

Title:	Flaps Instructions for Use		
Doc #:	MCD-IFU-007	Rev: 3	Effective Date: Draft
Originator: M. Parke	Owner: Marketing		DCN#: DCN-20-158

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:

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 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 or film. The patient is to bite down on the bite-tab with the back of the sensor or film next to on their tongue.

CONTRAINDICATIONS TO USE

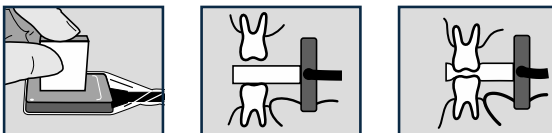
Use of Microcopy Flaps is contraindicated on any patient who is allergic to any of the components of the product. Do not reuse. Flaps are single-use. 

CLINICAL PRECAUTIONS AND WARNINGS:

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

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.

TRACEABILITY

Each package includes a **Lot number**  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 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.
	Authorized European representative	Indicates the Authorized representative in the European Community.		Medical Device	Indicates a medical device that needs protection from light sources
	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.		Date of Manufacture	Symbol for date of manufacture.
	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.			

CONTACT INFORMATION:


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REVISION HISTORY:

Revision Control Log			
Rev. #	Effective Date	Change Description	DCN
3	Draft	Revision to instructions and update ISO symbols, and add lot number configuration.	DCN-20-158
2	17Jul2020	Revision to instructions to add clarification and add MDR symbols	DCN-20-066
1	17Feb2020	New	DCN-20-020