

ScleralEase™

All-in-One Scleral Lens Application and Removal Tool

Product Description	Code	Basic UDI-DI
ScleralEase - Dispenser of 1	SCLE-1	3770020907586
ScleralEase - Dispenser of 4	SCLE-4	3770020907555

Intended Use

ScleralEase is intended to assist individuals with the application and removal of scleral contact lenses. It features an integrated, dual-function design that enables both application and removal using a single device.

Intended Users

ScleralEase is intended for individuals who wear scleral lenses as recommended by their eye care professional.

Warnings

- Choking hazard. Keep this and all other medical devices away from small children.
- ScleralEase is a reusable device for single-user only to prevent cross-contamination.
- Extended or intensive use beyond the recommended 3 months may compromise the ScleralEase performance and safety.
- Stop using the ScleralEase in case of pain and/or discomfort, and consult your eye care professional.

Precautions

- **Before using for the first time**, and after each use, clean the device with 70% isopropyl alcohol and allow it to air dry. If the device is cleaned just before use, make sure it is completely dry before application - applying isopropyl alcohol near the eyes can pose a risk.
- Please handle the device with clean hands. Keep it away from substances such as hand cream, hair gels, nail polish remover and any oxidizing agents.
- If the small tip touches the eye, don't pull - slide it to the corner while turning until it releases. The large tip shouldn't attach under normal use, but if it does, release the vent and gently pull away. If there's pain or injury, contact your eye care professional.

Instructions for Use

1. Choose Your Method

- Without suction:** Hold the ScleralEase using the flat sides at the base to help guide and position the lens onto your eye
- With suction:** Use your forefinger and thumb to pinch the vent holes on the ScleralEase while placing the lens. This creates a gentle suction to hold the lens in place.

Application

2. Place the Lens on the ScleralEase

- Place your clean scleral lens on top of the ScleralEase (large side of the device).

- Fill your scleral lens with solution following the scleral lens device instructions for use.

3. Apply the Lens onto Your Eye

- Hold the eye lids open.
- Carefully place the scleral lens on the surface of the open eye.
- If using suction: Once the lens touches your eye, release your thumb and forefinger from the vent to remove suction.
- Gently pull the ScleralEase away, leaving the lens on your eye.

4. After application

- If the lens surface needs remoistening, dip the truncated portion into contact lens solution, move the truncated portion wiper up and down the lens until the desired wetting is achieved.

Removal

- Moisten the tip of the remover with sterile saline solution (small side of the ScleralEase).
- Place the remover tip against the outer third of the scleral lens until suction is achieved.
- Gently pull the scleral ease away from the eye to allow the scleral lens to be removed from the surface of the eye.

Always follow the advice and instructions given by your eye care professional for the best technique.

Cleaning

After each use, clean ScleralEase with 70% isopropyl alcohol and allow it to air dry completely before storing it in the vial. Ensure the air channel remains clear and free from debris. Replace every 3 months or sooner if wear or damage is observed.

Reporting of Serious Incidents

All serious incidents in relation to the ScleralEase must be reported to ODC Industries via email:

quality@odc-industries.com

If you reside in the EU, all serious incidents in relation to the ScleralEase must also be reported to the Competent Authority of the Member State in which it occurred.

Waste Disposal

Dispose of ScleralEase and packaging according to local regulations in force at the moment of disposal.



Manufacturer



Keep away from sunlight



Caution



Medical Device



Consult instructions for use



Single patient multiple use



Date of Manufacturer



Unique device identifier



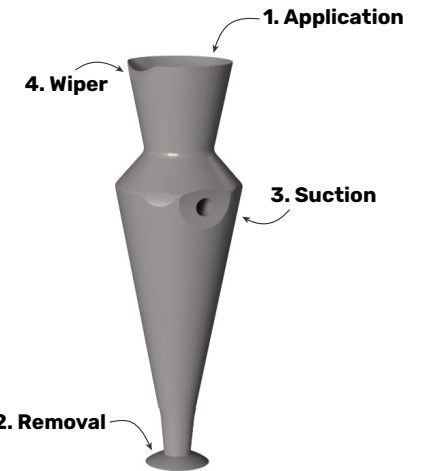
Catalogue number



Batch code



ODC Industries
Rue Thomas
Edison
ZA Bois Vert
Ploërmel
56800
France



Product Functions

1. Application

Ergonomic Applicator Design: Optimized for stable placement of the lens onto the ocular surface.

2. Removal

Refined Remover Geometry: Designed with a tapered shaft for enhanced grip and precision during removal.

3. Suction

Optional Suction Use: Features an integrated vent system, offering users the flexibility to apply the lens using either suction or non-suction techniques.

4. Wiper

Cutaway "Squeegee" Edge: Allows gentle squeegeeing of the lens after insertion to improve post-insertion comfort and vision.