

<b>Title:</b>	<b>Instructions for Use (IFU) – NeoDrys® Saliva Absorbents</b>		
<b>Doc #:</b>	<b>MCD-IFU-004</b>	<b>Rev:</b>	<b>4</b>
<b>Originator:</b>	Emily Brayman	<b>Owner:</b>	Quality
		<b>Effective Date:</b>	20May2021
		<b>DCN#:</b>	DCN-21-061

**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:**

The NeoDry products are manufactured in two sizes, Large and Small. The NeoDrys are manufactured with two backing types, Reflective, a metalized film backing, and Original, a white backing. The NeoDrys are used to absorb saliva from the parotid gland. They have a semi-permeable barrier to capture the saliva with super absorbent particles and trap the saliva within the body of the NeoDrys. Within the NeoDrys is a core stiffener to offer cheek retraction as the product expands with saliva.

**INDICATIONS**

The NeoDrys are used to absorb moisture from the parotid gland for up to 15 minutes. The super absorbent polymer traps moisture as a gel when in contact with saliva. The NeoDrys core stiffener provides cheek retraction to facilitate procedures far back in the oral cavity. The NeoDrys backings brighten the oral cavity during procedures and the medical grade poly netting adhere gently to the tissue to stay in place yet removes easily with water spray.

**CONTRAINDICATIONS TO USE**

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

**CLINICAL PRECAUTIONS AND WARNINGS:**

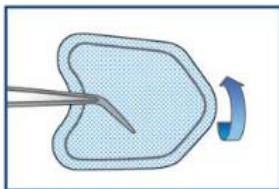
- Discard any damaged NeoDrys immediately.
- Microcopy NeoDrys are for SINGLE-PATIENT-USE ONLY in a dental setting.
- To remove without tissue irritation, release adhesion with ample water spray to the buccal side of the NeoDrys.
- Non-toxic by ingestion. If product bursts, remove as much as possible from mouth. Rinse mouth thoroughly with plenty of water. If adverse symptoms appear, seek medical attention.
- Always keep track of Lot Numbers of NeoDrys to ensure traceability.

**CLINICAL USE:**

Select the NeoDrys size which adequately covers the buccal mucosa.

**Step #1**

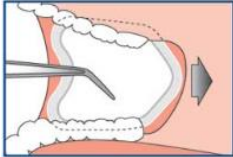
- Insert the NeoDrys as shown with the color side against the cheek.



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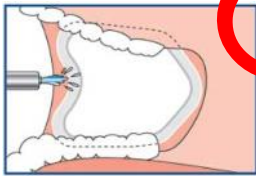
**Step #2**

- Point the NeoDrys to the back of the mouth as shown. In a few seconds, the NeoDrys will begin to adhere to the tissue and stay in place.



**Step #3**

- Important:** To remove without irritating tissue, release adhesion with ample water spray to the buccal side of the NeoDrys.



**STORAGE**






Microcopy NeoDrys should be stored in a dry, closed container. Improper storage conditions will shorten the shelf life and 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.
<span style="border: 1px solid black; padding: 2px;">LOT</span>	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.

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	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.		Date of Manufacture	Symbol for date of manufacture.
	Medical Device	Indicates device is designed and intended for medical use.		Keep Dry	Indicates a medical device that needs to be protected from moisture.
	DEVICE for professional use only	(ref US FDA CDRH) Indicates device shall only be used by a trained professional.		Authorized European representative	Indicates the Authorized representative in the European Community.
	Importer	Indicates the entity importing the medical device into the country.			

**CONTACT INFORMATION:**



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**REVISION HISTORY:**

Revision Control Log			
Rev. #	Effective Date	Change Description	DCN
4	20May2021	Add symbol	DCN-21-061
3	17Jul2020	Update symbols for MDR	DCN-20-066
2	17Feb2020	Updated EC Rep per CC-MC-19-015	DCN-20-034