

POLYMERS FOR INSTRUMENTS

Acetal Copolymer (POM C)

This flagship material from the 80's and 90's ultimately replaced PA6 or PA66 that both demonstrated low performance over repeated steam-sterilization cycles.

Historically, Westlake Plastics (and MTD in Europe) was the first to offer the orthopaedic industry such a material with the following benefits:

- wide range of colours to code the various sizes of ancillary instruments,
- batch traceability,
- compliance with USP VI and FDA standards.



However this material has a few drawbacks:

- degradation to steam-sterilization (134°C) depending on part design,
- poor resistance to acid agents (bleaching is rather frequent),
- weight: density of 1.42,
- Not polishable.

Machinability

Machining is easy and no particular problem is encountered with chips. Surface finish is very shiny.

Standards

On top of compliance with FDA standards, all basic POM C TICONA M25 colours were tested under ISO 10993-5/10/11 conditions.

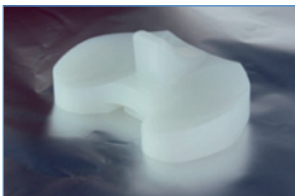
Applications

HIP:

- Trial head.
- Trial insert.
- Impactor parts (limited resistance + degradation through repeated sterilization).

KNEE:

- Trial tibial plateau.
- Trial patellar button.
- Impactor parts (limited resistance + degradation through repeated sterilization).



SHOULDER:

- Trial humeral cupula.
- Contraindication: Thin and long parts of measuring rule type, sterilization container.
- Since 2004 PROPYLUX HS is preferred to POM C for all these applications.

Propylux HS

As an exclusive Westlake Plastics material, PROPYLUX HS has become a reference in orthopaedic polymers along with Radel R (PPSU).

PROPYLUX degradation occurs during sterilization but the material recovers its initial shape through the cooling process. This degradation facilitates contact with metal parts (helical inserts).

This material easily replaces POM C thanks to:

- price (similar to POM C, 3x less expensive than Radel R),
- dimensional stability highly superior to POM C,
- chemical resistance,
- very low weight (density of 0.9),
- 14 standard colours range,
- compliance with USP VI and FDA standards,
- available in bars (extrusion) and in plates (compression).



DRAWBACKS:

- Its weight: This material can float and prevent proper decontamination of the ancillary tools.
- Possible material retraction in case of handles with driving cap.
- Not polishable.
- Difficult to glue.

Machinability

Machining of Propylux is less easy than for POM C because chips are longer. However a short training makes manipulation of this material easy.

Surface is more « grainy » than with POM C.

Standards

On top of compliance with FDA standards, all PROPYLUX standard colours were tested under ISO 10993-5/10/11 conditions.

Applications are similar to POM C applications and can additionally be applied to:

- sterilization containers (rack),
- measuring rule

Radel R5500 (P.P.S.U.)

Developed in the early 2000's the colour range of Radel R offered an alternative to ULTEM 1000 (P.E.I.) used so far in technical applications.

ADVANTAGES:

- Mechanical resistance, principally to impact.
- Dimensional stability.
- Chemical resistance.
- Polishable.
- Compliant with USP VI and FDA standards.
- Translucent in natural state.
- Gluable.



DRAWBACKS:

- Radel has a poor tolerance to metal inserts. Its degradation through sterilization is limited but frequent. The material can break suddenly due to repeated cycles of steam sterilization.
- Its high cost.

Machinability

Radel machining is not the easiest. Indeed the turning process produces long chips, which are difficult to cut.

Standards

On top of compliance with USP VI, all basic RADEL R colours were tested under ISO 10993-5/10/11 conditions.

Applications: similar to PROPYLUX. Radel R is preferred for technically demanding applications (thin walls, mechanical constraints).

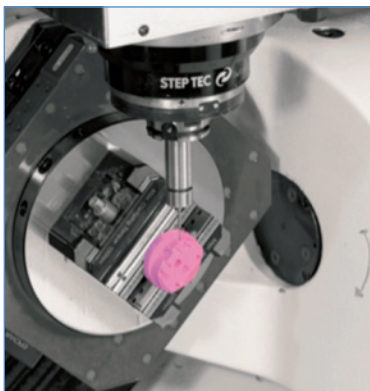
We also distribute other polymers such as ULTEM 1000 or ZELUX GS.

We do not consider ULTEM 1000 as a material with promising future for the following reasons:

- high breakability,
- low resistance to alkaline products,
- high cost.



ZELUX GS cannot be sterilized in autoclave. It is of single use with GAMMA sterilization and offers exceptional impact resistance.



Partner

Established in 1989, M.T.D. distributes Westlake Plastics medical polymers in Europe. Westlake Plastics is a world leader in extrusion and compression moulding technologies of high performance polymers.

M.T.D is remarkable for its high level of technical expertise in orthopaedic polymers and its high material supplies.

Since 2005 M.T.D. exclusively provides subcontracting machining services for all types of polymers to the European orthopaedic industry.

The company is ISO 9001 and ISO 13485 certified for its machining activity by the TÜV Rheinland.

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