NeoDrys® Flex Saliva Absorbents
Instructions for Use

CAUTION:
Rx Only. These instructions, in whole or in part, are not a substitute for formal training. Appropriate professional education is REQUIRED prior to using this device clinically. NeoDrys® Flex are intended to be used by qualified dental practitioners in dental clinics, hospitals, labs, or schools for dental applications.

DESCRIPTION:
NeoDrys® Flex is a sublingual saliva absorbent. It is designed to contour the lingual side of the lower arch. The product's super absorbent particles capture and trap saliva within the body of the Flex.

The sublingual absorbent is indicated to absorb moisture from the sublingual and submandibular glands for up to 15 minutes. Absorption time will vary based on patient saliva production.

INDICATIONS:
NeoDrys® Flex is designed to fit under the tongue and contour the lingual side of the lower arch to absorb saliva from the sublingual and submandibular saliva glands. The intended patient target group is any person requiring dental care.

CONTRAINDICATIONS TO USE

a) Use of NeoDrys® Flex are contraindicated on any patient who is allergic to any of the product components.
b) The maximum expected time per use for one Flex dry is 15 minutes.
c) Do not reuse.
d) Do **NOT** use the product if the package is opened or damaged.
e) Do **NOT** use a Flex dry if it is damaged.
f) NeoDrys® Flex are for SINGLE-PATIENT-USE ONLY and should be used exclusively in a dental setting.
g) To remove without tissue irritation, release adhesion with ample water spray to the tissue contacting side of the product.
h) Non-toxic by ingestion. If product bursts, remove as much as possible from mouth. Rinse mouth thoroughly with plenty of water. If adverse symptoms appear, seek medical attention.
i) Always keep track of Lot Numbers of NeoDrys® Flex to ensure traceability.

Failure to follow the instructions for use may lead to the following: leakage, allergic reaction, minor irritation and discomfort, and cross-contamination.

Notice: If a serious incident has occurred in relation to the device, the incident shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CLINICAL USE:

Sublingual Steps

1.  **2.**  **3.** 

- 1. Anterior: Separate the pair for one (1) Flex. Discard center tab.
- 2. Position for lingual anterior. Blue side towards tongue.

- 3. Important: To remove, gently spray with water on blue side.

-OR-

1.  2.  3.  4. 

- 1. Anterior: Separate the pair for one (1) Flex. Discard center tab.
- 2. Posterior: Fold white sides together
- 3. Position for lingual posterior.
- 4. **Important**: To remove, gently spray with water on blue side.
- Additional absorption is achieved by doubling (2) Flex and using them together.

STORAGE

Microcopy NeoDrys Flex should be stored in a dry, closed container. Improper storage conditions will shorten the shelf life and may cause malfunction of the product.

DISOPSAL

There are no special instructions for the disposal of the NeoDrys® Flex.

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.
Rx	DEVICE for professional use only	(ref US FDA CDRH) Indicates device shall only be used by a trained professional.		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.		Keep Dry	Indicates a medical device that needs to be protected from moisture.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.			

CONTACT INFORMATION:

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

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