

DEFINITIVE



Nature: 74% Silicone Hydrogel

Definitive is a new generation in lathe-cut hydrogel materials. The oxygen permeability of the material is the highest available to lathe-cut hydrogel manufacturers and is achieved by its unique blend of fluorosilicone and hydrophilic monomers. This patent pending composition has been optimised so that unlike other silicone hydrogels it machines like a conventional HW material but unlike conventional materials it does not dehydrate on the eye during wear. The advanced polymer matrix is inherently

surface wettable and consequently no surface modification techniques are required. Definitive is also extremely soft, with the same stiffness as a conventional mid-water content hydrogel it does not suffer from the mechanical complications associated with other silicone hydrogels.

Please note that throughout the whole manufacturing process no alcohol based cleaners or solvents should be used.

Material Characteristics:

Properties	Definitive
Classification	filcon V3
USAN	Efrofilcon A
Ionic or non-ionic	Non-Ionic
Oxygen Permeability at 35°C (ISO) $X10^{-11}$ (cm ² /sec)[mlO ₂ /(ml×mmHg)]	60
Oxygen Transmissibility at 35°C (ISO) 0.08ct $X10^{-9}$ (cm ² /sec)[mlO ₂ /(ml×mmHg)]/t	75
Swell Factor	1.63 at 20°C
Water Content	75% at 20°C by refractometer 74% at 20°C by weight
Refractive Index	1.3750 at 20°C 1.3730 at 35°C
Dry Refractive Index	1.5100 at 20°C
Light Transmission	>99%
Tensile Strength (MPa)	0.39
Elongation to Break (%)	180
Modulus (MPa)	0.35
Hardness (Shore D)	84
Handling Tint	Blue
Diameter	12.70mm
Thickness	Standard

Please note: These are typical values. Always check the certificate of compliance supplied with the goods for the actual values of the batch.



Diamond Tooling

Tooling	Radius (mm)
Rough	0.30 – 0.50mm
Fine	0.30 – 0.50mm

Machining Recommendations:

Spindle Speeds:	7000 – 10,000 rpm
Rate of Cut:	Roughing 0.40 – 0.80 mm @ 1.4mm / second Fine 0.03 – 0.05mm @ 0.70mm / second
Radius of Diamond Tool:	0.50mm or less (0.25 mm recommended) 2.5° negative top rake

Environment Control:

For best manufacturing conditions Contamac recommends 19-23°C with a relative humidity of 45%-60%.

Polishing

The recommended polishing compound is Contapol 2 with a spindle speed of 3500rpm and minimal weight. With the above machining recommendations polishing should require a maximum of 30 seconds.

Blocking

Use low temperature blocking wax with an operational temperature of less than 60°C such as Contamac Low Melt Wax.

De-Blocking

Recommend the use of Isopar E, Petroleum Ether or equivalent in an ultrasonic bath for dissolving blocking wax and cleaning the lens.

Hydration, Sterilisation and Storage of Definitive Lenses

The choice of saline for the hydration, sterilisation and storage of lenses can have an impact on the stability of the finished lens parameters. We recommend a commercially available, non-buffered saline solution, such as those used for irrigation during surgical procedures. The pH of the saline can be adjusted to the range of 7.0-7.4 if required by the addition of analytical grade anhydrous sodium carbonate. Such adjustment should be closely monitored and this can be achieved through use of a calibrated pH meter at a controlled temperature.

Experience has shown that performing initial hydration in saline at 2-5°C can be advantageous. To enable

wet checking of lenses prior to autoclave it is recommended that they are then held at 45±5°C overnight to ensure complete hydration. Either the glass vial containing the lens can be put into an appropriate incubator or the lens can be placed in a basket and put in a heated saline bath.

Once the lens is fully hydrated and has reached ambient temperature, digitally clean with a standard soft lens cleaning solution and inspect wet parameters at room temperature 19-21°C.

Alternatively if the wet parameters do not require checking then the 45°C hydration step is not essential, as autoclaving will complete the hydration process. For autoclaving, the lens should be placed in fresh non-buffered saline solution as described above and it should be ensured that no alcohol based cleaners are used throughout the process.

It is recommended that manufacturers should keep the heat treatment of the Definitive material to a minimum. For best results, exposure at the internationally recommended temperature of 121°C for sterilisation should not exceed 30 minutes. Ramp up and cool down cycles should be kept to a minimum. Validation of the autoclave using Definitive and in the recommended parameters suggested above is required by the FDA and ISO requirements.

Care Solutions

See separate document (“Definitive Recommended Solutions”)

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