

MC/tl Series
THERMOLAST® M

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

Typical applications

- Flexible Connections
- Mouthpieces
- Seals
- Soft touch
- Valves

Material advantages

- Adhesion to PP
- DMF listed
- Excellent compression set
- For injection molding and extrusion
- Free of animal based ingredients
- KRAIBURG TPE Medical service package (description below)
- Sterilizable (autoclave 134 °C, gammaradiation 2x35 kGy, EtO)
- Tested according to ISO 10993-5

Processing Method: Extrusion, Injection Molding

| | Color / RAL DESIGN | Hardness DIN ISO 7619-1 ShoreA | Density DIN EN ISO 1183-1 g/cm ³ | 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 % |
|---------------|--------------------|--------------------------------------|---|--|---|---|--|--|---|
| TM3MED | translucent | 27 | 0.880 | 6.5 | 750 | 10.0 | 15 | 28 | 47 |
| TM4MED | translucent | 36 | 0.880 | 8.0 | 800 | 11.5 | 16 | 26 | 43 |
| TM5MED | translucent | 46 | 0.880 | 10.0 | 850 | 14.5 | 19 | 32 | 46 |
| TM6MED | translucent | 56 | 0.880 | 11.0 | 750 | 17.0 | 22 | 33 | 51 |
| TM7MED | translucent | 68 | 0.890 | 13.0 | 800 | 23.5 | 30 | 38 | 55 |
| TM8MED | translucent | 80 | 0.890 | 15.0 | 750 | 32.5 | 38 | 46 | 59 |
| TM9MED | translucent | 89 | 0.890 | 16.0 | 650 | 46.0 | 40 | 54 | 69 |

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.



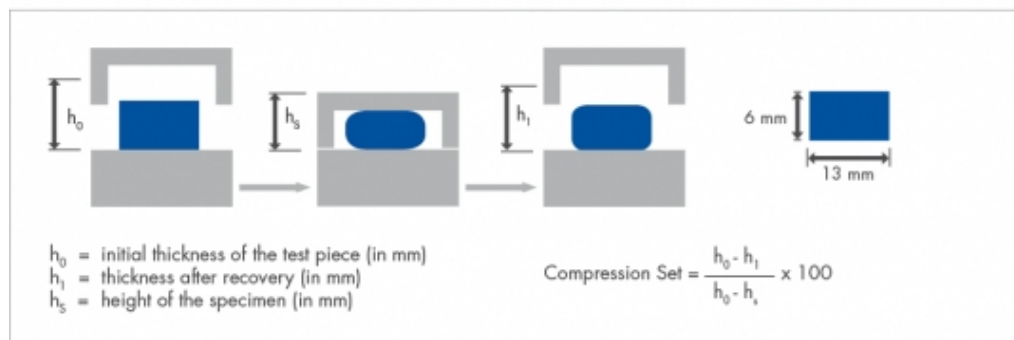
THERMOLAST® M Medical-Service-Package

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), 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

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.



The specimen is compressed by 25%. The compressed specimen is heated to the test temperature. DIN ISO 815 describes 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/tI Series
THERMOLAST® M
Processing Guideline Injection Molding

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|-------------------------|--|
| 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 color 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) |
| Predrying | 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). |
| 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/tI 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) |
| Predrying | 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. |

