Bite-Chek®
Instructions for Use

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:
Bite-Chek is made up of layers of laminate, ink, paper, medical grade adhesive, and coated film. It is to be used by qualified dental practitioners in dental clinics, hospital, lab, or schools for a dental application. Articulation film is a non-invasive device that can be used on children, adults, adolescents, or animals. Product claims to mark occlusal surfaces or contact points. It is offered as not sterilized; however, it is packaged in a controlled environment. Product is single-use and should NOT be re-processed and/or re-used.

INDICATIONS
Bite-Chek is an articulation film product made to mark the occlusal surface of the mouth. Marking surfaces can include zirconia, porcelain, composite, gold, eMax, or stainless steel.

CONTRAINDICATIONS TO USE
Use of Bite-Chek is contraindicated on any patient who is allergic to any of the components of the product. Do not reuse. The Bite-Chek are single-use.

CLINICAL PRECAUTIONS AND WARNINGS:

a) Carefully read package labels to ensure use of the appropriate device.
b) Failure to follow instructions may cause procedural delays or patient or user injury.
c) Prior to use, carefully inspect the product for signs of damage and/or deterioration.
d) Discard any damaged Bite-Chek immediately.
e) Bite-Chek are for SINGLE-PATIENT-USE ONLY, in a dental setting.
f) Discard immediately after use.
g) Used by a trained dental practitioner, assistant, or hygienist.
h) Always keep track of Lot Numbers of Bite-Chek to ensure traceability.

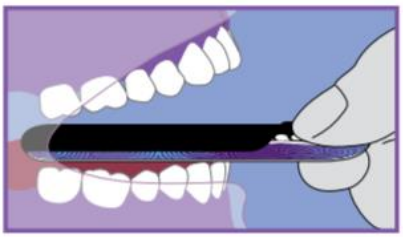
CLINICAL USE:

Step #1

- Dry the tooth surface.

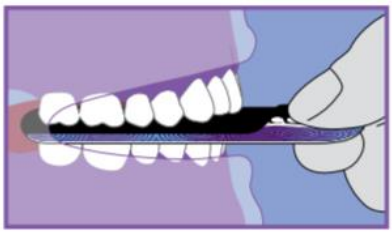
Step #2

• Position so film is on the teeth facing the center of the mouth.



Step #3

• Check occlusion



STORAGE

Bite-Chek should be stored in a dry, dust-free environment, outside of direct sunlight. Improper storage conditions may cause malfunction of the product.

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	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.
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.

MD	Medical Device	Indicates device is designed and intended for medical use.	Rx	DEVICE for professional use only	(ref US FDA CDRH) Indicates device shall only be used by a trained professional.
EC REP	Authorized European representative	Indicates the Authorized representative in the European Community.		Keep Dry	Indicates a medical device that needs to be protected from moisture.
	Importer	Indicates the entity importing the medical device into the locale			

CONTACT INFORMATION:

Microcopy
3120 Moon Station Rd. NW
Kennesaw, GA 30144, USA
sales@microcopydental.com
800.235.1863

EC REP
Obelis s.a.
Bd. Général Wahis 53
1030 Brussels, Belgium
mail@obelis.net
+ (32) 2. 732.59.54

CE

REVISION HISTORY:
MCD-IFU-005 Rev: 4
Date of issue: 20May2021