

# CELANESE PERFORMANCE MATERIALS

A BROAD RANGE OF ADVANCED SOLUTIONS FOR HEALTHCARE COMPONENTS

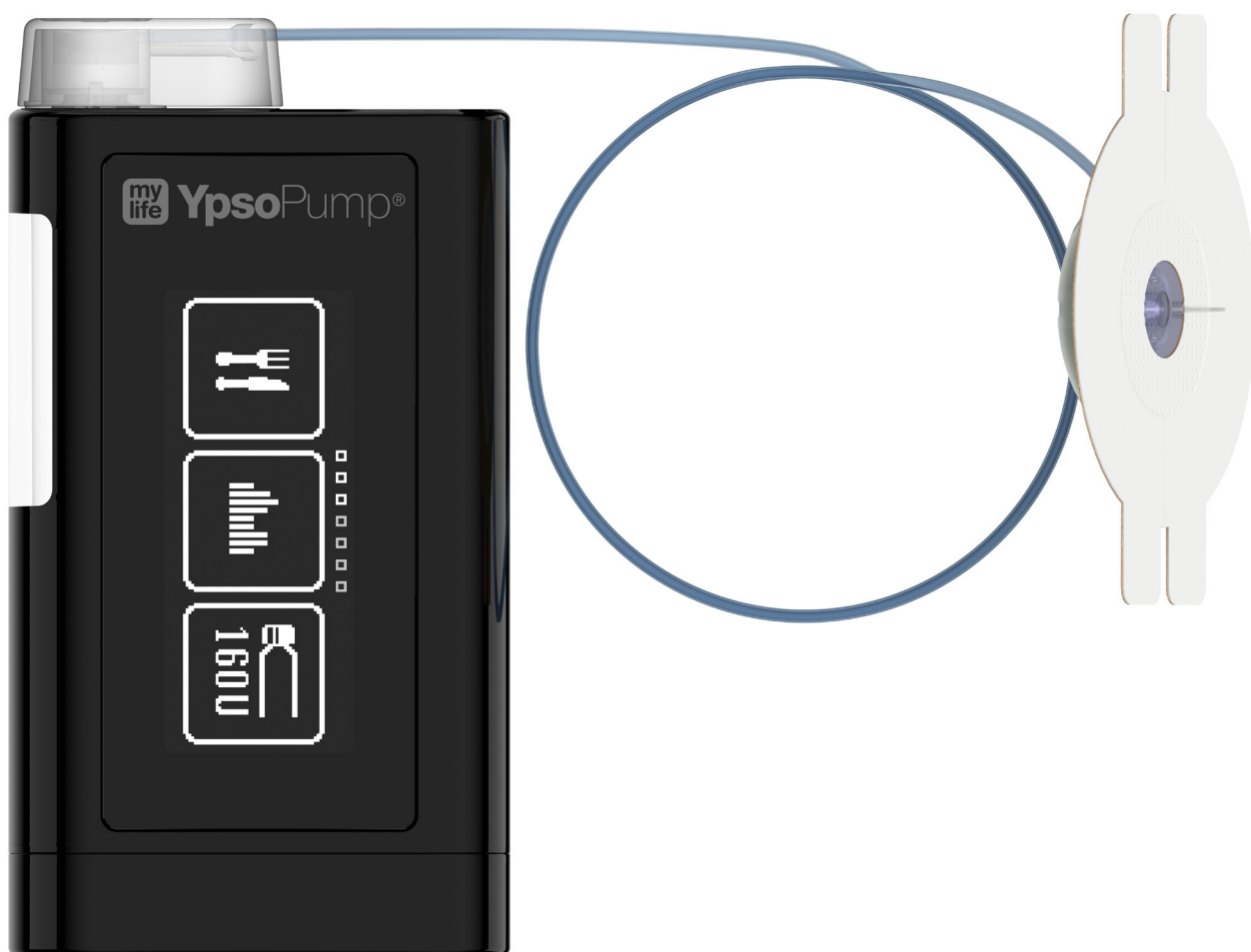


Photo courtesy of Ypsomed - US market approval pending

# CELANESE PERFORMANCE MATERIALS DELIVERS SCIENCE-BASED, HIGH QUALITY THERMOPLASTICS TO THE HEALTHCARE INDUSTRY.

THESE THERMOPLASTICS ARE USED IN THE MANUFACTURE OF DEMANDING COMPONENTS ACROSS MANY DIFFERENT HEALTHCARE SEGMENTS.

Celanese draws on its long experience in materials research, application development, technology, safety and regulatory compliance to provide expert support to healthcare product manufacturers, backed by its global manufacturing and supply strength.

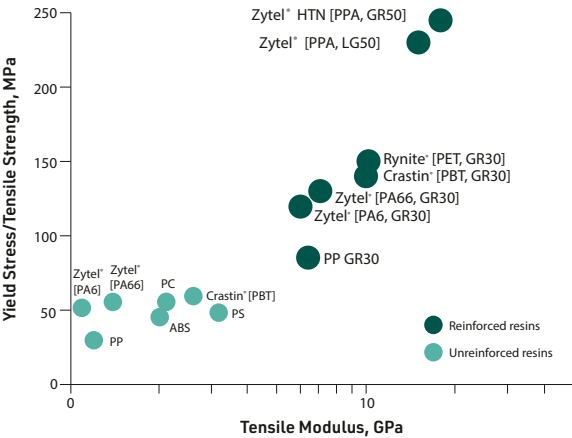
Depending on the specific application, Celanese can deliver an appropriate solution from its broad range of standard products, or from its portfolio of “Special Control” (SC) and “Premium Control” (PC) grades, which are differentiated by a greater degree of testing, manufacturing control and regulatory support.

## THE KEY PROPERTIES OUR MATERIALS CAN OFFER YOUR PRODUCTS

### HIGH STRENGTH

First and foremost, designers are looking for an optimum balance of strength, stiffness and toughness with excellent molding characteristics. The right balance of these properties is the key to designing components for maximum reliability, safety and manufacturability. Celanese, having the most metal-like behavior of any unreinforced plastic due to its very high crystallinity, is often the first choice for designers. Celanese also offers a wide range of reinforced engineering plastics for applications requiring even higher stiffness, strength and creep resistance (Figure 1).

FIGURE 1: STRENGTH AND STIFFNESS\*



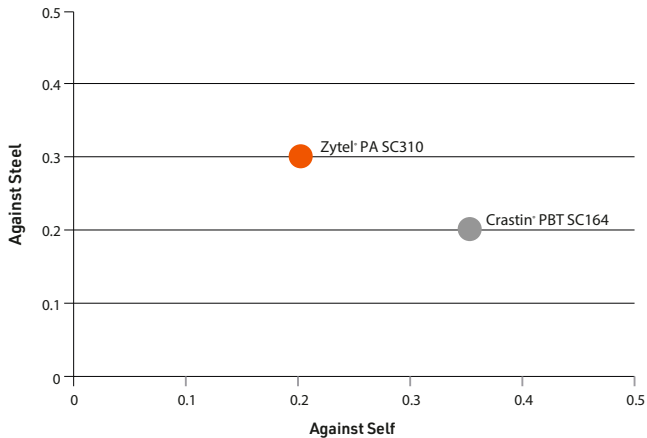
### LOW FRICTION

The selection of appropriate materials in a tribological system (whenever two surfaces rub against each other) is vital to ensure predictable performance and to avoid excessive or variable friction, stick-slip effects, squeaking or eventual total failure.

Secondary lubricants can address these issues but generally tend to be avoided by medical device manufacturers as they require added controls for quantity and placement, contamination control and add one more variable in manufacturing.

Celanese Performance Materials has extensive experience in product development and testing for low wear and friction applications across many industries and offers several grades for medical device manufacturers (Figure 2).

FIGURE 2: TYPICAL DYNAMIC COEFFICIENT OF FRICTION\*



\*Dynamic coefficient of friction values can be impacted by load, speed surface roughness, etc.



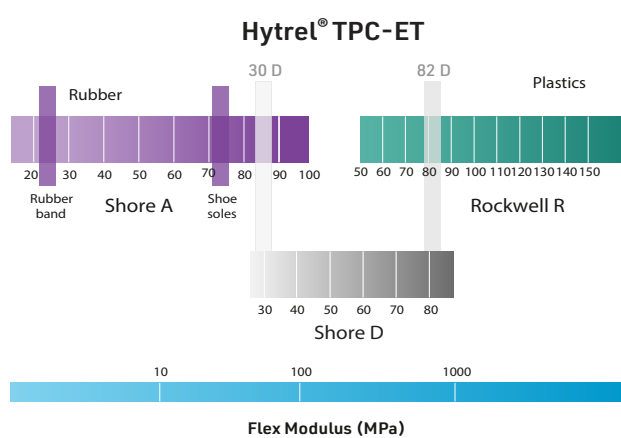
### FLEXIBILITY

For applications requiring maximum flexibility, Celanese Hytrel® TPC-ET—a plasticizer-free thermoplastic polyester elastomer (TPC-ET)—is an innovative solution.

Hytrel® TPC-ET is super-resilient, providing excellent flex fatigue resistance and spring-like properties, and can be used over a wide range of temperatures while still retaining its flexibility and mechanical properties. It enables the design of a variety of parts and products that combine the best features of both high-performance rubbers and flexible plastic materials.

Available in the range of 30 to 82 Shore D hardnesses, Hytrel® TPC-ET is also economical to process, using a variety of molding or extruding technologies (Figure 3).

FIGURE 3: FLEXIBILITY

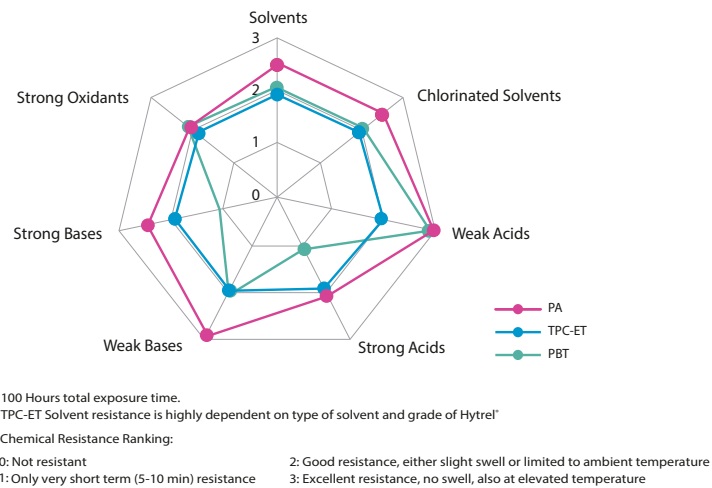


CHEMICAL RESISTANCE

One of the outstanding properties of semi-crystalline versus amorphous plastics is their resistance to many chemicals, which provides a major benefit in today's healthcare industry where a wide range of substances is used for analysis, cleaning and disinfection, or as a drug carrier or conserving agent.

Since factors such as temperature, chemical concentration, exposure time, part surface to weight ratio and the plastic component's stress level can all affect performance, it is highly recommended that a realistic end-use test be run to determine the suitability of a polymer grade in a particular application (Figure 4).

FIGURE 4: CHEMICAL RESISTANCE – HOSPITAL ENVIRONMENT



BARRIER PROPERTIES

Customers have sought solutions which protect healthcare personnel from patients' viruses and projections of bodily fluids (blood). They require materials that provide protection but should not prevent the evaporation and evacuation of sweat moisture. Unlike microporous structures, polymeric monolithic membranes made in Hytrel® TPC-ET specialty resins have no pores that can become clogged, and can provide excellent water vapor transmission for increased “wear” comfort as part of medical gown multi-layer structure.



STERILIZATION RESISTANCE

Sterilization is a vital day-to-day procedure in the healthcare sector, both for single-use and multiple-use devices, so it is important that materials used in medical components are not affected by this process.

The broad range of materials offered by Celanese Performance Materials provides a suitable solution for nearly every sterilization approach as noted in the table below. This allows manufacturers to select the best material for their specific application requirements (Table 1).

TABLE 1: CELANESE PERFORMANCE MATERIALS RESISTANCE TO STERILIZATION

Product	Sterilization process*				
	Autoclave <25 Cycles	Autoclave 25 – 100 Cycles	Gamma 1 Cycle	E-Beam 1 Cycle	EtO 1 Cycle
Celanese Zytel® PA66	1	1	1	1	
Celanese Zytel® PA612	1	1		1	
Celanese Hytrel® TPC-ET (from 30 to 82 Shore D)	2	2			
Celanese Crastin® PBT					

| Appropriate | Limited | Not Recommended 1 – Yellowing 2 – Softer Grades  
\* Steam: Ultrasonic wash at 87°C + 3 min at 134°C, Gamma: 40 kGy, E-Beam: 50 kGy, ETO: 50°C, 2 hr exp.



CELANESE PERFORMANCE MATERIALS – TYPICAL PROPERTIES OF “SC” AND “PC” GRADES

These products are manufactured according to Good Manufacturing Practice (GMP) principles and generally accepted in food contact applications in Europe\*\* and the USA when meeting applicable use conditions. These products are also tested against ISO 10993-5 and -11 and selected parts of USP Class VI. For details, individual compliance statements are available from

your Celanese representative. Table 2 is a condensed version. For a complete data sheet, please contact your Celanese representative.

The data contained herein reflects typical historical properties for our products and should be not be used to establish specification limits.

TABLE 2: SPECIAL CONTROL AND PREMIUM CONTROL GRADES FOR HEALTHCARE APPLICATIONS

		Property	Tensile Modulus	Yield Stress	Yield Strain	Strain at Break	Charpy Impact (notched)		Density	Mass Flow Rate	Temperature of Deflection under Load	Vicat Softening Temperature	Melt Temperature
		Unit	(Mpa)	(Mpa)	(%)	(%)	(kJ/m²)	(kJ/m²)	(g/cm³)	(g/10 min)	(°C)	(°C)	(°C)
		Test Condition	23°C	23°C	23°C	23°C	23°C	-30°C		2.16 kg	1.8 MPa	10N, 50°C/h	10°C/min
		Test Standard	ISO 527 -1/-2	ISO 527 -1/-2	ISO 527 -1/-2	ISO 527 -1/-2	ISO 179/1eA	ISO 179/1eA	ISO 1183	ISO 1133	ISO 75 -1/-2	ISO 306	ISO 11357 -1/-3
Product Family	Grade (Natural Color)	Description											
Hytrel® TPC-ET	PC938	30D durometer	24	1.8 (at 10% strain)		>300	No break	No break	1.07	5		80	177
	PC945**	40D durometer	60	4.6 (at 10% strain)		>300	No break	No break	1.16	5.6		109	152
	PC952	55D durometer	190			>300	N	-150(P)	1190	18	45	180	203
	SC956**/PC956**	55D durometer	180	11 (at 10% strain)		>300	No break	145(p)	1.19	8		180	201
	PC966**	63D durometer	280	15 (at 10% strain)		>300	120(P)	25	1.22	9		195	210
	SC969	63D durometer	260	15 (at 10% strain)		>300	120(P)	25	1.22	9		195	211
	SC976**	72D durometer	525	23 (at 10% strain)		>300	33	10	1.26	12.5		205	218
	SC988**	82D durometer	1180	34 (at 10% strain)		>300	15	5	1.28	12.5		213	221
Zytel® PA	SC310/PC310	High flow PA66	1400*	55*	25*	>50*	15*	3*	1.14		70		262
	SC315	High flow PA612	1700*	54*	18*	>50*	4*	3*	1.06		62		218
Crastin® PBT	SC164/PC164	High flow	2400	55	4	30	4	4	1.31	33	50		223
	SC169	Superior flow, low friction	2500	50	3.5	15	3		1290	46	50		224
	SC193	30% glass reinforced, low warp	9500	130 (at break)		2.5	10	9	1.44		180		225

<sup>1</sup>Homopolymer  
(P) Partial break  
\* Conditioned values for Zytel® PA (to 50% RH)  
\*\* Identified grades of Hytrel® TPC-ET do not have food contact support in Europe

Contact Celanese for material Safety Data Sheet, general guides and/or additional information about ventilation, handling, purging, drying, etc. ISO mechanical properties measured at 4 mm and all ASTM properties measured at 3.2 mm.

SPECIAL CONTROL\* GRADES

- Manufacturing according to GMP principles
- Food contact statements (EU/FDA)<sup>†</sup>
- Testing against selected parts USP Class VI
- Testing against relevant parts ISO 10993
- Sterilization data
- Global availability

PRODUCTS

- Hytrel® TPC-ET SC956 NC010, 55 Shore D hardness
- Hytrel® TPC-ET SC969 NC010, 63 Shore D hardness
- Hytrel® TPC-ET SC976 NC010, 72 Shore D hardness
- Hytrel® TPC-ET SC988 NC010, 82 Shore D hardness
- Zytel® PA SC310 NC010, high flow PA66
- Zytel® PA SC315 NC010, high flow PA6/12
- Crastin® PBT SC164 NC010, high flow PBT
- Crastin® PBT SC169 NC010, high flow, highly lubricated, PBT
- Crastin® PBT SC193 NC010, 30% glass reinforced, lower warpage, PBT

Hytrel® TPC-ET: plasticizer free thermoplastic polyester elastomer

\* Celanese reserves the right not to sell Special Control and Premium Control products for selected applications.

<sup>†</sup> Some Hytrel® TPC-ET grades may not have EU food contact statements, please check with your Celanese representative.

<sup>‡</sup> Contains silicone oil for enhanced frictional/wear performance.

CUSTOMER APPLICATIONS OF CELANESE PERFORMANCE MATERIALS:

- Valves and Pumps
- Dry Powder Inhalers
- Safety Devices for Syringes
- Pen Injectors
- Surgical Instruments
- Fluid and Gas Handling

- Diagnostics
- Wound Care
- Prosthetic

PREMIUM CONTROL\* GRADES

- Manufacturing according to GMP principles
- Food contact statements (EU/FDA)<sup>†</sup>
- Testing against selected parts of USP Class VI
- Testing against relevant parts of ISO 10993
- Sterilization data
- Global availability
- FDA drug master files available (DMF)
- Extended change notification

PRODUCTS

- Hytrel® TPC-ET PC938 NC010, 30 Shore D hardness
- Hytrel® TPC-ET PC945 NC010, 40 Shore D hardness
- Hytrel® TPC-ET PC952 NC010, 55 Shore D hardness
- Hytrel® TPC-ET PC956 NC010, 55 Shore D hardness
- Hytrel® TPC-ET PC966 NC010, 63 Shore D hardness
- Zytel® PA PC310 NC010, high flow PA66
- Crastin® PBT PC164 NC010, high flow PBT



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