Datasheet

MC/RS Series

THERMOLAST® M

The MC/RS Series is your material solution for applications requiring basic medical approvals such as ISO 10993-5. The series is characterized by excellent resealing properties. The compounds are produced exclusively by a special medical unit and available in translucent colors.

Typical applications

- Closures
- Infusion stoppers
- Membranes

Material advantages

- Adhesion to PP
- DMF listed
- Excellent compression set
- For injection molding and extrusion
- Free of animal basedingredients
- KRAIBURG TPE Medical service package (description below)
- Outstanding resealing properties
- Sterilizable (autoclave134 °C, gammaradiation 2x35 kGy, EtO)
- Tested according to ISO 10993-5

Processing Method: Extrusion, Injection Molding

	Color / RAL DESIGN	Hardness DIN ISO 7619 ShoreA	Density DIN EN ISO 1183-1 g/cm3	Tensile Strength [1] DIN 53504/ISO 37 MPa	Elongation at Break [1] DIN 53504/ISO 37 %	Tear Resistance ISO 34-1 Methode B (b)(Graves) N/mm	CS 72 h/23 °C DIN ISO 815-1 Method A %	CS 24 h/70 °C DIN ISO 815-1 Method A %	CS 24 h/100 °C DIN ISO 815-1 Method A %
TM3RST	translucent	33	0.890	7.5	800	12.0	9	20	30
TM4RST	translucent	43	0.890	9.0	850	14.0	11	23	30

[1] Deviating from ISO 37 standard test piece S2 is tested with a traverse speed of 200 mm/min.

All values published in this data sheet are rounded average values.
Specification limits are based on three-fold standard deviation from the average value.

This datasheet is an extract of the KRAIBURG TPE program. Please contact KRAIBURG TPE to select the compound suitable for the requirements.

MC/RS Series | THERMOLAST® M

THERMOLAST® M Medical-Service-Package

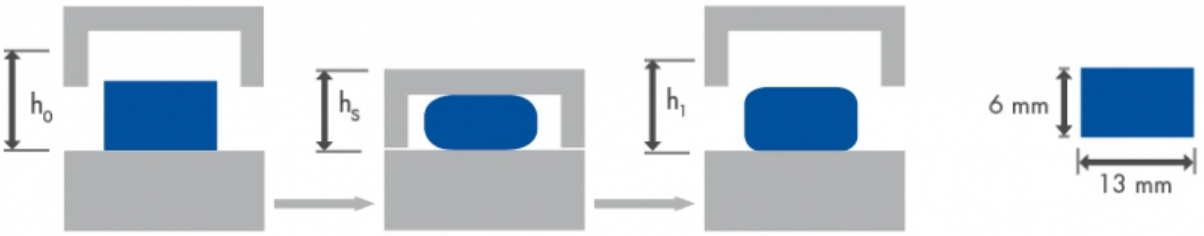
All medical compounds are tested according to ISO 10993-5 (Cytotoxicity) and listed under a Drug Master File.
Selected medical compounds are tested according to described medical basic approvals: USP Class VI (chapter 88), USP 661 (in vitro), ISO 10993-4 (Haemolysis, indirect in human blood), ISO 10993-10 (Intracutaneous Irritation) and ISO 10993-11 (Acute Systemic Toxicity). No changes in formulation or process (except of necessary adjustments e.g. due to new regulations).
If any changes are necessary, KRAIBURG TPE will inform the customers at least 24 months in advance.
THERMOLAST® M Compounds are produced on a dedicated medical compounding line.

Compression Set

MC/RS Series | THERMOLAST® M

Compression Set (acc. DIN ISO 815)

For the compression set testing the following specimen is used:
The specimen is a cylindrical disk shaped 6 mm thick and 13 mm in diameter.



h_0 = initial thickness of the test piece (in mm)
h_1 = thickness after recovery (in mm)
h_S = height of the specimen (in mm)

$$\text{Compression Set} = \frac{h_0 - h_1}{h_0 - h_s} \times 100$$

The specimen is compressed by 25%. The compressed specimen is heated to the test temperature. DIN ISO 815 discribes two methods.

Method A: The specimen is allowed to recover immediately after its aging in the oven and then cooled down to room temperature. After 30 minutes the thickness of the specimen is measured and the compression set calculated.

Method B: The specimen is cooled down to room temperature after its aging in the oven and then allowed to recover.

Test results gained from method B are in general higher than from method A.

MC/RS Series

THERMOLAST® M

Processing Guideline Injection Molding	
Cylinder temperature	180 - 200 - 220 °C, max. 250 °C (360 - 390 - 430 °F, max. 480 °F)
Hotrunner	Hot runner temperatures: 200 -250 °C (390 - 480 °F). The runner should be empty after a maximum of 2 - 3 shots.
Injection pressure	200 - 1000 bar (2900 - 14504 psi) (depending on the size and weight of the part).
Injection rate	In general, the fill time should not be more than 1–2 seconds.
Hold pressure	We recommend to derive the optimum hold pressure from determining the solidification point, starting with 40 % - 60 % of the required injection pressure.
Back pressure	20 - 100 bar; if colour batches are used, higher back pressure is necessary.
Screw retraction	If an open nozzle is used processing with screw retraction is advisable.
Mold temperature	25 - 40 °C (77 - 104 °F)
Pre drying	Pre drying of the material is not necessary; if surface moisture forms as a result of changes in temperature, the material should be dried for 2 - 4 hours at 60 - 80 °C (140° F).
Needle valve	With materials < 50 Shore A the use of a needle valve is advisable.
Screw geometry	Standard 3-zone polyolefine screw.
Residence time	The residence time is to be set as short as possible with a maximum of 10 minutes.
Cleaning recommendation	For cleaning and purging of the machine it is appropriate to use polypropylene or polyethylene. Machine must be PVC-free.

MC/RS Series

THERMOLAST® M

Processing Guideline Extrusion	
Cylinder temperature	160 - 180 - 200 °C, max. 250 °C (320 - 360 - 390 °F; max. 480 °F)
Screw geometry	Standard three-zone screw (e.g. polyolefin screw). The screw must be able to provide sufficient shearing.
L/D ratio	At least 25
Compression ratio	At least 3.5 : 1
Screens / breaker plate	A breaker plate and a screen pack are generally recommended in the extruder configuration in order to increase pressure.
Die land	<= 3 mm (<= 0,12 in.)
Extruder Head	Ca. 200 °C (390 °F)
Die temperature	Ca. 200 - 230 °C (390 - 450 °F)
Pre drying	Pre drying of the material is not necessary; if surface moisture forms as a result of changes in temperature, the material should be dried for 2 - 4 hours at 60 - 80 °C (140 - 175 °F).
Calibration	Generally not necessary; support elements may be required when extruding THERMOLAST® compounds with high hardness or when coextruding with standard thermoplastics.
Cleaning recommendation	For cleaning and purging of the machine it is appropriate to use polypropylene or polyethylene. Machine must be PVC-free.