A Patient Screening and Procedural Planning Tool for Transcatheter Pulmonary Valve Interventions

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Abstract

Due to the anatomic variability, pre-procedural clinical decision making for transcatheter pulmonary valve replacement in congenital heart disease patients is complex. This work describes a Fit Analysis software support application for the Harmony Transcatheter Pulmonary Valve device. This tool provides a comprehensive computational patient screening framework that predicts the feasibility of device implantation and recommends an acceptable device deployment location. The retrospective study results indicate that the Fit Analysis application was sufficiently accurate for clinical use. The Fit Analysis framework demonstrates that computational models may be used for structural heart patient screening and procedural planning.
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ABSTRACT

Background: Due to the variability of right ventricular outflow tract anatomy after treatment for congenital heart disease, pre-procedural clinical decision making for transcatheter pulmonary valve replacement is complex. This work describes a novel Fit Analysis software support application for the Harmony Transcatheter Pulmonary Valve (TPV) device. This supplemental tool has been adopted to provide a comprehensive computational patient screening framework for the Harmony TPV that predicts the feasibility of device implantation and suitable device deployment locations.

Objectives: This aim of this study was to determine the accuracy of the Fit Analysis application.

Methods: In this multicenter, retrospective study, anatomical measurements of candidate patients were recorded using computed tomography angiography scans. For each patient, the application compared anatomical dimensions to TPV device dimensions. An algorithm then predicted the sufficiency of device-anatomy apposition. The accuracy of the Fit Analysis technology was assessed by comparing the application’s screening predictions to real-world physician screening decisions made for the same patients.

Results: 64 patients screened for the Harmony TPV 25 device during the Pivotal and Continued Access Studies were included in the analysis. The Fit Analysis application agreed with physician decisions with an accuracy of 94%, a sensitivity of 94%, and a specificity of 90%.

Conclusions: The Fit Analysis application was sufficiently accurate for clinical use and may decrease the cost and time required to screen patients and reduce intra-procedural radiation exposure. This framework demonstrates that computational models may be used as powerful instruments for structural heart patient screening and procedural planning.

CONDENSED ABSTRACT

Due to the anatomic variability, pre-procedural clinical decision making for transcatheter pulmonary valve replacement in congenital heart disease patients is complex. This work describes a Fit Analysis software support application for the Harmony Transcatheter Pulmonary Valve device. This tool provides a comprehensive computational patient screening framework that predicts the feasibility of device implantation and recommends an acceptable device deployment location. The retrospective study results indicate that the Fit Analysis application was sufficiently accurate for clinical use. The Fit Analysis framework demonstrates that computational models may be used for structural heart patient screening and procedural planning.

Key Words: structural heart interventions; software support application; patient screening; procedural planning tool; congenital heart disease

Abbreviations: tetralogy of Fallot, TOF; right ventricular outflow tract, RVOT; computed tomography angiography, CTA; transcatheter pulmonary valve, TPV; transcatheter pulmonary valve replacement, TPVR; stereolithographic, SLA; pulmonary artery, PA; pulmonary regurgitation, PR; landing zone, LZ; Instructions for Use, IFU
1. Introduction

Approximately 20% of congenital heart defects include anomalies of the right ventricular outflow tract (RVOT), most often tetralogy of Fallot (TOF), which affects over 6,000 births per year in the U.S.\textsuperscript{1-4} Most patients with TOF undergo surgical repair early in life, which typically includes enlargement of the RVOT with a patch or conduit. Almost all patients with TOF will require procedures to treat pulmonary regurgitation (PR) and/or RVOT obstruction related to the initial repair. Prostheses used for pulmonary valve replacement are subject to structural degeneration and other problems, such that they have a limited lifespan and require reintervention. Over a lifetime, multiple valve replacements may be necessary, each of which entails risk and morbidity. A major challenge in the management of TOF is how best to protect the heart from abnormal loading related to RVOT dysfunction without subjecting the patient to inordinate risk from repeated invasive procedures.

Due to the variable native anatomy of TOF and surgical techniques, the size and shape of the repaired RVOT is highly variable across patients. This anatomic complexity complicates pre-procedural planning for transcatheter pulmonary valve replacement (TPVR).\textsuperscript{5,6} The physician must decide if the device will fit appropriately in each patient’s RVOT without migration or paravalvular leakage, as well as where to place the device within the RVOT to yield a stable implant with the intended functional outcome.

Prior to certain structural heart procedures, such as transcatheter aortic valve implantation, commercially available software tools can be used to segment pre-operative computed tomography angiography (CTA) images and measure selected anatomical landmarks.\textsuperscript{7} However, existing software products function as communication workflows, rather than clinical decision support tools. While these tools are useful for understanding a patient’s suitability for TPVR, they do not compute device fit or identify optimal implant locations within the RVOT.
Previous studies have used a combination of finite element and computational fluid dynamics analyses to model patient-specific device-anatomy interactions, and in selected cases to aid in clinical decision making for TPVR procedures. Developing and executing complex physics-based computational models often requires more than one day per patient, limiting this advanced approach to a small number of patients during clinical trials. Creating patient-specific finite element and computational simulations capable of predicting anatomic device fit for commercial-scale procedural planning would require new efficiencies, automation, and extensive model verification and validation.

The Harmony™ Transcatheter Pulmonary Valve (TPV) (Medtronic, Inc., Minneapolis, MN) system is the first commercially available non-surgical heart valve to treat PR after repair of TOF and related conditions without a conduit or prosthetic valve. The Harmony TPV provides a minimally invasive alternative to open-heart surgery, the current standard of care, and has yielded favorable early outcomes. The Harmony system comprises a TPV and a Delivery Catheter System. The TPV consists of a porcine pericardial tissue valve mounted on a self-expanding stent graft composed of six self-expanding nitinol wire struts and polyester fabric. The Harmony TPV is available in two sizes: the smaller TPV 22, which has six crowns per strut, and the larger TPV 25, which has nine crowns per strut (Figure 1).

Like other percutaneous devices for congenital heart disease treatment, there are challenges associated with patient selection and pre-procedural planning for the Harmony TPV. The Harmony device primarily relies on compression on both the inflow and outflow sections of the TPV within the RVOT anatomy to generate normal forces (chronic outward force) on the device-anatomy interface to anchor the device and prevent paravalvular leakage. In contrast to aortic and mitral transcatheter heart valve devices, the Harmony TPV device does not have a consistent well-defined anatomic landing zone where the device can be seated.
During the Harmony Early Feasibility Study, physicians and Medtronic personnel primarily relied on patient-specific stereolithographic (SLA) 3D-printed models created using CTA images, as well as graphical plots that displayed the perimeter measurements of the anatomy and device, to screen patients and to identify acceptable landing zones. Candidate devices were physically inserted into the SLA models of prospective patients and qualitatively assessed for adequate expansion, conformation of the device, and device-anatomy apposition. Device position could be adjusted manually to assess alternate implant locations. Prosthesis oversizing with respect to the native anatomy was assessed visually to infer the likelihood of migration and paravalvular leakage.

The SLA model evaluation process, although informative, was subjective, cost prohibitive ($800 per model), and both time- (10-day model turnaround time) and resource-intensive. To reduce the subjectivity, cost, and time of this process, development of a numerical algorithm to predict device-anatomy apposition was initiated during the Early Feasibility Study.16

The aim of the current study was to assess the accuracy of the resulting ‘Fit Analysis’ software application which is based on this numerical algorithm. The Fit Analysis support application is an optional tool that contributes to physicians’ decision-making when determining if a patient is an appropriate candidate for TPVR with the Harmony valve. For acceptable candidates, the tool estimates oversizing for both device sizes and the location and length of a viable landing zone within the RVOT.

2. Methods

2.1 Retrospective Study Design and Screening Criteria

The effectiveness of TPVR with the Harmony valve was evaluated in the prospective Early Feasibility, Pivotal, and Continued Access Studies.10-15 In these studies, physicians determined the suitability of patients for Harmony TPV implant by assessing whether there was adequate device
compression (‘oversizing’) along the length of the distal and proximal struts of the device, based on measurements from CTA images (Figure 2). If a patient was identified as an anatomic candidate for the Harmony TPV, patient-specific 3D-printed SLA models were sent to physicians for additional physical and visual assessment of device fit.

The objective of this retrospective study was to determine the accuracy of the Fit Analysis application in assessing patients enrolled in the Pivotal and Continued Access Studies. This study is limited to candidates for the TPV 25 device, which treats a significantly larger portion (95%) of the Harmony commercial patient population than does TPV 22. Written informed consent was obtained for enrollment in the Pivotal and Continued Access Studies and for analysis of imaging data.

2.2 Study Eligibility and Procedures

The Harmony TPV system is indicated for use in the management of pediatric and adult patients with severe PR (i.e., severe PR by echocardiography and/or PR fraction ≥ 30% by cardiac magnetic resonance imaging) and a native or surgically-repaired RVOT who are clinically indicated for surgical pulmonary valve replacement.¹⁷ Details of the Pivotal and Continued Access Studies were reported previously.¹⁶

Patients in the Pivotal and Continued Access Studies who were candidates considered for TPV 25 and underwent a CTA image analysis and fit evaluation were included in this retrospective study. Exclusion criteria included poor image scan quality. The screening process is outlined in Figure 3.

Once the CTA image was captured (Step 1 in Figure 3), anatomic measurements were recorded, and the Fit Analysis report was generated (Step 2). The anatomic information, along with SLA models, was reviewed by the implanting physician for an initial feasibility assessment (Step 3). The physician recommended either not to implant due to unacceptable device-anatomy fit (inadequate oversizing or
insufficient landing zone) or to have the case reviewed by the Screening Committee to determine suitability for implant (Step 4). The voting Screening Committee consisted of at least one non-implanting interventional cardiologist, a physician imager, and a cardiothoracic surgeon.

As shown in Figure 3, certain patients were not recommended for an implant by the Screening Committee due to complex anatomy, which typically reflected anatomic considerations not analyzed by the software. Most of these patients were recommended for TPV 25 reevaluation in the future, once the collective experience with TPV 25 was greater and suitability of the device for complex anatomic variations was better appreciated. A subset of patients recommended for Screening Committee evaluation were not reviewed due to completion of the Pivotal Study.

Screening recommendations from the Fit Analysis application were compared to Implanting Physician Evaluation (Step 3), rather than the decision of the Screening Committee, during which complex case considerations and operator experience were evaluated. If a prospective patient proceeded to the Screening Committee (Step 4), that patient was considered acceptable, regardless of the Screening Committee recommendation. If the patient was exited (deemed unsuitable for treatment with TPV 25) after the Implanting Physician Evaluation and prior to Screening Committee review, that patient was considered unacceptable.

2.3 Image Acquisition and Analysis

Electrocardiogram-gated multi-slice chest CTA images were used to evaluate the anatomic dimensions of the RVOT and pulmonary artery (PA), including the proximal left and right PA branches. Image acquisition followed standard scan parameters recommended as part of the study protocols. Medtronic imaging analysts then performed anatomic centerline-based measurements on the CTA images.
across the region of interest using 3mensio medical imaging software (Pie Medical Imaging BV, Maastricht, The Netherlands).

Image analysis consisted of cross-sectional measurements at small intervals along the length of the main PA and RVOT. Measurements started at the roof of the PA bifurcation and ended 10 mm into the right ventricle. Measurements were taken in 90% diastole and 30% systole, although only the measurements in end-diastole were used to compute device fit.

2.4 Harmony Screening Software

The Fit Analysis application utilizes anatomic dimensions, device dimensions, and device chronic outward force characteristics to predict the feasibility of device implantation (and a range of locations acceptable for device deployment) for individual patients. Measurements were imported from the CTA analysis into the Fit Analysis software, where they were compared to those of the device. The perimeter of the anatomic cross-sections was compared to the perimeter of the undeformed device to compute oversizing. The Fit Analysis software identified possible landing zones (LZ) where sufficient apposition is predicted at both the inflow and outflow regions of the device. An overview of the software inputs and outputs is shown in the Central Illustration.

The speed of the algorithm facilitated repetition of this assessment at all potential implant locations within the RVOT. In general, a prediction of adequate device oversizing at both the inflow and outflow of the device indicated a feasible implant location. Taken together, the set of feasible implant locations demarcated a suitable landing zone which was reported to the implanting physician.

The underlying numerical algorithm works as follows: For any given device implantation location $X$ within the PA anatomy, the algorithm can chart the local oversizing $OS(x)$ along the entire length of the device, $x$, relative to the neighboring anatomy. The average oversizing, $\overline{OS}$, is calculated separately for
two regions of interest, $L$, on the device: the outflow and inflow. Average oversizing is used to assess if appropriate interference exists between the device and the patient’s anatomy.

The calculated average oversizing for each region (outflow and inflow) will vary with device implant position $X$ within the PA anatomy. Figure 4 shows an example of the analysis at one possible device position $X$. For this implant position, the average oversizing $\bar{OS}(X)$ is calculated as the average of the local oversizing $OS(x)$ over the region of interest $L$. Although the outflow is used in this example, analogous equations are used for the inflow region calculations. Average oversizing is recalculated for all potential implant locations ($X$) from the PA bifurcation to the right ventricle.

This algorithm can estimate the average device oversizing $\bar{OS}(X)$ for a given implant site $X$, based on the perimeter-derived diameters of the anatomy and the device. Although device fit in the native RVOT is primarily a function of anatomic size (i.e. diameter at different levels and length), it may also depend on shape. While the perimeter-based diameter approach initially created in the Early Feasibility Study considered dimensionality, it did not consider morphology, such as ellipticity and curvature. The algorithm was therefore extended to give the software user the optional ability to also consider shape in terms of the average ellipticity and curvature of the patient’s anatomy.

Experimental benchtop testing, utilizing simplified anatomic representations, was performed to determine the impact of ellipticity and curvature on TPV 25 device oversizing. This allowed the numerical algorithm to incorporate a shape modification factor that increases or decreases the predicted oversizing based on the magnitude of the ellipticity and curvature. In general, more curvature decreases (negatively impacts) the algorithm’s oversizing prediction, while more ellipticity increases (positively impacts) the oversizing prediction. Figure 5 shows a highly curved RVOT, which would decrease the algorithm’s estimated oversizing.
2.5 Device Oversizing Requirement

Experience from the Harmony clinical studies, finite element modeling of device-anatomy interactions, and validated benchtop testing informed the minimum required inflow (10%) and outflow (11%) oversizing recommended in the Instructions for Use (IFU), $O_{S_{IFU}}$, to ensure adequate anchoring of the device. The algorithm calculates average oversizing based on anatomic size and shape (if selected by the software user) for various implantation sites and identifies which implant locations satisfy the oversizing requirement ($\overline{O_S}(X) \geq O_{S_{IFU}}$).

2.6 Landing Zone Requirement

The calculated oversizing ($\overline{O_S}(X)$) varies with implant location $X$. A landing zone can be defined as the set of contiguous implant locations over which the oversizing criterion, ($\overline{O_S}(X) \geq O_{S_{IFU}}$), is satisfied. If this set of locations spans a length greater than or equal to 3 mm, the predicted landing zone is defined as viable.

A 3 mm LZ requirement was applied to the Fit Analysis results to account for inter-observer imaging analyst variability. This requirement ensured that patients would have an adequate landing zone regardless of the analyst. Patients with a 1-2 mm LZ in the Fit Analysis report are not considered to have met the landing zone requirement. Figure 6 shows how the algorithm identifies a viable landing zone.

2.7 Software Output

After computing the average oversizing over a range of virtual implant locations, the Fit Analysis software outputs a plot that shows the shape of the device overlaid on the anatomy within the acceptable implant location (Figure 7). At all virtual implant locations, plots were generated to represent the device overlaid on the anatomy. The shaded colors at the inflow and outflow sections indicate the comparison
between the computed average oversizing and the oversizing requirement and follows a traffic light methodology: acceptable, displayed by green ($\overline{OS}(X) \geq OS_{IFTU}$); borderline, displayed by yellow ($\overline{OS}(X) \geq 50\% \times OS_{IFTU}$); unacceptable, displayed by red ($\overline{OS}(X) < 50\% \times OS_{IFTU}$).

The proposed landing zone was illustrated on simulated intra-operative fluoroscopic images based on the pre-operative CTA, which were generated in 3mensio (Figure 8). These images provide estimates for initial angiographic angles to optimize profiling of the implant zone (within the positioning limits for most fluoroscopy systems), with the aim of improving procedural efficiency and minimizing adjustment of projections and patient radiation exposure. Additionally, an image of the device was overlaid on the pre-operative CTA images at the level of the acceptable landing zone, providing a virtual implant and a general sense of scale (Figure 8).

3. Results

3.1 Model Assessment

The Fit Analysis application development process followed relevant international standards for medical device software development. Verification and validation activities were performed to ensure compliance with functional and performance requirements.

A total of 64 patients from 7 centers in the US and Canada who were considered potential candidates for the TPV 25 therapy during the Pivotal and Continued Access Studies were included in this analysis (Figure 3). Patients considered acceptable in the Implanting Physician Evaluation (Step 3 in Figure 3) and correctly classified as acceptable by the Fit Analysis application were used to calculate the sensitivity. Patients considered unacceptable in the Implanting Physician Evaluation and correctly classified as unacceptable by the Fit Analysis application were used to calculate the specificity.
3.2 Model Performance

The results from the TPV 25 ‘Size & Shape’ model validation are included in the error matrix in Table 1. The algorithm achieved an accuracy of 94%, a sensitivity of 94%, and a specificity of 90%. The results indicate strong agreement between physician decisions and software predictions. Perimeter plots for the three patients that the software incorrectly classified as unacceptable are shown in Figure 9.

4. Discussion

This anatomic patient screening algorithm predicts if a viable TPV 25 landing zone exists for candidate patients. Using CTA scans of prospective Harmony patients, Medtronic measures anatomic cross-sections along the length of the RVOT and PA for both end-diastole and end-systole, which are used as inputs to the model. For a given implant location, the model compares the perimeter of the anatomic cross-sections in diastole with the perimeter of the undeformed device to compute average oversizing. If selected by the software user, this oversizing prediction has the optional ability to be updated (modified based on empirical observations) to account for the impact of curvature and ellipticity. The oversizing is compared to the IFU requirements to determine if sufficient oversizing exists at each potential implant site.

To be considered a viable candidate, sufficient oversizing must be predicted for all possible implant sites within a continuous region spanning at least 3 mm. As an intra-operative visual aid, this region (the target landing zone) is superimposed on fluoroscopic images. A representation of a virtually implanted device, positioned at the identified landing zone on a pre-operative CTA image, is also provided.

Diastole, rather than systole, is used to compute oversizing, as diastole is considered the worst-case for device migration due to the larger force of the retrograde pressure load on the closed leaflets. Moreover, the main PA length is shorter and the dimension of the muscular RVOT is larger during
diastole, which are expected to decrease the likelihood of an adequate landing zone. This conservative requirement may reduce the number of potential implant locations compared to a systolic assessment, although we have not attempted to determine whether and how often an algorithm using systolic measurements would yield a different prediction.

Through a retrospective study of candidate patients for the Harmony TPV 25 device, the accuracy of the Fit Analysis software was validated by comparing the application’s predictions to physicians’ screening decisions. Overall results demonstrated that the application was sufficiently accurate when compared to expert physician decisions.

The Fit Analysis software support application contributes to procedural planning and the determination of an appropriate landing zone within the RVOT. Additionally, the application has significantly decreased the amount of time and cost required to screen patients, ultimately allowing more patients to be evaluated and treated. Finally, the simulated fluoroscopy images that show the target implant location may be used as an intra-operative resource to decrease patient radiation exposure. To our knowledge, the Harmony Fit Analysis software is the first software support application available in the U.S for commercial structural heart interventions. In the future, anatomic measurements from magnetic resonance imaging rather than CTA may potentially be suitable as inputs to the model, which would decrease patient radiation exposure and offer broader screening availability.

4.1 Limitations

This study was retrospective and limited to clinical use with physicians experienced with the Harmony TPVR procedure. This study did not assess the accuracy of the Fit Analysis software for predicting successful Harmony valve implant or the actual location of implant. However, the study validates the software’s accuracy relative to physician decision making, which is acceptable for a clinical
screening tool intended only to support and assist preliminary physician-led screening. The application is not intended to make a final determination or decision on patient viability for treatment or device selection and does not constitute medical advice or replace the independent medical judgment of a trained and licensed physician with respect to any patient needs or circumstances.

The Fit Analysis application does not consider the effect of complex congenital heart disease structural anomalies, such as focal RVOT narrowings or irregular shapes that can affect procedural planning, non-anatomic patient exclusion criteria, or operator-related implant variation. Therefore, the output of the Fit Analysis application was compared with the initial implant feasibility decision of the implanting physician, rather than the decision of the Screening Committee, which evaluated complex case considerations and operator experience, as described above.

Several assumptions were made during development of the algorithm. The model does not account for variable device shortening related to constrained expansion, device fit in end-systole, compliance of the anatomy, shape/geometry features more complex than simple curvature or ellipticity, CTA image uncertainty, non-anatomic patient factors, or operator-related implant variation.

5. Conclusions

Since the Harmony system has become commercially available in the U.S., over 1,800 patients have been screened using the Fit Analysis application, 66% of whom were found to have an acceptable landing zone, and 528 implants have been completed at 66 different centers. Physicians have not elected to order patient-specific SLA models from Medtronic for any cases, demonstrating the improved digital Fit Analysis framework relative to the previous screening process.

The Fit Analysis application considers device mechanics, imaging science, and clinical experience in a computational framework that has translated into an effective and efficient software support tool for
a structural heart device. Based on this precedent, it can be expected that more computational tools designed for planning structural heart interventions will be provided by industry to clinicians in the future.

PERSPECTIVES

- **What Is Known?** Due to highly variable anatomy in patients with repaired TOF, pre-procedural planning for transcatheter pulmonary valve replacement is complex.

- **What Is New?** The Fit Analysis software support application provides a patient screening framework for the Harmony TPV that predicts the feasibility of device implantation and an acceptable location for device deployment for individual patients.

- **What Is Next?** In the future, more computational tools for planning structural heart procedures may be provided by industry to clinicians.

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Figure Legends

**Figure 1. Harmony transcatheter pulmonary valves.** The smaller Harmony size, TPV 22, and the larger Harmony size, TPV 25. Images reproduced with permission from Medtronic, Inc.

**Figure 2. CTA image of the RVOT indicates the general sizing considerations for determining appropriate fit of the TPV 25 valve.** Adequate oversizing is required where the inflow and outflow portions of the device will sit, without compression of the central valve housing component of the Harmony TPV 25 device. Images reproduced with permission from Medtronic, Inc.

**Figure 3. Flow chart of the physician screening process workflow.**

**Figure 4. Overview of oversizing calculation.** Local oversizing $OS(x)$ is averaged over the region of interest $L$ to generate average oversizing $\overline{OS} \%$ at position $X$ relative to the upper anatomic reference. The region of interest in this example is the device outflow region. A different implant position $X$ will result in a different average oversizing.

**Figure 5. 3D reconstruction of CTA images is from a prospective Harmony valve patient with a highly curved RVOT.**

**Figure 6. Fit Analysis oversizing calculation, comparison to IFU requirements, and landing zone generation.**

**Figure 7. Device overlaid on patient’s anatomy.** Device overlaid on patient’s anatomy in the acceptable landing zone; the ‘Outflow LZ’ label shows the landing zone location (top). Device overlaid on patient’s anatomy with plots showing different potential implant locations within the RVOT for a prospective patient and traffic light colors at the inflow and outflow,
indicating the comparison between the computed oversizing and the oversizing requirement (bottom).

**Figure 8. Simulated fluoroscopic images in 3mensio.** Overlaid landing zone (top); virtual implant of the device at the level of the landing zone on 3D and simulated angiographic representations from the pre-operative CTA (bottom).

**Figure 9. The three patients that the software incorrectly classified as unacceptable.**

Patient D, while reaching the oversizing requirements at a potential implant location, did not meet the 3mm LZ length requirement.

**Central Illustration. Fit Analysis Workflow.** A CTA image of the patient was captured and sent to Medtronic, which recorded the centerline-based measurements along the length of the pulmonary artery. The Fit Analysis software utilized these measurements to estimate device oversizing at potential implant locations and to compute a landing zone.
Figures

Figure 1. Harmony transcatheter pulmonary valves.

Reproduced with permission from Medtronic, Inc.
Figure 2. CTA image of the RVOT indicates the general sizing considerations for determining appropriate fit of the TPV 25 valve.

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Figure 3. Flow chart of the physician screening process workflow.

Step 1
Chest CT Angiogram Capture (n=64 patients)

Step 2
Anatomical measurements recorded & Fit Analysis Report generated by Medtronic (n=62)

Step 3
Implanting Physician Evaluation: Anatomical measurements & SLA models (n=62)

Step 4
Screening Committee (n=52)

Analysis not conducted: poor image scan quality (n=2)

Physician recommended not to implant due to unacceptable device-anatomy fit (n=10)

Screening Committee recommended not to implant due to complex anatomy (n=5)

Pivotal Implants completed: patient exited prior to a Screening Committee decision (n=8)

Proceed with Implant (n=39)
Figure 4. Overview of oversizing calculation.
Figure 5. 3D reconstruction of CTA images is from a prospective Harmony valve patient with a highly curved RVOT.
Figure 6. Fit Analysis oversizing calculation, comparison to IFU requirements, and landing zone generation.

1. Calculate average oversizing based on size & shape

2. Repeat at all implant locations within the RVOT in 1mm increments

3. Identify landing zone i.e., a continuous set of implant locations where the predicted (inflow and outflow) average oversizing satisfies IFU oversizing requirement
Figure 7. Device overlaid on patient’s anatomy.
Figure 8. Simulated fluoroscopic images in 3mensio.
Figure 9. The three patients that the software incorrectly classified as unacceptable.
Central Illustration. Fit Analysis Workflow.

Table 1. Harmony Fit Analysis model assessment results

Fit Analysis TPV 25 ‘Size & Shape’

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