DEFINITIVE

TECHNICAL DATA

Contamac developed Definitive, the first latheable silicone hydrogel material. It became the benchmark for a new generation of lathe-cut silicone hydrogel materials, winning the Queen's Award for Innovation in 2016. In addition to providing increased oxygen permeability, its unique surface qualities and outstanding level of on-eye comfort ensure that Definitive is ideal for producing a wide range of lens designs while supporting corneal health.

Please Note: Regulatory requirements and standards vary from country to country, and are constantly evolving. As a global company we want to be sure we provide you with detailed technical information, specific to your market, where appropriate, rather than using the condensed and simplified technical information on the website. If you need to use technical data for quality paperwork, or for a regulatory submission, please contact your account manager to obtain this precise and detailed information to support your regulatory requirements, we will be happy to help.

Material Characteristics

PROPERTY	DEFINITIVE 74
Oxygen Permeability (ISO) at 35°C (Barrer)	60
Water Content at 20°C by Weight (%)	74
Swell Factor at 20°C	1.62
Refractive Index at 20°C - Hydrated	1.38
Refractive Index at 20°C - Dry	1.52
Modulus - Elasticity (MPa)	0.40
Tensile Strength (MPa)	0.75
Elongation to Break (%)	225
UV Blocker	Available
Classification (ANSI)	Efrofilcon A VB 3
Classification (ISO)	Efrofilcon A 5B (60) [74%]
USAN	Efrofilcon A

Please note: Some values may have been rounded for presentation purposes. Please contact your account manager for further details.

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Material and Lathing Recommendations

LATHE FUNCTION	DAC INCHES/MINUTE	REM µ/SECOND	OPTOFORM mm/MINUTE
Rough Cut Amount (mm)	0.40 (0.30 - 0.50)	0.40 (0.30 - 0.50)	0.40 (0.30 - 0.50)
Rough Feed Rate	4 (3 - 4)	1666 (1250 - 1666)	100 (75 - 100)
Rough Spindle Speed	8500 (7000 - 9000)	8500 (7000 - 9000)	8000 (7000 - 9000)
Rough Cut Amount (mm) (Last Pass)	0.10 (0.05 - 0.15)	0.10 (0.05 - 0.15)	0.10 (0.05 - 0.15)
Rough Feed Rate (Last Pass)	2 (1.5 - 2.5)	1000 (633- 1066)	50 (38 - 64)
Rough Spindle Speed (Last Pass)	8000 (7000 - 9000)	8000 (7000 - 9000)	8000 (7000 - 9000)
Final Feed Rate	2 (1.5 - 2.5)	833 (633- 1066)	50 (38 - 64)
Final Spindle Speed	7500 (7000 - 8000)	7500 (7000 - 8000)	7500 (7000 - 8000)
Final Cut Amount (mm)	0.05 (0.05 - 0.10)	0.05 (0.05 - 0.10)	0.05 (0.05 - 0.10)

Environment Control

For best manufacturing conditions Contamac recommends 21°C (± 2) with a relative humidity of 45% - 60%.

Polishing

The recommended polishing compound is Contapol 2 with a spindle speed of 3500 rpm 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 60°C such as Contamac Low Melt Wax.

De-Blocking

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

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Hydration, Sterilisation and Storage

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 7.00 -7.40 if required by the addition of analytical grade anhydrous sodium carbonate. Such adjustment should be closely monitored and this can be achieved with the 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°C (± 5) 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 keep the heat treatment of 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 REGIME

Multi Purpose Solutions

Multi-purpose solutions are the preferred choice for use with Definitive. Stability studies across a range of the most readily available products have shown compatibility with all products tested.

Hydrogen Peroxide Solutions

Peroxide solutions may be used with Definitive, but exposure to peroxide should be limited by using a disc-based system preferably. Should a tablet neutraliser be used, it is recommended that the tablet be added at the same time as the solution.
Systems that typically use a neutralising solution and allow lenses to remain in contact with the fully active, un-neutralised solution for extended periods should be avoided. If such systems are used then there is a risk that the stability of the lenses will be compromised.

Enzymatic Cleaners

Enzymatic cleaners may be used, if required, with Definitive.

Contamac does not recommend the use of alcohol based cleaners with Definitive.

Please note that we make no comments on the efficacy of any solutions for lens cleaning, disinfection or general performance. These recommendations and comments only refer to compatibility with the lens material. For efficacy claims, please refer to solution manufacturers' literature.

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