

Proxi-Chek® Instructions for Use (IFU)

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:

Proxi-Chek is an interproximal articulation tool that marks tight contacts when seating a crown. Proxi-Chek is made up of layers of medical grade laminate, black and cyan ink for print, plastic, 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 adults, children, and animals. Product claims to mark interproximal surfaces or contact points. It is offered as not sterilized; however, it is packaged in a controlled environment. Product is single-patient-use and should NOT be re-processed.

INDICATIONS

Proxi-Chek is an articulation film product made to assist in the placement of prosthesis. Prosthesis can include crowns, bridges, inlays, onlays, implant crowns, etc. made up of zirconia, porcelain, composite, gold, eMax, or stainless steel.

CONTRAINDICATIONS TO USE

Use of Proxi-Chek is contraindicated on any patient who is allergic to any of the components of the product. Do not reuse. The Proxi-Chek is a single-patient-use product. Reusing the product can cause contamination, premature failure, and increase risk of tearing.

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 Proxi-Chek immediately.
- e) Proxi-Chek are for SINGLE-PATIENT-USE ONLY, in a dental setting.
- f) Discard immediately after use.
- g) Always keep track of Lot Numbers of Proxi-Chek to ensure traceability. Lot numbers are listed in the format of PRMMDDYY, which correspond to the manufacturing date. For example, Proxi-Chek created on July 10, 2018 the lot number would be PR071018.
- h) Used by a trained dental practitioner.

CLINICAL USE:**Step #1**

- Dry prosthesis and tooth surface.



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Step #2

- For anterior, use straight. For posterior, face crease up and fold down, pinch for two seconds.



Step #3

- Release for a 90° angle.



Step #4

- Position film next to adjacent teeth and insert prosthesis.
- Slightly tug to create mark.



Step #5

- Remove prosthesis.
- Adjust at mark.
- Repeat until prosthesis seats.



STORAGE

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

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CONTACT INFORMATION:














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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.
	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.		Date of Manufacture	Symbol for date of manufacture.
	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.
	Medical Device	Indicates device is designed and intended for medical use.		Keep away from sunlight	Indicates a medical device that needs protection from light sources
	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.		CE marking	Signifies European technical conformity.
	Keep Dry	Indicates a medical device that needs to be protected from moisture.			

REVISION HISTORY
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