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Medical Device & Diagnostic Industry

COVER STORY >> METALS

Managing Price Volatility of Precious Metals

Fluctuating markets for platinum can leave device OEMs disappointed, or worse. They need to have a plan for managing market risk and for stabilizing metal prices.

Stuart Bestrom

The worldwide financial market turmoil in the last quarter of 2008 presents new challenges to businesses in 2009. Extreme fluctuations in oil, commodities, and stocks have served to remind financial and purchasing executives that unstable prices can have sudden and unexpected effects on the financial performance of medical device companies. During the past four years of rising metal prices, a few metal sourcing managers have outsmarted the market to lock in a low price. But the rest took no action to stabilize prices or to lock in a firm price. They have seen market prices plunge. With recent declines in precious metals, device companies are asking to renegotiate contracts at the lower prices, even if they were happy to keep the contracts in place during the ramp-up period.

Medical device manufacturers should seek vertically integrated suppliers with direct access to platinum-group metals sources that help reduce risks in volatile metal markets. A supplier with precious metals experience can provide ways to reduce risk, control costs, and ensure uninterrupted supply of critical parts in uncertain times. Varied metal cost management programs, just-in-time (JIT) inventory supply agreements, and the use of platinum-substitution alloys are just some of the opportunities available to help limit variability in medical device component costs.

Applications for Platinum-Group Metals

Precious metals, in a large variety of alloy compositions, can be fabricated as tubing, foil, sheet, or wire to be incorporated into medical devices. Platinum can be micromachined to shapes with tolerances as low as ±0.0002 in. The medical device market were estimated to grow at least 10% to more than $300 billion in 2008. And the electrophysiology (EP) catheter market, a primary area for electrodes and marker bands, is growing at 10.5% CAGR.[1] Precious metals for the medical device market, particularly platinum, are ideal because they do not corrode inside the human body. These metals are highly conductive and are radiopaque, meaning they provide visibility during x-ray and fluoroscopic procedures. As a result, platinum and its alloys are finding increasing use in medical implant applications. Some of the applications for these metals include atrial fibrillation catheters, coils, pacemaker tips, and defibrillators. EP catheters are a significant application because the guidewire, radiopaque markers, and electrode tips may all use some form of precious metal.

Cardiac rhythm management (CRM) and neurostimulation are also sectors that use platinum at a growing rate. One device uses a platinum marker band to provide an image during fluoroscopy. Another employs the material's conductive properties in an electrode array to deliver the signal to the ring or tip electrode.

Management Programs

Precious metals are an important commodity with ongoing price volatility. Often, the precious metal value is the most costly single item of an entire device. In fact, internal data indicates that up to 90% of the cost of medical wire may be a result of the precious metal value. In 2007, the platinum market experienced a supply shortage that contributed to a 35% price increase, followed by further increases in 2008 from $1500 to $2300 per troy ounce. In late 2008, the price settled back to 2006 levels in response to the global economic and financial slowdown. Figure 1 (p. 50) examines the fluctuating costs of various precious metals.

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Because a single spool of wire can cost more than $20,000, wild price fluctuations are a significant challenge. In an attempt to control this cost, large device companies may appoint someone to act as something of a commodities trader to play the market and gain a competitive price to lower manufacturing costs. These companies spend considerable effort obsessing over daily metal prices and trying to buy at just the right time. If they guess correctly, they can save money. However, just as in the U.S. stock market, they are more likely to buy too early or too late to get the best result.

The performance of many purchasing managers can be measured by purchasing price variance (PPV), the difference between the budgeted or expected price and the actual price. When prices rise suddenly, purchasing managers are forced to explain why the PPV has increased with no warning. Many buyers would prefer to purchase precious metal parts at a stable price, with on-time deliveries that support production schedules, and that match the budget projections. They may find such stability preferable to the variability of unexpected savings or losses from year to year and even month to month.

Medical device makers should ensure that their metal fabricators have the ability to use all available options to minimize exposure to unnecessary costs and risk associated with market changes. It is also important that metal fabricators be vertically integrated so that they have uninterrupted access to precious metal supplies via multiple sources.

Actual mining operations and secondary refiners are the two primary sources of precious metal. South African mines provide approximately 70% of the total platinum supply, and Russia and North America supply the balance of material. In 2007, safety shutdowns, geological and equipment problems, and a difficult labor environment combined to reduce output by 5% in South Africa and 2% from other countries. The global supply is expected to decrease an additional 4.2% in 2009.[2] This supply decrease, combined with a weakening U.S. dollar, caused the large price spikes in late 2007 and early 2008. Forecasting platinum in 2009 is difficult in the current economic environment so the price could vary from $700 to $1400 per oz depending on the world economy.

Secondary refiners buy, break down, and smelt the recovered scrap into a form that can be refined and returned as commercially pure platinum, palladium, or rhenium. Automotive catalytic converters and jewelry are primary sources of this refined supply. Metal fabricators with access to both of these sources are a liquidity hub for precious metals with the ability to move the deposits from one facility to another. Large metal fabricators that have metal at all production sites do not have to rely on third parties (that may not have a stake in the success and profitability of the final customer) to sell or deliver the necessary metal.

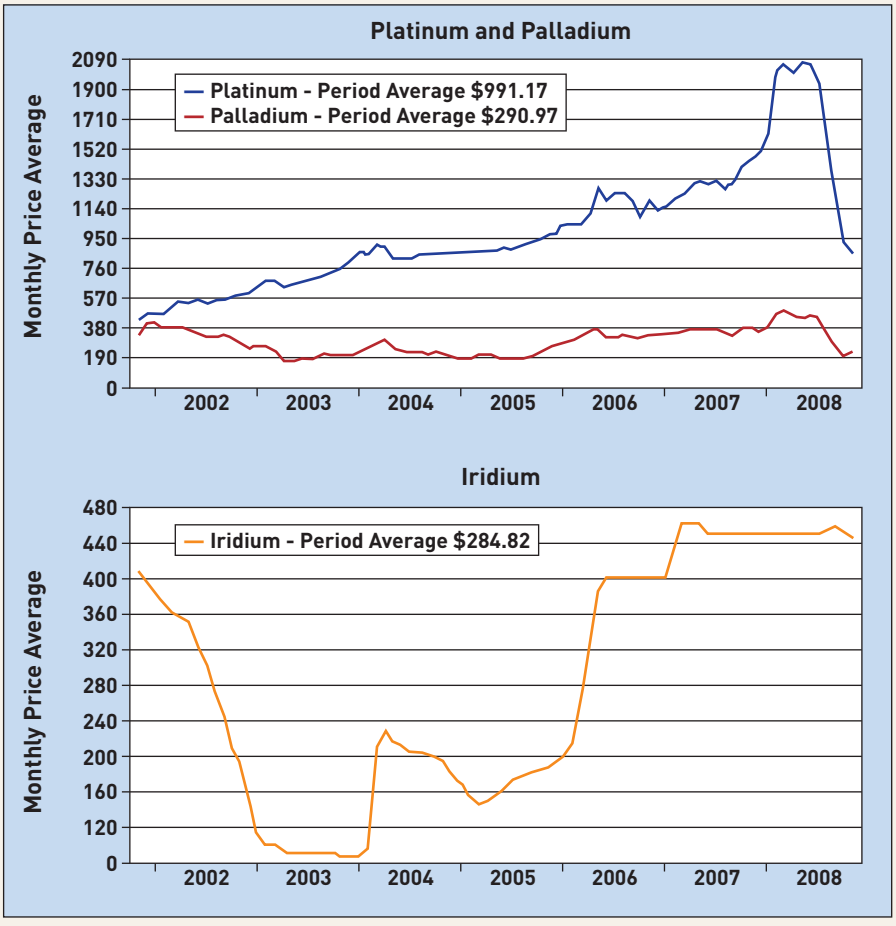


Figure 1. Market prices for platinum, iridium, and palladium change daily based on economic conditions, supply and demand, local unrest, and rumors. Prices have varied up to 400% over the past seven years. Prices in this figure are from November 2001 to November 2008.

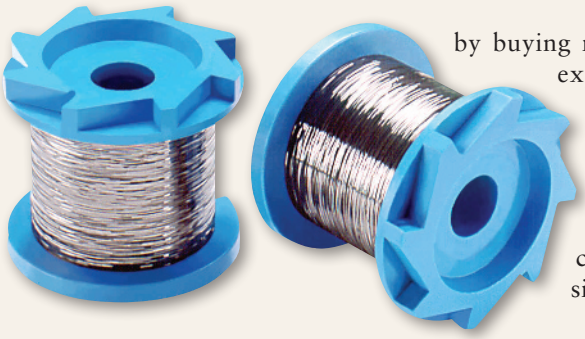
Pricing Programs

Large companies providing precious metal fabrication manage manufacturing on a metal-neutral basis. This means that they do not own the precious metals used to fill customer orders. The final price of a part is broken down by fabrication cost and a metal cost. OEMs have options to manage metals used for purchase orders based on company resources and expectations for price stability.

Day-of Metal Price. For example, the day-of metal price program is typically used by small and medium-sized medical component manufacturers that want the supplier to handle all details of product supply and delivery. In this program, the supplier manages the precious metals required for manufacturing, and then bills the customer for the finished product and its metal on one invoice. The metal is typically invoiced to the customer at the market price on the day after shipment. The final price can vary due to market movements between order

date and actual shipment, but the supplier handles all responsibility related to procurement and refining of the metal.

One purchase order with multiple delivery dates may have different prices for each delivery date. This is because metal prices also vary along the course of the purchase order commitment. The day-of program provides the most comprehensive service to customers, but there is some risk because the final price for a product is not known until the day after shipment. Such variability can be difficult for purchasing and accounting departments, which are accustom to fixed prices and repetitive invoices with the same totals month after month.



A single spool of platinum wire can cost more than $20,000.

Committed Stock. Other OEMs may prefer to know the exact purchase order cost at time of order. A committed stock program is one in which the metal is purchased on an agreed-upon date—usually the date of the purchase order—and is the best option under those conditions. The final cost is fixed regardless of market fluctuations during the time between order placement and actual shipment. The committed metal stock is held in a pool account, and the OEM makes withdrawals as needed for actual orders. The program is most useful for medium and large companies using at least 500 oz of precious metal per year. Purchasing managers are assured of fixed prices that generally please accounting and purchasing departments, but they may feel slighted if the market metal prices plunge the day after the order is placed. In the second half of 2008, customers using this program were disappointed when the price of platinum dropped almost 50% in four months. A few had locked in contracts at $1600 per oz for micromachined platinum/iridium components, and the price later dropped below $1000. On the other hand, when the market prices rise during production, the buyer is not affected and the supplier must absorb the cost.

Consignment Metal. Device companies using large, repeatable quantities of precious metals for a variety of applications may elect to manage and hold their own metal inventory using open market conditions. This consignment metal program puts all responsibility for market price risk on the shoulders of the OEM, but it can mitigate risk by buying metal for stock in advance of expected demand when market prices are low. The customer-supplied precious metal is deposited into the suppliers' consignment account in advance of upcoming orders. Of course, this program requires significant investment in inventory and handling costs related to the large variety of precious metals, but the costs may be offset if market purchases are timed properly. Variations of this program can also be more effective by working directly with the trading and marketing groups of companies that provide metal procurement and fabrication services.

Just-in-Time Inventory and Working with Suppliers

Suppliers can provide support for OEMs' JIT inventory systems to enable more options for cost savings. Comprehensive JIT inventory strategies can improve the return on assets by reducing in-process inventory and its associated ordering and carrying costs. JIT strategies for precious metals also allow manufacturers to avoid the risk of theft, loss, or damage to high-value metals.

The JIT philosophy sees inventory as incurring costs, or waste, instead of adding and storing value. Although the potential savings with JIT are attractive, there can be some risk if raw-material suppliers cannot guarantee same-day, on-time shipments with no shortages. To mitigate the risk of downtime caused by shortages, manufacturers should be sure that their metal suppliers can provide multiple stocking locations for finished-goods inventory. Large OEMs that have plants on various continents often insist that suppliers have backup sources or regional stock to limit lapses in delivery.

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Second-tier suppliers, or small metal fabricator companies, which do not have guaranteed supplies of precious metals, are more likely to encounter short-term market aberrations when prices spike. To limit this risk,

PROPERTY	PLATINUM 10% IRIDIUM	PALLADIUM 10% RHENIUM	PALLADIUM 5% RHENIUM
Maximum impurities	1500 ppm	5000 ppm	5000 ppm
Density	21.53 g/cm^3	12.29 g/cm^3	11.71 g/cm^3
UTS as drawn	155 ksi	230 ksi	140 ksi
UTS annealed	55 ksi	80 ksi	50 ksi
Elongation as drawn	2% minimum	2% minimum	2% minimum
Elongation annealed	20% minimum	20% minimum	20% minimum
Electrical resistivity	24 μΩ.cm	32.5 μΩ.cm	21.5 μΩ.cm

Table I. Platinum-substitution alloys such as palladium-rhenium provide opacity and mechanical properties equal to platinum-iridium or platinum-tungsten alloys.

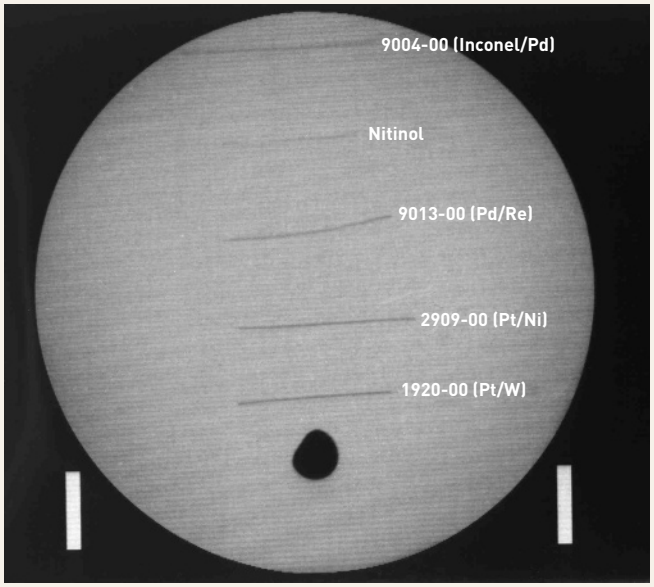

Figure 2. A comparison of platinum and palladium alloys shows that the types are equally visible for fluoroscopy procedures.

device companies should use suppliers that are vertically integrated with a reliable supply source for precious metals so that there are no lapses in regular shipments.

JIT inventory management also allows the OEM to make use of comprehensive security used by precious metal suppliers. Transport, storage, and manufacturing of large amounts of precious metals requires high levels of security including armored cars, secure storage, and employee screening via metal detectors at production floor access points. It also requires frequent inventory counting to spot missing inventory that, although it may weigh only a few ounces, can be valued at more than $3000. OEMs can delegate this responsibility to the supplier so that the OEM only holds 2–3 days of material instead of 2–4 weeks. The small metal parts are portable and easily recycled for scrap value, so limited inventory reduces the risk of loss and eliminates the need for extensive security procedures.

Platinum-Substitution Alloys

As the price for platinum continues to rise, the search for equivalent lower-cost alternatives has increased. Some of these alloys, using less-expensive precious metals, have been found to offer equivalent, or sometimes better, performance (see Table I on p. 52).

For example, Ovalum develops products for chronic and acute total occlusions in the coronary and peripheral arteries. It has developed a low-cost disposable chronic total occlusion (CTO) crossover guidewire using Biomed radiopaque palladium alloys. The alloy was the lowest-cost material for the application, which uses minimally invasive cardiology and interventional radiology. The palladium alloy costs about 70% less than platinum.

All such alloys are manufactured using the same basic process steps. First, the alloy is blended and induction melted in a vacuum chamber with an inert atmosphere. Next, the alloy is extruded to an intermediate size via high pressure and temperature processes. Then the rod is fabricated to the final shape using rolling mills and carbide and diamond dies. Electrical discharge micromachining processes can create custom-designed parts with tolerances as low as 0.0002 in.

Palladium 10% rhenium is another alloy with proven success as an alternative to platinum/iridium for EP and atrial fibrillation catheter wire. Properties such as elongation and tensile strength have shown equivalent performance. Comparable opacity in the wavelength range of fluoroscopy is shown in Figure 2. Also, the softer characteristics of palladium and accompanying higher ductility can be easier to manufacture to various forms. Interestingly, palladium has the highest magnetic susceptibility of platinum-group metals. However, when it is alloyed with group IV–VI transition metals, rhenium in particular, that magnetic susceptibility is reduced. Lower magnetic susceptibility improves magnetic resonance imaging comparability.

Although the lower-cost alloys offer new options for medical device designers, platinum iridium alloys may always be preferred for some applications. It is a higher-strength metal that work-hardens faster and therefore tends to have higher strength and lower ductility than a similarly work-hardened palladium alloy. Regardless of the performance of alternative alloys, some OEMs may prefer to stay with a proven metal because any change in composition may require new validation and lengthy testing. The highest potential benefit may come from more-metal-intensive applications such as micromachined components.

Stabilizing Costs

The properties of precious metals can be exploited to provide unique medical components that improve patient quality of life. The daily market price fluctuations cause large PPV totals for large medical device suppliers, resulting in unplanned, unbudgeted expenses. As companies re-evaluate their exposure to unnecessary risk in an uncertain economic climate, they are asking for help from the metal fabricators to control this raw-material expense. Precious metal components for devices should be procured from metal fabricators that have direct relationships with mining and refining supply sources. Such relationships ensure raw material availability and knowledgeable advice on the most cost-effective metal procurement strategy according a company's expected volume, inventory strategy, and aversion to risk.

A thoughtful metal management strategy can provide stable year-to-year prices that allow purchasing managers to focus their time on controllable expenses. And, ongoing development of lower-cost metals offers new avenues to lower-cost materials with excellent performance characteristics. With proper planning and foresight, medical device companies can hedge risks associated with the turbulent world commodities market—one that has hurt individual consumers and companies of all sizes.

References

1. "Cardiovascular Catheters and Systems" Global Industry Analysts (San Jose) Industry Report, April 2008.
2. "Platinum 2008 Interim Review," (internal data, Johnson Matthey Medical; November 2008 ■