

PerfectaDAM

Instructions For Use

IMPORTANT

Read this 'Instructions for Use' document before handling. This product is for use by dental professionals only. PerfectaDAM is a light-reflecting, light-cured resin barrier for the isolation of tissue adjacent to the tooth being whitened.

IDENTIFICATION

Product Name	PerfectaDAM
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

004/0205 PerfectaDAM 4 x 1.2ml Syringe and 8 tips

INDICATIONS FOR USE

For isolating adjacent gingiva during a tooth whitening procedure.

APPEARANCE/SHADE

Blue

COMPOSITION

Organic Matrix: UDMA, HEMA

Inorganic Fillers: Micro/Nano Silica

Additives: Initiator, Catalyst, Stabiliser, Others

CONTRAINDICATIONS

Do not use in patients with a known sensitivity/allergy to methacrylic monomers.

PRECAUTIONS

Do not use after the expiry date.

INSTRUCTIONS FOR USE

Isolation procedure

1. Remove the cap from the syringe. Insert and twist the tip securely onto the syringe.
2. Hold the tip away from the patient and any persons, express a small amount of the PerfectaDAM.
3. Place self-supporting plastic cheek retractors in the patient's mouth. Rinse and air-dry the teeth thoroughly, paying special attention to the gingival third.
4. Express PerfectaDAM on to the gingiva, creating a barrier 4-6mm wide and approximately 1.5-2mm thick.
5. Light cure the PerfectaDAM, using a scanning motion, for 20 seconds, keeping the tip approximately 1cm away from the barrier and tissue.
6. When protecting tissue adjacent to fewer teeth, light cure the barrier for approximately 3-5 seconds per tooth.
7. A dental instrument such as an explorer may be used to check the resin is fully cured.

Clean up Procedure

1. After thoroughly vacuuming off whitening gel, rinse teeth with air/water syringe and vacuum. Lift PerfectaDAM from gingiva surface using an explorer or similar instrument and tweezers. The cured barrier will usually lift in its entirety or in large sections.
2. Remove PerfectaDAM from and interproximal areas using explorer and/or floss, and rinse.

CAUTION

1. PerfectaDAM designed for sale and use by qualified dental care professionals only.
2. PerfectaDAM contains methacrylic monomer. Methacrylic monomer can cause an allergic reaction in some patients.
3. Do not use PerfectaDAM for patients allergic to or hypersensitive to methacrylic monomers.
4. If PerfectaDAM causes an allergic reaction or oversensitivity, discontinue use immediately.
5. If PerfectaDAM comes in contact with the eyes, thoroughly flush the eyes with water and immediately contact an ophthalmologist.
6. DO NOT USE PerfectaDAM after the indicated expiration date on the syringe.
7. If refrigerated storage is used, allow product to reach room temperature prior to use.

STORAGE AND USE

1. Do not expose PerfectaDAM to elevated temperatures, or to intense light.
2. Store at a temperature between 2° and 27°C.
3. Ambient temperatures routinely higher than 27°C may reduce shelf life.
4. Shelf life at room temperature is 24 months.
5. See outer packaging for expiry date.
6. Do not store materials in proximity to products containing Eugenol.

CAUTION

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

SYMBOLS GLOSSARY

	Medical Device		Catalogue number
	Consult instructions for use		Batch Code
	Caution		Use by date
	Keep away from direct sunlight		Unique device identifier
	Temperature limit		Manufacturer
	Importer		EU Conformity mark
	Authorised Representative in the European Community		