

# All Razor And No Blades: Is “Big Iron” Back In Vogue?



The conventional wisdom in the medtech industry is to pursue the “razor-razor blade” business model, as each placement of capital equipment generates a lucrative annuity of recurring revenues from disposables. The corollary to this conventional wisdom is that so-called “big iron” is to be avoided. But that view is no longer the only one that counts, Health Advances CEO Mark Speers argues.

## BY MARK SPEERS

There is a wave of “big iron” companies emerging in the medtech industry that are unabashedly challenging conventional business model wisdom, with many combining multiple big iron technologies into “bigger iron” innovations to cure intractable diseases that have evaded other treatment approaches.

Medtech industry panelists at the 2018 Wilson Sonsini Goodrich & Rosati’s (WSGR) Medical Device Conference addressed this theme and provided the impetus for this this article. The panelists included Rafael Torres, senior vice-president at Varian Medical Systems; Maurice Ferré, chair and CEO at Insightec; Jay Watkins, chair at RefleXion; and Rod Young, chair and CEO at CyberHeart.

**T**he razor-razor blade business model is pervasive in the medtech industry. As the conventional wisdom, it has a compelling logic. Each equipment placement leads to a lengthy revenue annuity. For example, over a seven-year lifetime, the average volumetric infusion pump will consume over 1,500 proprietary IV set cassettes and the average breast biopsy device will consume about 3,500 needles.

For most razor-razor blade companies, disposable revenues dwarf capital revenues. For example, desktop chemistry analyzer company **Abaxis Inc.**’s revenue mix for fiscal year 2018 (ending Mar. 31, 2018) was 22% capital and 78% disposables. Even **Intuitive Surgical Inc.** – with its installed base of surgical robots still growing rapidly (system revenues grew 15% in 2017) – booked calendar year 2017 revenues (excluding service revenues) comprised of 36% capital and 64% instruments and accessories.

Capital equipment placements create competitive barriers, as they increase customers’ switching costs. Once the equipment is placed, space must be allocated, utilities connected, biomedical engineering tests run to validate the equipment, and the relevant staff members must be trained. It requires adjustment and commitment by the buyer, who, in addition, must ensure the procurement department has entered the reordering of disposables into its materials management system, and also that clinical staff have become familiar with the new device system’s idiosyncracies.

### Space To Place And Training Essential Factors

The two most significant factors in this list are space and training. In most hospitals, especially in inpatient care departments like ICUs and ORs, the accumulated technology is gradually invading the space available in already-crowded rooms. Purchasing com-

mittees tend to guard any remaining space very carefully, which raises the hurdle for new technology adoption further still. And once space has been allocated, those committees will fight against additional placements of what they might want to describe as redundant equipment.

Training also requires a big upfront commitment, as most clinical departments want all of their relevant employees cross-trained on virtually all equipment. The staff counts – taking into account that many departments are staffed 24/7 – can be considerable. It is easy to see that, once all staff is using a particular piece of equipment competently, any notion of replacing that equipment and starting over is daunting.

Given that the annuities of disposables are so enticing and that customer barriers to adopting new technologies are so significant, many razor-razor blade competitors give away, loan or greatly discount their capital to customers. Health Advances typically advises the first entrants in a category against this tactic, as it believes it is better to wait an extra three to four months for the funds to be appropriated. Not only does the company realize the significant immediate cash flow of at least recouping the cost of the capital, but the customer is typically more committed to truly adopting the technology (instead of agreeing to take capital for free and not using any disposables).

For later entrants to a category, the subsidization of the capital equipment placements is often an essential tactic, as customers are reluctant to buy a replacement for equipment that is not yet fully depreciated.

### Wave Of Big Iron Companies Emerging

There has been a wave of new capital-intensive medtech companies founded and funded over the last several years, some of which are shown in the table. In fact, there has been a surge in capital raised over the last 12 months. As examples, **Insightec Ltd.** raised \$150 million in a private round in December 2017, **RefleXion Medical Inc.** raised \$100 million in a private round in April 2018, and **Neuronetics Inc.** raised \$107.5 million in its IPO in June 2018.

Some of these companies are actually combining multiple big iron technolo-

### Exhibit 1

## Examples Of The New Wave Of Founded And Funded Capital Intensive Medtech Companies

COMPANY	HEADQUARTERS	TECHNOLOGY/ INITIAL INDICATION	FUNDS RAISED TO DATE
Neuronix Ltd	Yoqneam, Israel	Interlace cognitive training with magnetic stimulation: Alzheimer's disease	N/A
Neuronetics Inc.	Malvern, PA	Transcranial magnetic stimulation: Major depressive disorder	\$295 million
Insightec	Tirat Carmel, Israel	MR-guided focused ultrasound: Essential tremor	\$400 million
RefleXion	Hayward, CA	Biology-guided radiotherapy: Early-stage and metastatic cancer	\$164 million

gies into a single machine. RefleXion, for example, combines diagnostic quality CT, stereotactic radiotherapy and novel PET imaging into its biology-guided radiotherapy, where PET signals from the tumors themselves precisely target radiation therapy at the cancer nearly instantaneously, uniquely enhancing the industry's targeting and tracking capabilities. Insightec combines MRI and ultrasound into its MR-guided focused ultrasound to accurately ablate targeted parts of the brain or tumors.

Even **Varian Medical Systems Inc.** appears to be doubling down on big iron. Historically focused on mid-sized radiation therapy equipment, it has now entered the proton beam therapy business, where industry reports peg capital equipment prices at around \$25 million. In its fiscal year 2017 (ending Sept. 29, 2017), the Varian Particle Therapy segment booked revenues of \$182.5 million.

### Fund-Raising Variables Can Mean Substantial Challenges

The panelists at the WSGR Medical Device Conference (June 21-22, 2018, San Francisco, CA) acknowledged that most venture capitalists dislike capital-intensive medtech companies. These companies are big cash users for two main reasons, which can represent substantial challenges.

Firstly, they often encounter high cash requirements to build prototypes and

early inventories. As an example, RefleXion's first proof-of-concept prototype cost \$12.5 million. This was a high-stakes investment made solely to validate the core technology. Many of the big iron companies are pursuing substantial FDA labels and therefore require clinical trials involving multiple sites. Each site obviously needs its own equipment, again putting high demands on cash. And as a company plans a market launch, it must build sufficient inventory so that it can fulfill orders. As this equipment inevitably requires numerous customized components and circuit boards, companies are often encouraged to place larger orders in order to capture significant cost discounts, leading to further additional cash requirements.

Secondly, these companies inevitably encounter extremely long sales-cycle times so that SG&A expenses mount well before any revenues are booked.

These two challenges raise the stakes for early fund-raising rounds and to lead venture capitalists quickly rejecting most of these opportunities. As an example, Jay Watkins, founder of RefleXion, was turned down by about 50 venture capitalists. He finally discovered that Antoine Papiernik, of Sofinnova Partners, disagreed with the conventional wisdom and invested in RefleXion on the basis that "capital equipment is medtech's best kept secret."

In general, the WSGR panelists agreed that entrepreneurs should look beyond traditional medtech venture capitalists. Insightec's Maurice Ferré suggested that family offices have become much more sophisticated, and Asian investors are also good prospects. Indeed, Ferré recently raised \$150 million, \$100 million of which was invested by Koch Disruptive Technologies. Entrepreneurs are also advised to consider pharmaceutical companies if their technologies are synergistic with drugs. As an example, Watkins described how he met with Pfizer Inc. to suggest partnering around its PET agent, and then discovered that Pfizer was much more interested in Reflexion's prospects for debulking cancer patients so that they would benefit more from its oncology drugs. Both Pfizer and Johnson & Johnson have invested in Reflexion.

Pharmaceutical company investments highlight an insight with which all the WSGR panelists agreed: The fundraising headline needs to be "What you do, not how you do it." The panelists pointed out that many medtech entrepreneurs, proud of their technologies, start conversations with gambits such as, "I have a robot company" or "I have an image-guided company." This orientation waves an immediate red flag for investors. Investors would rather be assured that the entrepreneur is focused on an unmet need, and would say something like, "I treat non-operable cancer" or "I treat neuro conditions refractory to drug therapies." As Varian's Torres explained, "At the end of the day, clinical and economic evidence will win. If you have the data, the form of the technology – capital or disposable – becomes irrelevant."

Each of the WSGR panelists took the opportunity to share the significant trials that each of their companies are undertaking to prove the clinical utility of their technologies well beyond the evidence required by FDA for regulatory approval.

### Pricing Innovation Business Models And Value-Based Pricing

There are several business models available to capital-intensive companies to mitigate some of the disadvantages of not utilizing disposables. The most obvious is to generate annuities from service contracts and software licenses and up-

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*Customers are typically more committed to truly adopting a technology if the company can avoid give-aways, loans and discounts.*

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grades. Varian, with approximately 8,000 of the 13,000 LINAC installed base globally, generates over 50% of its revenue on service and software.

Some companies go to great lengths to generate annuities when their devices do not require disposables. For example, Zeltiq Aesthetics Inc., an aesthetics company marketing *CoolSculpting* to non-invasively apply cryolipolysis to destroy fat, created an intangible disposable. Zeltiq, now owned by Allergan PLC, sells its capital equipment and then collects a "per-click" charge for each use. The company justifies these charges as defraying its massive investments in both consumer advertising to generate primary demand, and in practice marketing, to assist its customers in marketing their practices.

Like Zeltiq, because of its differentiation in its market, Insightec sells its capital equipment and charges a per-click price for each use of the equipment. According to Ferré, a hospital breaks even after 20 procedures per year. This is a lucrative approach, but because he believes in the durable effect of his technology, Ferré would prefer to move to a value-based pricing system where customers receive a fee for each patient's additional year of sustained effectiveness. In other words, if the essential tremor patient is still not experiencing exaggerated tremors on each anniversary of the procedure, the insurer would pay the hospital an additional payment. The hospital would, in turn, pay some of this fee to Insightec. Rod Young, of CyberHeart Inc., also likes the value-based pricing structure for his therapy for arrhythmias, as durability is a major shortcoming of current electrophysiology ablations that his technology may improve upon.

One of the big strategic questions for some capital equipment companies is whether to conduct trials and request regulatory approvals as monotherapies or only as part of combination therapies in conjunction with drugs. Both Insightec and Reflexion are evaluating opportunities in these areas. Because payers are accustomed to paying high prices for each dose of chemotherapy, they may be more inclined to pay a high price for a device-drug combination therapy than for a device by itself. Likewise, drug companies – realizing that these

devices might prove synergistic with their drugs – may be willing to fund the trials and eliminate this burden from device company budgets.

Large capital sales – especially for non-replacement equipment – often take years to materialize. The higher the price tag, the greater the number of decision makers and the more scrutiny the decision receives. In fact, these decisions often require the approval of a sequence of two or three committees, including the Capital Spending Committee, which only meets once each year at most hospitals to finally decide on spending. Because of long sales cycles, it is extremely difficult for executives to confidently forecast quarterly revenues. This challenge confronts executives later in their companies' evolutions, particularly when preparing for an IPO or sale.

In order to minimize the lumpiness of its reported capital sales, **Pyxis Products**, a pioneer in automated medication cabinets, only rented its equipment to hospitals in its early years. Although this required more working capital than selling the equipment, the optics of its financials in its early years were very compelling. Just assume that Pyxis placed 50 units in its first quarter and 40 in its second quarter. Had it sold each cabinet, its sales would have decreased by 20% in the second quarter. Instead, due to its rental pricing model, its sales actually grew by 80%! Only when **Omni-**

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– Rafael Torres

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**cell Inc.** became a competitor willing to sell its cabinets outright was Pyxis forced to match this practice.

### The Industry's Best-Kept Secret No More

Over the course of the WSGR's panel's discussion, the challenges of capital-intensive businesses appeared to become more surmountable, and indeed, the sector was no longer the industry's best kept secret. In fact, Watkins heartened the entire audience with a refreshing perspective: “Capital is, in fact, disposable. The replacement cycle is just on a timeframe of every seven years instead of every use.”

While capital-intensive companies may need to invest more cash upfront in product development and long sales cycles, companies that can successfully deliver true clinical and economic value will see these impediments eventually transform into competitive barriers in their favor, leading to lucrative installed bases as the companies become more resilient. ▶

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