March 17, 2020 Sanyo Special Steel Co., Ltd. IDS Co., Ltd.

First Domestically Produced Material Used as 3D Powder

Practical Application of 3D Printer Powder for Manufacturing Dental Equipment

-Making further contributions to the stable and inexpensive supply of dental prosthetics through the use of 3D printing-

IDS Co., Ltd. (Representative Director: Seiichi Aida; Main office: Bunkyo, Tokyo; hereinafter "IDS"), a dental materials and products manufacturer, acquired <u>pharmaceutical approval</u> for the use of 3D printer powder (a cobalt-chrome-molybdenum alloy: Co-28Cr-6Mo) developed by Sanyo Special Steel Co., Ltd. (Representative Director: Higuchi Shinya; Main Office: Himeji, Hyogo Prefecture; hereinafter "Sanyo Special Steel"), with the cooperation of Dr. Yoshimitsu Okazaki, a Chief Senior Researcher at the Health Research Institute of the Life Science and Biotechnology division of the National Institute of Advanced Industrial Science and Technology. As a result, the 3D printer powder developed by Sanyo Special Steel will be **the first domestically produced material** to be put to practical use as a 3D printer powder used for manufacturing dental equipment.

Until now, dental equipment manufacturers in Japan have had no choice but to rely on 3D printer powder imported from overseas, but this pharmaceutical approval makes it possible for such manufacturers to turn to domestically produced materials, and we can expect to see an even greater spread of stable and inexpensive supplies of <u>dental</u> <u>prosthetics</u>, and other similar materials, using 3D printers. (Please refer to "Explanation of Terms" for details on the underlined terms)

■Background

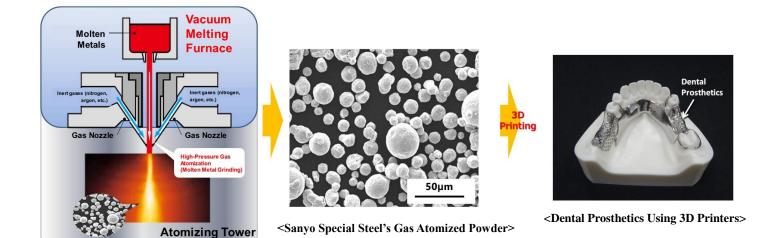
Dental treatment can often involve the use of complicated, three-dimensional dental prosthetics such as partial dentures and full dentures. Traditionally, such complex dental prosthetics were made through casting, welding, and other labor-intensive efforts, but in 2018, IDS, along with Dr. Okazaki at the National Institute of Advanced Industrial Science and Technology, acquired pharmaceutical approval for the use of a cobalt-chrome alloy-based 3D printer powder developed overseas.

This has made it possible to efficiently construct dental prosthetics, but since domestic manufacturers have heretofore had no choice but to rely on importing 3D printer powders from overseas, which are subject to the effects of fluctuations in foreign exchange rates, among other issues, a key obstacle to the further dissemination of dental prosthetics made by 3D printers in Japan has been the stable supply of domestically produced materials that have received pharmaceutical approval.

The materials used for dental treatment must be of high quality, meeting strict standards regarding composition and mechanical properties, among other elements, of the material in order to ensure safety for use in humans, while also being capable of being developed via a production system that allows for stable supply.

Sanyo Special Steel is able to efficiently manufacture high-quality, metallic powders with few impurities through the use of the gas atomizing method, which sprays metals that have been melted in a vacuum atmosphere with inert gases such as nitrogen and argon. Sanyo Special Steel further boasts a diverse lineup of production equipment capable of producing batches as small as 2kg per batch to as large as 2t per batch, the largest size batch in the world, which allows it to respond to a variety of needs such as trial production for development all the way to mass production and has helped it garner a top-class share of the domestic market for gas atomized metallic powders.

The 3D printer powder developed by Sanyo Special Steel is a high-quality spherical powder that is well-suited for 3D printers, and allows for the creation of high-density, molded objects, and has seen a variety of applications in various fields, such as moldings, air and spacecraft, and energy-related materials. Thanks to this metallic powder receiving pharmaceutical approval, we believe it is now possible to provide a stable supply of high-quality 3D printer powder boasting high production capabilities and advanced technology for manufacturing dental equipment.



< Manufacturing Metallic Powder through the

(Nitrogen Atm

Gas Atomizing Method>

■Details

In order to further spread the use of dental prosthetics made with 3D printers, IDS, while receiving support from Dr. Okazaki of the National Institute of Advanced Industrial Science and Technology to receive material evaluation and pharmaceutical approval, managed to attain pharmaceutical approval for the use of powder developed and manufactured by Sanyo Special Steel. As a result, the 3D printer powder developed by Sanyo Special Steel will be the first domestically produced material to be put to practical use as 3D printer material used for manufacturing dental equipment.

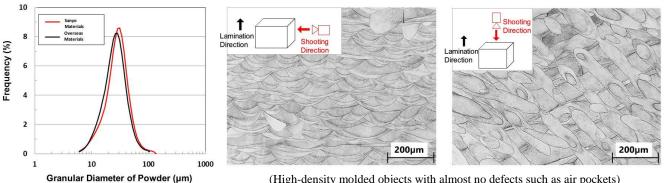
The 3D powder developed by Sanyo Special Steel for use in dental equipment, through the use of advanced composition and powder size control technology, meets international standards (ASTM-F75), and has been adjusted to have a low-impurity alloy composition (refer to Table (1) below) and a particle size distribution commensurate to materials from overseas that have already received pharmaceutical approval (refer to Graph (2) below).

Sanyo Special Steel installed a high-grade vacuum melting gas atomizer in Powder Factory 2, which boasts a high degree of air cleanliness, thereby securing atomization conditions optimal for manufacturing high-quality, spherical powders optimized for use in 3D printers. Sanyo Special Steel has further introduced powder processing processes to enhance the spherical quality of the powders produced, and the 3D printed materials produced using such powder are molded products of nearly 100% density (refer to Photomicrograph (3) below) and realize mechanical properties nearly identical to materials produced overseas (refer to Table (4) below).

	Composition (mass %)									
	Co	Cr	Мо	Si	Fe	Mn	С	Ni		
Sanyo Materials. *1	Bal.	28	6	0.7	0.07	0.7	0.11	<0.1		
(ASTM-F75 Standards) *2	Bal.	27-30	5-7	<1.0	<0.75	<1.0	<0.35	<0.5		

^{*1.} Analysis value (example)

<(1) Alloy Composition of 3D Printer Powder>



(High-density molded objects with almost no defects such as air pockets)

^{*2} Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants

	Hardness (HRC)	Tensile Strength (MPa)	0.2% Yield Strength (MPa)	Elongation (%)	Fatigue Strength (MPa) (107cycles)	
Sanyo Materials	44	1190	760	20	500	
Overseas Materials	35-45	1200±150	800±100	24±4	500	
(ASTM-F75 Standards)*	-	655 or greater	450 or greater	8 or greater	-	

^{*}Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants

<(4) Mechanical Properties of 3D Printed Products Using Sanyo Materials>

■Anticipated Effects of Products at Issue, and Future Plans

We expect that, as it is now possible to manufacture dental prosthetics via 3D printing using 3D printing powder produced domestically by Sanyo Special Steel, we will see further dissemination of stable and inexpensive provision of dental prosthetics thanks to benefits such as reductions in manufacturing time.

In addition to seeking out further applications of this cobalt-chrome-molybdenum alloy in other medical materials, such as artificial bones and joints, we also intend to apply the corrosion and abrasion-resistant qualities of the alloy in industrial areas, such as the development of molding and cutting tools.

End

Inquiries regarding this matter should be made to:

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IDS Co., Ltd. (TEL: 06-6378-7714)

[Explanation of Terms]

◆Pharmaceutical Approval

In accordance with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, pharmaceuticals and medical devices can only be sold after receiving approval from the Ministry of Health, Labour and Welfare. As metals for use in dental equipment represent a relatively low risk of harm to humans, they are typically evaluated via third-party organizations in accordance with standards for medical equipment, but as this product is a new technology using 3D printers, they will need to first be evaluated for efficacy and safety, among other factors, by the Pharmaceuticals and Medical Devices Agency, an independent administrative institution, and then receive approval from the Ministry of Health, Labour and Welfare.

◆ Dental Prosthetics

Refers to prosthetic single-tooth or multi-tooth restorations, as well as partial dentures and full dentures, that are meant to restore the functions (biting, etc.) of teeth lost through cavities, periodontal diseases, external injuries, and other complications.

End