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Urethane Potting Material for Artificial Kidney

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The kidneys perform many vital functions, including removing toxins from the body through urine. Patients whose kidney functions have significantly deteriorated due to diseases such as renal failure require artificial dialysis (hemodialysis) to remove waste products and excess water from their bodies. According to a survey conducted by the Japanese Society for Dialysis Therapy, the number of patients requiring dialysis in Japan has increased every year and reached to approximately 350,000 at the end of 2021. Consequently, the demand for artificial kidneys used for dialysis has been increasing every year. In this article, we introduce our urethane potting material for artificial kidneys, which has been developed to reduce the curing time compared with conventional products.

What is an Artificial Kidney?

The kidneys are vital organs responsible for many functions, such as removing waste materials and excess water from the body, regulating electrolytes to keep the blood's PH balance from becoming acidic, and secreting hormones. There are several ways to purify the blood, but the most common is dialysis. Dialysis is a method in which blood is withdrawn from the body, processed to remove waste products and excess fluids, and then returned to the body. The device (dialyzer) used for this process is generally called an artificial kidney **(Figure 1)**.
A typical artificial kidney is cylindrical, about 30 cm long, with a plastic housing containing about 10,000 thin hollow fibers, each as thin as a few strands of hair **(Figure 2)**. The hollow fiber has a hole in the center like a straw. Blood is forced into the bundle of these follow fibers and the dialysate (an aqueous electrolyte solution with a concentration close to that of body fluid) flows outside of the fibers. These fibers are made of a semi-permeable membrane with microscopic holes that allow small molecules to pass through but not large ones, and through this membrane the blood withdrawn from the body comes into contact with the dialysate, allowing only small molecules such as urea and uric acid, which are waste products, and excess water to pass to the dialysate side, while keeping larger molecules such as blood cells and beneficial proteins on the blood side. In dialysis, the blood is purified by repeating this circulatory filtration process.

Potting Materials for Artificial Kidneys

Potting material for artificial kidneys is an adhesive that bundles the two ends of hollow fibers used in artificial kidneys and fixes these two ends to the housing. Potting materials for artificial kidneys must be blood compatible and highly safe because they come into contact

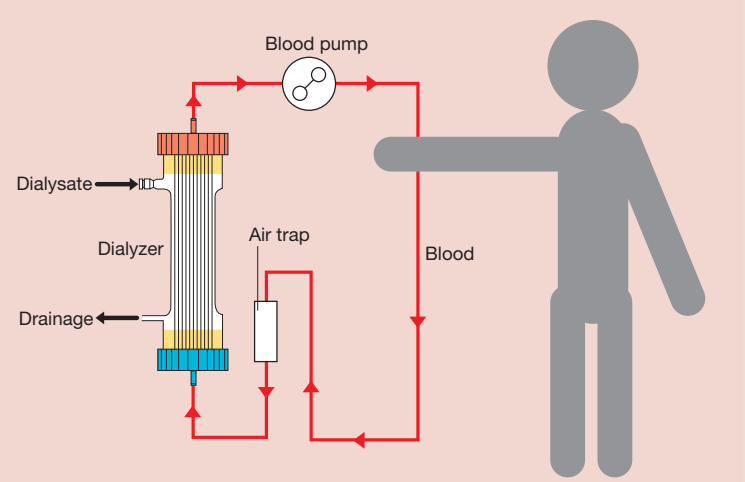

Fig. 1 Schematic diagram of dialysis

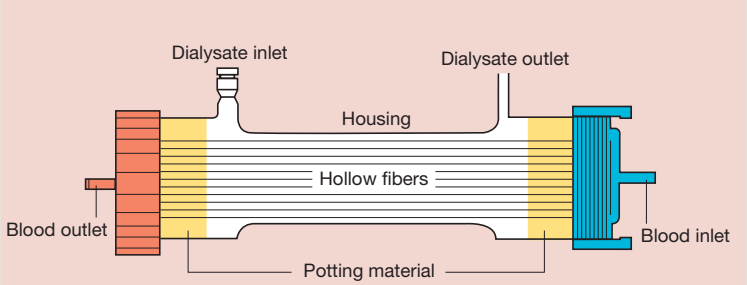

Fig. 2 Structure of Hollow Fiber Dialyzer

with the patient's blood. The most common type of potting material for artificial kidneys is a two-component urethane potting material consisting of an isocyanate and a polyol component. This is because urethane is not only well suited for blood compatibility and excellent adhesion to the hollow fiber and housing, but also has moderate hardness, flexibility, and strength. Another reason is that the raw materials, isocyanate and polyol have low viscosity and can react and solidify under mild conditions.

From a safety and proven track record standpoint, urethane potting materials are primarily composed as shown in **Table 1**.

In addition to this, substances with catalytic properties are added to the polyol component. While tin (Sn) catalysts are used in some foreign countries, metal catalysts cannot be used in Japan, due to safety concerns. Instead, polyols containing amino groups and other substances capable of accelerating curing reactions are used instead.

Molding Method and Required Functions/ Properties of Potting Material

The molding process of artificial kidney using potting material is as follows **(Figure 3)**. (1) The main component (isocyanate component) and curing agent (polyol) are mixed using a two-component mixer. (2) Hollow fibers are placed inside the housing, and the mixture of (1) is injected into both ends of the housing while centrifuging rotating to mold the hollow fibers. (3) After centrifugal molding, it is taken out for curing. (4) The unnecessary part is cut off to open the hollow fibers, attach caps, rinse with water, and package. Then, the product is sterilized and used as the final product for patients in hospitals.

In order to bundle the hollow fibers tightly and to securely affix them to the housing, the potting material must penetrate uniformly only into the hollow fiber ends. For this purpose, as much as possible, a potting material with the low viscosity and slow thickening rate is preferred. On the other hand, if the viscosity is too low and the thickening rate is too slow, the potting material may penetrate through the holes of the hollow fiber into the interior of the hollow fiber, and even if the unwanted portion is cut off, a blockage may remain, causing problems. Therefore, the balance between viscosity and thickening speed during reaction and curing process is an important point in the development of potting materials.

Table 1 Composition of urethane potting material

Components			Composition	Low viscosity	Rapid cure	Safety
Main component	Prepolymer	Polyols	Castor oil	Not bad	Good	Good
			Modified castor oil	Good	Good	Good
			PPG	Good	Good	Good
		Polyisocyanates	MDI	Good	Good	Good
			TDI	Good	Good	Not bad
			HDI	Excellent	Bad	Not bad
	Monomer components		MDI*	Excellent	Good	Good
			TDI*	Excellent	Good	Not bad
			HDI*	Excellent	Bad	Not bad
Curing agent	Polyol components		Castor oil	Not bad	Good	Good
			Denatured castor oil	Good	Good	Good
			Amine-based polyol	Bad	Excellent	Good
			PPG	Excellent	Good (adjustable)	Good

PPG: polypropylene polyol, MDI: diphenylmethane diisocyanate, TDI: toluene diisocyanate, HDI: hexamethylene diisocyanate
*Including modified forms

Our Potting Material

We have developed and sold the POLYMEDICA products of urethane potting materials for artificial kidneys, utilizing our accumulated expertise and knowledge of polyurethane. POLYMEDICA MA-130 / MB-130 is our versatile potting material, which has been well received for its moderate viscosity and thickening speed, as well as for their high safety.

In recent years, as the number of patients with declining in kidney function has increased, there

has been a growing demand for raising productivity in the production of artificial kidneys. Raising productivity requires both low viscosity to improve the filling ability between hollow fibers, and fast curing to shorten the curing time before cutting. Typically, the curing process can be accelerated by increasing the content of amino group-containing polyols, which are known for their cure accelerating properties. However, this approach has presented challenges during the injection process, such as an increase in the viscosity of the mixed solution during injection and a reduced usable time (the time during which the mixed solution can be injected). Thus, the desire for both low viscosity and fast curing appeared to be conflicting. Nevertheless, leveraging our expertise in polyol design technology, we have successfully achieved both low viscosity and fast curing and have developed POLYMEDICA MA-6002 and MB-6002 (currently in development).

Figure 4 shows the curing behavior of POLYMEDICA MA-6002 / MB-6002. The horizontal axis represents the production time of the artificial kidney, and the vertical axis represents the degree of cure. The degree of cure is referenced to viscosity until gelation and hardness after gelation. The blue line shows the conventional potting material, and the red line shows the fast curing "POLYMEDICA MA-6002 / MB-6002". The red line shows lower viscosity after mixing and indicates superior permeability. Furthermore, due to its fast curing, it shows an ideal behavior by reaching a cuttable hardness in a shorter time.

Table 2 and **Figure 5** show the performance, properties, and curing behavior of POLYMEDICA MA-6002 / MB-6002 compared to our conventional product POLYMEDICA MA-130 / MB-130. POLYMEDICA MA-6002 / MB-6002 has lower viscosity after mixing, but cures faster after gelation, resulting in increase the productivity. This balance of low viscosity and fast curing in POLYMEDICA MA-6002 / MB-6002 can significantly contribute to increase the productivity of artificial kidney

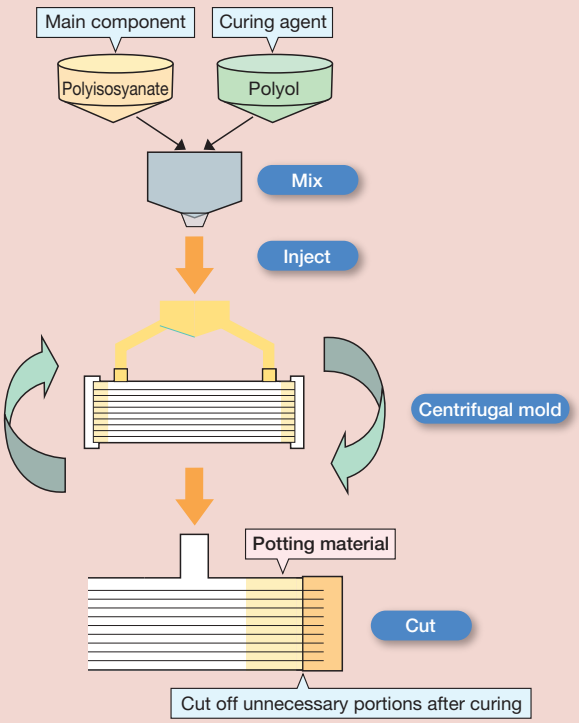

Fig. 3 Schematic of applying process of potting material for artificial kidney

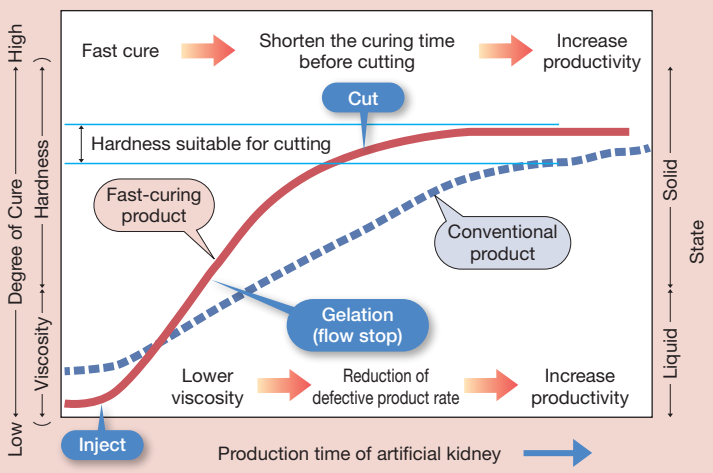

Fig. 4 Image of curing behavior and productivity of artificial kidneys

Table 2 Performance and physical properties of our potting materials

	Product Name	Appearance	Viscosity (mPa·s)	Mixing ratio	2-liquid mixing viscosity (After 2 min)*1 (mPa·s)	Time to reach 50 Pa-s*2 (minutes)	Hardness after curing JIS D instantaneous value*3	
							20min later	48hr later
	POLYMEDICA MA-6002 (Main component)	Yellow liquid	1100	54/46	1100	6.7	36	53
	POLYMEDICA MB-6002 (Curing agent)	Yellow liquid	750					
Conventional	POLYMEDICA MA-130 (Main component)	Yellow liquid	2000	51/49	3200	4	25	65
Conventional	POLYMEDICA MB-130 (Curing agent)	Yellow liquid	1000					

*1 Value measured after mixing the two liquids at 25°C for 30 seconds and allowing to stand for 2 minutes.
*2 Time required from the start of mixing to the point where the viscosity reaches 50 Pa-s after mixing the two liquids at 25°C for 30 seconds.
*3 Instantaneous values measured by pressing a JIS D hardness tester after curing at 50°C for a specified period of time.

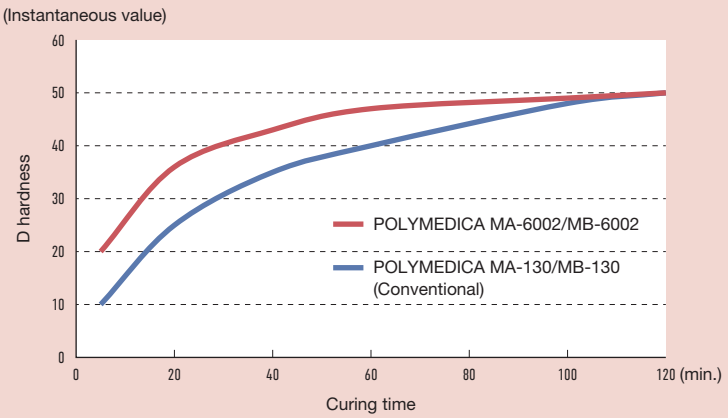

Fig. 5 Curing speed after gelation of potting material

Please contact our company sales representative when handling our company products.
Also be sure to read the "Safety Data Sheet" (SDS) in advance.
It is the responsibility of the user to determine the suitability and safety in the intended use.

production. **Table 2** shows its performance and physical properties. These are representative values, and can be customized to meet each customer's specific conditions, such as injecting, flowability, and molding conditions.

Future plan

Our potting material is suitable for artificial kidney applications as it is used to fix both ends of the hollow fiber and housing, but it can also be used as potting material for household water purifiers and large industrial water purifiers with a similar structure. One distinctive feature of the POLYMEDICA products is that it does not use metal catalysts from the point of view of environmental pollution and toxicity, and uses a metal-free catalyst based on our catalyst design technology. In the future, it is predicted that there will be a need for further emphasis on safety, not only in terms of productivity improvement but also in terms of reducing leachables from the potting material, considering environmental pollution and toxicity, and we are developing the products in this regard. The POLYMEDICA products contribute to SDG Goal 3, "Good Health and Well-Being," by continuing to provide safe, high-quality products. We will continue offering safe and high-quality products not only in Japan but also in countries and regions around the world, in line with the SDG's goal of ensuring health and well-being for all.

References

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Nikkan Kogyo Shimbun, Ltd.,

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In Japan
Sales & Marketing Dept. of Biotechnology & Medical Division
https://www.sanyo-chemical.co.jp/eng/

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