

# Pressure Spot Indicator

## Instructions for use

EN

Carefully read the instructions prior to use.

### Product description

Coltène Pressure Spot Indicator (PSI) is a two-component pressure spot material based on condensation-type polysiloxane. After manual mixing of base and catalyst, the PSI materials form a paste which is used individually as dental pressure spot material.

### Composition

Condensation-type silicone elastomer, medium-bodied consistency

- Polysiloxane
- Colour: light green

### Indications for use

- Recognition of pressure spots on dentures
- Determining the need for relining
- Testing of the exact fitting of inlays, crowns, bridges and cast brackets

### Contraindications

- Do not use in case of known allergies to ingredients of the Pressure Spot Indicator
- Material combinations with pressure spot materials of other manufacturers are not permitted

### Safety instructions

#### ⚠ WARNING

- Eyes, respiratory organs and skin can be irritated by PSI Catalyst
- Impressions that come into contact with the oral mucosa may be contaminated. Observe disinfection instructions
- Only supplied to dentists and dental laboratories or upon their instructions
- Protective glasses are recommended. In case of contact with eyes, rinse immediately with water and consult an ophthalmologist
- Avoid direct skin contact
- Always wear protective gloves when working (vinyl gloves are recommended)
- Do not swallow or ingest
- Close tube immediately after use!

#### NOTICE

- After removal of PSI from the restoration or denture base, it is necessary to remove residues by sandblasting or by using alcohol.
- Contains nano materials (bonded particles)

### Side effects / Interactions

No harmful reactions or secondary effects on patients and / or dental personnel have been reported.

### Users / Patient target groups

The use of PSI in the patient's mouth may only be undertaken by specialist personnel such as dentists and dental assistants with special qualifications. Suitable for all patient groups.

### PROPER USE

#### Dosage

Dispense PSI Catalyst and PSI on a mixing block in two equal strands. Make sure that the tubes are closed immediately after use.

#### Application time



Intensive mixing, high temperatures or overdosage of the catalyst speed up the setting; low temperatures and underdosage of the catalyst slow down the setting.

### Mixing

Take up one component (PSI Base or Catalyst) with spatula and spread evenly on the other component. Then pick up both components with the spatula and spread out on the mixing block. Repeat this procedure until the mixture is homogeneous. Please observe the specified processing times.

### Impression

Coat basal denture surface and insert restoration. Hold in situ until the material has set completely. Remove restoration and indicate the pressure points with a marking pen (= interrupted layer). Remove material and correct marked surfaces by grinding.

### Test methods for correct application

Material residue needs considerably more time to set at room temperature than in the patient's mouth. You should therefore check intraorally if the material is set before removing from the mouth. If the manual pressure test does not leave a pressure mark in the impression material after the time specified in the chapter on „Dosage“, the impression can be removed from the patient's mouth. However, if the test leaves a visible pressure mark in the material, the material is not yet fully set.

### Cleaning & Disinfection

After removal of PSI from the restoration or denture base, it is necessary to remove residues by sandblasting or by using alcohol. Afterwards it needs to be controlled visually. Please have a look at the IFU of the restoration or denture base material for further cleaning and disinfection instructions.

### Shelf life and storage

- Expiry date: see label on primary packaging
- Storage temperature: 15-23°C / 59-73°F
- Relative humidity: 50% ± 10%
- Shelf life after first opening, 3 months

Protect against exposure to heat and sun. Avoid extreme temperature fluctuations. Close tubes immediately after use.

### Disposal

PSI can be disposed in small quantities in household waste. PSI material, which gets in contact with the patients mouth, must be disposed according to the country-specific regulations.

### Technical data according to ISO 4823

The technical data were determined at 23 °C / 73 °F and 50 % relative humidity.

Mixing time:	0:30 min
Total processing time:	2:15 min
Oral setting time (35°C/95°F):	3:00 min
Mixing ration Base / Cat:	10ml/1.4ml 10g / 1.4g

### Reporting obligation

All serious incidents occurring in conjunction with this product must be reported immediately to the manufacturer as well as to the competent authority.

SAFETY DATA SHEET  
[www.coltene.com](http://www.coltene.com)

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### Glossary



Consult instructions for use



Keep away from sun light



Temperature limitation



Marking of Conformity Europe



Legal Manufacturer



Expiry Date



Batch Code



RX only



Medical Device



Manufacturing Date



Unique Device Identifier



European Authorized Representative



Reference Number

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