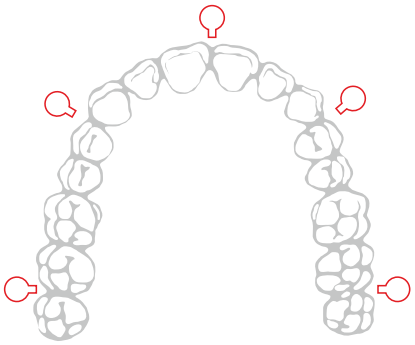
Instructions for use · X-ray balls (Röntgenkugeln)

Radiopaque reference points for CBCT and CT



Example: arrangement of 5 X-ray balls in the jaw. At least 3 balls per jaw, far apart.



Example: section through denture or radiographic template. The balls remain fully visible, the stem can be shortened.

1. Intended purpose

The X-ray balls are radiopaque reference points. They are attached to a denture or radiographic template and are used during a CBCT or CT scan to match the radiographic data with the scan data of the dental laboratory in planning software such as coDiagnostiX. This matching is the basis for planning dental implants.

The X-ray balls have no measuring function. The balls are not intended for calibrating X-ray equipment.

2. Users

For dentists and physicians (e.g. oral and maxillofacial surgeons), dental technicians and their trained staff only, in accordance with these instructions for use. Not for lay persons.

3. Patients

Patients for whom implant planning with CBCT or CT is intended. Only for the duration of the radiographic scan, less than 60 minutes, in contact with intact oral mucosa. Whether the scan is indicated is decided by the practitioner.

4. Contraindication

Known allergy or hypersensitivity to methacrylates.

5. Side effects and residual risks

No side effects are known. In case of hypersensitivity to methacrylates, irritation or allergic reactions of the mucosa are possible. Residual risks: swallowing or inhalation of a loose ball (see Warnings); incorrect matching of the data if a ball is displaced or poorly visible (see Directions for use, steps 7 to 9).

6. Directions for use

1. Recommended: before attaching the balls, temporarily reline the denture so that the denture base fits accurately and is clearly shown in the scan and the radiograph.
2. Inspect the balls before use. Do not use damaged balls or balls with a broken stem.
3. Use at least 3 balls per jaw. If the restoration contains metal, use 4 or 5 balls.
4. Place the balls on the vestibular side, as far apart as possible, not directly next to metal.
5. Outside the mouth, grind a small recess into the denture or template for each ball. Insert the stem, shortened if necessary, and fix it with light-curing resin (not supplied).
6. The balls must remain fully visible. Do not cover them with resin.
7. Before insertion into the mouth, check that each ball is firmly attached.
8. After the scan, check in the radiographic image that all balls are clearly visible.
9. Before removing the balls, digitise the denture with the balls, preferably with a laboratory scanner (upper and lower side). A laboratory scan is more accurate than a second CBCT scan of the denture alone (dual scan).

7. Warnings

– Loose balls are small parts: risk of swallowing or inhalation. Attach the balls outside the mouth only and check that they are firmly attached before insertion.
– Single use: do not reuse after use on a patient.
– Non-sterile.
– Not for consumption.
– Keep out of the reach of children.

8. After use

On a denture that the patient continues to wear: remove the balls only after the denture has been scanned (see Directions for use, step 9) and before the denture is returned to the patient. Until then, the patient does not wear the denture.

On a dedicated radiographic template, the balls may remain for further scans of the same patient. Dispose of removed balls with practice waste.

9. Storage and shelf life

Store dry, protect from sunlight and heat. Use by the date on the label (10 years from manufacture).

10. Reporting of incidents

Any serious incident in relation to the device shall be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

11. Product

X-ray balls, diameter 5.0 mm, with attachment stem. Material: light-cured methacrylate-based resin with radiopaque fillers. Packs of 5, 10 or 25.

Class I medical device according to Regulation (EU) 2017/745 (MDR).

12. Other languages

These instructions for use are available electronically in other languages and in their current version at implant-oris.de/ifu. On request, we will send a printed copy free of charge within 7 days.

Symbols on the label

CE	CE marking
MD	Medical device
LOT	Batch code
UDI	Unique device identifier
	Manufacturer
	Use-by date
NON STERILE	Non-sterile
	Do not re-use
	Consult instructions for use (also electronic)

Manufacturer

Crimmitschauer Dentallabor GmbH, Bahnhofstraße 8, 08451 Crimmitschau, Germany

Distributor

implant oris, www.implant-oris.de, +49 (0)3762 94 10 546

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