

# A Generic Era in Medical Device Manufacturing

With patents beginning to expire for brand name medical device products, competition will have the opportunity to emerge in the form of generic alternatives. This opens up the potential for medical device manufacturers to market new products to the industry that offer innovative features and differing styles. This article examines the implications of this occurrence and the opportunity it brings.

*By Richard Kuntz*

Over the last two decades, technical improvements in the development of medical devices have helped create a thriving \$80 billion-a-year industry. The expansion of innovative and original medical device manufacturing techniques has yielded remarkable progress; but throughout this growth, standard-of-care devices have largely been ignored given their maturity in the product life cycle. Fortunately, these products are once again being thrust into the forefront of innovation as the availability of generic alternatives to branded medical devices presents an opportunity for new competition and a reduction in healthcare costs.



**The Universal Circumcision Clamp**; GMD's first generic surgical device

For decades, large device manufacturers have benefited from price increases on patent-protected surgical devices. These patents create barriers to entry for new competitors, enabling prices to continue to rise with little regulatory control and often with few, if any, additional innovation or improvements on those devices. However, as patents expire, competitors are allowed to enter markets originally dominated by brand names. Generic Medical Devices (GMD) is the first such company to capitalize on these allowances by developing generic versions of standard-of-care surgical products no longer under patent protection.

As generic alternatives become available in the second quarter of 2007, the impact on OEMs is likely to be immediate and encompassing. By offering efficacious products costing significantly less than brand name counterparts, the market for generic surgical devices is likely to grow quickly and steadily.

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Published on Medical Design Technology (<http://www.mdtmag.com>)

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Hospitals, surgical centers, and third-party payors are limited in procurement based on strict fiscal budgets. However, with generic device prices estimated to be about two-thirds of the current market price, these organizations will now have access to high-quality, lower cost alternatives and benefit from an escalation in purchasing power, allowing them greater access to devices and treatments for patients.

As a result of the increased purchasing power of hospitals, surgical centers, and third-party payors, OEMs will profit from greater demand for surgical devices and increasing production quantity—in short, opening the door to a new “generic” revenue stream. Brand named companies will face the greatest challenge in choosing how to contend with this new competition. To protect their market share, brand name manufacturers will need to respond by introducing lower cost alternatives of their own or adjusting to the new market prices. Either way, the healthcare industry wins as brand name companies compete to match their generic counterparts and overall prices on expensive surgical devices drop.

Currently, GMD occupies an industry of one, but with thousands of surgical devices in production for which generic models could be developed, there is considerable room for emerging generic manufacturers. Ideally, each company would focus on a unique device segment in order to best meet increasing demand and maintain the highest levels of safety and efficacy.

Generic products will drive down the cost of standard-of-care devices, make room in a burdened healthcare system for new innovation, and, most importantly, give more patients access to cutting-edge treatments by correcting decades of unregulated price inflation. GMD’s entrance into the device industry has opened the doors to a whole new market opportunity for OEMs and new generic device manufacturers—and the potential impact on the market is just now being defined.

### ONLINE

For additional information on the technologies and products discussed in this article, visit Generic Medical Devices Inc. at [www.genericmedicaldevices.com](http://www.genericmedicaldevices.com) [1].

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