

**CONTROLLED FORM** 

#### **CAUTION:**

Professional use only, R. 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. Dry-It Saliva Absorbents are intended to be used by qualified dental practitioners in dental clinics, hospitals, labs, or schools for dental applications.

#### **DESCRIPTION:**

The Dry-It products are manufactured in two sizes, Large and Small. The Dry-It Saliva Absorbents 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 Dry-It Saliva Absorbents. Within the Dry-It Saliva Absorbents is a core stiffener that aids cheek retraction as the product expands with saliva.

#### INDICATIONS AND INTENDED USE:

Dry-It Saliva Absorbents are indicated for anyone requiring dental care. Dry-It Saliva Absorbents are intended 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 Dry-It Saliva Absorbents core stiffener provides cheek retraction to facilitate procedures far back in the oral cavity. The Dry-It Saliva Absorbents 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's Dry-It Saliva Absorbents is contraindicated on any patient who is allergic to any of the components of the product. Components of the product are the following: Polyethylene, Polyester, Polypropylene, Wood Cellulose, and Polyacrylate Polymer.

## **CLINICAL PRECAUTIONS AND WARNINGS:**

- a) Do **not** use the product if package is opened or damaged. Discard any damaged Dry-It Saliva Absorbents immediately.
- b) Do **not** use if the product is damaged.
- c) The Dry-It Saliva Absorbents are single use.
- d) To remove without tissue irritation, release adhesion with ample water spray to the buccal side of the Dry-It Saliva Absorbents.
- e) 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.
- f) Always keep track of Lot Numbers of Dry-It Saliva Absorbents to ensure traceability.

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

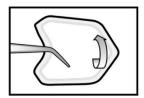
## **CLINICAL USE:**

Select the Dry-It Saliva Absorbents size which adequately covers the buccal mucosa.

#### Step #1

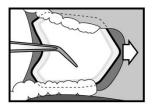
• Insert the Dry-It Saliva Absorbent as shown with the absorbent pad against the cheek.





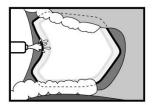
## Step #2

• Point the Dry-It Saliva Absorbent to the back of the mouth as shown. In a few seconds, the Dry-It Saliva Absorbents 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 Dry-It Saliva Absorbent.



## **STORAGE:**

Microcopy Dry-It Saliva Absorbents should be stored in a dry, closed container. Improper storage conditions will shorten the shelf life and may cause malfunction of the product.

### **DISPOSAL**

- Each used saliva absorbent must be disposed in a biohazards waste container.
- Each unused saliva absorbent may be disposed in a regular waste container.

### **PRODUCT SHELF LIFE**

• Product shelf life is four (4) years unless product is damaged.





## **TRACEABILITY:**

Each package includes Lot number	LOT	on its	امطدا
Each package includes Lot number		OHILS	abei

This number must be quoted in any correspondence regarding the product.

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

To request a paper IFU free of charge, please contact Microcopy at <a href="mailto:sales@microcopydental.com">sales@microcopydental.com</a> or 800.235.1863, and an IFU will be delivered within seven (7) days.

## **SYMBOLS:**

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<b>~</b>	Manufacturer	Indicates the medical device manufacturer.	2	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.	i	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.	<del>*</del>	Keep Dry	Indicates a medical device that needs to be protected from moisture.
R <sub>x</sub>	DEVICE for professional use only	(ref US FDA CDRH) Indicates device shall only be used by a trained professional.		Importer	Indicates the entity importing the medical device into the locale



#### **CONTROLLED FORM**



Distributor

Indicates the entity distributing the medical device into the locale



Distributor

Indicates the entity distributing the medical device into the locale

### **CONTACT INFORMATION:**



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