

# Instructions For Use (IFU)

## Cobalt Chrome (CoCr) UCLA Abutment

For use with Prima™ Implant System

CoCr abutments and associated surgical, restorative and dental laboratory components

### **1. Description**

Keystone Dental CoCr UCLA Abutments are designed for use with PrimaConnex® straight and tapered implants to provide support and retention for multi-unit (splinted) screw-retained restorations in the mandible or maxilla.

The system consists of the abutment, abutment screw, and a plastic modeling aid. The CoCr abutment is packaged together with an abutment screw to allow the clinician to have the components required for clinical use. The abutments are manufactured from CoCr material which conforms to ISO5832-12 and ASTM F1537-08 and the abutment screw is manufactured from titanium alloy (Ti 6Al-4V E.L.I.) which conforms to ASTM F136.

### **2. Intended use/indications:**

CoCr Abutment is intended for use in conjunction with PrimaConnex SD and RD implants in partially or fully edentulous mandibles and maxillae, in support of multiple-unit screw-retained restorations.

### **3. Contraindications:**

Do not use in cases of hypersensitivity to one or more of the metals contained in the alloy.

### **4. Warnings:**

Dental implant surgery and the restoration of implants involves complex dental procedures that are not without risk. It is the obligation of the clinician to inform the patient about the nature and risk(s) of the procedure(s).

Achievement of a satisfactory outcome requires appropriate training prior to implant system use. Improper technique and/or inadequate training can lead to implant failure and/or loss of supportive bone. Dental implants and prosthetics systems may only be used by dentists or physicians who have had appropriate education and training. Proper clinical and radiographic evaluation of the patient should be performed prior to any implant placement.

Implants can break in function for any number of reasons. It is important that the clinician use an adequate number of implants in order to provide support to, and distribute the load between, the abutments. Implants should not be placed if there is not sufficient alveolar bone width and height to surround and sustain the implant. Abutments are provided in a non-sterile state and are intended for single use only. Under no circumstances should re-use be attempted.

For Laboratory Technician:

- Do not inhale dust and vapors when machining
- Ensure suitable air extraction/ventilation at the workplace and corresponding machinery

### **5. Side effects:**

The potential exists for allergies to the metals contained in the alloy.

### **6. Interactions:**

Avoid occlusal and approximal contact between different alloy types.

### **7. Technical data:**

Chemical composition (mass-%):

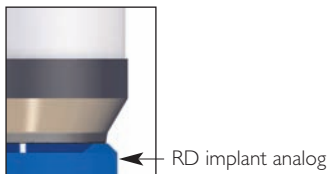
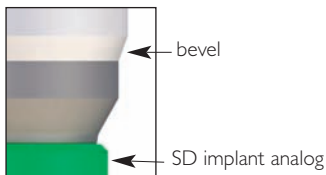
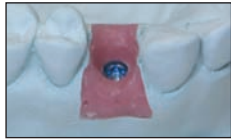
66% Co; 28% Cr; 6% Mo; (<1% Nickel)

## 8. Soldering:

Keystone Dental recommends a low Nickel, Cobalt Chromium Molybdenum alloy for repair and connection soldering of the CoCr alloy.

## 9. Procedure:

Where indicated, please refer to the Prima Implant System Prosthetic Manual (4409-0256) for additional information.



### Clinical Step 1 -

Take an implant level impression. Follow the procedure for a UCLA impression, described on pages 3-7 of the Prima Implant System Prosthetic Manual. Send the impression to the lab with an opposing arch model and a bite registration.

### Laboratory Step 1 -

Attach the implant analogs to the impression posts. Follow the procedure for UCLA Master Model Fabrication as described on page 36 of the Prima Implant System Prosthetic Manual.

### Laboratory Step 2 -

Place the CoCr Abutment on the master model. The plastic sleeve can be used while sculpturing the tooth. For use with SD Prima implants, place so that the bevel is at the bottom as shown in the image to the left. For use with RD Prima implants, place so that the bevel is at the top.

Reduce the chimney of the CoCr Abutment so that it is out of occlusion with the plastic sleeve in place.

### Laboratory Step 3 -

Casting:

- Use cobalt/chromium alloys and propane/oxygen or acetylene/oxygen

Soldering:

- Regular solders on a Co-Cr-Mo basis can be used
- Never use a gold or palladium solder with cobalt/chromium alloys

Welding:

- After casting the framework, fit it to the prefabricated CoCr cylinders. Using a laser weld, weld the cylinders to the framework at the marginal region and the top.

### Clinical Step 2 -

Confirm the passive fit in the mouth, following the UCLA metal framework try-in procedure on page 38 of the Prima Implant System Prosthetic Manual.

### Laboratory Step 4 -

Apply porcelain following standard laboratory procedures.

### Clinical Step 3 -

Ensure the bridge is clean before connection to the implants.

### Clinical Step 4 -

Make sure the bridge fits passively on the implants. For fastening, use titanium abutment screws and the Quad driver together with the torque wrench and tighten to 30 Ncm.

## Prima™ SD/RD CoCr UCLA Abutment, Multi-Unit

For additional information, please refer to the Prima Implant System Prosthetic Manual (4409-0256), UCLA Abutment System pages.



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