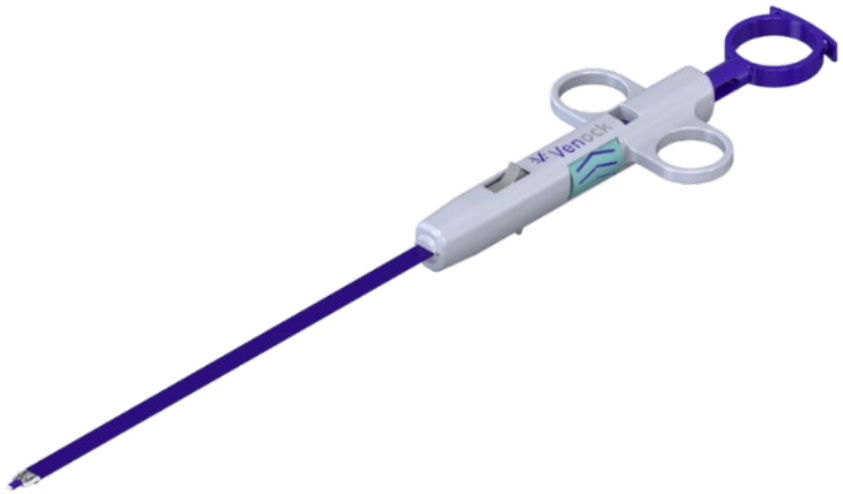
White paper

Driving Cath lab and Health System Efficiencies in Cost and Time Savings through Product Innovation

Venock Vascular Closure Device for Large Bore Venous Access Sites

Introduction



Several future large bore venous access therapies are currently either in development or in clinical trials. Therapies are getting increasingly complex (especially if one considers all the collapsible and deployable mitral and tricuspid valve devices) and venous entry is the preferred path.

Some of the many valve prostheses under development are illustrated here in Figure 3 (mitral) and here in Figure 1 (tricuspid). Together they represent the next wave of cardiovascular innovation which will fundamentally change the standard of care for many cardiovascular diseases.

Because of current cath lab capacity issues, hospitals are desperate for ways to increase efficiency so that patient turnover is improved. The advent of these new large venous bore therapies will have a significant negative impact on this capacity issue. The **current closure method** for large bore venous access sites involves **30-60 minutes of manual compression followed by 5 to 6 hours of bedrest** with a compression bandage.

The **Venock large bore venous closure device** is the first and only such device that will singularly close large bore (>8 mm, 24 Fr) access sites in the femoral vein following a transcatheter procedure. This device will provide significant time savings by **attaining full closure in one minute and allow for near immediate patient ambulation which will result in significantly faster discharge.** Venock will provide much needed patient turnover that

will result in greater cath lab efficiency, an outcome that will greatly benefit hospitals.

But even more important to Venock as a company from a strategic point of view, are the benefits to the global MedTech developers, who provide new novel transcatheter therapies. Studies by Terumo and Medtronic to support this assertion will be presented in this White Paper.

Although the Venock device can be used for small and midsized bore access sites, its **chief value is found in the large bore realm**, where there is no clear, efficient solution. Indeed, some of the many current therapies that require large bore venous access sites are Mitral / Tricuspid valve repair and replacement, ECMO, and leadless pacemaker. Venock is developing multiple sizes of the device to capture all venous therapies.

Early preclinical studies with the Venock prototype showed that its closure principle can effectively be used in large bore arterial access sites as well.

A broad pipeline of indications reduces business risk for the Venock device.

Consider the Medtronic Micra™ device, a leadless pacemaker, which is implanted by a cardiologist through a 27 Fr (9 mm) access site in the femoral vein. In contrast to the common surgical pacemaker implant, there is no need for a surgical procedure during the implant of the Micra. Note that the traditional (surgical) pacemaker annual market is 1 million worldwide and 250,000 in the US alone. The leadless pacemaker is expected to take up 50% of the full pacemaker market.

In this case, if the Venock device (providing full closure in 1 minute) was substituted for the standard manual compression closure procedure, at least 30 minutes would immediately be saved per procedure. Accounting for the reduced recovery time from quicker and less traumatic closure, up to 4 hours of ward time can be saved during each patient's recovery. As a result, more leadless pacemakers could be implanted over the same time frame in an outpatient setting.

A closure device that reduces procedure and recovery time can result in same-day discharge and reduced overall cost

The Journal of Atrial Fibrillation published a study which concluded that "same-day discharge after MICRA TPS placement appears to be safe and feasible". Furthermore, the Medtronic reimbursement guide shows that the outpatient cost (CPT Code 33274, Slide 15) is $16,402 while the inpatient cost (ICD-10-PCS Code: 02PA3NZ, Slide 18) is $22,692.

Consequently, the Venock device could enable an early discharge, potentially saving $6,290 per patient.

Venock

Time Savings Leads to Cost Savings in the Cath lab

A study which compared general small bore femoral access to radial access in the cath lab revealed a time savings of roughly a half hour (20 – 40 minutes).

This time savings was shown to provide a cost savings of up to $1,716 per procedure. With 2,000 such procedures per year at the University of Illinois at Chicago (UIC), a midsize clinic where one of the studies was carried out, such a savings would be $3.4M.

The paper indicated that a reduction in bleeding complications (which results in significant time savings) is the main reason many operators switch to transradial access. One researcher noted that "Even if access site bleeding complications are rare, they add significant costs to a hospital's bottom line". The study concludes that "There is no doubt that healthcare reform will favor programs that can reduce length of stay, use of resources and complications. This will eventually translate into reimbursement restructuring that favors outpatient programs."

Considering that the **Venock device will provide time savings at least as much** as that indicated in this study, a mid-sized clinic could save more than $3.4 million annually, based on 2,000 patient per year. With the projected cost of 2,000 Venock devices being roughly $500k, the **annual net savings for the hospital would be roughly $3M**.

The Venock device will provide quick and efficient site closure that will directly reduce bleeding complications which, as stated above, routinely "add significant costs to the hospital's bottom line".

The Venock device is such a device that will drastically "reduce length of stay, use of resources, and complications".

Improving Patient Turnover with the Venock Device

The Venock team has created a graphical analysis outlining a day of procedures in one cath lab using closure by manual compression vs closure by the Venock device (Figure 1). Assumptions in the analysis are as follows:

- 1 hour for a large bore venous procedure
- 30 minutes of compression for hemostasis
- 5 hours of bedrest in the ward for each manual compression patient
- 1 hour of bedrest in the ward for each Venock patient
- 30-minute room cleanup between procedures
- Same day discharge cutoff at 18:00

This analysis shows that using manual compression allows for the treatment of 5 patients with 2 requiring an overnight stay (i.e., 40%). Conversely, using the Venock closure device would allow for the treatment of 2 additional patients per working day (i.e., 40% more) and while completely avoiding the need for any overnight stay.

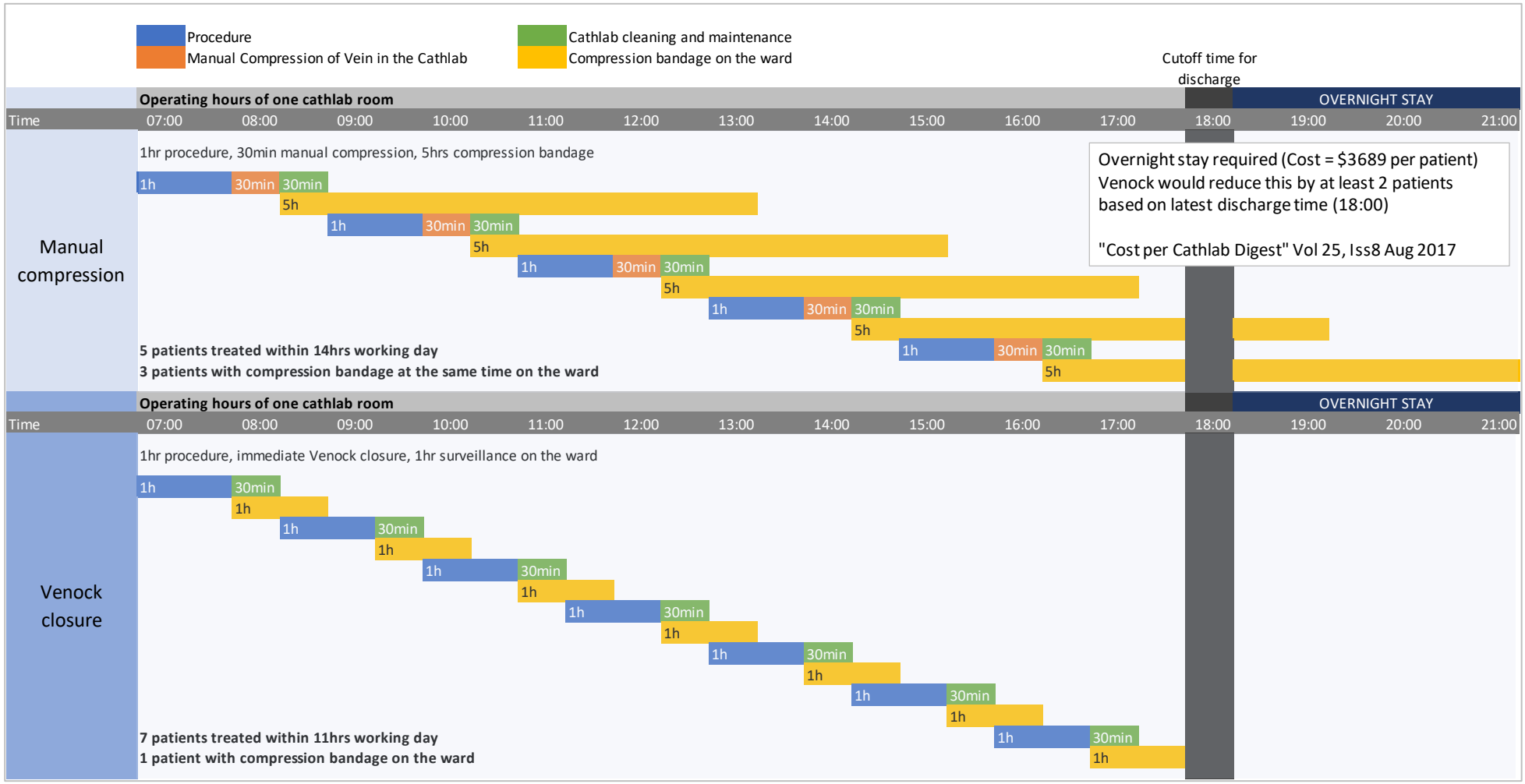


Figure 1: Cath Lab Workflow and Time Saving Advantages Using Venock's Closure System

Improved Cath lab Efficiency from Venock Device Drives Greater Sales for MedTech Companies

As mentioned earlier, it is in the interest of global MedTech companies that cath labs become more profitable so that they are able to increase sales of their therapeutic products and latest cardiac technologies.

Therefore, corporations such as Terumo and Medtronic are driving to improve cath lab efficiency to support their business.

Medtronic's Integrated Health Solutions (IHS) group, presented a case study publishing data from a Dutch hospital. This data demonstrates that gaining just 30 minutes each day per cath lab enabled the treatment of >15% more patients. This was achieved with constant resources and corresponds to a gain in the value of cath lab use of $170,000 per year.

In comparison, the Venock device would save more than 30 minutes "per patient", instead of just "per day", providing a far greater benefit as multiple patients routinely are treated each day in a given cath lab.

Medtronic's IHS group recognizes that "Every second of every Cath lab is worth $1 in revenue" (see IHS brochure; slide 3)

The benefits for Medtronic are:

- Improved operational efficiency, "do the same with less", resulting in savings
- Increased operational capacity, "do more with the same or less", resulting in incremental revenue (see IHS brochure; slide 6)

Additionally, a Study in Cath lab Profitability was presented by Gary Clifton, Vice President of Terumo Business Edge. This study found that discharging a patient on the same day of a procedure rather than having an overnight stay saved $3,689.

Using the graphical analysis in Figure 1, the Venock device would save up to twice that or $7,378 per day, by enabling 2 more patients to be discharged.

Furthermore, the publication states that the average profit margin per cath lab procedure for the hospital is currently negative $215 (-1%), which massively reinforces the need for cost savings. But it goes on to say that "If we examine the total hospitalization costs reported and account for length of stay, the average per night cost was reported at $1,169.86 nationally" and "if hospitals on average reduced 1 night from their length of stay or reduced their total costs by the reported $1,169.86 per case, the average margin will improve from -1% to 6% per case." Thus, a higher rate of same day discharges will drive these transcatheter procedures towards profitability.

The Venock device can provide these savings to the hospital by allowing for early discharge of patients.

It is very common that outpatient procedures cost less than those that require hospitalization of the patient, even if it is the same procedure (see the reimbursement rates for Micra; inpatient vs outpatient, for example). And in the case of a same day discharge with the reimbursement being the same amount as that of a hospital stay, the outpatient procedure would definitely be more profitable than the inpatient.

One might suggest that the hospital would schedule patients so that outpatient procedures are only done in the morning to avoid necessitating an overnight stay during recovery.

Alternatively, having the Venock device available (which is simple to use and inexpensive) would allow for more flexibility in patient scheduling.

Patients who are ready for their procedure would not have to wait for treatment until the following morning to avoid an overnight stay during recovery.

Additionally, more flexibility in procedure scheduling will enable greater cath lab utilization, which further improves cost savings.

Overall, the Venock device allows for more efficient cath lab capacity utilization and higher patient turnover, while drastically saving time and cost during recovery.

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CAUTION: The Venock system is not approved for sale or investigational use.