

RAYDEN© INC.

Quality Disposable Dental Products

Articulating Products

Instructions for Use

DEVICE PURPOSE / INTENDED USE

Articulating Products are used to mark occlusal contacts between the maxillary and mandibular teeth and identify the distribution of occlusal forces.

Materials:

Articulating Paper – Paper or tissue with wax ink coating

Articulating Film – Polyester film with wax ink coating

INDICATIONS FOR USE

The Articulating Products are indicated for temporary use during dental procedures to mark occlusal contacts between the maxillary and mandibular teeth to enable adjustment.

CONTRAINDICATIONS

The following contraindications apply to Articulating Paper and Film:

- Patients with known allergy the materials of construction.

WARNINGS

- If a patient experiences allergic reaction, immediately remove the Articulating Products, remove markings from teeth, and advise patient to seek medical care.

CAUTIONS

- For single use only
- Federal (USA) law restricts the sale of this device by, or on the order of, a licensed dental professional.

METHOD OF STERILIZATION

Raydenco disposable dental products are delivered non-sterile to the end user.

METHOD OF DISINFECTION

Raydenco disposable dental products do not require disinfection prior to use.

CONDITIONS OF STORAGE

The product should be stored in at ambient temperature and protected from bio-contamination.

NOTICE: Report any serious incident that has occurred in relation to this device to the Manufacturer and the competent authority of the Member State in which the user and/or patient is established.

OPERATION AND USE

1. Dental Articulating Product is placed between the upper and lower teeth of the patient.
2. Apply light pressure by closing the mouth to mark and identify contact point.
3. Articulating Product markings may be wiped or rinsed off surfaces as necessary.
4. When marking is completed remove the Articulating Product and dispose.
5. Dispose of used Articulating Product according to facility procedures.
6. This product is a non-sterile single-use medical device.

PACKAGING / LABELING SYMBOLS USED



CE mark of conformity



Do not reuse



Product lot code



Authorized Representative



Keep Away from Sunlight



Medical Device



Product code



Manufacturer



Manufacture Date



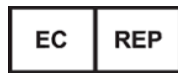
Non-Sterile



Not Made with Natural Rubber Latex



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Revision	CR #	Description of Change
00	2025-004	Initial Release