# **Dental Dam**

SH-IFU-001(B)\_01
Instruction for Use

SANCTUARY HEALTH SDN. BHD.

#### **Intended Use:**

Dental dams are thin sheets of latex or non-latex used as a barrier during endodontic procedures.

# For devices intended to use together:

Dental Dam Accessories (Dental Dam Clamps, Dental Dam Punch, Dental Dam Forceps and Dental Dam Frames)

#### **Duration of use:**

It is intended for continuous use for less than 60 minutes during dental procedures.

## **Storage conditions:**

Latex dental dam and non-latex dental dam are easy to aging, and the condition of preservation of the product is very sensitive. Many variable factors (especially temperature) can affect this material. Therefore, the storage temperature should be below 40°C (104°F).

# **Warranty Period:**

In order to achieve the best usage effect, dental dam should be used before the expiry date as stated on colour box. Expiration of latex and non-latex dental dam are 5 years from the manufacturing date. Consideration of product storage at the recommended condition shall be practiced to ensure the mentioned shelf life.

### **Product Specification:**

# **Dental Dams Product Specifications:**

Dental Dams	Dimension		Colour
Latex	127mm x 127mm (5" x 5") 152mm x 152mm (6" x 6")	Thin	Green/ Blue
		Medium	
		Heavy	
		Thin	Black
		Medium	
		Heavy	
		Thin	Silk Blue
		Medium	
		Thin	Pink
		Medium	
		Heavy	
Non-Latex	127mm x 127mm (5" x 5")	Medium	Purple
	152mm x 152mm (6" x 6")		2 Tones Blue

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# Basic principles which medical device works on and their features

- (i) Place the Dental Dam in a flat surface.
- (ii) Determine the affected tooth. Choose the right size of the disc hole at the punch and punch a hole approximately 2mm diameter on the dam.
- (iii) Use a forceps to hold/enlarge the clamp and place the metal clamp to the punched hole.
- (iv) Place the dam with clamp on the affected tooth.
- (v) Place the dental dam frame outside the mouth to hold excess dam material.

#### **Caution/ Recommendation:**

- Single use only
- Recommended for professional use only
- This product contains natural rubber latex which may cause allergic reactions (It is only applicable for latex dental dam).

#### Warning:

Do not use the products if you found any holes or tearing. Reuse of the device can lead to cross-contamination or cross-infection.

## Disposal of the devices:

Follow local disposal procedure as per user facility.

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## Manufactured by:

#### Sanctuary Health Sdn. Bhd.

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#### **Importer:**

MedEnvoy UK Limited 85, Great Portland Street, First Floor, London, W1W 7LT

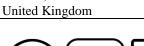
## **United Kingdom Authorized Representative:**

Sanctuary Health has appointed the below UK A.R:

## Wellkang Ltd

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