INSTRUCTIONS FOR USE

Semi-Indirect Procedure
(recommended for new users)

OVC™
One Visit Crown

RHONDIIUM™
SEMI-INDIRECT PROCEDURE

There are two ways to complete an OVC₃ restoration; the semi-indirect procedure and the direct procedure. For new users we recommend using the semi-indirect procedure. For experienced users we recommend either procedure. See the reverse of this booklet for instructions on the direct procedure.

1. Prep and measure the tooth

Clinical Tip: Check the bite with occlusal paper while the local anaesthetic is taking effect. Then reduce any obvious opposing cusps that might cause occlusal interference.

Prepare the tooth using minimally invasive principles, allowing at least 1mm of clearance in the central fossa and 1.5mm at the cusps and marginal ridges. Avoid all undercuts (Figure A).

Clinical Tip: Add pronounced bevelled margins for better bonding, shade blending, easier matrix application and easier identification of the crown margins. Ensure the contact points are broken.

Very deep defects can be built up using the green or blue OVC wedges, within 2-3 mm of the occlusal plane. This will help with the retention of the McDonald Matrix Band™.

A confirmation can be made when trying-in the Replica. The Replica occlusal anatomy should match the general configuration of the tooth. If the Replica anatomy is incorrect, then select a more appropriate sized OVC3.
Clinical Tip: It is more accurate to measure the mesial-distal distance once the tooth is reduced and the contacts are removed. Another option is to take a bite registration impression at initial consult and use a Selector Key to measure the impression.

Open the selected OVC₃ case (Figure C).

Hold the Replica handle using tweezers and place on the prep to confirm its M-D fit over the prep. Ask the patient to gently bite down with Replica in place. Ensure there is adequate occlusal clearance – the Replica should have sufficient space to move when the handle is gently tugged (Figure D).

Also check the Replica has not been tilted due to an opposing cusp – adjust opposing dentition if required.

Clinical Tip: Spray the underside of the Replica with an occlusal spray to identify where further reduction of the prep is needed after the patient bites down (Bausch Arti-Spray® Occlusion-Spray).

2. Place McDonald Matrix Band™

Carefully place the McDonald Matrix Band™.

Step 1: Place the distal side of the matrix band into the gingival crevice first and secure it with a wedge.

Step 2: Since the matrix band is now trapped in place by the wedge, you can now manipulate the mesial side of the matrix band into place and use another wedge to secure the mesial side of the matrix band. Ensure that the bevel on the top edge of the band is slightly above the marginal ridge of the neighbouring tooth.

Step 3: The matrix band is now held in place. You are now able to use both hands to tighten the matrix band with...
Ideally the McDonald Matrix Band™ can be tightened enough to seal the cavity margins without using a wedge. If the margins are not 100% sealed then use a Stretch Wedge™ (refer to Direct Procedure Step 3), or other wedge as appropriate.

**Clinical Tip:** Occasionally, the band does not reach the neighbouring tooth’s contact point. Cutting a “dress-maker’s dart” in the band with scissors or high-speed hand-piece can assist with flaring the band (Figure F).

1. Using a finger to press the orange toggle against the tooth while tightening (Figure E).

2. Hold the orange toggle in place with tweezers or forceps while tightening.

Ensure that the matrix band is tight. The McDonald Matrix Band™ can be unscrewed and re-tightened if adjustments are necessary.

Lightly burnish the contact points to ensure the matrix band is touching the neighbouring teeth.

Complete a build up if necessary. Apply a thin layer of separating agent to the tooth prep (Rubber-Sep® TAUB or Pro-V Coat® Bisco) and gently air-dry with triple syringe. Rubber-Sep® is recommended but is contraindicated when latex allergy is present.

**IMPORTANT IF USING PRO-V COAT®:** If you have used bonding agent to do a build-up, you need to thoroughly remove any oxygen inhibited resin layer by either light-curing through the separating agent or by scrubbing the surface.
Use a flat-plastic instrument to horizontally align the OVC₃ fissures with neighbouring teeth (Figure J).

Inadequate removal may result in difficulty removing the OVC₃. Placing a double layer of separating agent may also aid easier removal.

Clinical Tip: Some clinicians prefer to get the patient to GENTLY close into centric occlusion to set the occlusal height.

When you are happy with the position of the OVC₃, remove excess material around the periphery with a fine carving instrument and then light-cure the occlusal surface for at least 30 seconds* (Figure K).

*Based on a 1,000 mW/cm² curing light
Clinical Tip: Deliberately leaving a ledge on the buccal side helps removal of the OVC₃.

4. Remove the OVC₃ and the separating agent

Loosen the McDonald Matrix Band and remove the OVC₃ and band together, with either a strong hand-instrument or some forceps. Crown-removal forceps, sturdy hemostats or even lower root forceps work well. Before touching the intaglio surface of the crown, light-cure it immediately after removal to ensure that it is fully cured (Figure L).

IMPORTANT: The separating agent must be entirely removed from the OVC₃ and the tooth preparation. If using Rubber-Sep®, peel off the rubber. If using Pro-V Coat®, take extra care to remove all the Pro-V Coat®. Air abrasion is effective. If this is not available, thoroughly clean the surface with pumice and a prophy brush. Isopropyl alcohol can also be used to remove the Pro-V Coat®. Remember to clean the proximal surfaces.

5. Trim and polish the OVC₃

Use your preferred method to trim and remove excess material from the OVC₃ (Figure M).

We recommend partially trimming the buccal surface, and doing the final contouring after the OVC₃ is bonded in place. The lingual and proximal
surfaces usually only need minimal rounding and polishing.

To form tight contacts, apply a resin bonding agent of your choice to the proximal surfaces, air thin and light-cure. The matrix band is only 30 microns and therefore only a very thin additional layer of resin is required.

There are two ways to do this:

**A.** Use a thick bonding agent such as Optibond FL or Optibond XTR which creates a sufficiently thick layer by itself. After light-curing, wipe away the oxygen inhibited layer.

**B.** Use a thin bonding agent, air-dry and cure. Then paint a thin layer of flowable onto the proximal surfaces, air blow to spread the flowable and light-cure. **Clinical Tip:** Use a low viscosity flowable as thixotropic flowable resins can be too thick for this application.

Polish and trim the OVC₃ until you are satisfied.

**Warning:** Any contamination of the intaglio surface with bonding or flowable resin may affect the crown fit.

6. **Cement the OVC₃ in place**

Try-in the OVC₃ to confirm tight contact points and good fit then cement as usual.

Use dual-cure resin-based luting cement to bond the OVC₃ crown in place. **DO NOT** use self-etching GIC-type cements as these do not bond with sufficient strength.

Recommended dual-cure luting cements include Panavia 5 (Kuraray), Multilink II (Ivoclar), RelyX Ultimate (3M).

**Clinical Tip:** Use the included Green OVC Wedges when cementing the OVC₃ to quicken the clean-up of the luting cement.
CLEANING

- Selector Keys, OVC Wedges, Stretch Wedges™, McDonald Matrix Band™ and Replicas are single use only.
- For Hex Stick cleaning instructions see Hex Stick Instructions For Use

POST-OPERATIVE

As with standard dental treatment, advise patient to return if there is any discomfort or a problem with the restoration is experienced.

STORAGE

Store the OVC₃ at 1°C to 25°C (34°F to 77°F). When not in use, keep containers closed, protect contents from moisture and contaminants.

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See Instructions for Use
Dentist Use Only
Single Use Only
Use by

CE 0086
Federal (USA) law restricts this device to sale by or on order of a licensed dentist.

INTRODUCTION

To gain maximum satisfaction and benefit from these products, carefully read the OVC₃ Procedure for detailed step-by-step instructions. The OVC₃ Instructions for Use/Procedure Manual is available from Rhondium Ltd at the address shown at the end of this document and on the Rhondium website.

INDICATIONS FOR USE

The Rhondium OVC₃ is intended for restoration of permanent teeth with a single unit crown.

The OVC₃ restoration procedure is a chairside, one visit procedure to restore structurally compromised posterior teeth in need of full coverage. It is indicated for cases normally restored with an onlay or a partial crown. It can also be used to increase the vertical dimension by building up the posterior teeth.

PRECAUTIONS AND WARNINGS

1. Carefully read and understand all instructions before use.
2. For use on permanent teeth only.
3. Use of blue light protective eyewear by clinicians and patients throughout the procedure is recommended.
4. Follow manufacturers’ recommendations for all materials used during the procedure.
5. Patients with bruxism must follow preventative treatment such as the wearing of night splints.
6. The clinician’s decision to restore a tooth using the Rhondium OVC₃ should be based upon the optimal clinical needs of the patient.

CONTRAINDICATIONS

- The OVC₃ direct clinical procedure requires that the McDonald Matrix Band™ can be held in a stable position and if this is not possible the OVC₃ is contraindicated. A build-up with the OVC Wedge can help with the matrix band stability.
- It is contraindicated to place the OVC₃ on an old composite margin.

CONTRAINDICATIONS

- The OVC₃ direct clinical procedure requires that the McDonald Matrix Band™ can be held in a stable position and if this is not possible the OVC₃ is contraindicated. A build-up with the OVC Wedge can help with the matrix band stability.
- It is contraindicated to place the OVC₃ on an old composite margin.
A professional assessment of oral health, chewing habits, and patient concerns should be factored into the decision.

7. Proper adaptation of the margin is needed for optimal marginal integrity. Adaptation and smooth finishing of the crown margin (buccal, lingual, interproximal) are needed to reduce the likelihood of leakage and gingival tissue irritation.

8. Finish and polish steps help to maintain shine and stain resistance.

9. If a crown margin is not properly adapted to the tooth preparation, the integrity of the margin may not be comparable to margins produced using a well executed traditional fabrication technique.

10. Continue to monitor crown margins during routine check-ups.

PRODUCT PRESENTATION

The OVC₃ is provided in an OVC₃ Refill Pack.

An OVC₃ Refill Pack consists of:
- 1 OVC₃ in the selected size
- 2 McDonald Matrix Bands™
- 2 Stretch Wedges
- 1 Replica in corresponding size
- 2 OVC Wedges
- 1 Selector Key
- 1 IFU QR Card

An OVC₃ Refill Pack is available individually or as part of a Kit, where a Kit contains a selection of tooth types and sizes.

DESCRIPTION OF COMPONENTS

The OVC₃ is a hybrid ceramic crown made of two parts. A cured anatomical occlusal layer and an uncured sub-layer that allows customization of the OVC₃ to the tooth preparation. Both layers are made of the same material.
The anatomy of each OVC₃ type is common to two teeth, the first and second of each tooth group. For example, OVC₃ 4/5 (US) 15/14 (FDI) can be used to restore a first or second upper right premolar.

Available OVC₃ tooth types:

<table>
<thead>
<tr>
<th>Tooth Group</th>
<th>OVC₃ Type (Tooth Number)</th>
<th>US</th>
<th>FDI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Premolar</td>
<td>UPM 4/5 12/13</td>
<td>14/15</td>
<td>24/25</td>
</tr>
<tr>
<td>Upper Molar</td>
<td>UM 2/3 14/15</td>
<td>16/17</td>
<td>26/27</td>
</tr>
<tr>
<td>Lower Premolar</td>
<td>LPM 20/21 28/29</td>
<td>34/35</td>
<td>44/45</td>
</tr>
<tr>
<td>Lower Molar</td>
<td>LM 18/19 30/31</td>
<td>36/37</td>
<td>46/47</td>
</tr>
</tbody>
</table>

Each tooth type is available in:
- Shades **A2 HT** and **A3 HT** (High Translucency)
- Five different sizes - **XS S M L XL**

**Replica**

A disposable plastic replica of the cured portion of the OVC₃, with a handle, matching the selected tooth type and size.

The Replica is used to confirm that the occlusal clearance obtained during tooth preparation is sufficient. It serves as a confirmation of the size selection and suitability.

The Replica also provides a good visual of the overall 3D position of the OVC₃ on the prep and the relationship with adjacent and opposing dentition.

**OVC Wedges**

These are single-use plastic wedges used for deep gingival procedures. They come in two sizes, green are small and blue are large. Each pair come as a right and left wedge. The wedges may be placed from the buccal or lingual aspect with the concave, smooth area facing the preparation. Green OVC wedges are in each refill and Blue OVC wedges are in kits.
Selector Keys

These are single-use gauges made of transparent red plastic, available in four types:
- Lower Premolar (LPM)
- Lower Molar (LM)
- Upper Molar (UM)
- Upper Premolar (UPM)

Selector Keys have a dual function. One is to determine the mesial-distal (M-D) distance of the damaged tooth so that the correct OVC$_3$ size is selected. The second function is to facilitate the spot curing of the center of the OVC, using the hole in the handle, to lock the vertical dimension.

McDonald Matrix Band™

The McDonald Matrix Band™ is a single-use circumferential matrix band pre-contoured for each tooth shape and size. It is placed around the preparation, tightened with a Hex Stick (supplied separately), to shape the uncured ceramic sub-layer of the OVC$_3$.

Stretch Wedge™

Stretch Wedges are flossed between the teeth and pulled tight to create separation and securely hold the matrix band in place. They are gentle on the papillae and have adjustable separating force (the harder you pull the more separation you get).
INSTRUCTIONS FOR USE

Direct Procedure

OVC\textsuperscript{3}™
One Visit Crown

Direct Procedure

RHONDIIUM™
DIRECT PROCEDURE
There are two ways to complete an OVC₃ restoration; the semi-indirect procedure and the direct procedure.

For new users we recommend using the semi-indirect procedure, see the reverse of this booklet. For experienced users we recommend using either the direct or semi-indirect procedure depending on each individual case.

OVC₃ DIRECT PROCEDURE

1. OVC₃ Selection
Measure the mesial-distal distance of the affected tooth using the Selector Key to determine the OVC₃ size needed, and choose the size that is nearest (Figure A).

2. Tooth Preparation
Clinical Tip: Check the bite with occlusal paper while the local anesthetic is taking effect. Then reduce any obvious opposing cusps that might cause occlusal interference.
Prep the tooth, allow at least 1 mm of clearance in the central fossa and 1.5 mm at the cusps and marginal ridges (Figure B).†
Clinical Tip: Bevel the margins for better bonding, shade blending and easier McDonald Matrix Band™ placement.

Check opposing and adjacent
Clinical Tip: Spray the underside of the Replica with an occlusal spray to identify where further reduction of the prep is needed after the patient bites down (Bausch Arti-Spray® Occlusion-Spray).

Deep defects should be built up, prior to using the matrix band, to within 2-3 mm of the occlusal plane using the green or blue OVC wedges. This will help with the retention of the McDonald Matrix Band™ and the Stretch Wedge™.

3. Place McDonald Matrix Band™

Carefully place the McDonald Matrix Band™.

Step 1: Place the distal side of the matrix band into the gingival crevice and perform corrections if needed (e.g. over erupted cusps, poorly contoured adjacent restorations).

Open the appropriate OVC₃ case (Figure C).

Hold the Replica handle using tweezers and place on the prep to confirm its M-D fit over the prep. Ask the patient to gently bite down with Replica in place. Ensure there is adequate occlusal clearance – the Replica should have sufficient space to move when the handle is gently tugged (Figure D).

Also check the Replica has not been tilted due to an opposing cusp – adjust opposing dentition if required.
If using Stretch Wedges, slowly stretch the Stretch Wedges a few times prior to use. This strengthens the wedges and allows for increased interproximal separation (Figure F).

**Step 2:** Since the matrix band is now trapped in place by the wedge, you can now manipulate the mesial side of the matrix band into place and use another wedge to secure the mesial side of the matrix band. Ensure that the bevel on the top edge of the band is slightly above the marginal ridge of the neighbouring tooth.

**Step 3:** The matrix band is now held in place. You are now able to use both hands to tighten the matrix band with a Hex Stick (supplied separately). There are a few ways to do this.

1. Using a finger to press the orange toggle against the tooth while tightening (Figure E).

2. Hold the orange toggle in place with tweezers or forceps while tightening.

Ensure that the matrix band is tight.

**Clinical Tip:** The McDonald Matrix Band™ can be unscrewed and re-tightened if adjustments are necessary. Ideally the McDonald Matrix Band™ can be tightened enough to seal the cavity margins without using a wedge. If the margins are not 100% sealed then use a Stretch Wedge™, or other wedge as appropriate.

Floss the Stretch Wedges down at an angle to avoid damaging the band or cutting the Stretch Wedge™. Pull Stretch Wedges very firmly to create separation. This step can be repeated for extra separation.

Some dentists prefer wooden wedges to create separation.
Use standard direct composite bonding techniques (etch and bond) to cover the tooth preparation. Optibond FL (Kerr Dental) or Clearfil SE Bond (Kuraray Dental) are recommended.

Gently burnish proximal zones of the matrix band as required to form a good emergence profile and ensure the band is touching the neighbouring teeth. Do not over-burnish.

If required, build up the proximal boxes with composite or flowable resin to just below the contact point. Optionally, seal the beveled margins with a small amount of flowable and then cure.

Use a ball burnisher or flat instrument to hold the matrix band against the adjacent mesial tooth while curing. Repeat for distal (Figure G).

Do not cover the contact points with composite (Figure H).

Re-burnish contact points to ensure the matrix band is touching the neighbouring contacts (Figure I).

4. OVC₃ Placement

Apply a small amount of flowable composite on the tooth to prevent bubble formation (do not cure).

Remove the OVC₃ from the packaging by fully inverting the black film (Figure J).
Use your fingers to form the uncured sub-layer of the OVC₃ into a rounded cone-shape (Figure K).

Place the OVC₃ inside the matrix band and gently depress until the marginal ridges are aligned with the centric occlusion to set the occlusal height. Check buccal/lingual alignment with remaining tooth structure, make corrections if necessary.

Using the Selector Key hole, spot cure for 3-5 seconds* to secure vertical dimension (Figure N).

Using a flat-plastic instrument to horizontally align the OVC₃ fissures with neighbouring teeth (Figure M).

Clinical Tip: Some clinicians prefer to get the patient to GENTLY close into the marginal ridges of the neighbouring teeth (Figure L).†

Using a sharp carving instrument remove the excess material and adapt the remainder to form natural contours (Figure O).
5. Remove the McDonald Matrix Band

Remove the any wedges (Stretch Wedges can be removed by flossing out or cutting with scissors).

Loosen the McDonald Matrix Band™ by turning the screw counterclockwise with a Hex Stick.

Remove the matrix band by levering the buccal side with a flat-plastic instrument.

The lingual side of the band can also be cut with scissors or a handpiece to aid in removal.

6. Finish the OVC₃

Fully cure each surface for 20 seconds*.

Polish and adjust the restoration as required.

High speed diamond burrs can be used for large reductions, then use polishing burrs or discs for a final polish.

Check the bite and adjust if necessary to complete the restoration.

† Notes:
1 - With the direct procedure - do not paint the prepared tooth surface with a separating agent.
2 - Do not apply bonding agent to the OVC₃.
3 - Do not trim the hard OVC₃ occlusal layer prior to seating on the prepared tooth.
4 - There should be sufficient uncured composite available on the OVC₃, do not add uncured composite.

*Based on a 1,000 mW/cm² curing light
CLEANING

- Selector Keys, OVC Wedges, Stretch Wedges™, McDonald Matrix Band™ and Replicas are single use only.
- For Hex Stick cleaning instructions see Hex Stick Instructions For Use

POST-OPERATIVE

As with standard dental treatment, advise patient to return if there is any discomfort or a problem with the restoration is experienced.

STORAGE

Store the OVC at 1°C to 25°C (34°F to 77°F). When not in use, keep containers closed, protect contents from moisture and contaminants.

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