Flaps
Instructions for Use

CAUTION:
Rx Only. These instructions, in whole or in part, are not a substitute for formal training. Appropriate professional education is REQUIRED prior to using this device clinically. Flaps are intended to be used by qualified dental practitioners in dental clinics, hospitals, labs, or schools for dental applications.

DESCRIPTION:

Flaps products are manufactured in two sizes, Original and Long depending on the size of the patient's mouth. Flaps are single-use bite tabs for digital sensor and film x-rays which allow the patient to comfortably bite down. Flaps allows full occlusion and visual reference for accurate image positioning and reading. Flaps have an adhesive surface which sticks firmly to the x-ray sensor or film. Flaps are made from soft polyethylene foam and are latex free. They are perfect for horizontal or vertical bitewings, or periapical x-rays using either parallel or bisecting angle technique. Flaps help prevent gagging.

INDICATIONS
Flaps are indicated for anyone requiring dental care. Flaps are intended to hold and stabilize an x-ray sensor in the patients mouth to make for more accurate readings. Flaps have an adhesive side which sticks to the sensor or film. The patient is to bite down on the bite-tab with the back of the sensor or film next to their tongue.

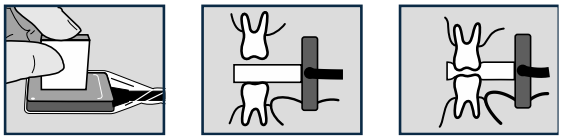
CONTRAINDICATIONS TO USE
Use of Microcopy Flaps is contraindicated on any patient who is allergic to any of the components of the product. The product is made of Polyethylene foam and Acrylic based pressure sensitive adhesive. Do not reuse. Flaps are single-use.

CLINICAL PRECAUTIONS AND WARNINGS:

a) Microcopy Flaps are for SINGLE-PATIENT-USE ONLY, in a dental setting.
b) Do **NOT** use the product if package is damaged or opened. Discard any damaged flaps immediately.
c) Do **NOT** use if the product is damaged.
d) Non-toxic by ingestion. If swallowed by patient, Seek appropriate medical attention.
e) Always keep track of Flaps lot numbers to ensure traceability.

Failure to follow the instructions for use may lead to the following: allergic reaction, procedural delay, minor discomfort, and cross-contamination.

CLINICAL USE:
Select the Flaps size which adequately fits into the patient's mouth.



Step #1

- Stick Flaps on the image side of the x-ray sensor or film. Flaps will adhere to the plastic.
- ***Required:*** *snug-fitting sensor protective sheaths!*

Step #2

- Position the x-ray sensor or film and instruct the patient to bite the Flaps. Take the x-ray.

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STORAGE

- Microcopy's Flaps should be stored a cool dry environment and protected from direct sunlight.
- Improper storage conditions may cause product malfunction.

DISPOSAL

- Each used Flaps must be disposed in a biohazards waste container.
- Each unused Flaps may be disposed in a regular waste container.

TRACEABILITY

- Each package includes a **Lot number** LOT on its label.
- This number must be quoted in any correspondence regarding the product.

NOTICE: if a serious incident has covered in relation to the device, the incident shall be reported to the manufacturer and if applicable, the competent authority of the Member State in which the user and/or patient is established.

To request a paper IFU free of charge, please contact Microcopy at sales@microcopydental.com or 800.235.1863, and an IFU will be delivered with seven (7) days.

SYMBOLS:

	Manufacturer	Indicates the medical device manufacturer.		Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
LOT	Lot Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.		Consult instructions for use	Indicates the need for the user to consult the instructions for use.
CE	CE marking	Signifies European technical conformity.		Do not use if package is open or damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
EC REP	Authorized European representative	Indicates the Authorized representative in the European Community.	MD	Medical Device	Indicates a medical device that needs protection from light sources
REF	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.		Date of Manufacture	Symbol for date of manufacture.
Rx	DEVICE for professional use only	(ref US FDA CDRH) Indicates device shall only be used by a trained professional.		Keep Dry	Indicates a medical device that needs to be protected from moisture

	Keep away from sunlight	Indicates device is designed and intended for medical use.		Importer	Indicates the entity importing the medical device into the locale
	Distributor	Indicates the entity distributing the medical device into the locale			

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