

## Latex Dental Dam – User Instructions



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### Device Description

#### **General description**

Latex rubber dams are manufactured from natural rubber latex. The dental dam is used as a protective oral barrier during endodontic procedures to reduce the risk of infection, to isolate the working area, to prevent particles or small objects making their way into the patient's airways and to improve patient comfort.

The product consists of squares of material either 128mm (5inches) or 152mm (6 inches) square of thickness between 0.12mm and 0.28mm depending on the requirements of the practitioner and the procedure. The specifications are quoted subject to manufacturing tolerances. The product has a fine coating of magnesium silicate powder (talc) for ease of handling and needs to be stored in the box provided when not in use.

#### Indications for use

The dental dam is a single use, non-invasive, none sterile device that is designed to be used only by qualified dental professionals for the described purpose.

#### Counter Indications

It is the responsibility of the dental practitioner to determine if the use of dental dam is appropriate for each individual patient. Latex dental dams should not be used in situations where the skin in the relevant area is broken, the patient has a known latex allergy or sensitivity to type IV allergens or other clinical considerations indicate that it should not be used.

## Symbols



Warning Symbol



Read Manuals



Presence of Latex



Dental Dam is a Class I medical device and complies with Medical Device Directive (93/42/EEC)



Flammable



Single use



### WARNINGS

- The product is only to be used by a qualified dental practitioner trained in the use of dental dams
- Do not use the dental dam pad if there is any sign of damage. Please dispose of any damaged items according to local regulations
- Do not use the dental dam product for any other purpose that that stated in this manual.
- See Sections below for the storage, use and transportation guidelines.
- The product should only be used before the expiry date indicated on the box
- Do not use the product on children unless under the supervision of a qualified practitioner
- This product is for single use only. It is not suitable for cleaning.

## COMPOSITION

Natural rubber latex plus essential processing chemicals and pigments with a surface coating of talc.

## HEALTH HAZARDS

Natural rubber latex dental dams should not be used on persons who are susceptible to natural rubber latex allergies but is otherwise considered non-hazardous and safe for use

The product contains processing additives including dithiocarbonate that may cause sensitisation by skin contact and give rise to Type IV Allergies. Persons who know they are susceptible to dithiocarbonates should avoid contact with the product.

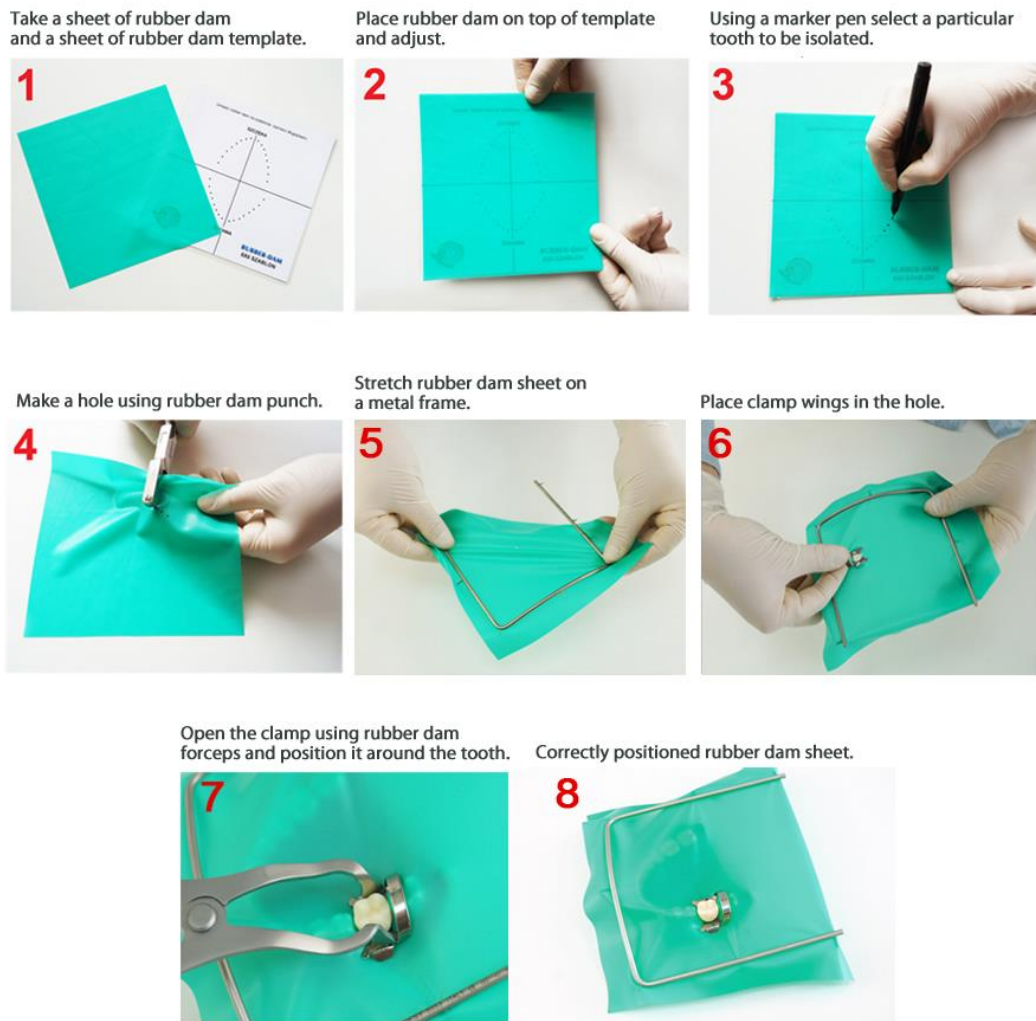
Talc is considered non-hazardous in the quantities present on the product, but contact should be avoided with broken skin.

## FIRE HAZARD

The product is flammable and should be kept away from naked flames during handling and storage. No smoking restrictions should be observed in storage and handling areas.

## Usage

Please see below Standard operational guidance:



Please note: The hole punch must be designed for this purpose and in good condition as failure to punch a clean hole in the product may result in tearing.

Do not use damaged, torn or discoloured sheets. If the sheet tears at any time in preparation or usage it should be discarded immediately.

This is a single use product and should be discarded according to local regulations after use.

## Transportation and Storage Instructions:

**At all times when transporting and storing the product the following requirements should be observed: -**

**Temperature:**

Store below 26°C and away from direct sources of heat

**Humidity:**

Avoid damp storage conditions

**Light:**

Protect from prolonged exposure to light, in particular u.v. and bright sunlight.

**Metals:**

Avoid contact with copper and copper containing alloys.

**Oils and solvents:**

Avoid contact with oils, solvents and greases.

**Fire:**

Keep away from naked flames

**Packaging:**

The product should be transported and stored in the box provided. The box should be closed when not in use.

If there are any signs of damage to the packaging on receipt of the product, please return it unopened to your supplier and a replacement will be provided.

The expiry date of the product is indicated on the box. Do not use the product after the expiry date.

## Service Requirements

There are no service requirements for the product

## Cleaning Requirements

This is a single use product and so there are no cleaning requirements for the product.

## Translation

The manufacturer cannot take responsibility for the accuracy of the translation of these instructions into other languages.