In elderly patients, severe symptomatic aortic stenosis is often caused by the build-up of calcium (mineral deposits) on the aortic valve’s leaflets (flaps of tissue that open and close to regulate the one-way flow of blood through the aortic valve). This build-up of calcium on the leaflets impairs the aortic valve’s ability to fully open and close. As a result, the narrowed valve allows less oxygen-rich blood to flow from the lungs to the brain and rest of the body which may cause symptoms like severe shortness of breath and extreme fatigue.

**Treatment**

While open-chest surgery to replace the aortic valve is the gold standard treatment for severe symptomatic aortic stenosis, there are some patients who are not eligible for surgery or considered at high risk for surgery. These patients may be candidates for a therapy called transcatheter aortic valve replacement (TAVR), which allows Heart Teams to replace a diseased aortic heart valve without open-chest surgery. TAVR enables the placement of a balloon-expandable heart valve into the body with a tube-based delivery system called a catheter. This tube-based system allows the valve to be inserted through an incision in the leg and into an artery (transfemoral procedure), or through an incision between the ribs and then through the bottom end of the heart called the apex (transapical procedure). The transapical procedure is only available to certain high-risk patients who are not candidates for the transfemoral procedure because they do not have appropriate access through their leg artery.

A Heart Team will conduct a comprehensive evaluation to determine whether the TAVR procedure is an appropriate therapeutic option. In certain cases, TAVR may not be an option because of co-existing medical conditions or disease processes that would prevent the patient from experiencing the expected treatment benefit or because the risks outweigh the benefits. For those who are candidates for TAVR, this therapy may provide relief from the often debilitating symptoms associated with severe symptomatic native aortic valve stenosis. TAVR is a significant procedure involving general anesthesia, and placement of the valve is associated with specific contraindications as well as serious adverse effects, including risks of death, stroke, damage to the artery used for insertion of the valve, major bleeding, and other life-threatening and serious events. In addition, the longevity of the valve’s function is not yet known. Please refer to the Instructions for Use or Patient Brochure for complete information on warnings, contraindications and serious adverse events.

**More Information**

More information about the TAVR procedure can be found at [http://newheartvalve.com/](http://newheartvalve.com/)
I mentioned medical conditions.

Components of a prosthetic valve, thickening, stenosis; device degeneration; paravalvular or transvalvular leak; valve regurgitation; hemolysis; bioprosthesis include, but may not be limited to the following: cardiac arrest; cardiogenic shock; emergency cardiac surgery; cardiac failure or failure of delivery system and/or accessories; and valvular tearing or trauma. Additional potential risks specifically associated with the use of the bioprosthesis which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; femoral AV fistula or pseudoaneurysm; reoperation; peripheral effusion or cardiac tamponade; embolization including air, calcific valve material or thrombus; thrombus formation, plaque dislodgment, and embolization may result in myocardial infarction, stroke, distal peripheral occlusion, and/or death; infection including septicemia and endocarditis; heart failure; myocardial infarction; valve leaflet dehiscence; renal insufficiency or renal failure; conduction system injury (defect) which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; femoral AV fistula or pseudoaneurysm; reoperation; peripheral ischemia or nerve injury; restenosis; pulmonary edema; pleural effusion; bleeding; balloon rupture; balloon separation following balloon rupture; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia or to contrast media; hemoptysis; syncope; pain or changes at the access site; exercise intolerance or weakness; inflammation; anemia; heart murmur; fever; mechanical failure of delivery system and/or accessories; and valvular tearing or trauma. Additional potential risks specifically associated with the use of the bioprosthesis include, but may not be limited to the following: 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; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflets retraction, stent creep, suture line disruption of components); prosthetic valve, paravalvular or transvalvular leak; valve embolization; non-stentless; device explants; nonstructural dysfunction; and non-emergent reoperation. All listed risks may include symptoms associated with the above mentioned medical conditions.

IMPORTANT RISK INFORMATION

EDWARDS SAPIEN TRANSCATHETER HEART VALVE WITH THE RETRORFLEX 3 DELIVERY SYSTEM

Indications: The Edwards SAPIEN transcatheter heart valve, model 9000TFX, sizes 23 mm and 26 mm, is indicated for transfemoral delivery in patients with severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency and with ejection fraction >20% who have been examined by a heart team including an experienced cardiac surgeon and a cardiologist and found to either be: 1) inoperable and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis; or 2) to be operative candidates for aortic valve replacement as determined by the Society of Thoracic Surgeons predicted operative risk score ≥ 8% or are judged by the heart team to be at ≥ 15% risk of mortality for surgical aortic valve replacement. Indications: The RetroFlex 3 delivery system is indicated for the transfemoral delivery of the Edwards SAPIEN transcatheter heart valve. Contraindications: The bioprosthesis and delivery system 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 is an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments. 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 sterile, non-pyrogenicity, and functionality of the devices after reprocessing. Incorrect sizing of the bioprosthesis may lead to paravalvular leak, migration, embolization and/or annular rupture. Accelerated deterioration of the bioprosthesis may occur in patients with an altered calcium metabolism. Bioprosthesis must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Bioprosthesis leaflets misshapen or damaged during any part of the procedure will require replacement of the bioprosthesis. Caution should be exercised in implanting a bioprosthesis in patients with clinically significant coronary artery disease. Patients with pre-existing mitral valve disease should be carefully assessed prior to implantation of the bioprosthesis to ensure proper bioprosthesis positioning and deployment. Patients presenting with combination AV low flow, low gradient should undergo additional evaluation to establish the degree of aortic stenosis. Do not use the bioprosthesis if the tamper evident seal is broken, the storage solution does not completely cover the bioprosthesis, the temperature indicator has been activated, the bioprosthesis is damaged, or the expiration date has elapsed. Do not mishandle the RetroFlex 3 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 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 chromium, nickel, molybdenum, manganese, copper, 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 for years. In addition, contrast media may affect the liver and kidneys. Regular medical follow-up is advised to evaluate bioprosthesis 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 Material Safety Data Sheet available from Edwards Lifesciences. Do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended in patients at risk for prosthetic valve infection and endocarditis. Bioprosthetic valve recipients should be maintained on anticoagulant and antplatelet therapy (e.g. clopidogrel or ticlopidine [75 mg/day]) for 6 months post-procedure and aspirin (75-100 mg/day) for life, except when contraindicated, as determined by their physician. The safety of the bioprosthesis implantation has not been established in patients who have: pre-existing prosthetic heart valve or valve repair device in any position; severe ventricular dysfunction with ejection fraction of <20%; and hypertrophic cardiomyopathy with or without obstruction (HOCM). Safety, effectiveness, and durability have not been established for valve-in-valve procedures. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: non-calcified aortic annulus; congenital unicusp or congenital bicuspid aortic valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation >3+); pre-existing prosthetic heart valve or prosthetic ring in any position; severe mitral annular calcification (MAC), severe (>3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as: leukopenia (WBC <3000 mm3), acute anemia (Hb <9 g/dL), thrombocytopenia (platelet count <50,000 cells/mm3), 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; native aortic annulus size <18 mm or >25 mm as measured by echocardiogram; significant aortic disease, including abdominal aortic or thoracic aneurysms 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; iliofemoral vessel characteristics that would preclude safe placement of 22F or 24F introducer sheath such as severe obstructive calcification, severe tortuosity or vessels size less than 7 mm in diameter; and bulky calcified aortic valve leaflets in close proximity to coronary ostia. Potential Adverse Events: Potential risks associated with the overall procedure including potential access complications associated with standard cardiac catheterization for the transfemoral access procedure, 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; infundibulum injury; cardiovascular injury including perforation or dissection of vessels, ventricle, myocardium or valvular structures that may require intervention; annular tear or rupture; pericardial effusion or cardiac tamponade; embolization including air, calcific valve material or thrombus; thrombus formation, plaque dislodgment, and embolization that may result in myocardial infarction, stroke, distal peripheral occlusion, and/or death; infection including septicemia and endocarditis; heart failure; myocardial infarction; valve leaflet dehiscence; renal insufficiency or renal failure; conduction system injury (defect) which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; femoral AV fistula or pseudoaneurysm; reoperation; peripheral ischemia or nerve injury; restenosis; pulmonary edema; pleural effusion; bleeding; balloon rupture; balloon separation following balloon rupture; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia or to contrast media; hemoptysis; syncope; pain or changes at the access site; exercise intolerance or weakness; inflammation; anemia; heart murmur; fever; mechanical failure of delivery system and/or accessories; and valvular tearing or trauma. Additional potential risks specifically associated with the use of the bioprosthesis include, but may not be limited to the following: 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; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflets retraction, stent creep, suture line disruption of components); prosthetic valve, paravalvular or transvalvular leak; valve embolization; non-stentless; device explants; nonstructural dysfunction; and non-emergent reoperation. All listed risks may include symptoms associated with the above mentioned medical conditions.

RETROFLEX BALLOON CATHETER

Indications: The RetroFlex balloon catheter is indicated for valvuloplasty of a stenotic aortic valve prior to implantation of the Edwards SAPIEN transcatheter heart valve. Contraindications: Other than standard risks associated with insertion of a cardiovascular catheter, there are no known contraindications for valvuloplasty. The patient’s medical condition could affect successful use of this catheter.
catheter. Warnings: The device is designed, intended, and distributed for single use only. Do not resterilize or reuse the device. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g. kinked or stretched), or the expiration date has elapsed. Precautions: Special considerations associated with the use of this device prior to transcatheter heart valve implantation refer to the bioprosthesis instructions for use. This catheter has not been tested with any transcatheter valve other than the Edwards SAPIEN transcatheter heart valve. Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon. The device is not intended for post-dilatation of deployed transcatheter heart valves. While exposed within the body, device advancement and retrieval should not be done without the aid of fluoroscopy. Do not advance or retract the device unless the balloon is fully deflated under vacuum. Potential Adverse Events: Complications associated with standard catheterization, balloon valvuloplasty, and the use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media, injury including perforation or dissection of vessels, thrombus formation, plaque dislodgement and embolization that may result in myocardial infarction, stroke, distal peripheral occlusion and/or death, arrhythmia development, cardiac perforation, conduction system injury, hematoma, infundibulum injury, annular tear or rupture and/or valve leaflet dehiscence, severe valve insufficiency, valve restenosis, valve damage, balloon rupture, balloon separation following balloon rupture, valvular tearing or trauma, thromboembolic events, and infection. Refer to the Edwards SAPIEN transcatheter heart valve with the RetroFlex 3 delivery system instructions for use for a full list of potential adverse events.

EDWARDS TRANSFEMORAL BALLOON CATHETER: The Edwards transfemoral balloon catheter is indicated for valvuloplasty of a stenotic aortic valve prior to implantation of the Edwards SAPIEN transcatheter heart valve. Contraindications: Other than standard risks associated with insertion of a cardiovascular catheter, there are no known contraindications for valvuloplasty. The patient’s medical condition could affect successful use of the device. Warnings: The device is designed, intended, and distributed for single use only. Do not resterilize or reuse the device. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g. kinked or stretched), or the expiration date has elapsed. Precautions: For special considerations associated with the use of this device prior to transcatheter heart valve implantation, refer to the bioprosthesis instruction for use. Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon. The device is not intended for post-dilatation of deployed transcatheter heart valves. While exposed within the body, device advancement and retrieval should not be done without the aid of fluoroscopy. Do not advance or retract the device unless the balloon is fully deflated under vacuum. Potential Adverse Events: Complications associated with standard catheterization, balloon valvuloplasty, and the use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media, injury including perforation or dissection of vessels, thrombus formation, plaque dislodgement and embolization that may result in myocardial infarction, stroke, distal peripheral occlusion and/or death, arrhythmia development, cardiac perforation, conduction system injury, hematoma, infundibulum injury, annular tear or rupture and/or valve leaflet dehiscence, severe valve insufficiency, valve restenosis, valve damage, balloon rupture, balloon separation following balloon rupture, valvular tearing or trauma, thromboembolic events, and infection. Refer to the Edwards SAPIEN transcatheter heart valve with the RetroFlex 3 delivery system instructions for use for a full list of potential adverse events.

CRIMPER Indications: The crimper is indicated for use in preparing the Edwards SAPIEN transcatheter heart valve for implantation. Contraindications: No known contraindications. Warnings: The device is designed, intended, and distributed for single use only. Do not resterilize or reuse the device. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed. Precautions: For special considerations associated with the use of this device prior to transcatheter heart valve implantation, refer to the bioprosthesis instructions for use. Potential Adverse Events: No known potential adverse events.

EDWARDS SAPIEN TRANSCATHETER HEART VALVE WITH THE ASCENDRA 3 DELIVERY SYSTEM Indications: The Edwards SAPIEN transcatheter heart valve, model 9000TFX, sizes 23 mm and 26 mm, is indicated for transapical delivery in patients with severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency and with ejection fraction > 20% who have been examined by a heart team including an experienced cardiac surgeon and a cardiologist and found to be operative candidates for aortic valve replacement but who have a Society of Thoracic Surgeons operative risk score ≥ 8% or are judged by the heart team to be at a ≥ 15% risk of mortality for surgical aortic valve replacement. Indications: The Ascendra 3 delivery system is indicated for the transapical delivery of the Edwards SAPIEN transcatheter heart valve. Contraindications: The bioprosthesis should not be used in patients who cannot tolerate prolonged anticoagulation/antiplatelet regimens 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 is an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments. The devices are designed, intended, and distributed for single use only. Do not re-sterilize or reuse the devices. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Incorrect sizing of the bioprosthesis and use of an inappropriate delivery system may result in early paravalvular leak, paravalvular dehiscence, migration, embolization, transplant failure, and/or death. Accelerated deterioration of the bioprosthesis may occur in patients with clinically significant coronary artery disease. Patients with pre-existing mitral valve devices should be carefully assessed prior to implantation of the bioprosthesis to ensure proper bioprosthesis positioning and deployment. Patients presenting with combination AV low flow, low gradient should undergo additional evaluation to establish the degree of aortic stenosis. Do not use the bioprosthesis if the tamper evident seal is broken, the storage solution does not completely cover the bioprosthesis, the temperature indicator has been activated, or the bioprosthesis is damaged, or the expiration date has elapsed. Do not mishandle the Ascendra 3 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 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. Care should be exercised in patients with hyperkalemia, magnesium, manganese, copper, 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. The safety and efficacy of the transapical procedure has only been evaluated in those patient populations where the transfemoral procedure delivery is not suitable. Precautions: Long-term durability has not been established for the bioprosthesis. Regular medical follow-up is advised to evaluate bioprosthesis performance. Glutaraldehyde may cause sensitization of the skin, eyes, ears, 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 Material Safety Data Sheet available from Edwards Lifesciences. To maintain proper valve leaflet coaptation, do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed. Precautions: Special considerations associated with the use of this device prior to transcatheter heart valve implantation, refer to the bioprosthesis instructions for use. Potential Adverse Events: No known potential adverse events.

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characteristics/comorbidities: non-calcified aortic annulus; congenital unicuspid or congenital bicuspid aortic valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation > 3+); pre-existing prosthetic heart valve or prosthetic ring in any position; severe mitral annular calcification (MAC), severe (> 3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as: leukopenia (WBC < 3000 mm³), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/mm³), 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; native aortic annulus size < 18 mm or ≥ 25 mm as measured by echocardiogram; 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; bulky calcified aortic valve leaflets in close proximity to coronary ostia. Potential Adverse Events: Potential risks associated with the overall procedure including standard cardiac catheterization for the transapical access procedure, 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; infundibulum injury; cardiovascular injury including perforation or dissection of vessels, ventricle, myocardium or valvular structures that may require intervention; annular tear or rupture; pericardial effusion or cardiac tamponade; embolization including air, calcific valve material or thrombus; thrombus formation, plaque dislodgment, and embolization that may result in myocardial infarction, stroke, distal peripheral occlusion, and/or death; infection including septicemia and endocarditis; heart failure; myocardial infarction; valve leaflet dehiscence; renal insufficiency or renal failure; conduction system injury (defect) which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; femoral AV fistula or pseudoaneurysm; reoperation; peripheral ischemia or nerve injury; restenosis; pulmonary edema; pleural effusion; bleeding; balloon rupture; balloon separation following balloon rupture; anemia; abnormal kidney function (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia or to contrast media; hematoma; syncope; pain or changes at the access site; exercise intolerance or weakness; inflammation; angina; heart murmur; fever; mechanical failure of delivery system and/or accessories; suturing of a peripheral coronary artery; and valvular tearing or trauma. Additional potential risks specifically associated with the use of the bioprosthesis include, but may not be limited to the following: cardiac arrest; cardiogenic shock; emergency cardiac surgery; cardiac failure or low cardiac output; coronary flow obstruction/transvalvular flow disturbance; injury at the site of ventricular access that may require repair; device thrombosis requiring intervention; valve thrombosis; device embolization; device migration or malposition requiring intervention; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, stent creep, suture line disruption of components of a prosthetic valve, thickening, stenosis); device degeneration; paravalvular or transvalvular leak; injury to the mitral valve; valve regurgitation; hemolysis; device explants; nonstructural dysfunction; non-emergent reoperation. All listed risks may include symptoms associated with the above mentioned medical conditions.

ASCENDRA BALLOON AORTIC VALVULOPLASTY CATHETER Indications: The Ascendra balloon aortic valvuloplasty catheter is indicated for valvuloplasty of a stenotic aortic valve prior to implantation of the Edwards SAPIEN transcatheter heart valve. Contraindications: Other than standard risks associated with insertion of a cardiovascular catheter, there are no known contraindications for valvuloplasty. The patient's medical condition could affect successful use of this catheter. Warnings: The device is designed, intended, and distributed for single use only. Do not resterilize or reuse the device. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device or use it if it if the packaging or any components are not sterile, have been opened or are damaged (e.g. kinked or stretched), or the expiration date has elapsed. Precautions: For special considerations associated with the use of this device prior to transcatheter heart valve implantation, refer to the bioprosthesis instructions for use (IFU). This catheter has not been tested with any transcatheter valve other than the Edwards SAPIEN transcatheter heart valve. Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon. The device is not intended for post-dilatation of deployed transcatheter heart valves. While exposed within the body, device advancement and retrieval should not be done without the aid of fluoroscopy. Do not advance or retract the device unless the balloon is fully deflated under vacuum. Potential Adverse Events: Complications associated with standard catheterization, balloon valvuloplasty, and the use of angiography include, but are not limited to allergic reaction to anesthesia or to contrast media; thrombus formation, plaque dislodgment and embolization that may result in myocardial infarction, stroke, distal peripheral occlusion and/or death, arrhythmia development, cardiac perforation, conduction system injury, hematoma, infundibulum injury, annular tear or rupture and/or valve leaflet dehiscence, severe valve insufficiency, valve restenosis, valve damage, balloon rupture, balloon separation following balloon rupture, valvular tearing or trauma, thromboembolic events, and infection. Reference the Edwards SAPIEN transcatheter heart valve with the Ascendra balloon catheter instructions for use for a full list of potential adverse events.

ASCENDRA 3 INTRODUCER SHEATH SET Indications: The Ascenda 3 introducer sheath set is indicated for the introduction and removal of devices used with the Edwards SAPIEN transcatheter heart valve. Contraindications: 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. Do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g. kinked or stretched), or the expiration date has elapsed. Should not be used in patients with left ventricular aneurysm. The Ascenda 3 introducer sheath set must be used with a 0.035” guidewire. Precautions: No known precautions. Potential Adverse Events: Complications associated with standard surgical approach and use of angiography include, but are not limited to allergic reaction to anesthesia or to contrast media, stroke, distal peripheral occlusion and/or death. Reference the Edwards SAPIEN transcatheter heart valve with the Ascenda 3 delivery system instructions for use for a full list of potential adverse events.

CRIMPER Indications: The crimper is indicated for use in preparing the Edwards SAPIEN transcatheter heart valve for implantation. Contraindications: No known contraindications. Warnings: The device is designed, intended, and distributed for single use only. Do not resterilize or reuse the device. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed. Precautions: For special considerations associated with the use of this device prior to transcatheter heart valve implantation, refer to the bioprosthesis instructions for use. Potential Adverse Events: No known potential adverse events.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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