

Latex-Free Dam Instructions for Use

IMPORTANT

Read this 'Instructions for Use' document before handling. This product is for use by a professional only.

SPECIALLY FORMULATED FOR USE IN DENTISTRY

IDENTIFICATION

Product Name	Non Latex Dam 6 x 6 pk 20
Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hampshire, SO40 3WX, UK
Company Phone No.	+44 (0) 2380 866 677

PRODUCT CODE – REF

004/0046	Non Latex Dam 6 x 6 Medium Blue pk 20	004/0050	Non Latex Dam 6 x 6 Medium Blue pk 80
004/0047	Non Latex Dam 6 x 6 Heavy Blue pk 20	004/0051	Non Latex Dam 6 x 6 Heavy Blue pk 80

INDICATIONS FOR USE

Polyisoprene latex free rubber dams are manufactured from synthetic polyisoprene polymer which has physical properties similar to those of natural rubber latex but without the proteins that occur in natural rubber latex that may cause allergic reactions. 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 dental dam is a single use, non-invasive, non-sterile device that is designed to be used only by qualified dental professionals for the described purpose.

CONTRAINDICATIONS

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

INSTRUCTIONS FOR USE

1. Take a sheet of latex-free dam and a dental dam template.
2. Place latex-free dam on top of template and adjust.
3. Using a marker pen, select which tooth is required for isolation.
4. Make a hole using Perfection Plus's dental dam punch.
5. Stretch latex-free dam on to a metal/plastic dam frame.
6. Place dental dam clamp in the hole and position around the tooth.

The dental dam punch must be in good condition, as failure to punch a clean hole could result in the dental dam tearing.

STORAGE

The product is flammable and should be kept away from naked flames during handling and storage.

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

Avoid damp storage conditions and keep out of direct sunlight.

Avoid contact with copper, copper containing alloys, oils, solvents and greases.

The box should be closed when not in use.



WARNING!

Polyisoprene is considered non-hazardous and is safe for use by persons who know they are susceptible to natural rubber latex allergies.

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. N-Nitrosamine by-products of dithiocarbonate are typically <10µg/kg (93/11/EEC limit for bottle teats) when tested by BSEN12868.

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

Caution



Should a serious incident in relation to the product occur, it should be reported to the manufacturer and the competent authority.

LOT NUMBER AND EXPIRY DATE

The above are printed on each package and should be quoted in all correspondence which requires identification of the product. Do not use the product after this date. See product box for lot.



Perfection Plus Ltd
6 Westwood Court
Brunel Road
Hampshire
SO40 3WX, UK
www.perfectionplus.com



Perfection Plus EU Ltd
The Black Church
St Mary's Place.
Dublin, Ireland,
D07 P4AX
Regulatory@perfectionplus.com



Advena Ltd
Tower Business
Centre
2nd Floor Tower
Street
Swatar, Malta

