

Title:	Flaps Instructions for Use		
Doc #:	MCD-IFU-007	Rev: 1	Effective Date: 17Feb2020
Originator: M. Parke	Owner: Marketing		DCN#: DCN-20-020

CAUTION:

Rx Only. These instructions, in whole or in part, are not a substitute for formal training. Appropriate professional education is STRONGLY RECOMMENDED prior to using this device clinically.


DESCRIPTION:

The Flaps products are manufactured in two sizes, Original and Long. Both sizes of Flaps are dependent on the size of the patient’s mouths. Flaps are a single-use bite tabs for digital X-Ray sensors, allowing for the patient to comfortably bite down so that dental professionals may get an accurate reading of the patients mouth. They have an adhesive surface which is meant to stick firmly to the X-Ray sensor. Flaps are made from soft polyethylene foam and are latex free.

INDICATIONS

Flaps are designed 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. The patient is to bite down on the bite-tab with the back of the sensor along 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. Do not reuse. Flaps are single use. 

CLINICAL PRECAUTIONS AND WARNINGS:

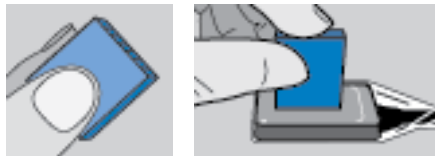
- a) Discard any damaged Flaps immediately.
- b) Microcopy Flaps are for SINGLE-PATIENT-USE ONLY, in a dental setting.
- c) Always keep track of Lot Numbers of Flaps to ensure traceability.
- d) Non-toxic by ingestion. If swallowed by patient, could be a choking hazard. Seek appropriate medical attention.

CLINICAL USE:

Select the Flaps size which adequately fits into the patients mouth.

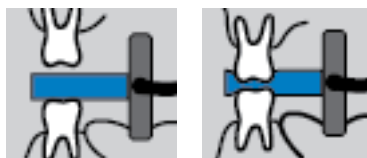
Step #1

- Position the adhesive side onto the X-Ray sensor. Flaps will also stick on to a plastic X-Ray cover.



Step #2

- Position the X-Ray sensor with the Flaps bite-tab attached so that the tongue is pressed against the back of the sensor and the bite-tab is comfortably being bitten by the patient.



Title:	Flaps Instructions for Use		
Doc #:	MCD-IFU-007	Rev: 1	Effective Date: 17Feb2020
Originator: M. Parke	Owner: Marketing		DCN#: DCN-20-020

Step #3

- The cushioned bite-tab allows full occlusion and visual reference for image positioning.

STORAGE






Microcopy’s Flaps should be stored a cool dry environment, with low humidity. These products do not expire.

TRACEABILITY

Each package includes **Lot number** LOT on its label.

This number must be quoted in any correspondence regarding the product.

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 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.			

CONTACT INFORMATION:



Microcopy Dental
3120 Moon Station Rd. NW
Kennesaw, GA 30144



Obelis s.a.
Bd. Général Wahis 53
1030 Brussels, Belgium

Title:	Flaps Instructions for Use		
Doc #:	MCD-IFU-007	Rev: 1	Effective Date: 17Feb2020
Originator:	M. Parke	Owner: Marketing	DCN#: DCN-20-020

REVISION HISTORY:

Revision Control Log			
Rev. #	Effective Date	Change Description	DCN
1	17Feb2020	New	DCN-20-020