bioctris foil while the material is still soft. Mark the laboratory silicone and Transil with a waterproof pen to obtain an exact repositioning of the matrices.
3. Sealing the dies: Apply your isolating agent in two coats. Apply the first layer slightly more generously than the second one and make sure to fully cover all areas of the die. Watch out for sharp edges in particular. Allow the first layer to react for 3 minutes. Subsequently, apply the second layer of your isolating agent in a thin coating, invert the die and allow to dry for 3 minutes.
4. Preparing the die for the vacuum-forming process: Before removing the Bioctris Single from the packaging, adjust the height of the model carrier in the vacuum former so that the distance between the model and the upper rim of the container is 2 to max. 3 cm. If necessary, further adjust the height by means of the spacer rings. Finally, check the position of the membrane.
5. Vacuum-forming the Bioctris Single:
   - Version A: Application of Bioctris in the Vectris VS1 framework former; Position the die in the framework former, apply a small amount of your light- (and dual)-curing composite cement to the die to keep Bioctris Single in place while it is one the die. Remove the Bioctris Single from the light-protected package, place Bioctris Single on the die using tweezers and lightly press it into place. Next, cover the Bioctris Single with a Bioctris foil to reduce the inhibited layer. Then, close the Vectris VS1 unit and start Program 1 to commence the vacuum-forming and polymerization process. The program takes 10 minutes to complete.
   - Version B: Application of Bioctris outside the Vectris VS1 framework former: Remove the Bioctris Single from the light-protected package and place it on the die with tweezers. Place the Transil matrix on the Bioctris Single in the correct position, push it downwards and mount the die on the model carrier of the Vectris VS 1.
6. Removing the framework from the die: After completion of the vacuum-forming process, first remove the Bioctris foil or Transil matrix from the framework and then carefully remove the framework from the die while it is still warm. If the restoration is removed at a later stage, it is advisable to warm up the stone die by means of water vapor. The framework exhibits an even layer thickness after it has been removed from the die.
7. Finishing: Remove large areas of excess material with a separating disk and then trim the remaining excess material with cross-cut tungsten carbide burs. It is advisable to use a slow rotational speed and light pressure. The thickness of the walls, which is 0.3 to 0.4 mm after the vacuum-forming process, must not be reduced by grinding. Trim the margins by approx. 0.5 mm to the inner edge of the chamfer or shoulder preparation. Make sure that the framework continues to be supported by the die after having trimmed the margins.

B. 3-unit anterior bridges

1. Starting situation: Fabricate a master model or a model with detachable segments on the basis of the impression in the usual manner. Expose and mark the preparation margin. It is advisable to apply a sealer to harden the surface and to protect the stone die from abrasion. The application of the sealer must not cause any changes in the dimension of the stone die. Subsequently, a spacer can be applied, if this is the customary method of working.
2. Fabricating the duplicate model for the vacuum-forming process: Bridge constructions for the anterior region in particular often involve sharply pointed incisal edges. As these edges are prone to delamination du ring the vacuum-forming process, a duplicate model has to be prepared. The master model is utilized to contour the pontic (including the pontic/abutment contact layer). to check the fit of the restoration and to veneer the framework. Pour the original impression a second time and create a small duplicate model for the vacuum- forming process. Make sure to eliminate undercut areas to facilitate the subsequent application of the Transil matrix. Remark: A silicone, polyether or similar material should be used for impression taking as these materials provide an optimum reproduction of detail. Additionally, the impressions taken with these materials can be poured several times. Hydrocolloid and alginate materials are unsuitable and, besides, cannot be poured more than once.
3. Contouring pontic: First, seal the dies with a wax/stone or resin/stone separator. Form the pontic on the master model in a shape- and cusp- supporting manner similar to the metal-ceramic technique, using wax or composite (Light Tray). This step helps to obtain a homogeneous layer thickness in the following veneering material. The palatal or lingual abutment/pontic contact layers should exhibit the following dimensions: surface: at least 3 x 3 mm; thickness: at least 0.3 mm and joint face of the connector: at least 3 x 3 mm. It is advisable to contour the pontic insert in a shape-and cusp-supporting design, depending on the space available. Check the pattern in the articulator and adjust as necessary. If a full wax-up has been prepared, the wax rim may be used for checking purposes. Tip: The pontic can be contoured using a tray material (Light Tray) and adjusted by grinding after completion of the polymerization process.
4. Transferring the pontic to the duplicate model: Transfer the fully contoured pontic to the duplicate model and use a small amount of wax to hold it in place. Black out the basal surface of the pontic using laboratory silicone (Sil-Tech) in order to ensure that the following Transil matrix can be removed easily. It is important to black out this area since it will determine the way in which the Bioctris Frame wraps around the Bioctris Pontic. The portion of the basal surface that is in contact with the laboratory silicone should not be too wide. The following instructions should be observed when transferring the pontic to the duplicate model:
    a. Reduce the basal surface of the duplicate model and prepare retention.
    b. Transfer the pontic to the duplicate model and hold it in place with a small amount of wax.
    c. Black out the reduced basal surface using laboratory silicone (Sil-Tech).
    d. Reduce the blocked out area by means of a scalpel or bur.
5. Fabricating the Transil matrix: Separate the laboratory silicone with a thin coat of Vaseline to prevent the two silicone materials from sticking to each other. Insert the Transil cartridge into the dispenser, mount a fresh mixing tip and apply Transil to the die and pontic in a single step. Transil should be applied in a layer thickness of approx. 3 to 6 mm to obtain sufficient stability. The setting reaction may be accelerated by using a hot air dryer. After the material has set, smooth out the exterior surface and form it into a conical shape to enhance the passage of light. Subsequently, remove the Transil matrix from the die. Tip: A Bioctris foil may be used to smooth out the exterior surface while it is still soft. In order to facilitate the flowing off of Bioctris matrix material, small spillways may be cut into the palatal and labial portions of the laboratory silicone after the Transil matrix has been removed.
6. Sealing the dies: After having removed the matrix and cleaned the duplicate model, apply two layers of your isolating agent. Apply the first layer slightly more generously than the second one and make sure to fully cover all areas of the die. Watch out for sharp edges in particular. Allow the first layer to react for 3 minutes. Subsequently, apply the second layer of your isolating agent in a thin coating, invert the model and allow it to dry for another 3 minutes.
7. Preparing the dies for the vacuum-forming process: Before removing the Bioctris Single from the packaging, adjust the height of the model carrier in the vacuum former so that the distance between the die and the upper rim of the container is 2 to max. 3 cm. If necessary, the height may be further adjusted with the help of the spacer rings. Finally, check the position of the membrane.
8. Placing Bioctris Pontic into the Transil matrix and vacuum-forming the pontic: Slightly moisten the Transil matrix with your light – (and dual)- curing composite cement to facilitate the adaptation of Bioctris Pontic strips. Remove the Bioctris Pontic from the light-protected package, cut it to the desired length, remove it from the foil and place it into the Transil matrix using tweezers. Observe the schematic below when filling in the individual Bioctris strips. Place the Transil matrix on the duplicate model in the correct position, push it into place and mount the model on the model carrier of the Vectris VS1. Start program 1 to commence the vacuum-forming and polymerization process. The program takes 10 minutes to complete.
9. Vacuum-forming the Bioctris Frame: Remove only the Transil matrix; leave the pontic on the duplicate model. Remove any Bioctris matrix material that has been squeezed downwards, using an appropriate instrument. If the pontic inadvertently comes off along with the Transil matrix, carefully remove it from the matrix and reposition it on the duplicate model. Do not grind or contaminate the pontic. Subsequently, remove the Bioctris Frame from the light-protected package and place it on the Bioctris Pontic. Do not cut slits into the Bioctris Frame. Place the Transil matrix over the duplicate model, push it into place and position the model at the centre of the container in the framework former. Start Program 1 to commence the vacuum-forming and polymerization process. The program takes 10 minutes to complete.
   Tip: If it is impossible to avoid modifications involving grinding, then sandblast the entire pontic surface with type 100 Al2O3 at 1 bar (14,5 psi) pressure. After sandblasting, remove residue by tapping it off and not by cleaning the surfaces with steam or an air gun. If necessary, a clean disposable brush may be used for this purpose. Apply your silane in a water / alcohol solution immediately after having removed the residue. Use a disposable brush to apply the liquid and allow it to react for 60 seconds. Disperse excess material with oil-free compressed air and replace the pontic on the duplicate model.
10. Removing the framework from the die : Upon completion of the vacuum forming process, remove the Transil matrix and lift the framework from the die. If the framework cannot be readily removed, warm up the frame- work and the duplicate model by means of a steam jet and then try again. Remove excess material using a separating disk while the framework is still on the model. Subsequently, carefully remove the framework from the die.
11. Finishing: Remove excess material in the marginal areas with cross-cut tungsten carbide burs. It is advisable to use a slow rotational speed and light pressure. The thickness of the walls, which is 0.3 to 0.4 mm after the vacuum forming process, must not be reduced by grinding. Trim the marginal areas by approx. 0.5 mm to the inner edge of the chamfer or shoulder preparation. Make sure that the framework continues to be supported by the die after trimming the margins.

C. 3-unit inlay-retained bridges

1. Starting situation: Fabricate a master model or a model with detachable segments on the basis of the impression in the usual manner. Expose and mark the preparation margin. It is advisable to apply a sealer to harden the surface and to protect the stone die from abrasion. The application of the sealer must not cause any changes in the dimension of the stone die. Subsequently, a spacer can be applied, if this is the customary method of working.
2. Fabricating the duplicate model for the vacuum forming process: For inlay-retained bridges, the abutment teeth are cut to obtain an appropriate cavity for the abutment/pontic contact surface. Consequently, a duplicate model has to be prepared. The master model is utilized to contour the pontic (including the pontic/abutment contact layer), to check the fit of the restoration and to veneer the framework. Pour the original impression a second time and create a small duplicate model for the vacuum-forming process. Make sure to eliminate undercut areas to facilitate the subsequent application of the Transil matrix. In addition, reduce the cusps of the abutment teeth in such a way that the height of the cavity measures at least 0.5 mm to enable the Bioctris fibres to adapt to the cavity effectively. The height may be marked with a pencil to facilitate the following reduction. Tip: A silicone, polyether or similar material should be used for impression taking as these materials provide an optimum reproduction of detail. Additionally, the impressions taken with these materials can be poured several times. Hydrocolloid and alginate materials are unsuitable and cannot be poured more than once.
3. Contouring the pontic: First, seal the dies with a wax/stone or resin/stone separator. Contour the pontic on the master model in a cusp-supporting manner similar to the metal-ceramic technique, using wax or composite (Light Tray). This step helps to obtain a homogeneous layer thickness in the following veneering material. The occlusal abutment/pontic contact area in the cavity should exhibit the following dimensions: cover the entire surface of the cavity, length of the abutment/pontic area in the cavity: at least 4 mm, thickness of the contact layer: at least 0.3 mm and joint face of the connector: at least 3 x 3 mm. Check the pattern in the articulator and adjust as necessary. If a full wax-up has been prepared, the wax rims may be used for checking purposes. Tip: The pontic can be contoured using a tray material (Light Tray) and adjusted by grinding after completion of the polymerization process.
4. Transferring the pontic to the duplicate model: Transfer the fully contoured pontic to the duplicate model and use a small amount of wax to hold it in place. Black out the basal surface of the pontic using laboratory silicone (Sil-Tech) in order to ensure that the following Transil matrix can be removed effortlessly. It is important to black out this area because this determines the way in which the Bioctris Frame is wrapped around the BVieoccttrriiss Pontic. The portion of the basal surface that is in contact with the laboratory silicone should not be too wide. It is advisable to follow the following instructions to transfer the pontic to the duplicate model:
    a. Reduce the basal surface of the duplicate model and prepare retention
    b. Transfer the pontic to the duplicate model and use a small amount of wax to hold it in place
    c. Black out the reduced basal surface using laboratory silicone (Sil-Tech)
    d. Reduce the blocked out area by means of a scalpel or bur
5. Fabricating the Transil matrix: Separate the laboratory silicone with a thin coat of Vaseline to prevent the two silicone materials from sticking to each other. Insert the Transil cartridge into the dispenser, mount a new mixing tip and apply Transil to the die and pontic in a single step. Transil should be applied in a layer thickness of approx. 3 to 6 mm to obtain sufficient stability. The setting reaction may be accelerated by using a hot air dryer. After the material has set, smooth out the exterior surface and form it into a conical shape to enhance the passage of light. Subsequently, remove the Transil matrix from the die. Tip: A Bioctris foil may be used to smooth out the outer surfaces while the matrix material is still soft. In order to facilitate the flowing off of the Bioctris matrix material, small spillways may be cut into the palatal and labial portions of the laboratory silicone after the Transil matrix has been removed.
6. Sealing the dies: After having removed the matrix and cleaned the duplicate model, apply your isolating agent in two coats. Apply the first layer slightly more generously than the second one and make sure to fully cover all areas of the die. Watch out for sharp edges in particular. Allow the first layer to react for 3 minutes. Subsequently, apply the second layer of your isolating agent in a thin coating, invert the model and allow it to dry for another 3 minutes.
7. Preparing the model for the vacuum-forming process: Before removing the Bioctris Pontic from the packaging, adjust the height of the model carrier of the vacuum former so that the distance to the upper rim of the container is 2 to max. 3 cm. If necessary, the height may be further adjusted with the help of the spacer rings. Finally, check the position of the membrane.
8. Placing Bioctris Pontic into the Transil matrix and vacuum-forming the pontic: Slightly moisten the Transil matrix with your light - (and dual)- curing composite cement to facilitate the adaptation of the Bioctris Pontic strips. Remove the Bioctris Pontic from the light-protected package, cut it to the desired length, remove it from the foil and place it into the Transil matrix using tweezers. Insert the individual strips as indicated in the schematic below. Then place the Transil matrix on the duplicate model in the correct position, press it into place and mount the model on the model carrier of the Vectris VS1 framework former. Start Program 1 to commence the vacuum-forming and polymerization process. The program takes 10 minutes to complete.
9. Vacuum-forming the Bioctris Frame: Remove the Transil matrix but leave the pontic on the duplicate model. Remove any Bioctris matrix material that has been squeezed downwards, using an appropriate instrument. If the pontic inadvertently comes off along with the Transil matrix, carefully remove it from the matrix and reposition it on the duplicate model. Do not grind the pontic and avoid contaminating it. Subsequently, remove the Bioctris Frame from the light-protected package and place it on the Bioctris Pontic. Do not eut slits into the Bioctris Frame. Place the Transil matrix over the duplicate model, push it into place and position the model at the centre of the container in the framework former. Start Program 1 to commence the vacuum forming and polymerization process. The program takes 10 minutes to complete.
   Important: If it is impossible to avoid modifications involving grinding, then sandblast the entire pontic surface with type 100 Al2O3 at 1 bar (14,5 psi) pressure. After sandblasting, remove residue by tapping it off and not by cleaning the surfaces with steam or an air gun. If necessary, a clean disposable brush may be used for this purpose. Apply your silane in a water / alcohol solution immediately after having removed the residue. Use a disposable brush to apply the liquid and allow it to react for 60 seconds. Disperse excess material with oil-free compressed air and replace the pontic on the duplicate model.
10. Removing the framework from the die: Upon completion of the vacuum forming process, remove the Transil matrix and lift the framework from the die. If the framework cannot be readily removed, warm up the frame- work and the duplicate model by means of a steam jet and then try again. Remove excess material using a separating disk while the framework is still on the model. Subsequently, carefully remove the framework off the die.
11. Finishing: Remove excess material in the marginal areas with cross-cut tungsten carbide burs. It is advisable to use a slow rotational speed and light pressure. The thickness of the walls, which is 0.3 to 0.4 mm after the vacuum forming process, must not be reduced by grinding. The pontic/abutment contact layer should cover the entire surface of the cavity.

Further descriptions are available on request.

Bioctris®

Bio Composants Médicaux

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Instructions for use
Bioctris®

Description

Bioctris® is a light-curing, translucent, tooth-coloured framework material. It is part of the category of fibre reinforced composites (FRC = Fibre Reinforced Composite). It consists of several layers of fibre wafers and uniaxially oriented fibre bundles embedded in an organic polymer matrix. This matrix assures a strong bond and homogeneously distributes the masticatory forces exerted on the veneering material throughout the framework.

Composition (% by weight)

	Bioctris® Single	Bioctris® Pontic	Bioctris® Frame
Glass fibres	44-46	64-66	49-51
Dimethacrylate	48-50	30-32	44-46
Inorganic charges, pigments	5-6	3-4	5-6
Stabilizers, catalysts	<1	<1	<1

Working times

Bioctris® materials are sensitive to light. The working time of the material depends on the layer thickness and the prevailing light conditions. The times listed below represent mean values at a light intensity of 3000 lux, which corresponds to the light encountered in a well-lit working space. Be aware of the maximum time limit when removing the Bioctris® framework materials from the packaging.

	Working time (min)
Bioctris® Single	2'30
Bioctris® Pontic	3
Bioctris® Frame	2'30

Indications

The indications are the following ones:

- Adhesive cementation
  - Frameworks for anterior and posterior crowns ;
  - Frameworks for 3-unit anterior and posterior bridges in conjunction with Transil ;
  - Frameworks for 3-unit inlay-retained bridges in conjunction with Transil.
- Temporary cementation
  - Frameworks for long-term temporaries intended for a maximum duration of wear of 12 months

Contraindication

– Fabrication of bridge frameworks without using Transil
– Fabrication of posterior Bioctris® frameworks without cusp support, if Transil is not used
– Bioctris® frameworks for bridges consisting of 4 or more units
– Bioctris® frameworks for inlay-retained bridges consisting of 4 or more units
– Cantilever extension bridges
– More than 4 fixed, permanent Bioctris® units per quadrant
– Rehabilitation of quadrants with Bioctris® frameworks without sufficient support by the remaining tooth structure
– Conventional cementation of fixed Bioctris® restorations
– Metal-free temporary restorations intended for a period of wear longer than 12 months
– Patients with occlusal dysfunctions or parafunctions, such as bruxism, etc
– Patients who practise insufficient oral hygiene
– Inability to meet the manufacturer's preparation guidelines and recommended minimum layer thicknesses
– Veneering of permanent Bioctris®-based restorations using composites that are not indicated (no methacrylate composite) for Bioctris®
– All uses not explicitly stated as indications by the manufacturer

Side effects

Side effects are not known to date. In rare cases, an allergic reaction may occur. Bioctris® must not be used if the patient is suspected or known to be allergic to any of the material's ingredients.

Bioctris®

Storage

- Store unopened and opened packages of Bioctris® framework material at 12-28ºC.
- Store opened Bioctris® packages in a place that is protected from light and use up the contents as soon as possible.
- Observe the notes on the storage and dates of expiration of the individual packages.
- Do not use materials after the date of expiration.

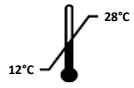
Guarantee – Limited liability

The guarantee is limited to the quality of the product: any defective product will be replaced. The Batch Number must be cited in all correspondence which asks for identification of the product.
This product has been developed for use in dentistry and must always be used according to the Directions. Any harm resulting from a failure to comply with these provisions, incorrect handling or utilisation for purposes other than those indicated in the Directions, will not be the manufacturer's responsibility. Before every use, the user is obliged to check the compatibility of the equipment with the intended application: in consequence, he or she is entirely liable for use of the product and any associated damages.

Note

Product reserved for use in dental applications.

Keep out of the reach of children.



Store between 12°C and 28°C, in its original closed packaging.


May cause an allergic skin reaction.


See the User's Manual.


Prevent exposure to light.


Single use

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