



A safe part of the medical and pharmaceutical industry

# THERMOLAST<sup>®</sup> M



*CUSTOM-ENGINEERED TPE AND MORE*

## KRAIBURG TPE's recent situation in the medical market

In the past KRAIBURG TPE provided two compounds on his portfolio which are appropriate for the use in medical applications.

- [FD/M – Serie](#) (Adhesion to PP)
- [FD/Co/1Vt-Serie](#) (Adhesion to PC, ABS and PC/ABS)

## KRAIBURG TPE in the medical market today

KRAIBURG TPE has defined the medical device market as a new strategic market field!

### Objectives:

- Becoming the leader of innovation and authority of the medical and pharmaceutical industry for TPE-S
- Maximum of product safety, quality and reliability
- The new THERMOLAST® M Portfolio and the unique medical-service-package are our future!

## A safe part of the medical and pharmaceutical industry

THERMOLAST® M was developed for applications up to the liability risk of indirect blood contact.

All THERMOLAST® M Materials are able to be in contact with pharmaceutical mediums, which will be lead in the human body, rather to the blood circuit.



## THERMOLAST® M Portfolio MT – Serie: TMxMED



### Applications:

Gaskets, Valves, medical Hoses,  
Soft-Touch, flexible Connections, etc.

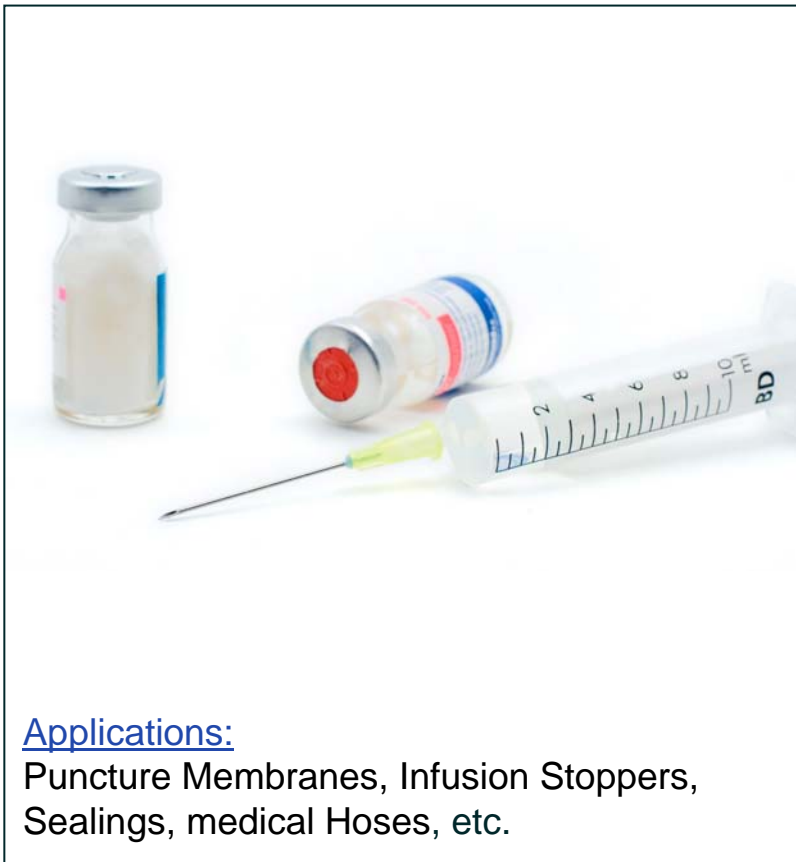
### Compound properties:

- Gamma-Sterilization (2 x 35kGy)
- Hot Steam-Sterilization (134° C)
- EtO-Sterilization
- Translucent
- Excellent compression-set
- Adhesion to PP and HDPE
- Hardness from 30 until 70 Shore A
- Drug Master Files und Medical

### Approvals according to:

- USP Class VI
- ISO 10993-5 (Cytotoxizität)
- ISO 10993-10 (Sensibilisation)
- ISO 10993-11 (Systemtoxizität)
- USP 6.6.1 (chemical/physical interactions)

## THERMOLAST® M Portfolio MT/RS – Serie: TMxRST



Applications:

Puncture Membranes, Infusion Stoppers,  
Sealings, medical Hoses, etc.

Compound properties:

- Gammasterilization (2 x 35kGy)
- Hot Steam-Sterilization (134° C)
- EtO-Sterilization
- Excellent resealing properties
- Excellent compression-set
- Hardness 35 and 45 Shore A
- Translucent
- Adhesion to PP and HDPE
- Drug Master File and Medical Approvals according to:
  - USP Class VI
  - ISO 10993-5/-10/-11
  - USP 6.6.1
  - Extractable Study for TM3RST

## THERMOLAST® M Portfolio MT/HE – Serie: TMxHET



### Applications:

Drip Chambers, Squeeze Bottles, Luer Lock, etc.

### Compound properties:

- Gammasterilization (2 x 35kGy)
- Hot Steam-Sterilization (134° C)
- EtO-Sterilization
- High transparent
- Adhesion to PP
- Hardness 55 Shore D
- Excellent elasticity
- Drug Master File and Medical Approvals according to:
  - USP Class VI
  - ISO 10993-5/-10/-11
  - USP 6.6.1

## THERMOLAST® M Portfolio MT/CO & MT/CO/RS – Serie: TMxADT

**Sample Materials are available,  
Product Launch 2Q 2009**



Applications:

Drip Chambers, Squeeze Bottles, Luer Lock,  
etc.

Compound properties:

- Gammasterilization (2 x 35kGy)
- EtO-Sterilization
- Adhesion to PC, ABS and PC/ABS
- Good resealing properties (for 30 and 40 Shore A)
- Very good compression-set
- Translucent
- Hardness from 30 until 60 Shore A
- Drug Master File and Medical Approvals according to:
  - USP Class VI
  - ISO 10993-5/-10/-11
  - USP 6.6.1
  - Extractable Studie for TM3ADT



## THERMOLAST® M Portfolio MT/CR – Serie: TMxCRT

**Sample Materials are available,  
Product Launch 2Q 2009**



Applications:

For all applications in contact with aggressive mediums (z. B. Isopropanol)

Compound properties:

- Gammasterilization (2 x 35kGy)
- EtO-Sterilization
- Excellent media-resistance (e.g. Isopropanol)
- No oil migration
- Adhesion to PP
- Hardness 55 Shore A
- Translucent
- Excellent elasticity
- Drug Master File und Medical Approvals according to:
  - USP Class VI
  - ISO 10993-5/-10/-11
  - USP 6.6.1

## THERMOLAST® M Portfolio MT/BP – Serie: TMxBPT

**Technical feasibility is ongoing; Sample materials are available  
Product Launch 4Q 2009**



Applications:

For all applications which requires excellent barrier-properties to oxygen and steam

Compound properties:

- Gammasterilization
- EtO-Sterilization
- Excellent barrier-properties
- Adhesion to PP and HDPE
- Hardness 50 Shore A
- Very good Resealing properties
- Translucent
- Drug Master File und Medical Approvals according to:
  - USP Class VI
  - ISO 10993-5/-10/-11
  - USP 6.6.1

## THERMOLAST® M Portfolio MT/SY – Serie: TMxSYT

**Technical feasibility is ongoing; Sample materials are available  
Product Launch 4Q 2009**



Applications:  
Injection plugs

### Compound properties:

- Gammasterilization
- EtO-Sterilization
- Hot Steam-Sterilization (134° C)
- 65 Shore A
- Permanent, not migrating, sliding properties on topas, glass and PP
- Translucent
- Adhesion to PP
- Drug Master File and Medical Approvals according to:
  - USP Class VI und 6.6.1
  - ISO 10993-5/-10/-11

## The THERMOLAST® M Service-Package

- All medical compounds in the portfolio are tested according to all the described medical approvals and are deposited in a Drug Master File
- Extractable studies for selected compounds, which have especially been developed für applications with contact to pharmaceutical media
- No change in formulation or process, except of necessary adjustments due to new regulations.
- An obligation to inform our customers at least 24 months in advance if any changes to resin formulations or processes are necessary due to change in regulations
- At least 24 months delivery stability in the change-over period
- One special medical compounding line for production
- Global sales, technical and development service

## Advantages of THERMOLAST® M in comparison to:

### Medical rubber and EPDM/PP

- Optimal reliability with the unique KRAIBURG TPE Medical service package
- No chemical cross linking of the compound is taking place
- Optimal purity of used raw materials is guaranteed
- Easy processing and shorter cycle times
- Possibility of processing in 2-K injection moulding
- Translucent compounds are available
- Compliance with clean room processing standard is easier with THERMOLAST® M than with medical rubber
- No post-processing of the medical device are necessary (e.g. flashes) :  
Time saving | Cost saving | Optimal cleanliness of the compound

## Advantages of THERMOLAST® M in comparison to:

### Medical silicon

- Optimal reliability with the unique KRAIBURG TPE Medical service package
- No chemical cross linking of the compound is taking place
- Optimal purity of used raw materials compared to solid silicon is guaranteed
- Shorter cycle times
- Lower costs of raw materials
- THERMOLAST® M provides the possibility of processing in 2-K injection moulding
- Less demands on injection machines and tools compared to silicon (expense factor 2:1)
- No further treatments of the medical device are necessary (e.g. flashes) :  
Time saving | Cost saving | Optimal cleanliness of the compound

We stand for

Speed ☼

Innovation ☼ Reliability ☼

Service ☼ Quality ☼ Flexibility ☼

You will find more information under [www.kraiburg-tpe.com](http://www.kraiburg-tpe.com).



**Thank you for your attention!**