ELIX POLYMERS

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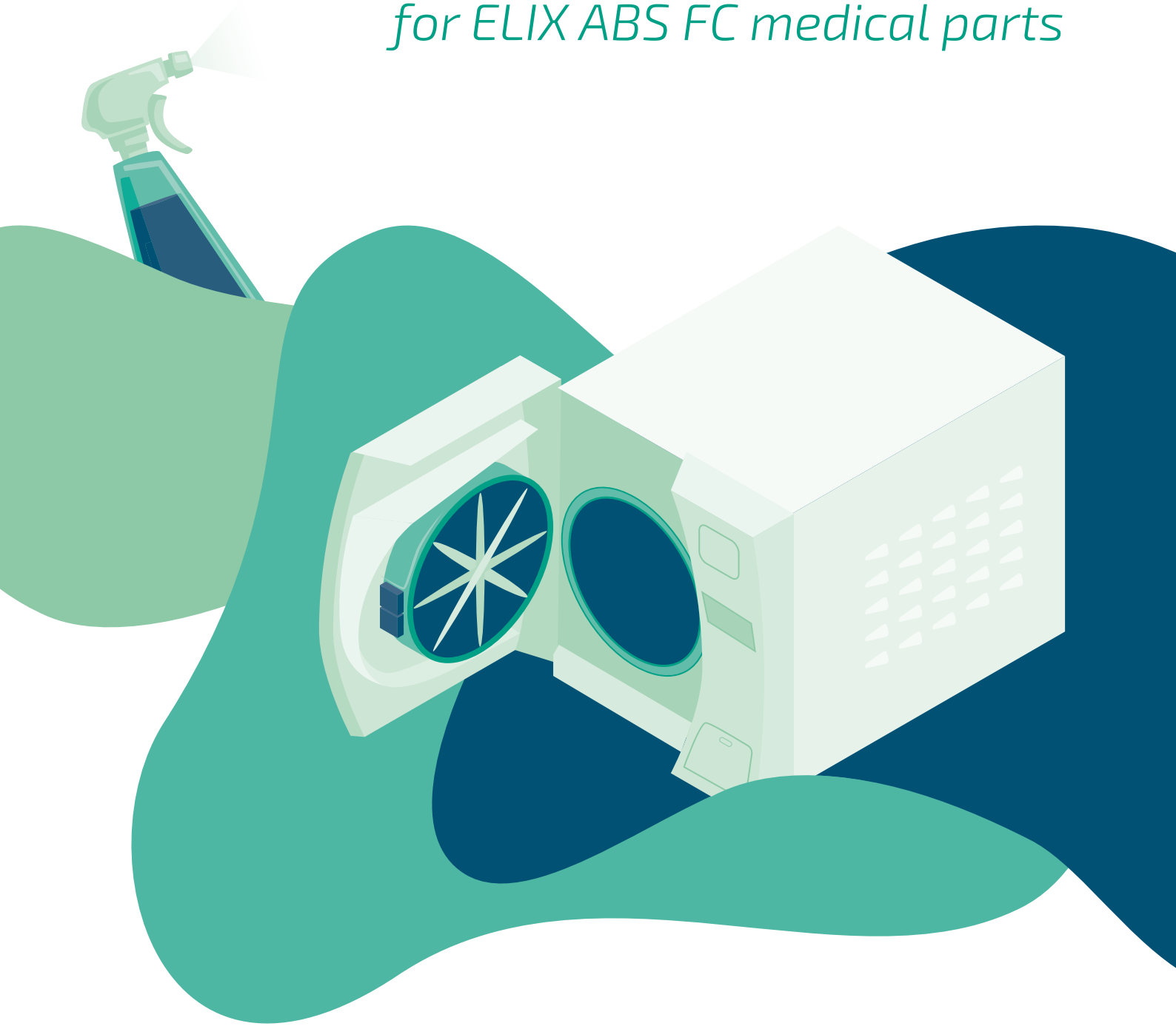
Cleaning, Disinfection and Sterilisation methods

for ELIX ABS FC medical parts



Cleaning, Disinfection and Sterilisation methods
for ELIX ABS FC medical parts

Medical devices made of ELIX FC ABS material may need to be cleaned, disinfected and/or sterilised. This short guide provides information about ELIX ABS FC chemical resistance to typical used cleaning agents and chemical substances.

Cleaning / Disinfection

Thanks to their good chemical resistance, ELIX Medical ABS FC grades can be cleaned and disinfected with a wide range of products available in the market. However, chemical resistance of the finished parts will be a function of several different parameters such as the type of chemical, temperature, duration of exposure or contact, concentration of the medium (pure substance or dilute), environmental conditions, stress situation inside the moulded part and external stresses that may be applied to the part. We thus recommend carrying out additional tests under the specific conditions that will prevail in practice.

The table below shows the chemical resistance level of ELIX ABS FC materials after contact exposure to the specified chemical substance:

Cleaning / Disinfection Substance	ELIX ABS M203 FC	ELIX ABS M205 FC
Deionised water	Good	Good
Saline solution	Good	Good
Hydrogen Peroxide solution	Good	Good
Diluted alcohols (ethanol, propanol etc.)	Good	Good
Ammonia 4% water – ammonium hydroxide	Good	Good
Sodium hypochlorite 3-5% water	Good	Good
Alkaline solutions	Good	Good

Specific chemical resistance tests on ELIX FC medical grades have also been conducted with different disinfection products for medical devices normally used in hospitals and easily available in the market. The results are reported in the following table:

Disinfection products available on the market	Main composition	ELIX ABS M203 FC	ELIX ABS M205 FC
Surfa'Safe Premium®	Didecyldimethylammonium chloride (<2.5%), Amines (<2.5%)	Good	Good
Meliseptol Foam Pure®	Propanol (20%) Didecyldimethylammonium chloride (0.25%)	Good	Good
Clinell Alcohol Wipes Red®	Isopropanol 70%	Good	Good

Depending on the medical device application, the medical ABS part may be exposed to internal or external stresses during contact with the cleaning / disinfection agent and during its functional use. For this reason ELIX can perform tests combining both stress and chemical contact at the same time in the tested specimens, according to ISO 22088-3 (Bent Strip Method) and perform subsequent tensile tests.

When additional external stress was applied, no cracks were detected after 24h with the product Surfa'safe Premium. No cracks were detected either with material M205FC and the product Meliseptol, and a better chemical resistance than material M203FC to this product was observed. The disinfectant Clinell Alcohol Wipes Red showed the most aggressive attack with both M203FC and M205FC at those conditions.

In addition to cleaning / disinfection substances, accidental contact with other chemical substances is also possible, but the level of risk of the presence of such chemicals depends on the application and in the case of medical devices may be very low. However, a list of complementary chemicals and chemical resistance level of ELIX FC grades is provided in the table below:

Substance	ELIX ABS M203 FC	ELIX ABS M205 FC
Dilute organic and inorganic acids	Good	Good
Oils and greases	Good	Good
High-boiling aliphatic hydrocarbons (e.g. White spirit)	Good	Good
Aromatic hydrocarbons	To be avoided*	To be avoided*
Concentrated acids	To be avoided*	To be avoided*
Ethers	To be avoided*	To be avoided*
Esters	To be avoided*	To be avoided*
Ketones	To be avoided*	To be avoided*
Chlorinated hydrocarbons	To be avoided*	To be avoided*

**These media cause incipient dissolution, incipient swelling, whitening and stress cracking in Elix ABS.*
The information provided above shall be considered as a guide to the behaviour of ELIX ABS to" face-to-face" chemicals.

Sterilisation

When medical device sterilisation is required before use, three alternative methods are available: Irradiation (Gamma or E-beam), Ethyleneoxide (EtO) and Steam Sterilisation (Autoclave).
Parts moulded from ELIX ABS M203FC and ABS M205FC materials can be sterilised using radiation (Gamma or E-beam), or ethylene oxide. Steam sterilisation (autoclave) is not recommended as it uses steam heated to 121-134 °C, exceeding the thermal resistance of the material.

Sterilisation method	ELIX ABS M203 FC	ELIX ABS M205 FC
 Irradiation (gamma, e-beam)	✔	✔
 Ethylene oxide (EtO)	✔	✔
 Steam sterilisation (autoclave)	✖	✖

The sterilisation method and the number of sterilisation cycles that a part made from ELIX ABS M203FC or ABS M205FC materials can withstand will vary depending upon the type/grade of resin, part design, processing parameters, sterilisation temperature, and chemical environment. We recommend Manufacturers to evaluate each device to determine the sterilisation method and the number of permissible sterilisation cycles that are appropriate for the specific end-use requirements.

ELIX ABS M203FC and ABS M205FC plaques were sterilised by Gamma Irradiation at a dosage of approx. 25.0 to 40.0 KGy and ethylene oxide prior to biocompatibility testing with positive results.