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) Always keep track of Lot Numbers of Bite-Chek to ensure traceability.
  h) Used by a trained dental practitioner, assistant, or hygienist.

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* on its label. This number must be quoted in any correspondence regarding the product.

SYMBOLS:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="icon" alt="Manufacturer" /></td>
<td>Indicates the medical device manufacturer.</td>
</tr>
<tr>
<td><img src="icon" alt="Do not reuse" /></td>
<td>Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.</td>
</tr>
<tr>
<td><img src="icon" alt="Lot Code" /></td>
<td>Indicates the manufacturer’s batch code so that the batch or lot can be identified.</td>
</tr>
<tr>
<td><img src="icon" alt="Consult instructions for use" /></td>
<td>Indicates the need for the user to consult the instructions for use.</td>
</tr>
<tr>
<td><img src="icon" alt="CE marking" /></td>
<td>Signifies European technical conformity.</td>
</tr>
<tr>
<td><img src="icon" alt="Do not use if package is open or damaged" /></td>
<td>Indicates a medical device that should not be used if the package has been damaged or opened.</td>
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</tbody>
</table>
Title: Instructions for Use (IFU) – Bite-Chek®

Doc #: MDC-IFU-005 Rev: 1 Effective Date: 13Nov2018

Originator: Emily Brayman Owner: Quality DCN#: DCN-18-038

CONTACT INFORMATION:

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

DENTEQ Medical Technologies
Hafenstrasse 12 76344,
Egenstien-Leopoldshafen, Germany
Fax: +49-7247 944843

CE

REVISION HISTORY:

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<th>Effective Date</th>
<th>Change Description</th>
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<td>1</td>
<td>13Nov2018</td>
<td>New</td>
<td>DCN-18-038</td>
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