

ONE-STEP MAINTENANCE SYSTEM FOR SOFT CONTACT LENSES CONTAINING HYDROGEN PEROXIDE WITH COLOUR INDICATOR.

This system consists of 360 disinfecting solution and 36 neutralizing tablets.

It disinfects and cleans all kind of soft contact lenses (disposables, daily and extended use). The system guarantees full disinfections mainly because it does not produce oxygen-bubbles during the disinfecting step and the system is faster than the rest of peroxide ones. In an hour the lenses are ready to use them.

The neutralizing tablet acts as follows:

1. It breaks down all the hydrogen peroxide when the contact lenses have been totally disinfected and to turn the medium into a STERILE, PRESERVATIVE- FREE saline solution that is fully compatible with the eye, so the contact lens does not have to be rinsed afterward.
2. The neutralization of the peroxide can be observed because the solution becomes yellow.
3. The wetting agent, HPC, increases the comfort of wear.
4. This tablet reduces the disinfection and neutralization process to 1 hour.

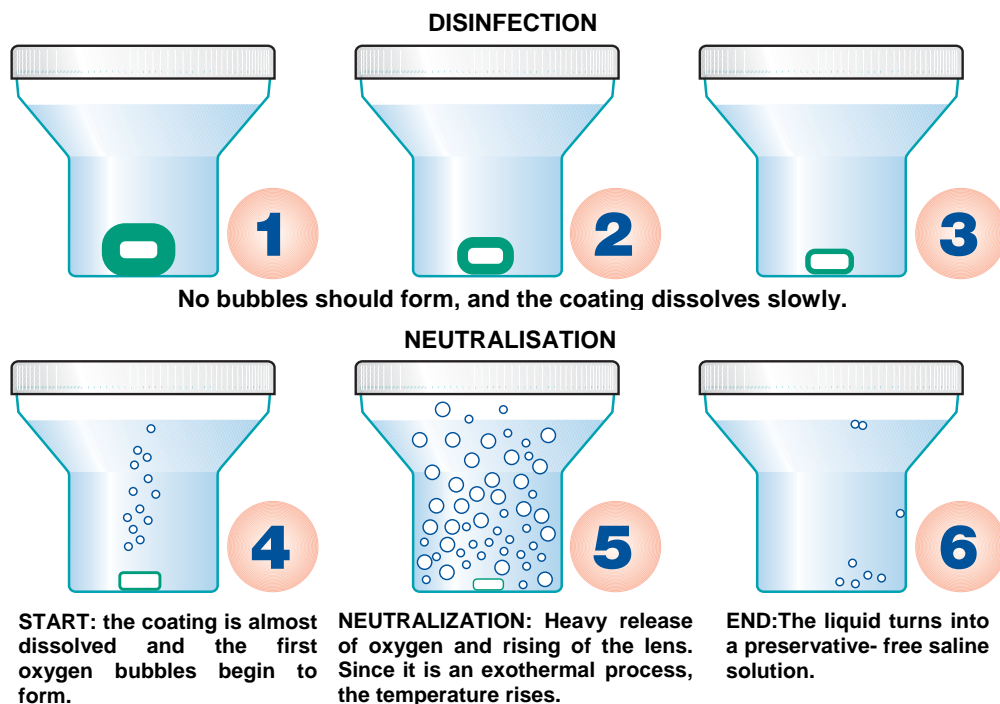
COLOUR INDICATOR

The colour indicator is vitamin B2, riboflavine 5-phosphate.

If we use this vitamin inside the neutralization tablet we will get a yellow solution which will never be harmful for the different parts of the eye. The effect of the vitamin B2 on the eye is very favourable specially on little scratches and irritations on the cornea.

The yellow pigment doesn't affect or tint the contact lens. In case this could ever happen, the colour will disappear using saline solution or just with the daylight UV radiation.

Figure 1. How the system acts.

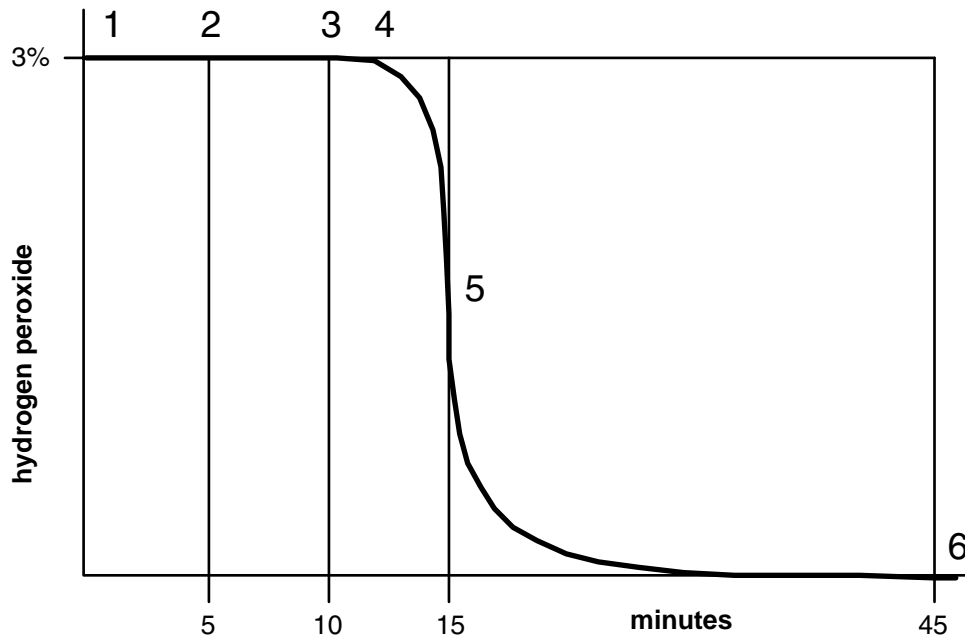


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The function of the neutralizing tablet is to break down all the hydrogen peroxide when the contact lenses have been totally disinfected (it takes about 12 minutes for a 3% hydrogen peroxide concentration) and to turn the medium into a STERILE, PRESERVATIVE-FREE saline solution that is fully compatible with the eye, so the contact lens does not have to be rinsed afterwards. The neutralization of the peroxide can be observed because oxygen bubbles are released.

Microbial catalase is the principle active responsible to neutralize hydrogen peroxide completely. We decided to change catalase from bovine origin to microbial in order to avoid BSE risk.

Figure 2. Neutralization curve



Tests in our laboratories demonstrated that the peroxide solution takes no longer than 9 minutes to reduce media of 10^8 microorganisms (CFU)/ml of *Ps. Aeruginosa*, *S. Epidermidis* and *Aureus*, *Serratia M.*, *E. Coli* and *Candida Albicans* by 99.9%. Therefore we can assure that the system guarantees full disinfection of the contact lenses before the neutralization process starts (the moment when oxygen bubbles start to be given off strongly).

The neutralizing tablet has an activity of around 5000 international units so it does not take longer than 15 minutes to neutralize the hydrogen peroxide. When the tablet is dissolved completely, a final solution is obtained in less than one hour. This solution does not contain any preservative and is neutral pH.

The clinical tests performed with 50 soft contact lens users who tried the system on a daily basis for 5 months demonstrated that the product is totally harmless, and there were no cases of rejection of the system.

The enzymatic activity of the neutralizing tablet is approximately 5000 IU, so it does not take more than 15 minutes for all the hydrogen peroxide to be broken down. The total dissolution of the tablet leads to a change in the pH and an incorporation of salts that turn the medium into a neutral isotonic solution in less than one hour.

The system lasts 30 months, as long as it is not removed from the protective container. The catalase becomes unstable at temperatures over 40 °C, so we recommend that during the summer the product should not be kept in warm places, e.g. inside cars exposed to direct sunlight.

The lens case has a small expansion chamber and valves (holes in the lid of the storage case) to let out the oxygen that is released during the neutralization of the peroxide.

The massive release of bubbles during the neutralization has the effect of rinsing the lenses thoroughly.

The final solution does not contain any preservative and as such cannot be used as a lens storage solution for more than 48 hours.

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COMPARISON OF THIS PEROXIDE SYSTEM WITH OTHER ONE-STEP SYSTEMS.

In one-step systems, direct contact between the lens and the peroxide is necessary to provide disinfection.

In a test of all of the one-step systems on the market, oxygen bubbles appeared on the lens surface during disinfection with all of the systems except for ours. This difference explains why this is the only one-step system that guarantees disinfection, because the appearance of bubbles blocks direct contact between the lens and the peroxide.

To guarantee the absence of oxygen bubbles during disinfection (twelve minutes from the addition of the tablet), the tablet has a coating that has been sufficiently proven to be tolerated by the eye.

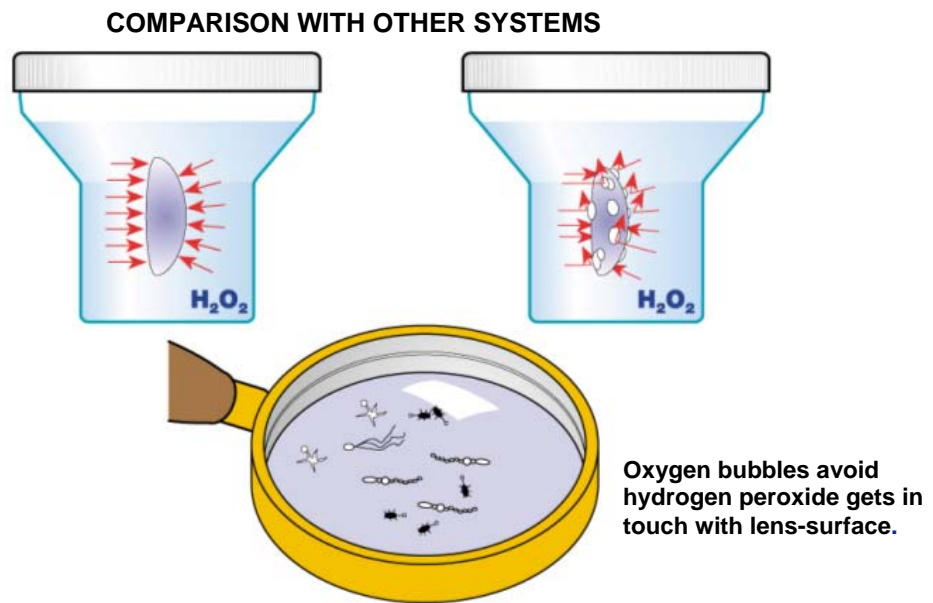


Figure 3 compares the performance of our peroxide system with other one-step peroxide disinfection systems. The system used by Disop is the only one that respects the disinfection area: 3% hydrogen peroxide for 12 minutes, the rest of the systems neutralize the peroxide to a greater or lesser degree during the first 12 minutes, which creates oxygen bubbles that inhibit disinfection when they adhere to the lens surface.

Figure 3. Comparison between one-step peroxide systems

