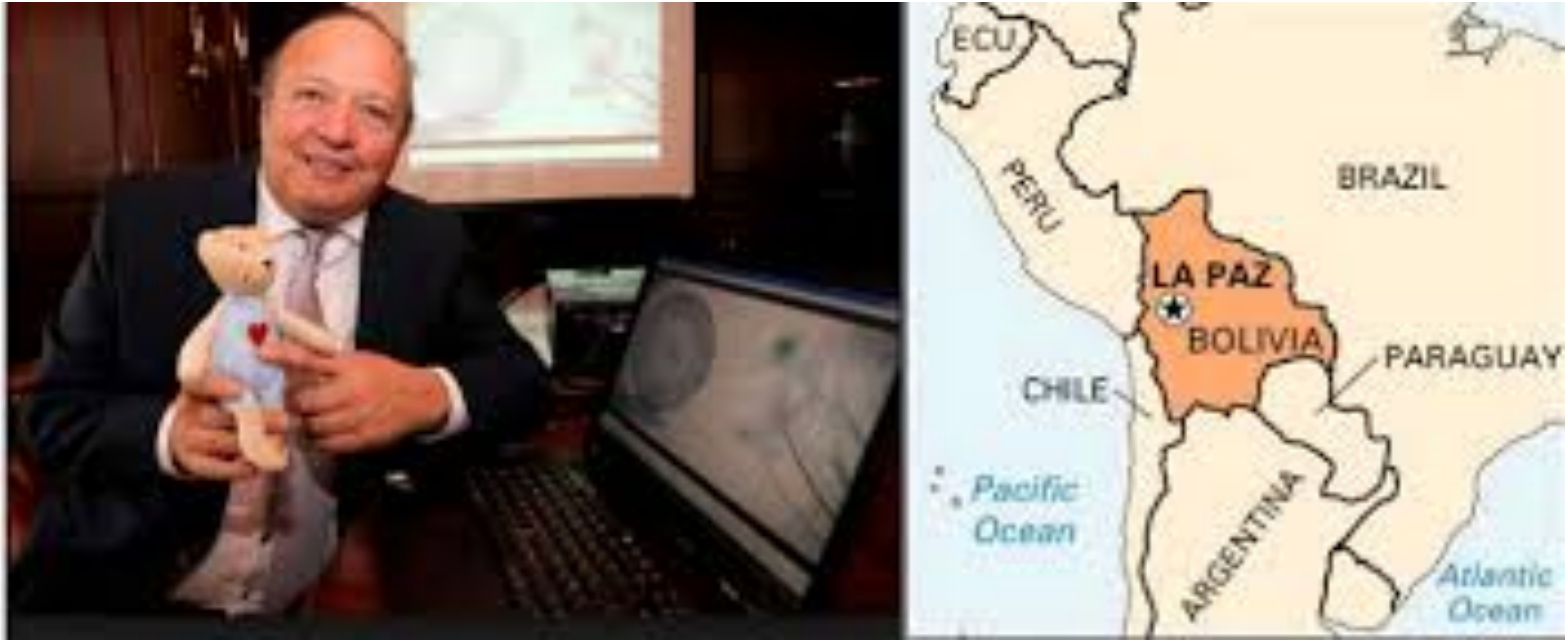
Dr. Franz P. Freudenthal



With his unique inventions (including a device knitted from threads of high-tech alloy by indigenous craftswomen), Franz Freudenthal saves children from congenital heart defects.

Dr. Franz P. Freudenthal MD a great Jewish man in South America

Franz P. Freudenthal was born in La Paz, Bolivia to Germans in Bolivian immigrant parents. He was inspired to enter medicine by his grandmother, Dr. Ruth Tichauer of Wrischinski, who was born in Königsberg in 1910 and died in La Paz in 1995. He used to go with her as a child on her medical visits in remote rural areas of Bolivia. She was a pioneer in family planning and in outpatient treatment of tuberculosis, and shared her philosophy of life with Freudenthal. He attended the Higher University of San Andrés in La Paz for his undergraduate studies, then did his internship at Children's Hospital of La Paz. He decided to specialize in pediatric cardiology. His wife, Alexandra Heath, is also a doctor. The couple received scholarships to take specialized training in Germany. He performed his first operation on a child in Germany in the 1990s. Freudenthal became interested in medical devices. He was part of a team that in March 1998 reported encouraging results of tests on neonatal lambs for occlusion of patent ductus arteriosus with a double-helix device at RWTH Aachen University, Germany. The devices used memory-shaped double-cone stainless steel coils mounted on a titanium/nickel core wire. Freudenthal said that by the age of 25 he had treated more than 20 sheep with devices, and at the age of 29 had treated his first patient, a child that could not be cured in any other way.

After returning to Bolivia in 2003 the Freudenthals founded Kardiozentrum, a center for diagnosis and treatment of congenital heart disease. They also created PFM Bolivia, to develop and market medical devices. In 2014 Freudenthal was heading a team of 80 young innovators on a new project to develop a treatment for strokes. Freudenthal has taken out a number of patents including a left atrial appendage occlusion device, embolization device, tissue clip, tissue tack, snare mechanism for surgical retrieval and deployment device for cardiac surgery.

Nit Occlud device Freudenthal is known for his Nit Occlud device for treatment of an infant heart problem. The prototypes were first tested on sheep, and since then have been used successfully by Freudenthal on hundreds of children, and have been exported around the world. The device treats a congenital disorder in the heart known as a patent ductus arteriosus (PDA).This occurs when the ductus arteriosus blood vessel, which bypasses the lungs before a baby is born, fails to close up soon after birth. The affected infant suffers from labored breathing, failure to gain weight and other problems. The condition is much more common in Bolivia, where the country around La Paz is at an elevation of 4,000 metres (13,000 ft), than in other places. The device is made from a single wire of nitinol, a flexible alloy of nickel and titanium. Nitinol was originally developed by the US military. The tiny Nit Occlud devices are small and intricate, and difficult to mass-produce. Instead they are woven by Aymara women in a "clean room". It takes about two hours to make each device. The device can be placed without an invasive operation, using cardiac catheterization. Nitinol is able to memorize its shape. The device is folded up and inserted into a catheter which is inserted into the groin and then run through blood vessels to the position in the heart where it is to be placed. The device is released and returns to its original shape, blocking the hole that caused the heart problem. By using a minimally invasive approach the technique addresses the concerns of some indigenous people of Bolivia that to manipulate the heart is to desecrate the soul. It takes about 30 minutes to place the device.

Technically, the Nit-Occlud ASD-R, is a double-umbrella, self-expanding, self-centering and premounted device knitted from a single nitinol wire without any soldering or protruding clamps or screws. The Nit-Occlud is similar to other self-expandable devices, which have provided excellent long-term clinical outcomes. The device has a unique shape that offers various advantages and a special snare-like release mechanism. It ranges in size from 8 to 30 millimetres (0.31 to 1.18 in) in stent diameter. The first human implantation was done at the La Paz Kardiocentrum by Alexandra Heath and coworkers. 53 implantations were made by this group from May 2007 to February 2011. Four attempts failed. Of the 53 implantations, complete closure occurred immediately in 71% of patients, and 100% after six months. Findings are generally very positive, although the erosion rate is not yet known.

In August 2014 it was announced that Freudenthal had won the "Innovators of America" award in the Science and Technology category for his occlusion device to cure congenital heart disease in children. The award is given by Innovative America, is sponsored by the CAF – Development Bank of Latin America and the Spanish CAF Ezentis group, and was to be presented in Medellín, Colombia.

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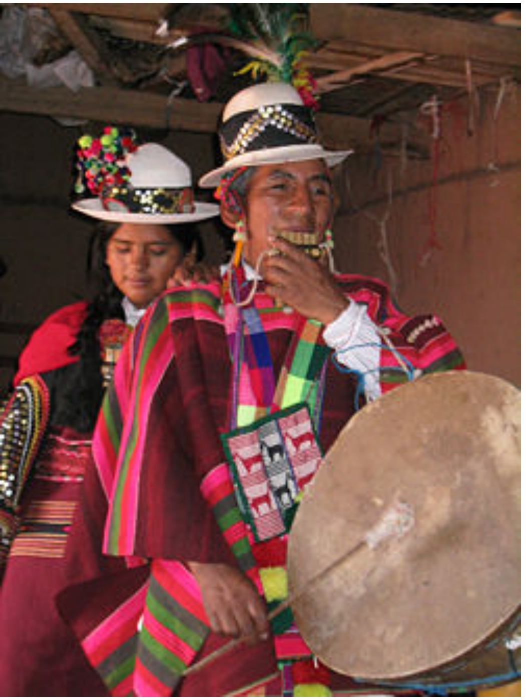

The Aymara or Aimara people are an indigenous nation in the Andes and Altiplano regions of South America; about 1 million live in Bolivia, Peru and Chile. Their ancestors lived in the region for many centuries before becoming a subject people of the Inca in the late 15th or early 16th century, and later of the Spanish in the 16th century. With the Spanish American Wars of Independence (1810–25), the Aymaras became subjects of the new nations of Bolivia and Peru. After the War of the Pacific (1879–83), Chile acquired territory occupied by the Aymaras.

Weaving Indigenous Textile Art Into Cardiac Devices

Heath A, Javois A, Freudenthal F.Weaving Indigenous Textile Art Into Cardiac Devices. JAMA. 2018 Mar 13;319(10):966-967. doi: 10.1001/jama.2018.0387

Congenital structural heart defects are more frequent at higher altitudes possibly because of effects of low oxygen tension on pulmonary vascular resistance.1 As pediatric cardiologists living in La Paz, Bolivia (altitude, 12 000 feet [4000 m]), we frequently encounter children with large functionally limiting defects—primarily patent ductus arteriosus with left atrial and ventricular dilation as large as the postductal aorta and atrial septal defects lacking appropriate borders for percutaneous occlusive therapy— that cannot easily be managed with commercially available devices. Because open corrective heart surgery is unimaginable for all but the most extreme cases in La Paz, Bolivia, we sought to develop an alternative percutaneous solution, a biocompatible occlusive device that would be durable across a lifetime of cardiac cycles. Commercial devices to occlude structural heart defects comprise wovenmesh discs that expand to fill the defect.Many of our patients are indigenous Aymara people for whom weaving is an essential skill. It occurred to us that the skills of Aymara weavers visible everywhere in the textiles of our culture might be used to develop an occlusive device unique to the needs of our patient population.We formed a multidisciplinary team of weaver artisans, biomedical engineers, and physicians to pursue the idea. The artisans helped us identify a weaving pattern appropriate to the materials and bioengineering requirements of the devices: the Andean cross or chakana, a simple cross with a superimposed square. Symbolically the chakana is said to represent pure symmetry of a universe without beginning, end, center, or direction. Practically, it was an already-familiar pattern and technique that could be used to weave a device of variable size using a single strand of material without soldered or welded connections so it could not corrode or break. The biomedical engineers helped us identify nitinol, a nickel-titanium alloy, as the ideal material because it is elastic and has structural "memory," so it can be collapsed and delivered within a catheter to the heart where it can expand to its original shape and occlude even the largest of structural defects. After extensive development and testing, we now have a team of about 40 craftswomen who undergo 4 months of training to perfect their weaving skills in the laboratory so they can reliably reproduce the double-disk net design of the occluders within basic requirements of quality control, sterilization, and proper chemical and physical treatment of the devices. The Aymara weavers repeat the familiar chakana pattern up to 120 times per device. The pattern is ordered in a systematic way but with a modified technique; instead of a flat loom used for traditional textiles, a circular mold is used, with cylindrical structures arranged so that the size and design are fixed. Most smaller devices can be woven in about 3 hours, whereas larger ones can take a day and a half. Early experience with the devices suggest excellent clinical outcomes with few or no complications.2-6The devices are easy to deploy, which minimizes procedure time and child exposure to imaging radiation, and their elasticity makes them minimally traumatic to friable vessels and structures of young children.

They are approved by regulatory authorities in Canada, the European Union, and South America for routine use in the closure of clinically significant atrial septal defects and patent ductus arteriosus in children and adults, and we continue to develop the devices and techniques in hopes that children in other areas of the world, including perhaps one day the United States, may have them as treatment options. Having visited many device-manufacturing facilities, we do not know yet of a machine capable of creating these complex microstructures. Only hands trained by several generations have this special ability, so these women weavers, with their training and qualification in processes and quality management, are human looms that, for now, exceed contemporary engineering standards . The true beauty of the devices lies in the simplicity of the design and deployment and in being a precise application and effective solution to a prevalent lethal health problem in the population of children we care for. By producing handmade devices, the Aymara indigenous people also transfer their culture and skills to the production of medical devices and affirm the relevance of their cultural heritage—integrating the past with the present, culture with science, and the prospect of death with the hope of life. Together with the Aymara people, we are writing a new story inside the children who carry these woven microstructures in their hearts.

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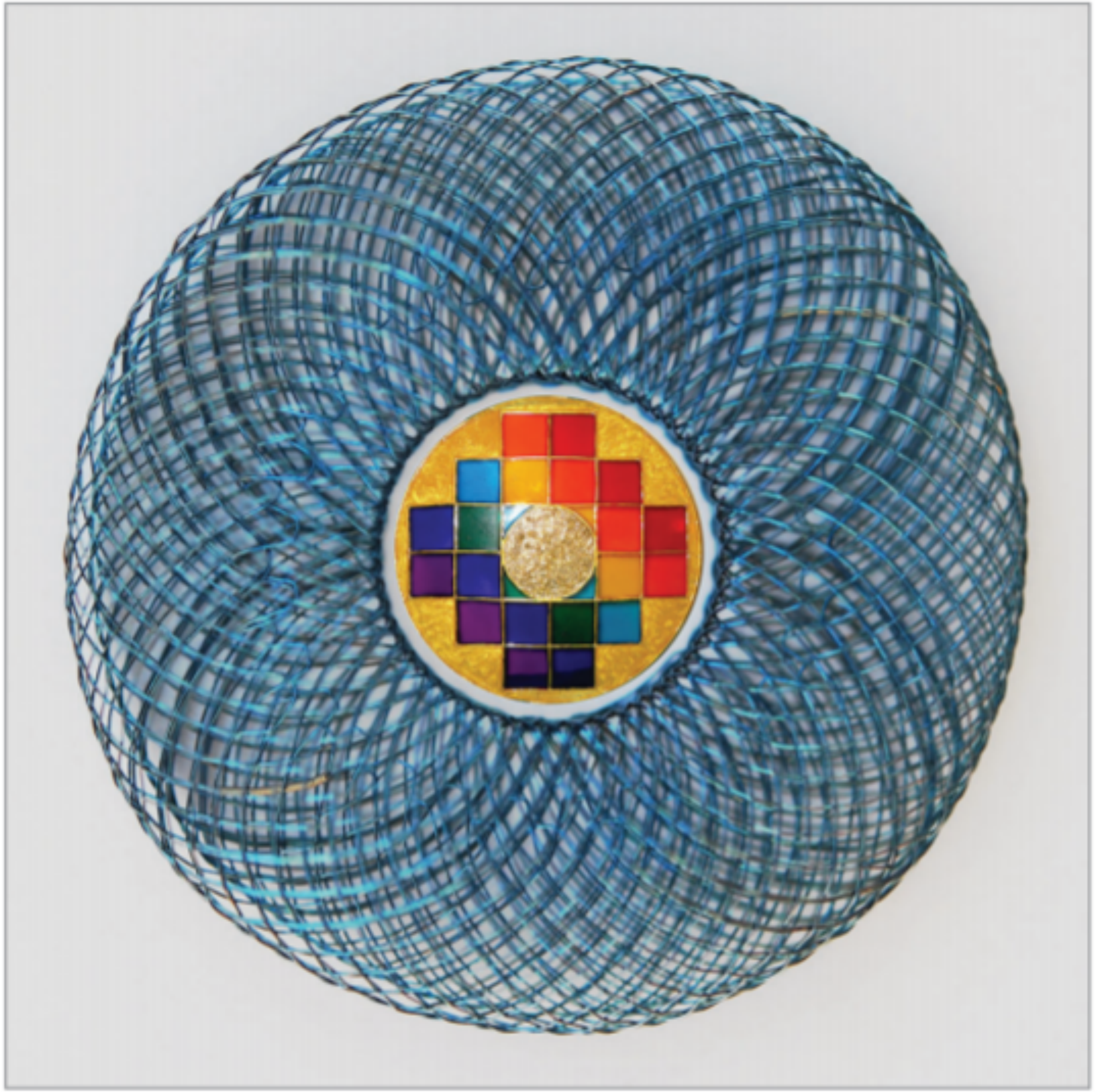

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Summary Video Weaving Indigenous Textile Art Into Cardiac Devices

Andean cross or chakana symbol within a Nit-Occlud ASD-R device; outer diameter, 35 mm; inner diameter, 12 mm. The traditional chakana pattern is familiar to Aymara weavers who repeat it up to 120 times to create the occluder devices.