Westlake plastics
LIFE IN POLYMERS

MODERN plastics
"Setting the Standards in Plastics Distribution"™
ISO 9001:2008 and ISO 13485:2003 Certified
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PPPROPYLUX® HS

The Clear Solution for Orthopedic Devices

PROPYLUX® HS rods are exclusively produced by Westlake Plastics.

PROPYLUX® HS products deliver the required attributes for orthopedic applications including biocompatibility, chemical resistance and dimensional stability.

Launched in 2004 by Westlake Plastics Europe, PROPYLUX® HS has gained wide acceptance by orthopedic device manufacturers in Europe.

At a similar price point as POM C, PROPYLUX® HS offers superior dimensional stability performance when processed through repeated 134°C autoclaving cycles. The material also provides excellent chemical resistance to disinfecting and cleaning solutions and exhibits a good balance of strength, toughness and ductility.

As such PROPYLUX® HS is well suited for use in applications including trial heads and cups for hip implants, knee provisional trials and impactor applications.

The PROPYLUX® HS product line consists of 15 colors and 13 diameters. All colored materials are made with FDA compliant ingredients and the shaped rods have been tested and comply with key parts of ISO 10993.

- Dimensionally Stable
- Chemically Resistant
- ISO 10993 & FDA Compliant
- Sterilisable in autoclave
- Laser markable
- Easy to machine

Regulatory Compliance

- The polypropylene resin conforms to FDA. 21 CFR 177.1520 as well as the USP Class VI
- Pigments conform to FDA 21 CFR 178.3297
- PROPYLUX® HS is FDA Master File listed. Contact Westlake Plastics for access authorization and further information.
- PROPYLUX® HS shaped colored materials have been tested and are compliant with key parts of ISO 10993 as outlined in the tables below :

ISO 10993 Testing	BKV010 Black	BLV070 Dark Blue	BLV080 LT Blue	BRV040 Brown	GRV080 Neon Green	GRV090 Dark Green	GYV110 Grey	ORV020 Orange	REV050 Red	YEV060 Yellow	WHV120 White
Chapter 5 Cytotoxicity	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Chapter 10 Part 1 Intracutaneous	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Chapter 10 Part 2 Maximisation/sensitization	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Chapter 11 Systemic toxicity	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

ISO 10993 Testing	AQV020 Aqua	MGV020 Magenta	VTV010 Violet	RUV010 Rust
Chapter 5 Cytotoxicity	✓	✓	✓	✓

Chemical Resistance Study : simulated worst-case cleaning process

Chemical resistance is a critical characteristic for orthopedic devices which undergo repeated cleaning and disinfection cycles over their lifespan . PROPYLUX ®HS offers excellent resistance to a wide range of chemicals including acidic and alkaline solutions. To highlight this on a comparative basis, PROPYLUX® HS along with POM C and PPSU were exposed to a worst case acidic cleaning process and evaluated for visible signs of attack.

- Machined trial heads washed in phosphoric acid (PH 2.5) for 10 minutes
- No rinsing
- Components were dried with hot air for 15 minutes

As shown in the photos and summarized in the table below, PROPYLUX® HS exhibited excellent chemical resistance and superior performance compared to POM C. This test highlights that Propylux offers an additional factor of safety against strong acids.

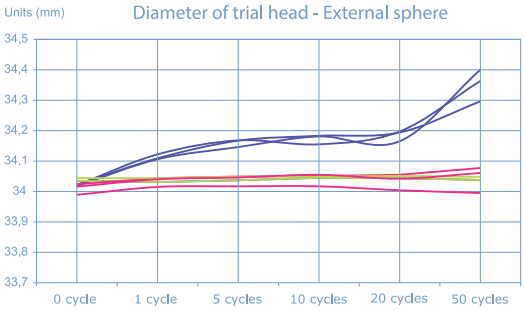
PPSU PROPYLUX HS POM C

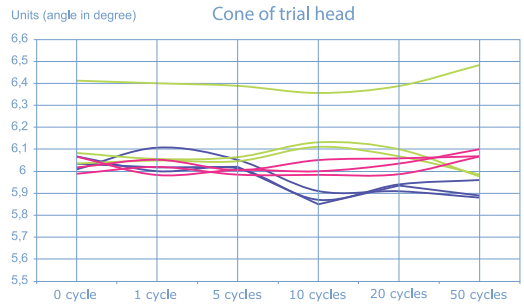
Effects of Disinfecting Process	POM C	PPSU	PROPYLUX® HS
Discoloration/Mottling	Moderate	None	None
Stress Cracking	Slight	None	None
Etching	Severe	None	None
Outgassing	Severe	None	None

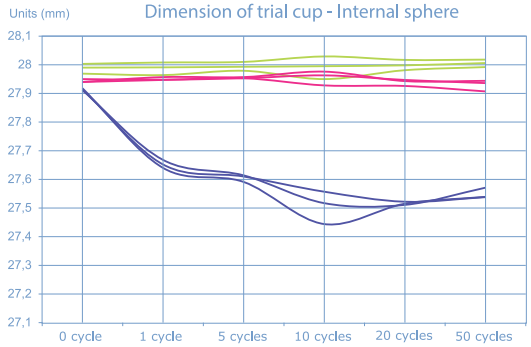
None = no visible change to exposed surfaces
Slight = changes noticeable with the naked eye affecting less than 25% of exposed surface
Moderate = changes noticeable with the naked eye affecting more than 25% of exposed surface
Severe = changes noticeable with the naked eye affecting more than 50% of exposed surface

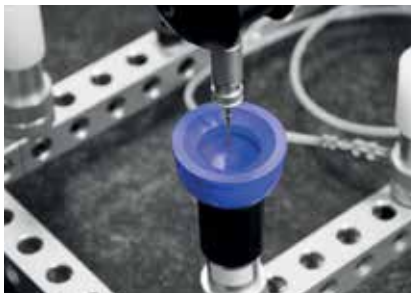
Dimensional Stability Study

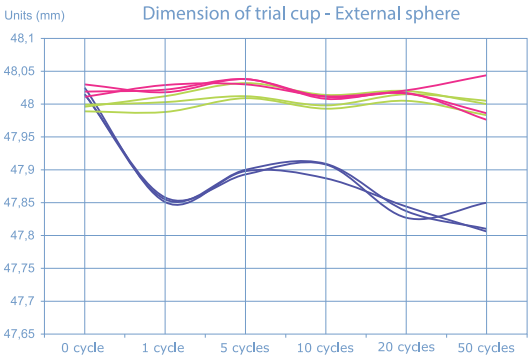
An internal study confirmed the ability of PROPYLUX® HS to maintain its excellent dimensional stability up to 50 autoclave cycles.
Trial hip parts (head & cup) were chosen to perform this test with the most critical parameters being evaluated with 3D CMM equipment.
In each case PROPYLUX® HS shows a far better dimensional stability than POM C and equivalent to PPSU.











Laser Engraving

All PROPYLUX® HS colors are suitable for laser engraving. Machine settings and results will vary depending on the type of laser marking system used.
The sample pieces in the picture on the left were marked using a fiber YAG laser system.

Machining

PROPYLUX® HS is easily machined into intricate parts with complex designs. We can provide technical advice on the machining of PROPYLUX® HS products.

Surface Finishing

We do not recommend polish finishing on PROPYLUX® HS as the material is too soft.
To eliminate machining marks we do recommend a bead ball blasting step. Glass or plastic balls may be chosen according to the color.

Case Study

We evaluated the impact on a knee trial price using PROPYLUX® HS or PPSU.
We chose a Posterior Stabilized, size 3 and thickness 14 mm as a mid-range item.
The stock shape used is a cut off diameter 3" rods in both cases.
Prices are based on Westlake Plastics standard price list.

- PROPYLUX® HS : $ 5.3
- PPSU : $ 20.5

For a quantity of 20 pieces for this particular reference machined parts would approximately cost:

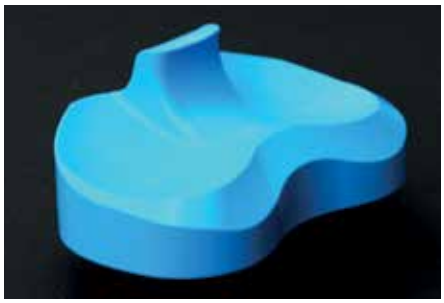
- PROPYLUX® HS : $ 35
- PPSU : $ 53

Considering a range of 5 sizes and 6 thicknesses (from 10mm to 20mm), launching a production of 20 parts per size in PROPYLUX® HS would help saving around $ 9000.

Conclusion

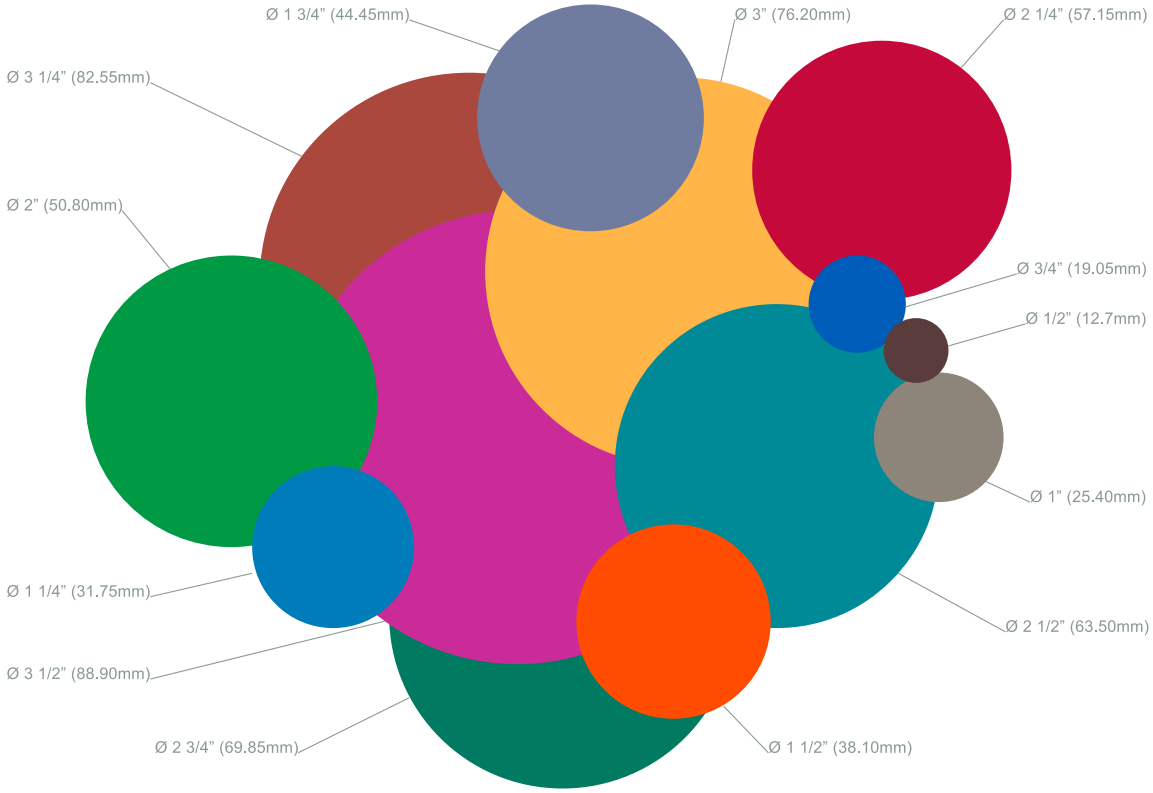
We have designed PROPYLUX® HS to be the most cost effective solution on the market. It offers excellent dimensional stability, chemical resistance and bio-compatibility compliance compared to other medical grade polymers available on the market today, and its color range is second to none. Westlake Plastics carries an extensive inventory to serve the orthopedic device market.

Please contact us for information on distributors serving your market.



STANDARD DIAMETER RANGE

Custom diameters are available upon request. Minimum order quantities would apply



2"and below, rod lengths = 96"
above 2", rod lengths = 48"

STANDARD COLOR RANGE

ISO 10993 Part 5 Part 10 Part 11	ISO 10993 Part 5 Part 10 Part 11	ISO 10993 Part 5 Part 10 Part 11	ISO 10993 Part 5 Part 10 Part 11	ISO 10993 Part 5 Part 10 Part 11
Dark blue* BLV070 WM	Dark green* GRV090 WM	Yellow* YEV060 WM	Red* REV050 WM	Brown* BRV040 WM
ISO 10993 Part 5 Part 10 Part 11	ISO 10993 Part 5 Part 10 Part 11	ISO 10993 Part 5 Part 10 Part 11	ISO 10993 Part 5 Part 10 Part 11	ISO 10993 Part 5
Black* BKV010 WM	Grey* GYV110 WM	White* WHV120 WM	Orange* ORV020 WM	Magenta* MGV020 WM
ISO 10993 Part 5 Part 10 Part 11	ISO 10993 Part 5	ISO 10993 Part 5 Part 10 Part 11	ISO 10993 Part 5	ISO 10993 Part 5
Light blue* BLV080 WM	Aqua blue* AQV020 WM	Neon green* GRV080 WM	Violet* VTV010 WM	Rust* RUV010 WM

* Tested and compliant to ISO 10993 chapters noted

Properties of the resin	ASTM Method	SI Units	English Units
PHYSICAL CHARACTERISTICS			
Density	D 1505	0.90 g/cm^3	0.90 g/cm^3
Water absorption	D 570	0.025 %	0.025 %
MECHANICAL CHARACTERISTICS			
Tensile Strength	D 638		
Yield		34.7 MPa	5.04 kpsi
Break		27.3 MPa	3.96 kpsi
Tensile Elongation	D 638		
Yield		4.6 %	4.6 %
Break		20 % - 60 %	20 % - 60 %
Tensile Modulus	D 638	20.1 MPa	292 kpsi
Izod impact (0.50")	D 256		
Notched		0.48 J/cm	0.90 ft-lbs/in
Un-notched		NB	NB
Hardness (R scale)	D 785	92	92
THERMAL CHARACTERISTICS			
Heat Deflection Temp at 66 psi	D 648	150	302
Heat Deflection Temp at 264 psi	D 696	71	160

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