TAVR 2020: Optimized Patient Care Pathway

Spotlight on HSHS St. Vincent Hospital and Prevea Health TAVR Program

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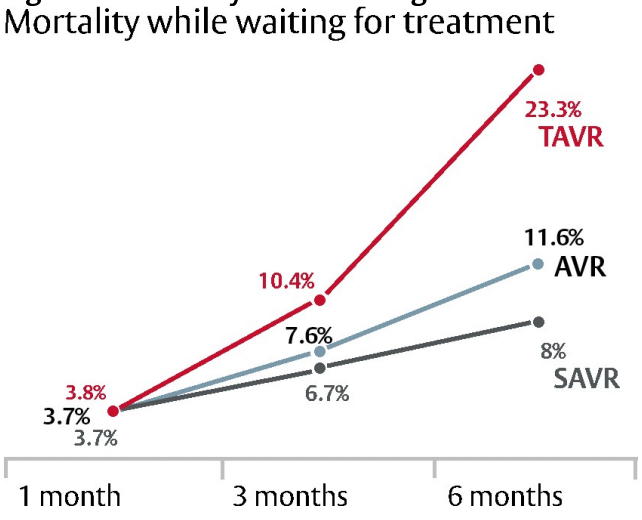
The transcatheter aortic valve replacement (TAVR) landscape is changing, with expanded indications and a projected increase in volume. TAVR is now positioned to become the standard for severe aortic stenosis patients, and TAVR programs will need to scale capacity to accommodate more screening and procedures.[1] With these opportunities and challenges come a need for optimized procedure planning to expedite the time to treatment for patients who have already been referred to existing TAVR centers.

Figure 1. Mortality while waiting for treatment[2]



TAVR treatment delays have been associated with mortality rates of 3.8% and 23.3% at one and six months respectively[2], and the 2019 US national average was approximately seven weeks from intake to treatment.[3]

This paper highlights the operational and clinical synergies implemented at St. Vincent/Prevea. From the start, its goals have been aligned across administrative and clinical team members and processes, which allowed access to TAVR for more patients with a reported positive impact on clinical outcomes. This program describes strategies and tactics such as:

- Up front and continuous planning with all team members equally involved, as it relates to infrastructure, people, and processes
- A culture of strong and trusting relationships with prompt communication and follow up, both within and across clinical and operational functions
- Proactive and consistent, yet flexible, processes with detailed documentation and attention to quality

Practices described by the St. Vincent/Prevea team have resulted in the program's **ability to treat approximately 100 TAVR patents per year;** they are detailed through the sections of this paper and included in a checklist at its conclusion.

PREVEA health

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Edwards

Profile

TAVR program information: TAVR procedures are performed at HSHS St. Vincent Hospital by Prevea Health, the major clinical/physician group, both located in Green Bay, WI. Prevea provides health care services to 80+ locations across Wisconsin. HSHS St. Vincent Hospital is a 255-bed, non-academic hospital, and part of the 15-hospital HSHS system across Illinois and Wisconsin. It is part of the four-hospital Eastern Wisconsin Division.

Participating physicians and their affiliations: The Prevea TAVR physicians include two heart surgeons, four interventional cardiologists, and one non-interventional cardiologist.

Valve center services:

- Nationally accredited imaging labs with cardiac CT and echo
- Treatment options including medical therapy and anticoagulation
- Valve interventions including repair or replacement, catheter-based interventions-ASD/PFO closure, balloon valvuloplasty
- Second opinions concerning valve diagnosis, severity, timing, and type of recommended intervention
- Continued follow-up care
- Patient and family education, support, and care

Volume: Approximately 100 TAVR procedures per year.

TAVR program coordinators: One valve clinic coordinator (VCC) who is a nurse practitioner (NP) and one full-time registered nurse (RN).

Cath lab staff:

- One Cath Lab nurse
- One Cath Lab scrub tech
- One monitor

Cardiovascular OR staff:

- One anesthesiologist
- One OR nurse
- One surgical scrub tech
- One perfusionist

Edwards staff are typically available to support the technology.

Procedure schedule: One consistent TAVR day per week in a hybrid OR with up to three cases per day completed by 1:00 p.m. or four completed by 4:00 p.m.

Clinical protocols aligned with a minimalist approach: This center follows a minimalist approach matched to patient needs, such as conscious sedation, no Foley catheters, and minimal lines.

Cohesive program: Operational goals in lockstep with clinical goals

Starting with TAVR program initiation, this center described its approach to "hit the ground running" with solid and melded operational and clinical perspectives and all key stakeholders involved. Although the team expected to do 50 TAVRs in the first year, they were able to do approximately 100 TAVRs in an economically viable way. This volume is a testament to the administration for investing in the program, as well as for providing the right infrastructure for clinical and operational effectiveness.

These aligned clinical and operational components include infrastructure, people, and processes.

"Our success originated from having a distinct plan from beginning to end and sticking to that plan, while also being able to pivot when things didn't go quite right. You can't just dip your toe in the water."

- Christopher Brabant, President and CEO HSHS St. Clare Memorial Hospital Executive Administrator Cardiovascular Services

Infrastructure: Appropriate and necessary capital and resources invested from the start

As they planned the infrastructure, they focused on future evolutions of the program and asked, "how can the program continuously improve, with safety and ideal patient outcomes in mind?" Executive Administrator of Cardiovascular Services, Christopher Brabant, noted that this plan was the foundation for the program, along with capital investment in equipment, resources, and supplies required to bring the plan to fruition.

They started with construction because they did not have a hybrid suite at the time. Then, they made decisions about what the program needed from structural and infrastructure perspectives, answering questions such as:

- "What is the ideal intake process and how does a best-practice valve clinic operate?"
- "What data will we need? Who will be involved in the analysis? How can we ensure a 'best-practice' IT infrastructure so we can mine data and communicate everything including prior authorization, screening, etc.?"
- "How will the procedure day be structured, both clinically and operationally? What is the ideal room layout and equipment? Who will be involved in doing what?"
- "What are exemplary post-procedure processes that we can model, and what criteria will we use for discharge?"
- "Because TAVR programs elsewhere are often seen as loss leaders, how can we make sure that our program at least breaks even or, preferably, is profitable?"

This plan included each aspect of the TAVR program. It was communicated so that every function knew the approach for other functions and how they were focused on a unified goal to achieve the best possible patient outcomes.

Initial investment and up-to-date technology accommodated and augmented the doctors' skill sets, giving them tools they needed to provide the best patient care possible. We created efficiencies early and right-sized the skills of physicians and support staff, which built upon the financial success of our program."

- Christopher Brabant

People: Inclusive and trusting relationships formed across all roles – administrative and clinical

As the program was established, the team members learned best practices from a sister hospital within the HSHS system. To do so, the entire team of more than 20 clinical and operational personnel boarded a bus and embarked on a six-hour journey each way. Most of that initial team remains, and they report fond memories of this opportunity to establish relationships and learn from one another.

After initial collaborative learning from their sister hospital, they established TAVR heart team meetings with *everyone* included. While TAVR team meetings are a practice implemented by many TAVR programs, the St. Vincent/Prevea program includes administrative roles such as clinical documentation integrity specialists (CDIS) and coding team members in those meetings, in addition to the clinicians who are traditionally involved.

From the CDIS team's perspective, attending these meetings helped them to:

- Clarify what they were seeing on charts
- Understand the norms for TAVR patients
- Build strong relationships with the providers

The way these relationships and communication channels were initiated has carried forward over the five years since the program started.

"On the bus trip to our sister hospital in Springfield IL, our team played TAVR learning games together, which helped us bond in a non-threatening way. Everyone united and we were all in it for the patient. On this trip, it was decided that whichever cardiologist read the echo and referred to the Valve Clinic would become the primary cardiologist if the patient was not already established with one."

- Dawn Nissen, NP, Valve Clinic Coordinator

Processes: Proactive and well-documented

As indicated earlier, the St. Vincent/Prevea TAVR program initially formed its exemplary processes through on-site training at a sister hospital. These included administrative processes such as clinical documentation integrity and coding and billing, as well as clinical processes over the patient journey from referral to discharge.

These operational and clinical processes are described in the next two sections.

Operational side: Aligned clinical documentation integrity (CDI), coding/billing, and data analysis processes

This TAVR program reports that its early and ongoing positive contribution margins result from quality documentation and cross-functional processes, as well as a shared understanding across CDI, coding/billing, and data analysis personnel.

Robust and unique CDI review process

This TAVR program's CDI process is uniquely robust in that every TAVR chart is reviewed for clinical documentation integrity. In some other TAVR programs, CDI reviews are conducted less frequently; however, the St. Vincent/Prevea program recognized immediately that a robust CDI process would benefit both health economics and clinical outcomes, as a vital part of the program's overall eco-system.

When the program started, every TAVR was concurrently reviewed, as shown in this table:

Role	Activity
CDI program facilitator	• Reviews TAVR schedule • Assigns *each* TAVR chart to a CDIS for daily concurrent review
CDIS	Asks, "Is there an MCC present during the episode of care?" • If yes, validates the clinical indicators • If no, sends the chart to another CDIS for a second review

According to the CDI team, as a program is starting up, it is a best practice to have a second CDI review on every TAVR chart. As the TAVR program matures and CDISs have fully mastered the process, a review on every chart is still necessary, but a second review is only required occasionally, such as to check that the appropriate acuity was captured.

"Our process enables us to be effective in validating and capturing appropriate chronicity of congestive heart failure. We want to carefully review provider documentation, looking for documentation of clinical indicators, such as ventricular function, activity tolerance, or abdominal distention. It is important we accurately capture the conditions affecting DRG assignment, as payers are scrutinizing the validity of secondary diagnoses codes. Our process helps us consistently receive appropriate payment after billing."

- Kim Burns, Clinical Documentation Specialist, Facilitator

Cross-functional education and communication

Cross-functional education and communication were beneficial in setting expectations from the start of the program. Examples of cross-functional education include:

- The CDIS team and nurse practitioners learned from one another about the CDI process and any co-morbidities that would influence patient outcomes
- Nurses learned what CDISs look for in charts
- Accurate coding and revenue cycle processes were disseminated up front to ensure they did not miss anything from day one of the TAVR program
- CDISs and coders learned what the other function needs for accurate billing
- For continuous learning, physicians were shown good documentation examples as well as ones with opportunities for improved accuracy

Cross-functional communication examples include:

- If a CDIS sees an item in the patient history, such as a co-morbidity that is not documented, they send a documentation clarification query to the provider for more information and always receive a timely answer
- If the data coordinator identifies a Kansas City Cardiomyopathy Questionnaire (KCCQ) item or other risk factors missing from a chart, she reaches out to the VCC or others on the TAVR team

These examples of effective education and open communication continue today.

Clinical side: TAVR program roles, resources, and documentation during the patient journey

The same proactive and open culture that this TAVR program enjoys on the operational side is also true on the clinical side.

Trusting relationships between team members and solid processes with the ability to pivot when needed

Team members across the hospital and private groups indicated that collaboration and trusting relationships across all roles led to a coordinated effort.

Early planning across all parties resulted in open communication and consistent processes. Subsequently, those relationships have facilitated ongoing improvements. When there is an opportunity to do something better, having team members from clinical and operational functions in weekly meetings allows all perspectives to be considered.

"We look at outcomes and complication rates; we've had a couple during our program's five years. To solve for these, we take a comprehensive look and determine if it was the process or something else. Our team's culture is one of standardization in process and approach."

- Christopher Brabant

Consistent and well-documented pre-procedure process

This program prides itself on its valve clinic's consistency and detailed documentation in the following areas.

1. Consistent roles and process with no bottlenecks

Effective patient throughput starts with the valve clinic's consistency, such as:

- **The VCC as the central hub** for all screening results and communication across patients, doctors, and other team members
- **One scheduler who keeps everything coordinated** to ensure nothing is missed
- **One nurse who serves as back-up support for the VCC** so they can maintain consistency while working around patient schedules with the valve clinic open for screening every weekday
- **The same weekly schedule each time,** with screening results compiled by the VCC on Wednesdays, the multidisciplinary heart team meeting on Thursdays, and TAVRs performed on Tuesdays

"As the VCC, I am the 'home base' person. I educate and interact with the patient, and I also lead the TAVR meetings every week to review all cases for the following Tuesday. I see every patient in consultation with the heart surgeon. Having a dedicated VCC who is committed, along with the multidisciplinary team, is key to the success of the program."

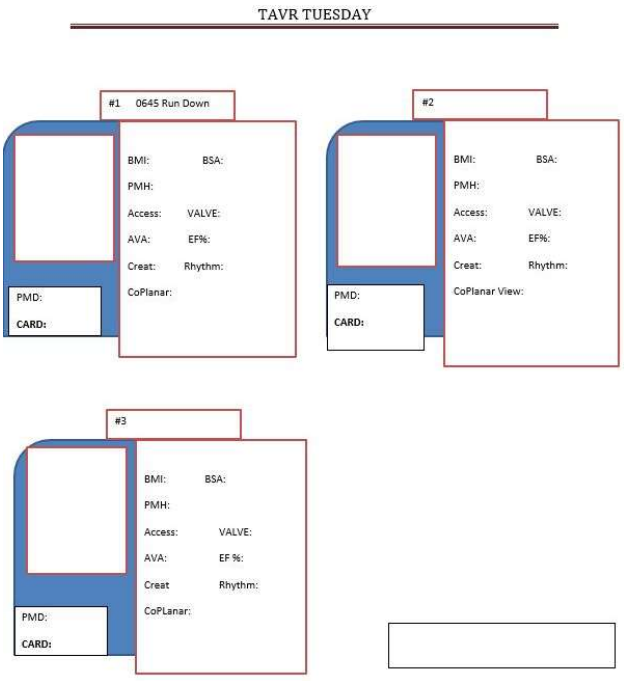
- Dawn Nissen

2. Detailed and templated documentation

The VCC painstakingly created detailed templates, which are consistently used in the pre-procedure and TAVR day care pathway. These templates include:

- CT surgery risk assessment template
- TAVR evaluation PPT template, which is compiled by the VCC and shared at Thursday's heart team meetings, with sections including:
    - Basic patient information
    - AS assessment by echo
    - Medical history
    - Laboratory studies
    - CT surgery risk assessment with a red, yellow, green dashboard summary
    - Conduction history
    - Aortic annulus and coronary height
    - Valve size selection
    - CT peripherals
    - Endovascular surgeon review notes
- TAVR multidisciplinary team meeting schedule
- TAVR Tuesday template (see figure 2)
- Provider requirement templates

Figure 2. TAVR Tuesday template



3. Preparation

The many planning and preparation activities during the pre-procedure care pathway mitigate potential bottlenecks experienced by other TAVR programs.

- **Prior authorizations (PAs) issues are prevented** through the VCC's careful documentation at the program's inception, and ongoing as payer requirements change; templates ensure requirements are accurately captured and there are no denials with patients required to wait for TAVR as a result
- **A focus on capacity and planning accordingly** prevents patients from waiting in the Cath Lab for a bed post-procedure which helps facilitate TAVR day flow
- **Setting patient and team expectations pre-procedure,** with a focus on knowing the patient, allows this program to anticipate complex cases, plan length of stay and discharge contingencies, and keep the patient with the same cardiologist when possible

"If you really know the patient, you can look ahead and anticipate potential pitfalls. We're thorough in preparing them for the procedure and aftercare. Most hospitals do the procedure well – but knowing our patients well is where we excel."

- Dr. Simil S. Gala, Interventional Cardiologist

Consistent and coordinated TAVR day process

This program's pre-procedure planning flows into its consistent and coordinated TAVR day process. TAVR day "best practices" include the following.

1. A small, dedicated team in year one that trained new team members in subsequent years

A consistent TAVR day process was developed in year one when the TAVR team comprised a small, dedicated team. Keeping the team narrow and focused allowed them to form routine processes. Starting in the second year, they rotated in new Cath Lab and CVOR team members to learn from the initial team. This helped with process optimization and cost containment, for example, by reducing unnecessary supplies.

2. Cross-functional education and communication

The program's culture of cross-functional education and communication holds true on the clinical side. The following examples illustrate this.

- All four interventional cardiologists follow roughly the same process and use the same equipment; they have open dialog about different styles and share best practices to arrive at a consistent procedure day, regardless of which cardiologist is on the schedule
- The CVOR and Cath Lab staff were all trained together, and they continue to cross-train as much as possible so they can rotate roles as needed

"I encourage the staff to find different roles to learn from. I might say, 'understand what anesthesia is focusing on during a TAVR,' or 'go learn about echos.' I encourage them to talk to everyone, including anesthesiologists, perfusionists, and physicians. And I also make sure they practice, practice, practice with dry runs. Even after 400 TAVRs, we still practice emergencies. Don't get stuck in your own role; learn others' roles."

- Michelle Bobusch, Catheterization Lab Manager

3. A defined TAVR day schedule and process

The St. Vincent/Prevea program's ability to set and adhere to a procedure day schedule is key in how the heart team describes its ability to:

- Often complete four TAVR cases by 4:00 p.m., which enables a consistent practice, along with patient expectation setting
- Achieve an average time between patients of under 30 minutes
- Consistently spend less than 30 minutes between patient pick up and puncture/lido

An example TAVR day schedule with two patients, is illustrated in Figure 3.

Figure 3. Example TAVR procedure day patient throughput schedule

	Procedure 1	Procedure 2
Mtg start time	7:45 a.m.	
Pt pick up time	8:00 a.m.	9:35 a.m.
Pt in room	8:06 a.m.	9:41 a.m.
Pt set up done	8:23 a.m.	9:57 a.m.
CVL MD scrub in	8:26 a.m.	9:59 a.m.
CVOR MD scrub in	8:27 a.m.	10:05 a.m.
Puncture/lido time	8:27 a.m.	10:00 a.m.
Big sheath inserted	8:35 a.m.	10:11 a.m.
Valve deployed	8:51 a.m.	10:25 a.m.
Sheath removed	8:55 a.m.	10:30 a.m.
CVOR MD breaks scrub	8:57 a.m.	10:31 a.m.
CVL MD breaks scrub	8:59 a.m.	10:34 a.m.
Pt leave room	9:14 a.m.	10:47 a.m.
Set up for next pt complete	9:27 a.m.	

The CVOR and Cath Lab team explained their coordinated efforts on TAVR day to achieve the results described, as follows.

- Two days prior to TAVR day, patients meet with the surgeon, anesthesiologist, and nurse practitioner
  - The pre-procedure echo is done at this time along with documentation that saves time on procedure day
  - While it is not always the same anesthesiologist, if it's a different one for the procedure, they have clear documentation from this pre-procedure visit; this collaboration across the anesthesia team helps on procedure day
- The evening before the procedure, all instruments and supplies, down to the blanket warmer, are pulled and placed in bins labeled with the patient case number; this avoids scrambling for needed instruments just before or during the procedure
- On procedure day, the team holds a brief morning meeting to make sure everyone is aligned
- The CVOR nurse owns the patient from pre-op until they arrive in the room, and from there works together with the Cath Lab staff to prepare and drape the patient
- The patient is prepared using minimalist procedures: no Foley catheters, central line, or arterial line
- The room is TAVR-dedicated and not an OR or Cath Lab; as a result, both the OR and Cath Lab staff are able to bring in needed supplies, which removes potential delays or dependencies
- The Cath Lab and CVOR nurses have defined roles that remain the same during the procedure and prevent duplicating tasks or getting in the others' way
- The CVOR nurse takes ownership again to bring the patient to recovery prior to picking up the next patient
- Meanwhile, the remaining Cath Lab and CVOR staff clean and prepare the room for the next patient; they do this themselves and do not wait for housekeeping

Conclusion

The St. Vincent/Prevea TAVR team described "best practices" that contribute to their aligned clinical and operational functions. This reported alignment results in optimized procedure planning in a way that contributes to the program's economic viability and positive patient outcomes.

TAVR programs are encouraged to consider how these, or similar practices, can be implemented at their sites.

Cohesive program: Operational goals in lockstep with clinical goals

- ✓ **Infrastructure:** Appropriate and necessary capital and resources invested from the start
- ✓ **People:** Inclusive and trusting relationships formed across all roles – administrative and clinical
- ✓ **Processes:** Proactive and well-documented

Operational side: Aligned clinical documentation integrity (CDI), coding/ billing, and data analysis processes

- ✓ Robust and unique CDI review process
- ✓ Cross-functional education and communication

Clinical side: TAVR program roles, resources, and documentation during the patient journey

- ✓ Trusting relationships between team members and solid processes with the ability to pivot when needed
- ✓ Consistent and well-documented pre-procedure process
  1. Consistent roles and process with no bottlenecks
  2. Detailed and templated documentation
  3. Preparation
- ✓ Consistent and coordinated TAVR day process
  1. A small, dedicated team in year one that trained new team members in subsequent years
  2. Cross-functional education and communication
  3. A defined TAVR day schedule and process

Disclaimers

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Important Safety Information

Edwards SAPIEN 3 THV System and Edwards SAPIEN 3 Ultra THV System

Indications: The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or mitral valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications: The valves and delivery systems are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

Warnings: Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation. There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments in high or greater risk patients. Incorrect sizing of the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-prosthesis mismatch), and/or annular rupture. Accelerated deterioration of the valve due to calcific degeneration may occur in children, adolescents, or young adults and in patients with an altered calcium metabolism. Prior to delivery, the valve must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve. Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease. Patients with pre-existing bioprostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment. Do not use the valve if the tamper-evident seal is broken, the storage solution does not completely cover the valve, the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. Do not mishandle the delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g., kinked or stretched), or if the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution, rinse solution, or to the valve. Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets. Failure to use slow, controlled inflation and prescribed nominal inflation volumes may result in balloon rupture, and lead to patient death or serious injuries associated with difficulty retrieving the delivery system and surgical intervention.

Precautions: Safety, effectiveness, and durability have not been established for THV-in-THV procedures. Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include, the presence of devices or thrombus or other abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach; and the presence of an Atrial Septal Occluder Device or calcium or abnormalities in the atrial septum preventing safe transseptal access. Special care must be exercised in mitral valve replacement if chordal preservation techniques were used in the primary implantation to avoid entrapment of the subvalvular apparatus. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: non-calcified aortic annulus; severe ventricular dysfunction with ejection fraction < 20%; congenital unicuspid aortic valve; congenital bicuspid aortic valve in low surgical risk patients; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation > 3+); pre-existing prosthetic ring in any position; severe mitral annular calcification (MAC); severe (> 3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as leukopenia (WBC < 3000 cells/mL), acute anemia (Hb < 9 g/dL),

thrombocytopenia (platelet count < 50,000 cells/mL), or history of bleeding diathesis or coagulopathy; hypertrophic cardiomyopathy with or without obstruction (HOCM); echocardiographic evidence of intracardiac mass, thrombus, or vegetation; a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated; significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater, marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta; access characteristics that would preclude safe placement of the 14F or 16F Edwards eSheath introducer set or the 14F Axela sheath, such as severe obstructive calcification, severe tortuosity, or diameter less than 5.5 mm (14F Axela or 14F eSheath introducer set) or 6 mm (16F eSheath introducer set or 14F Axela in subclavian access); excessive calcification at access site; bulky calcified aortic valve leaflets in close proximity to coronary ostia; a concomitant paravalvular leak where the failing bioprosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireform frame fracture); or a partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium. Residual mean gradient may be higher in a "THV-in-failing bioprosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting bioprosthetic valve be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

Potential Adverse Events: Potential risks associated with the overall procedure, including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography: death; stroke/transient ischemic attack, clusters, or neurological deficit; paralysis; permanent disability; respiratory insufficiency or respiratory failure; hemorrhage requiring transfusion or intervention; cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium, or valvular structures that may require intervention; pericardial effusion or cardiac tamponade; embolization including air, calcific valve material, or thrombus; infection including septicemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (AV) fistula or pseudoaneurysm; reoperation; ischemia or nerve injury; restenosis; pulmonary edema; pleural effusion; bleeding; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia, contrast media, or device materials; hematoma; syncope; pain or changes at the access site; exercise intolerance or weakness; inflammation; angina; heart murmur; and fever. Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; emergency cardiac surgery; cardiac failure or low cardiac output; coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring intervention; valve thrombosis; device embolization; device migration or malposition requiring intervention; left ventricular outflow tract obstruction; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis); device degeneration; paravalvular or transvalvular leak; valve regurgitation; hemolysis; injury to the mitral valve; device explants; mediastinitis; mediastinal bleeding; nonstructural dysfunction; mechanical failure of delivery system and/or accessories; and non-emergent reoperation.

Edwards Axela Sheath

Indications: The Edwards Axela sheath is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 Ultra delivery system.

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

Precautions: Caution should be used in vessels that have diameters less than 5.5 mm as it may preclude safe placement of the 14F Edwards Axela sheath. For subclavian/axillary vessels with the 29 mm Edwards SAPIEN 3 Ultra delivery system, caution should be used in vessels that have diameters less than 6.0 mm as it may preclude safe placement of the 14F Edwards Axela sheath. Use caution in tortuous or calcified vessels that would prevent safe entry of the sheath. Do not use the Edwards Axela sheath if the packaging sterile barriers and any components have been opened or damaged or the expiration date has elapsed. When inserting, manipulating or withdrawing a device through the sheath, always maintain sheath position. When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.

Potential Adverse Events: Complications associated with standard catheterization and use of angiography include, but are not limited to, injury including perforation or dissection of vessels, thrombosis and/or plaque dislodgement which may result in emboli formation, distal vessel obstruction, hemorrhage, infection, and/or death.

Edwards eSheath

Indications: The Edwards eSheath introducer set is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 and the Edwards SAPIEN 3 Ultra transcatheter heart valves.

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There is no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. The Edwards eSheath introducer set must be used with a compatible 0.035" (0.89 mm) guidewire to prevent vessel injury.

Precautions: Caution should be used in vessels that have diameters less than 5.5 mm or 6 mm as it may preclude safe placement of the 14F and 16F Edwards eSheath introducer set respectively. Use caution in tortuous or calcified vessels that would prevent safe entry of the introducer set. Do not use the Edwards eSheath introducer set if the packaging sterile barriers and any components have been opened or damaged. When inserting, manipulating or withdrawing a device through the sheath, always maintain sheath position. When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.

Potential Adverse Events: Complications associated with standard catheterization and use of angiography include, but are not limited to, injury including perforation or dissection of vessels, thrombosis and/or plaque dislodgement which may result in emboli formation, distal vessel obstruction, hemorrhage, infection, and/or death.

Edwards Crimper

Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN 3 Ultra transcatheter heart valve and the Edwards SAPIEN 3 transcatheter heart valve for implantation.

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

Precautions: For special considerations associated with the use of the Edwards crimper prior to THV implantation, refer to the THV Instructions for Use.

Potential Adverse Events: There are no known potential adverse events associated with the Edwards crimper.

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CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

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