QUADRANT
ENGINEERING PLASTIC PRODUCTS

STEAM STERILISATION

Steam sterilisation is commonly used in the medical industry for sterilising all kinds of re-usable equipment, devices, instruments, trays... and is conducted in a pressurised vessel that allows the presence of superheated saturated steam. The main purpose of sterilisation is to kill all micro-organisms on a certain part.

Before sterilisation the parts are normally cleaned with soap first, disinfected with alkaline products at 93°C next and finally put in a sealed aseptic packing. This special aseptic packing lets the steam through during the steam sterilisation process, but prevents the parts from being contaminated afterwards, during handling and storage. It is also transparent to be able to see which part is in the package. The parts are only removed from this packaging just before they are actually used.

A steam sterilisation cycle mainly consist of three phases:

- Phase 1 : pre vacuum cycle and pressure equilibrium cycle.
- Phase 2 : sterilisation
- Phase 3 : drying under vacuum.

Commonly used cycles are 121°C / 1 bar (overpressure) and 134°C / 2 bar but exceptionally even a very short cycle of 143°C / 3 bar is used.

To prevent corrosion of the whole system a boiler feed water additive is normally added to the water, that is used for the production of the steam. This product is normally neutral (pH-value of 7-8) to prevent chemical attack of the parts to be sterilised.

Plastics have some very interesting advantages over stainless steel and glass like low density, high impact resistance, design flexibility, easy processability and they also exhibit an excellent cost/performance ratio. These features make more and more designers tend to use them in medical equipment.

As a result of this evolution, the high cycle autoclavability of plastics has become a hot topic, so we decided to do a practical test on a number of Quadrant EPP materials.

The main purpose of this test was to determine the influence of repeated steam sterilisation on the mechanical properties and more particularly on the notched impact strength.

Results:

The table below shows the effect of repeated steam sterilisation on the CHARPY notched impact strength, measured according to ISO 179-1/1eA at 23°C on dry test specimens. The values in this table show the retention of the impact strength - in % of the original value - after exposure of the test specimens to a certain number of autoclaving cycles.

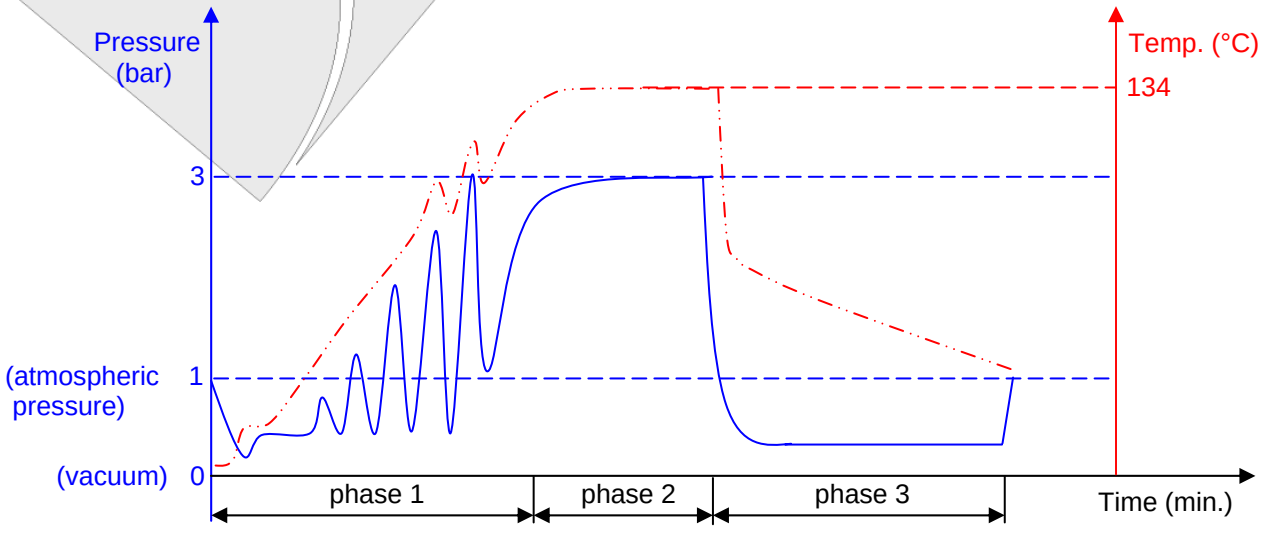
	Retention of CHARPY notched impact strength as a function of the number of autoclaving cycles (0 ⇒ 500)				
QEPP MATERIALS ⇓	**0**	**50**	**100**	**250**	**500**
ERTACETAL® C natural	100	83	80	58	x
ERTALYTE® natural	100	100	32	28	x
KETRON® PEEK-1000 natural	100	x	x	105	102
TECHTRON® HPV PPS	100	x	x	65	70
RADEL® PPSU 1000 black	100	x	x	102	102
PSU 1000 natural	100	x	x	62	54
ULTEM® PEI 1000 natural	100	x	x	95	94
SYMALIT® PVDF 1000 natural	100	x	x	105	100

x : not tested

Remarks:

1. The steam sterilisation was carried out in an autoclave in a hospital at a temperature of 134°C and an overpressure of 2 bar. During sterilisation, the temperature and the pressure was continuously monitored because the temperature of 134°C had to be maintained during at least 3 min, otherwise the sterilisation process was not valid and had to be repeated.
2. The boiler feed water additive was Claytaliquid, which had a pH value of 7-8. The concentration of this additive depended on the hardness of the water, but it was certainly very low.
3. A steam sterilisation cycle consisted of the following three phases :

Phase 1: from 0 to 15 min : pre vacuum cycle and pressure equilibrium cycle with some pressure pulses.
Phase 2: from 16 to 21 min : sterilisation at 134°C and 2 bar overpressure (at least 3 min).
Phase 3: from 21 to 34 min : drying under vacuum.



4. The ERTALYTE® specimens, which were subjected to 100 and 250 cycles, had become very brittle and showed very large cracks on the surface. As a result, the notched impact resistance quickly dropped below 30% of the original value.
5. After a few cycles the colour of the KETRON® PEEK-1000 specimens changed to an olive-green colour. This typical change in colour was only noticeable on a very thin surface layer.

CONCLUSIONS BASED ON THE EVOLUTION OF THE CHARPY NOTCHED IMPACT STRENGTH WITH THE NUMBER OF AUTOCLAVING CYCLES (*)

- The test results clearly show that SYMALIT® PVDF 1000 natural, ULTEM® PEI 1000 natural, KETRON® PEEK-1000 natural and RADEL® PPSU 1000 natural are very suitable for repeated steam sterilisation.

- Under the given autoclaving conditions, ERTACETAL® C natural offers acceptable autoclavability up to at least 250 cycles and TECHTRON® HPV PPS & PSU 1000 natural up to at least 500 cycles. ERTALYTE® natural on the other hand only successfully survives a little more than 50 cycles.

(*) conclusions based on the very often used criterion of an acceptable decrease of the considered physical property of 50% compared with the original value ; depending on the requirements imposed by the application, it may be necessary to examine the influence of the number of sterilisation cycles on other or additional physical properties such as surface aspect, unnotched impact strength, tensile or flexural strength, stiffness, …) and/or to adapt the evaluation criterion (e.g. only a decrease of 20% rather than 50% can be allowed).

P.S. Considering the inherently different properties of the plastics mentioned above, the influence of the design of the parts, cycle times, chemical environment (boiler feed water additives, etc.), the allowable number of sterilization cycles and final suitability of a chosen plastics material for a given application is to be determined by the user under practical operating conditions.