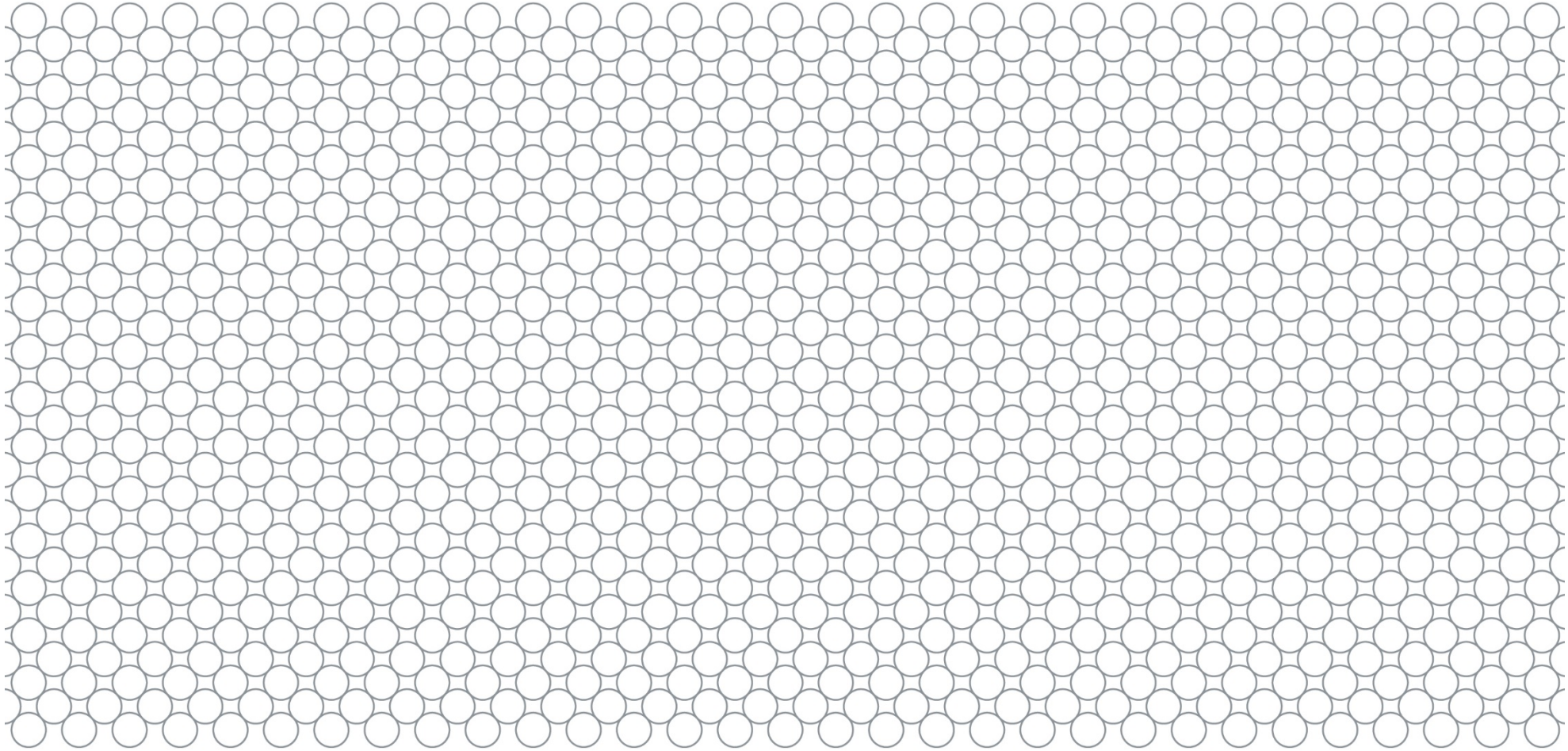
Instructions for use

CRS SET 10

REGISTRATION SET

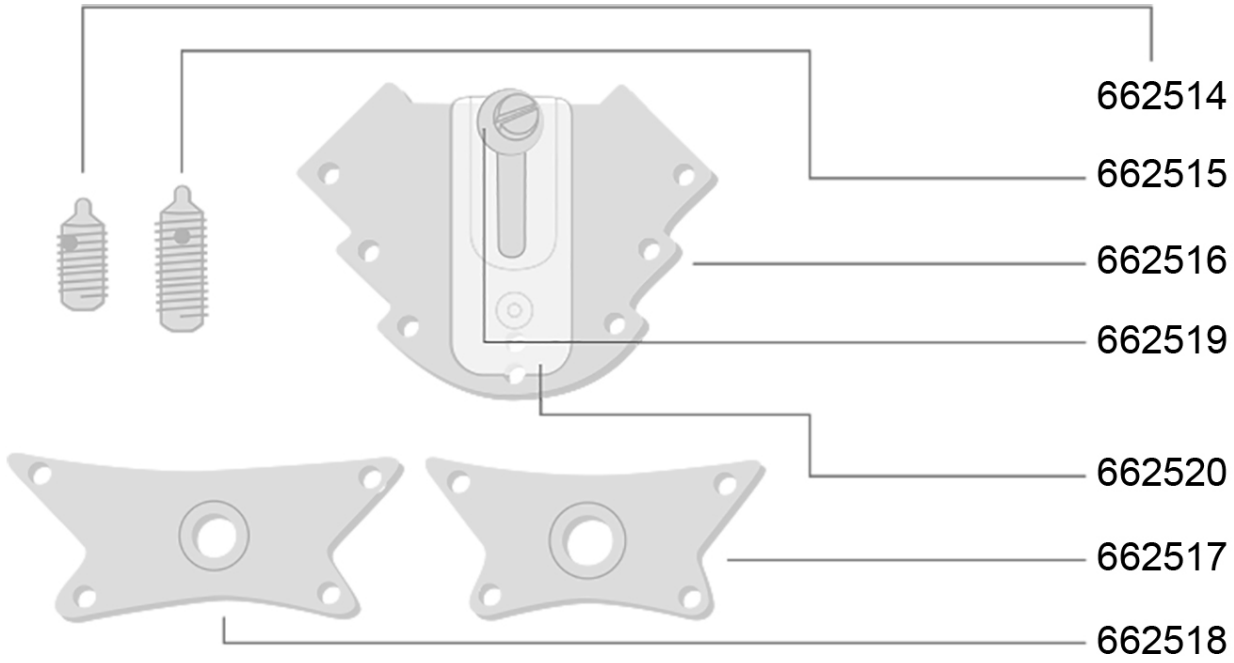


CANDULOR

ENGLISH

CRS SET 10
REGISTRATION SET

COMPONENTS



Please clean the individual components before initial use.

1. INTRODUCTION

Dear customer
We are delighted that you have decided to purchase the CANDULOR registration set CRS Set 10. This registration set is a technically advanced and high quality product manufactured using state-of-the-art technology. However, if used incorrectly, it can lead to risks. Please observe the notes and read the instructions for use. These instructions for use ensure the safe, appropriate, and economical use of the registration.

2. INTENDED USE

Intended Purpose
Intraoral registration

Use
For dental use only!

Description
The registration set is used to record the joint-related central position of the mandible for full dentures.

Indication
Determination of jaw relationship in complete edentulism

Contraindication
In the event of confirmed allergy to one of the constituents of the CRS Set 10

Limitations in use
The registration cannot be used for dentulous or partly dentulous situations.
Any other application not explicitly listed in these instructions for use.

Side effects
At present there are no known side effects.

Composition
Material 1.4305 (X8CrNiS18-9)*
Material 1.4301 (X5CrNi18-10)*
Material PC - Poly(2,2-bis[4-hydroxyphenyl]propyl carbonate)

*contains nickel

3. APPLICATION

Description of design and functions
The CRS Set 10 is an intraoral support pin registration device for the individual determination of the centric jaw position in edentulous patients.
The basic principle of the intraoral support pin method is based on McGrane's concept of a three-point support of the two jaw joints and the registration pin, which is placed in the center of the mandible. The support pin draws the typical image of an arrow point on a colored registration plate when the patient performs protrusion or limit movements laterally to the left and right from a dorsal position. The desired central position can then be fixed with the fixation plate and then the entire registration can be keyed three-dimensionally with a suitable material (e.g., registration silicone or plaster). Then the registration can be forwarded to the laboratory for further processing.

Processing

1. The anatomically formed bite templates are prepared in the laboratory and given to the dentist.

2. The back of the Papillameter scale has a small support, which is placed exactly on the incisal papilla of the patient. The measurement is taken using the scale while the upper lip is relaxed. This procedure should be repeated one to two times to achieve an accurate measurement result. This is then used to determine the wax wall height.

3. The Papillameter is placed on the papilla incisiva of the master model and the measurements taken from the patient are transferred to dividers or sliding calipers. The base edge is the best reference point on the model. This measurement is transferred to the wax wall height.

4. The maxilla template fabricated in the laboratory is placed in the mouth and checked to ensure it fits properly. The bipupillary line and Camper's level are checked using the bite fork and, if necessary, corrected using the Rim Former. The offset edge of the Rim Former is placed against the tuber tapers. The heated Rim Former is pressed forwards against the wax wall. This melts the entire wax wall parallel to the desired height.

5. Mark one point on the patient's chin and nose tip and measure the resting balance position with the sliding calipers. The patient must sit upright and keep his/her head straight for bite registration.

6. The mandible template fabricated in the laboratory is placed in the mouth and checked to ensure it fits properly. Here, the wax wall height should match up with the equator of the tongue.

7. Check the position of the wax wall templates with respect to each other as well as the vertical height. It should be 2–3 mm lower than the relaxed rest position. Drawing the center line on the maxilla.

8. Using these measurements, it is recommended to make a temporary articulation of the model.

9. The mandible registration plate is fixed to the occlusal level and notches are made in the wax wall to aid keying (Fig. 1).

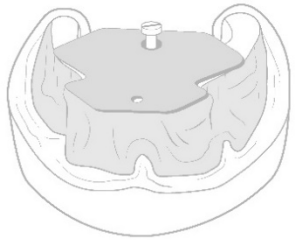


Fig. 1

10. The pin supporting plate is heated and immersed in the wax wall until the registration pin in regio 15/25 is positioned at the height of the occlusal level and is vertical. The wax wall is to be reduced such that there is no longer any contact between the upper and lower wax wall during the movements. Create notches to help with keying (Fig. 2).

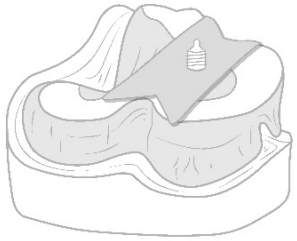


Fig. 2

11. Place the registration template in the mouth of the patient. Only the registration pin and registration template may touch each other during the registration procedure. While seated upright, the patient is instructed to move their mandible as far to the left as possible and then back to the center while the pin and registration plate are touching. This procedure is repeated on the right side two to three times. The patient is then asked to move their mandible to the front and back. This exercise is to prepare the patient for the actual bite registration procedure.

Attention: To avoid injury due to the pen, the patient must be instructed to place their tongue under the pen plate or in dorsal direction.

12. Using the CANDULOR Marker provided, generously paint the mandibular registration plate. The templates are then inserted and, following the dentist's instructions, the patient traces the angle by making anterior, posterior, and lateral movements of the mandible (Fig. 3).

13. Crosshair symbol drawn on the tip of the arrow (centric).

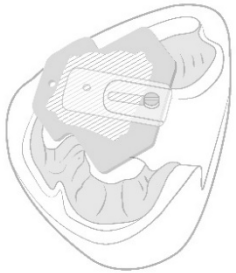


Fig. 3

14. To check the Gothic arch, the entire plate except for the crosshairs is painted again and the entire bite registration procedure is repeated. If the second Gothic arch is also positioned exactly on the crosshairs, the Plexiglas plate can be placed in the position of the tip of the arrow and fixed into place using the screw and washer (Fig. 4).

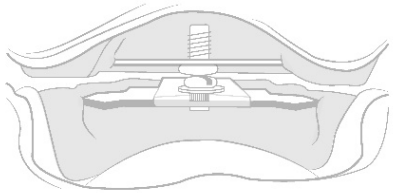


Fig. 4

15. The opening and closing movements are used to check in the mouth whether the registration tip snaps into the hole of the Plexiglas plate.

16. If this is the case, the position is cemented using registration silicone or impression plaster.

17. If this is not the case, the registration procedure must be repeated.

4. SAFETY NOTES

We recommend this section to all persons working with the registration or performing maintenance and cleaning work on the registration.

Intended use

When manipulating with the CRS Set 10 on the patient, always ensure that the patient's tongue is not injured by the writing tip of the pen.

Risks and hazards: aspiration and suffocation hazards

As the registration includes small parts which can become loose if not fixed properly, there is a risk that these parts can be swallowed.

Injury hazard

To avoid injury due to the pen, the patient must be instructed to place their tongue under the pen plate.

Safety cautions and danger warnings

The CRS Set 10 may only be used for the scope described in the following section. The intended use also includes:

- Observing the instructions, regulations, and notes in these instructions for use
- Correct maintenance and cleaning of the registration

Danger warnings

In the event of serious incidents that have occurred in connection with the product, please contact the manufacturer CANDULOR AG, Boulevard Lilienthal 8, 8152 Glattpark (Opfikon), Switzerland, website: www.candulor.com and your local health authority.

Any remaining stock must be disposed of in accordance with national legal regulations.

Safety data sheets can be found on our website at www.candulor.com.

The current instructions for use are available on the CANDULOR AG website in the download area: www.eifu.candulor.com.

Please ensure that you always have the latest version available, which you can find in the download section of the Candulor website.

If you wish to receive the instructions for use in paper form, please contact the manufacturer CANDULOR AG. To do this, please use the telephone number or the e-mail address on the last page of these instructions for use. The instructions for use will be sent to you free of charge by post within seven days.

5. SCOPE OF DELIVERY

Please check whether the scope of delivery is complete.

662513 – CRS Set 10

- 662514 – Registration tip, short 1 piece
- 662515 – Registration tip, long 1 piece
- 662516 – Registration plate 1 piece
- 662517 – Pin supporting plate, small 1 piece
- 662518 – Pin supporting plate, large 1 piece
- 662519 – Screw and washer for registration plate 6 pieces
- 662520 – Plexiglas plate 6 pieces
- 696276 – CANDULOR Marker 1 piece

6. NOTES ON CARE

Notes on cleaning

What	When	With what
Registration parts and screws (metal)	After each use	Sterilization in the autoclave at 134°C for 5:30 minutes, perform pre-vacuum method. Please observe the applicable standards.
Plexiglas plate (acrylic)	After each use	Disposal

Avoid any contact with strong acids and solvents (e.g., MMA, acetone). This prevents any damage to the surface treatment. Clean, sterilize or disinfect the parts after every use or contact with saliva or blood.

- Only use disinfectants suitable for stainless steel and light metals.
- Avoid any contact with strong acids, alkalis, or solvents.
- Clean with ultrasonic bath, water, steam jet, or sterilization equipment.

7. STORAGE INSTRUCTIONS

Store out of reach of children.

8. NOTES

The registration has been developed for dental use. Initial operation and handling must be conducted according to the instructions for use. CANDULOR does not accept liability for damages caused by use for a purpose other than stated or improper handling. The user is also responsible for confirming that the registration is suitable for the intended purpose before use, particularly if the purpose is not stated in the instructions for use.

EXPLANATION OF SYMBOLS

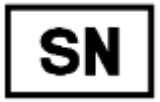
Catalogue number

Batch code

Use by date

Manufacturer

Date of manufacture



Serial number

Consult instructions for use on the website

Storage temperature

Keep away from sunlight

Medical device

Do not reuse

Authorized representative in the European Community

CE

Rx ONLY

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CANDULOR