VET SHIELD™
COLLAGEN CORNEAL SHIELD

DESCRIPTION:

The VET SHIELD™ Collagen Corneal Shield is a clear, pliable, thin film of highly purified bovine collagen that has been lightly cross-linked to provide the desired degradation time on the eye. The QS and 12-Hour shields are used primarily following cataract surgery and are intended to degrade completely on the eye under a patch within 1 day. The 24-Hour and 72-Hour shields are used primarily following ocular injections, corneal trauma, and non-traumatic corneal conditions. They are intended to be placed on a non-patched eye and will remain on the eye, similar to a contact lens, for approximately the number of hours indicated. They will partially degrade during their time on the eye.

The VET SHIELD™ Collagen Corneal Shield is designed to be placed over the cornea. It has a nominal diameter of 14mm and a compound base curve which approximates 9mm when hydrated. The shield is thicker in the center and thin out towards the edge. When hydrated, the water content of the shield is 65% to 85% depending on the degradation time.

The VET SHIELD™ Collagen Corneal Shield needs to be inverted before being placed on the eye. If the shield is not inverted, the eyelids will initially rub the edge of the shield which may lead to premature dislocation of the shield. Invert the hydrated shield as if it were a contact lens. The edge of the shield should point upwards, not outwards.

OASIS® Medical recommends that VET SHIELD™ Collagen Corneal Shield be hydrated in a sterile balanced salt solution for ophthalmic use, or a similar solution. The dehydrated shield is fragile. Avoid cracking it with forceps. Handle with care when hydrating the shield using viscous solutions as they may prevent the shield from seating securely on the cornea. This may result in the shield moving around and slipping off the cornea prematurely. Once applied to the eye, the hydrated shield will slowly absorb ocular fluids which contain collagenases and proteases. These enzymes cause the shield to slowly lose shape and eventually degrade. The QS and 12-Hour shields are usually retained in place by an eye patch. Degradation will usually be complete by the time the eye patch is removed.

The 24-Hour and 72-Hour shields will begin to move around on the eye as they start to lose shape and will eventually be pushed off the eye by the eyelids at approximately the number of hours indicated by the labeling.

This time can be highly variable based on the volume of ocular fluids and the concentration of enzymes in these fluids. Patients with dry eyes will generally find these shields take longer to lose shape due to lower tear volumes. Patients with diseased eyes may find these shields lose shape much faster due to the higher levels of enzymes in their tears. These shields will not be completely degraded by the time they come off the eye.

The VET SHIELD™ Collagen Corneal Shield allows ocular healing to take place by providing a protective barrier over the surface of the eye. As the shield gradually degrades, a thin layer of collagen is released which helps lubricate the eye.

INTENDED USE:

The VET SHIELD™ Collagen Corneal Shield is intended to protect ocular surface following surgery, injection, traumatic, and non-traumatic corneal conditions.

INDICATIONS FOR USE:

The VET SHIELD™ Collagen Corneal Shield are indicated for ocular surface protection for use in veterinary applications only. Quick Shield and 12-Hour shields are used primarily following cataract surgery and are intended to degrade completely on the eye under a patch within 1 day. The 24-Hour and 72-Hour shields are used primarily following ocular injections, corneal trauma, and non-traumatic corneal conditions.

CONTRAINDICATIONS:

Professional judgement must be used by the healthcare professionals in using VET SHIELD™ Collagen Corneal Shield on patients with infected, diseased, or contaminated corneas, or patients presenting with the following conditions:

- Acute external ocular infection
- Intraocular infection
- Blepharitis
- Chalazions
- Allergic reaction to collagen or bovine products

PRECAUTIONS:

Do not resterilize the shield as this will alter its degradation time. Do not use any shield taken from an opened or damaged package. Do not use if the sterile packaging is damaged. After use it should be properly disposed of according to medical waste guidelines of your facility.

Healthcare professionals should always use care in screening their patients for any known allergies to collagen or bovine derived products. In addition, patients should be monitored for reaction to the shield (i. e. conjunctival hyperemia and edema, erythema, lacrimation, and pruritus).

The 24-Hour and 72-Hour shields should only be applied by healthcare professionals experienced with contact lenses for prolonged wearing times.

Collagen shields should be removed from the patient's eye after 3 days as prolonged wearing can induce serious injury resulting from bacterial or fungal infection.

It is recommended that the eye be anesthetized prior to placing a collagen shield on the eye. The pH of collagen shields is low and can cause a temporary stinging sensation to the cornea until the surface pH of the shield is neutralized by ocular fluids. Alternatively, the surface of the shield can be neutralized by soaking the shield several times in fresh hydrating solution.

The collagen shield is not a vision correcting optical element and vision will be impaired through an intact shield.

Substantial literature has been published on the use of collagen shields to dose various drugs to the eye. However, OASIS® Medical has not conducted controlled clinical studies on the use of collagen shields with drugs and therefore CANNOT recommend treatment using collagen shields with drugs or the hydration of shields in ophthalmic pharmaceuticals. Published literature stresses the importance of using only topical strength drugs.

Certain suspensions may cause corneal abrasions due to particles in the drug. Certain drug combinations may cause precipitates which can cause corneal abrasions.

STORAGE:

VET SHIELD™ Collagen Corneal Shield should be stored at room temperature between 0°C and 25°C (32°F to 77°F). Avoid heat above 25°C (77°F) which can prolong the dissolution time of the shield. Avoid temperatures at or below freezing.

RECOMMENDED INSTRUCTIONS FOR USE:

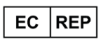
- Hydrate the shield prior to use for at least 3 minutes.
- Anesthetize the eye.
- Invert the shield before applying to the eye.
- Hydrate the eye and apply the shield. Ensure the shield is properly seated.
- Thoroughly hydrate the shield on the eye.
- The eye may be patched.

HOW SUPPLIED:

VET SHIELD™ Collagen Corneal Shield are supplied sterile by electron beam irradiation in a double peel tray. The inner tray is intended to be used to hydrate the shield. Lot Number and Expiration Date are printed on the packaging.

CAUTION:

Federal law (U. S. A.) restricts this device to sale by or on the order of a physician.

Symbol	English	Symbol	English	Symbol	English	Symbol	English
	Manufacturer		Batch code / lot number		Do not resterilize		No latex
	Authorized representative in the European Community		Catalogue number		Do not use if package is damaged		Consult Instructions For Use
	Authorized representative in Switzerland		Unique Device Identifier		Temperature limitation. Store between 0°C to 25°C (32°F to 77°F)		Medical Device
	Use-by date		Sterilized using irradiation with double sterile barrier system		Do not re-use		Patient Information Website