

# Pressure Spot Indicator

## Instructions for use

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Please read the Instructions for Use carefully before using the product. Keep for later reference.

## 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.

## INTENDED USE

Dental pressure spot indicating material.

## COMPOSITION

Condensation-type silicone elastomer, medium-bodied consistency

- Polysiloxane
- Colour: light green

## INDICATION

- 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

- Eyes, respiratory organs and skin can be irritated by PSI Catalyst
- Avoid direct contact with skin and eyes. In case of contact with eyes, rinse immediately with water and consult an ophthalmologist
- Avoid inhalation or ingestion
- Impressions that came into contact with the oral mucosa may be contaminated. Observe disinfection instructions
- 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 product shall be used by qualified dental professionals only. Suitable for all patient groups including children, elderly people and pregnant women.

## 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. Always wear protective gloves when working.

## 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.

Avoid using excessive amount of silicone for impression taking due to the risk of overflow material being swallowed.

## TEST METHOD 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.

## REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE

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/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

Dispose of waste according to applicable legislation. Special country-specific regulations may apply. Can be disposed together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge. (Only dispose of completely emptied packages.)

## TECHNICAL DATA

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.

In the unlikely event of inhalation, ingestion, eye contact, or similar incidents seek immediate medical attention from an appropriate medical specialist to mitigate potential harm.

## SAFETY DATA SHEET

[www.coltene.com](http://www.coltene.com)

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## GLOSSARY

	Consult instructions for use
	Keep away from sun light
	Keep dry
	Temperature limitation
	Marking of Conformity Europe
	Legal Manufacturer
	Expiry Date
	Batch Code
	Rx only
	Medical Device
	Manufacturing Date
	Unique Device Identifier
	European Authorized Representative
	Importer
	Reference Number

## COLTENE International Dental Group

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