SUMMARY OF PRIMARY CLINICAL STUDY

An investigational clinical study (THE MAGIC™ CARDIAC ABLATION FEASIBILITY STUDY - "MAGIC-FEST") was undertaken to evaluate the safety and effectiveness of the MAGiC ablation catheter.

Study Information

NCT06019845

EUDAMED Identification No.: CIV-23-10-044301

Investigational Device(s):	Magnetic Interventional Ablation Catheter – "MAGiC"
Indication:	MAGiC together with Stereotaxis RMNS is intended to be used during RF ablation to produce local lesions in cardiac tissue for the treatment of cardiac arrhythmias, for electrophysiological mapping, for sensing intracardiac electrograms, and for delivering stimulation pulses.
Study Stage:	Phase 1
Study Start Date:	January 4, 2024
Study Termination Date:	Study is currently in progress
Study Completion Date:	Study is currently enrolling
Stereotaxis Contact(s):	Betsy Lowry, Director, Clinical Affairs 973-723-6613
Coordinating Investigator:	Prof. med. Burkhard Hügl
Document Type:	Interim Clinical Study Report
Report Date:	October 7, 2025 Interim Study Report
Report Version:	B
Author(s):	Betsy Lowry, Director, Clinical Affairs

The study was carried out in accordance with Good Clinical Practice including the archiving of essential documents as required by the following:

International Standard Clinical investigation of medical devices for human subjects -- Good clinical practice ISO 14155:2020

This study was a prospective, single arm, unblinded, multi-center, interventional premarket investigation of MAGiC. There was no control group, randomization, or blinding in this clinical investigation.

The primary and secondary endpoints were selected to generate data to provide evidence of the safety and acute performance of MAGiC and the associated iConnect system. There was no specific sample size requirements by arrhythmia. The investigation sites made every effort to screen and enroll a variety of arrhythmias to collect the most meaningful use data. This investigation also allowed the physician to treat subjects as per their standard of care for the presenting arrhythmia to ensure that the data are reflective of real-world use. Secondary and exploratory endpoints are included to further characterize the safety and performance of

MAGiC and for scientific interest. Risks and adverse events were collected as primary and secondary endpoints to confirm the risks identified in the risk management process. No statistically powered hypotheses was being tested in this study.

Study summary

The first subject was screened on 02 January 2024 and enrolled on 04 January 2024. Up to the cutoff time of the interim clinical study report (October 7, 2025), a total of 81 subjects at 2 sites had been treated with the MAGiC catheter. Subjects enrolled in the study spanned a wide range of age (18-82 years), weight (50-140kg) and preexisting medical conditions. These subjects were treated for a range of cardiac arrythmias including: atrial fibrillation (AF), atrial flutter (AFL), atrioventricular reentrant tachycardia (AVRT), atrioventricular nodal tachycardia (AVNRT), focal atrial tachycardia (FAT), Wolff -Parkinson-White syndrome (WPW), premature ventricular contractions (PVC), and ventricular tachycardia (VT).

Acute procedural success was a primary efficacy endpoint for the study. As of the cutoff date for this report, ablation therapy with the MAGiC catheter had resulted in an acute success rate for treating atrial arrythmias of 100% which is better than published rates from large registry studies and 78% for ventricular arrythmias which is consistent with the published registry data for these type of procedures.

Lack of major device related adverse events was another primary safety endpoint for the study. Through the cutoff date for this interim report, there were no major adverse events attributed to the investigational device. All adverse events were recorded (including AEs that were unrelated to the study or procedure). Over the course of the study, 47 such adverse events were recorded, 9 of which were considered serious. None of the adverse events were attributed to a problem or failure with investigational device but were considered normal risks of the ablation procedure or were unrelated to the ablation procedure.

A sub-analysis of subjects with anatomical challenges due to prior congenital heart surgery was performed to assess the primary and secondary endpoints for this population. As of the cutoff date, seven (7) subjects matching this criterion were treated during the course of the study. Subjects treated for adult-onset arrhythmias with the MAGiC catheter presented with a broad range history of serious congenital heart conditions including: Tetralogy of Fallot, transposition of the great arteries, Epstein's anomaly, and ventricular septal defects with corresponding surgical modification such a Mustard procedure, or Senning procedure. This sub-group was selected for evaluation because these subjects have anatomical challenges that can prevent treatment with standard manual catheters and documenting the ability to treat these subjects with a magnetically navigated device is an important outcome of this study. Five (5) of the seven (7) subjects in this sub-group were treated for atrial flutter, one (1) for AVNRT and one (1) for WPW. All of these procedures were acutely successful with no reported adverse events.

Primary Endpoints

The objective of MAGiC-FEST is to document acute and chronic success rates along with device-related Major Adverse Events when using MAGiC with human patients. The primary endpoint is to document the acute procedural success across a range of treated arrhythmias. The data will be analyzed, and acute success presented with summary statistics by arrhythmia.

Acute Performance

Acute procedural success shall be assessed by evaluating the non-inducibility or lack of conduction of the index arrhythmia at the end of the procedure.

Acute Safety

The acute safety of MAGiC was assessed by the freedom from major adverse events (MAE) related to MAGiC. MAEs must meet the definition of Serious, occur prior to discharge, and be directly related to MAGiC for the purpose of this endpoint. MAEs include the following:

- Atrioesophageal fistula
- Cardiac perforation/ tamponade
- Cerebral infarct
- Death
- Major bleeding which requires transfusion of blood products
- Myocardial Infarct
- Phrenic nerve damage causing permanent diaphragmatic paralysis
- Pulmonary vein stenosis, if symptomatic
- Systemic embolism
- Unintentional persistent conduction AV Block
- Valvular damage (mitral, tricuspid)

Secondary Endpoints

Chronic Success

The percentage of subjects free from the treated index arrhythmia at the relevant chronic timepoint has been documented. Follow-up visits are ongoing and the chronic data in this report includes all the follow-up visits through the cutoff date of October 7, 2025. Note that to be counted as recurrence, the recurrent arrhythmia had to be the same arrhythmia as primary index arrhythmia and had to last at least 30 seconds. The data were analyzed, and chronic success presented by arrhythmia.

Safety Events

The rate of subjects experiencing investigational device-related adverse events and procedure-related adverse events was assessed. All Safety Events are presented as a percentage of subjects experiencing the event. All AEs have been recorded and assessed for severity, relatedness, and outcome.

Procedure Efficiency

To characterize procedure efficiency, the following variables have been recorded and presented:

- Procedure time (insertion of first sheath to removal of last sheath);
- Fluoroscopy duration and dose (DAP);
- Total ablation time (measured as the sum of all application durations);

Clinical Investigation Design

This study is a prospective, single arm, unblinded, multi-center, interventional premarket investigation of MAGiC. There is no control group, randomization, or blinding in this clinical investigation. There is no control group in this clinical investigation.

Ethical Considerations

No vulnerable populations (children, employees, prisoners, adults with limited mental capacity) have been included in this investigation. No study-specific procedures were performed until the subject provided written consent.

The study has been conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki (2013), with ISO 14155:2020, (EU) MDR 2017/745, and any regional and/or national regulations, as appropriate.

Inclusion Criteria

To participate in this clinical subject, the subject had to meet all the following inclusion criteria:

Inclusion Criteria

IC1. Adult (aged 18 or older at time of consent)

IC2. Eligible for ablation procedures of an atrial or ventricular arrhythmia per EHRA guidelines, with at least one (1) documented episode of the tachyarrhythmia to be treated within the previous six (6) months

IC3. Able to be safely exposed to magnetic fields

IC4. Willing and capable to attend scheduled follow up visits at the investigational site for the study duration (up to 12 months)

IC5. Willing and able to provide informed consent

Exclusion Criteria

Subjects were not eligible for clinical study participation if they meet any of the following exclusion criteria:

EC1. Unable to be safely exposed to magnetic fields due to MRI Unsafe device (implanted device or device that cannot be safely removed for the procedure)

EC2. Unable to remain comfortable or hemodynamically stable in the supine position for an extended period of time

EC3. Weight exceeding 200 kg (the weight limit of the table)

EC4. For female patients of childbearing potential: pregnancy at the time of the procedure or unwilling to take a pregnancy test

EC5. Presence of intracardiac thrombus at the time of the procedure

EC6. Where MAGiC would need to cross a prosthetic valve

EC7. Use of MAGiC in the coronary arteries

EC8. A history of sensitivity to foreign objects or extreme allergies

EC9. Acute illness or active systemic infection

EC10. Histological or anatomical abnormalities that may lead to post-operative complications including diminished resistance to infection

EC11. Hemodynamic instability

EC12. Unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation

EC13. Acute myocardial infarct (within the previous 30 days)

EC14. Recent cardiac surgery (within the previous 60 days)

EC15. Unstable angina

EC16. History of embolism (cerebrovascular accident, transient ischemic attack, systemic embolism) in the previous 30 days

EC17. Previous cardiac ablation within the previous 30 days

EC18. Concomitant arrhythmia(s) requiring active treatment at this time or in the 90 days prior to enrollment (Day -90 to Day 0)

EC19. Currently or in the 30 days prior to consent, participation in an interventional clinical trial

EC20. Significant uncontrolled or unstable medical problems which, in the opinion of the Investigator, would preclude enrollment in and completion of the study (limitation on survival).

EC21. Any reason or condition that, in the judgement of the investigator, makes the patient ineligible for the investigation.

EC22. For AF only: persistent AF (continuous AF lasting longer than 7 days)

EC23. For AF only: Presence of any device that would interfere with planned access: PFO occlusion/closure device, patch

Study Results

The following sections present the data gathered in the study up to the interim report cutoff date of October 7, 2025.

Disposition Of Subjects

A total of 91 subjects at 2 centers signed an Informed Consent Form. The accounting of subject participation in the study is shown below.

Table 1. Subject Disposition - ITT

Study Status	**MAGIC (N=91)**
Consent Signed	91 (100%)

Study Status	**MAGIC (N=91)**
Screen Failure Prior to MAGiC Insertion	10 (11%)
Treated	81 (89%)
Still in Follow-Up	10 (12%)
Completed	70 (87%)
Withdrawn	1 (1%)
Subject requested to be withdrawn after treatment	0 (0%)
Subject lost to follow-up / moved	0 (0%)
Subject Expired	1 (1%)
Subject withdrawn based on investigator decision	0 (0%)
Screen Failure after MAGiC inserted	0 (0%)
Other reason	0 (0%)

For the Per Protocol population, 10 subjects were excluded from the ITT population. These 10 subjects were not treated with the MAGiC catheter because they were unable to induce the arrhythmia and did not have an ablation performed.

Table 2. Subject Disposition – PP population

Study Status	**MAGIC (N=81)**
Treated	81 (100%)
Still in Follow-Up	10 (12%)
Completed	70 (87%)
Withdrawn	1 (2%)
Subject requested to be withdrawn after treatment	0 (0%)
Subject lost to follow-up / moved	0 (0%)
Subject Expired	1 (1%)
Subject withdrawn based on investigator decision	0 (0%)
Screen Failure after Randomization	0 (0%)
Other reason	0 (0%)

Table 3. Subject Disposition – Follow-Up Visits Performed

Visit	**N**	**Expected**	**% Complete**
Pre-procedure	81	81	100%

Procedure	81	81	100%
Discharge	80	80	100%
1 Month	80	80	100%
3 Month	78	80	98%
6 Month	42	42	100%
12 Month	27	34	79%

* *Visits are not counted in expected if they have not reached the end of the window, unless the visit has occurred, then it is counted in the N and the expected.*

Subject Demographics

The gender and ethnic breakdown for the Intent to Treat (ITT) population is shown in Table 4 and for the Per Protocol (PP) in Table 6. The number of female participants significantly outnumbered male participants by equivalent ratios in the cohorts. Most of the patient population was Caucasian. There were no differences in age or baseline height and weight.

Table 4. Subject Gender and Ethnic Group - ITT Population

Variable	**Category**	**MAGiC (N=89)**
Gender	Male	43 (47%)
	Female	48 (53%)
Ethnicity	Caucasian	88 (97%)
	Asian	3 (3%)
	Black	0 (0%)
	Other	0 (0%)

Table 5. Subject Age, Height, Weight - ITT Population

Variable	**Mean**	**Std Dev**	**n**	**Min**	**Max**	**Median**
Age (years)	52.79	15.84	91	18	82	54
Baseline Height (cm)	174.33	9.34	91	148	198	174
Baseline Weight (kg)	81.28	19.68	91	50	140	76

Table 6. Subject Age and Ethnic Group - PP Population

Variable	**Category**	**MAGiC (N=80)**
Gender	Male	38 (47%)
	Female	43 (53%)
Ethnic Group	Caucasian	78 (96%)
	Asian	3 (4%)
	Black	0 (0%)
	Other	0 (0%)

Table 7. Subject Age, Height, Weight - PP Population

Variable	Mean	Std Dev	n	Min	Max	Median
Age (years)	53.93	15.86	81	18	82	55
Baseline Height (cm)	174.10	9.44	81	148	198	174
Baseline Weight (kg)	81.77	20.01	81	50	140	77

Table 8. Medical History

Medical Condition	N	%
No Medical History	5	6.2 %
Angina – Stable	6	7.4 %
Angina - Unstable	1	1.2 %
Anxiety/Depression	21	25.9 %
Asthma	4	4.9 %
Atrial septal defect	1	1.2 %
Cancer	9	11.1 %
Cardiomyopathy	11	13.6 %
Carotid Artery Disease	3	3.7 %
Cerebrovascular Accident (CVA)	6	7.4 %
Chronic Obstructive Pulmonary Disease (COPD)	4	4.9 %
Congestive Heart Failure (CHF)	13	16.0 %
Coronary Artery Disease	5	6.2 %
COVID	31	38.3 %
Diabetes (IDDM)	1	1.2 %
Diabetes (NIDDM)	4	4.9 %
GERD	15	18.5 %
Heart Block	9	11.1 %
AV Heart Block	2	2.5 %
Left Bundle Branch Block (LBBB)	2	2.5 %
Right Bundle Branch Block (RBBB)	4	4.9 %
No specified type of heart block	2	2.5 %
Heart Valve Disease	7	8.6 %
Hypercholesterolemia	34	42.0 %
Hypertension	32	39.5 %
Hypotension	5	6.2 %
Ion Channel Disease	1	1.2 %
Ischemic Heart Disease	9	11.1 %

Medical Condition	**N**	**%**
Kidney Disease	5	6.2 %
Left Ventricular Hypertrophy	8	9.9 %
Myocardial Infarction	4	4.9 %
Obstructive Sleep Apnea	2	2.5 %
Peripheral Vascular Disease (PVD)	4	4.9 %
Pleural Effusion	1	1.2 %
Sick Sinus Syndrome	4	4.9 %
Structural Heart Disease	11	13.6 %
Other	94	
Abdominal hernia surgery	1	1.2 %
ADHD	2	2.5 %
Anemia	3	3.7 %
Angiodysplasia	1	1.2 %
Aortic aneurysm	1	1.2 %
Aortic stenosis	1	1.2 %
Appendectomy	1	1.2 %
Arthrosis	2	2.5 %
Asbestos Lung Disease	1	1.2 %
Atherosclerotic plaque	1	1.2 %
Benign Prostatic Hyperplasia (BPH)	2	2.5 %
Brady-tachycardia Syndrome	1	1.2 %
Bronchitis	1	1.2 %
Cardiac Arrest	3	3.7 %
Carpal Tunnel Syndrome	1	1.2 %
Cataract Surgery	1	1.2 %
Chest Pain	1	1.2 %
Chronic Autoimmune Thyroiditis	3	3.7 %
Chronic Gastritis	1	1.2 %
Chronic Tonsilitis	1	1.2 %
Compression Fracture	1	1.2 %
Cardiac Resynchronization Therapy Defibrillator (CRT-D)	2	2.5 %
Dilation of Aortic Root	1	1.2 %
Disseminated Sclerosis	1	1.2 %

Medical Condition	N	%
Duodenal ulcer	1	1.2 %
Gallbladder Polyps	1	1.2 %
Gastric Polyps	1	1.2 %
GI Bleeding	1	1.2 %
Headache / Migraine	2	2.5 %
Hemorrhoids	1	1.2 %
Hyperglycemia	1	1.2 %
Hyperthyrosis	1	1.2 %
Hypo Alfa-1-antipypsin	1	1.2 %
Hypokalemia	2	2.5 %
Hyponatremia	1	1.2 %
Hypothyroidism	1	1.2 %
ICD	6	7.4 %
Inguinal Hernia	1	1.2 %
Jaundice	1	1.2 %
Joint ligament surgery	1	1.2 %
Kidney Failure	1	1.2 %
Kidney Stones	2	2.5 %
Knee surgery	1	1.2 %
Lip – Cleft born	1	1.2 %
Liver Hemangioma	1	1.2 %
Lyme Disease	1	1.2 %
Melanoma	1	1.2 %
Osteoporosis	1	1.2 %
Pacemaker	3	3.7 %
Pleuritis	1	1.2 %
Prosthetic Left Hip	1	1.2 %
Psoriasis	1	1.2 %
Pulmonary Embolism	2	2.5 %
Right Ankle Surgery	1	1.2 %
Right ventricle aneurysm	1	1.2 %
Secondary Polycythemia	1	1.2 %
Shoulder surgery	1	1.2 %
Sjogren's Disease	1	1.2 %
Spondylarthritis	1	1.2 %
Syncope	2	2.5 %

Medical Condition	N	%
Thoracalgia	2	2.5 %
Tick-borne Encephalitis	1	1.2 %
Tonsillectomy	1	1.2 %
Tourette Syndrome	1	1.2 %
Transposition vasorum complete	1	1.2 %
Tuberculosis	1	1.2 %
Vein surgery in leg	1	1.2 %
Vena cava superior syndrome	1	1.2 %
Ventricular Septum defect	1	1.2 %
Vertigo	1	1.2 %

**Table categories to be added until enrollment is completed.*

Table 9. – Arrhythmia Treated

Arrhythmia	N	%
Atrial Flutter	8	9.9 %
Atrial Fibrillation	9	11.1 %
AVNRT	26	32.1 %
AVRT	2	2.5 %
Focal AT	1	1.2 %
PVC	23	28.4 %
VT	3	3.7 %
WPW	8	9.9 %
Other - substrate based ablation in scar area with fractionated potentials	1	1.2 %

There were 15 subjects that had 1 previous ablation, 2 subjects that had 2 previous ablations and 1 subject who had 3 previous ablations prior to the current one that was performed for the investigation.

Analysis of the Primary Endpoint

There were no subjects who had inducibility of the index arrhythmia at the end of the procedure.

Primary Endpoint – Performance

Acute procedural success was assessed by evaluating the non-inducibility or lack of conduction of the index arrhythmia at the end of the procedure. Table 10 provides the acute

procedural success by arrythmia. These results are shown alongside acute procedural success from large scale ablation registries for comparison.[1,2,3]

Table 10. Acute Procedural Success

Arrhythmia	N	% Success	Registry Benchmark
Atrial Flutter (AFL)	8	100%	96.0%
Atrial Fibrillation (AF)	9	100%	96.7%
AV Node Reentry Tachycardia (AVNRT)	26	100%	98.0%
AV Node Ablation	0	-	-
AV Reentry Tachycardia (AVRT)	2	100%	92.0%
Focal Atrial Tachycardia (FAT)	1	100%	84.3%
Premature Ventricular Contractions (PVCs)	23	78%	83.0%
Ventricular Tachycardia (VT)	3	67%	78.0%
Wolff Parkinson White Syndrome (WPW)	8	100%	92.0%
Other - substrate based ablation in scar area with fractionated potentials	1	100%	-

Primary Endpoint – Acute Safety

There were no subjects who experienced an acute safety event following their ablation procedure that was attributed to the investigational device through hospital discharge. The acute safety of MAGiC has been assessed by the freedom from major adverse events (MAE) related to MAGiC. MAEs must meet the definition of Serious, occur prior to discharge, and be directly related to MAGiC for the purpose of this endpoint.

Table 11. Acute Safety – MAEs due to device problem or failure

MAE	N	%
Atrioesophageal fistula	0	0%
Cardiac Perforation/tamponade	0	0%
Cerebral Infarct	0	0%
Death	0	0%
Major bleeding which requires transfusion of blood products	0	0%
Myocardial Infarct	0	0%
Phrenic nerve damage causing permanent diaphragmatic paralysis	0	0%
Pulmonary vein stenosis, if symptomatic	0	0%
Systemic embolism	0	0%
Unintentional persistent conduction AV Block	0	0%
Valvular damage (mitral, tricuspid)	0	0%

All Adverse Events (AEs) reported to Stereotaxis during the study have been reviewed and adequately reported to comply with applicable regulations (ISO 14155:2020 and/or (EU) MDR 2017/745). Investigators have been asked to classify whether an adverse event is considered serious or non-serious, whether it is anticipated or unanticipated as defined in the table below, and whether it is considered related to MAGiC or to the ablation procedure.

Arrhythmia recurrence by itself is considered a recurrence of the pre-existing condition and does not meet the definition of an AE.

There were a total of 47 adverse events reported as of the report cutoff date. Nine of these adverse events were considered serious. None of the serious events were considered by the investigators to be due to a problem or failure of the investigational device. Of the nine serious adverse events, three was considered to be related to the procedure (cardiac tamponade, AFC dex thrombosis and bleeding/hemorrhage/hematoma). Of the 38 remaining non-serious adverse events, all events were considered not related to the investigational device.

Of the 38 non-serious events, 22 were considered unrelated to the device or procedure, 9 of the events were considered possibly related to the procedure, 3 events were considered probably related and 6 events considered causally related to the procedure.

Table 12. – Listing of Serious Adverse Events

Adverse Event	**N**	**% of all AEs**
Arrhythmia, conduction disorder	2	4.3%
Arterial Spasm	1	2.1%
Cardiac Tamponade	1	2.1%
Other	4	8.5%
AFC dex thrombosis	1	2.4%
Chronic sinusitis	1	2.4%
Lung cancer	1	2.4%
Vertebral Fracture	1	2.4%

Table 13. – Listing of non-serious Adverse Events

Adverse Event	N	% of all AEs
Angina, chest pain	3	6.4%
Bleeding/hemorrhage/hematoma	3	6.4%
Fever	3	6.4%
Hypertension/Hypotension	3	7.3%
Nausea, vomiting	1	2.1%
Pain	9	19.1%
Other	16	34.0%
Acute bronchitis	1	2.1%
Acute tracheitis	1	2.1%
Chest discomfort	1	2.1%
COVID	1	2.1%
Dizziness, vertigo	1	2.1%
Duodenitis	1	2.1%
Gout	1	2.1%
Head injury	1	2.1%
Headache	1	2.1%
Hypothyroidism induced by amiodarone	1	2.1%
Leg Cramp	1	2.1%
Lumbosacral radiculopathy	1	2.1%
Ovarian Cyst	1	2.1%
Sinusitis	1	2.1%
Whopping cough	1	2.1%

Analysis of Secondary Endpoints

Secondary Endpoint - Chronic Success

Chronic success is presented as the percentage of subjects free from the treated index arrhythmia at the relevant follow-up timepoint. To be counted as recurrence, the recurrent arrhythmia must be the same arrhythmia as primary index arrhythmia and must last at least 30 seconds. The data have been analyzed, and chronic success presented by arrhythmia with summary statistics.

Table 14. Chronic Success

Freedom from treated index arrhythmia	Visits	Arrythmia Free	%
3 Month (SVT)	41	41	100%
3 Month AVNRT	31	31	100%
3 month AVRT	2	2	100%
3 month FAT	1	1	100%
3 month WPW	7	7	100%
6 Month (A Flutter)	3	3	100%
12 Month (Atrial Fib, PVC, VT)	15	13	87%
12 Month Atrial Fibrillation	4	3	75%
12 Month PVC	10	9	90%
12 Month VT	1	1	100%

** If a subject is still in a visit window and his visit has not occurred, they are not included.*

Secondary Endpoint - Safety Events

All Safety Events (adverse events related to device or procedure) have been presented as a percentage of subjects experiencing the event.

Table 15. All Safety Events (Device or Procedure Related)

Adverse Event	N	%	Relatedness	Severity	Outcome
Angina, chest pain	1	1.2%	Possibly to procedure	Moderate	Resolved
Bleeding/hemorrhage/hematoma	3	3.7%	Related to procedure	1 – Mild 1 - Moderate 1 - Severe	Resolved
Cardiac Tamponade	1	1.2%	Related to procedure	Severe	Death
Hypertension/Hypotension	1	1.2%	Probably to procedure	Moderate	Resolved
Nausea, vomiting	1	1.3%	Probably to procedure	Mild	Resolved
Pain	2	2.5%	Possibly to procedure	Moderate	Resolved
Pain	3	3.7%	Related to procedure	1 - Mild 2 - Moderate	Resolved
Pain	1	1.2%	Related to procedure	Moderate	Resolved
Other, AFC dex thrombosis	1	1.2%	Probably to procedure	Severe	Resolved

Adverse Event	N	%	Relatedness	Severity	Outcome
Other, chest discomfort	1	1.2%	Possibly to procedure	Mild	Resolved
Other, chest pain	1	1.2%	Related to procedure	Moderate	Resolved
Other, headache	1	1.2%	Related to procedure	Moderate	Resolved
Other, Leg Cramp	1	1.2%	Probably to procedure	Moderate	Resolved
Other, leg pain with hematoma	1	1.2%	Probably to procedure	Moderate	Resolved

Secondary Endpoint - Procedure Efficiency

To characterize procedure efficiency, the following variables have been recorded:

- Procedure time (insertion of first sheath to removal of last sheath)
- Fluoroscopy duration and dose (DAP)
- Total ablation time (measured as the sum of all application durations)

Table 16. Procedure Efficiency

Variable	Mean	Std Dev	n	Min	Max	Median
Procedure time (minutes)	89.54	43.85	81	31	230	85
Fluoroscopy Duration (minutes)	5.29	5.68	81	0	33.1	3.95
Total ablation time (seconds)	341.21	361.68	81	17	1914	220

Observed Device Deficiencies

There were 4 device deficiencies observed, two of them were recorded as poor catheter movement over the sheath. 1 device deficiency was recorded as a malfunction (due to a surface defect) and 1 device deficiency was recorded as malfunction and device failure (due to poor movement in the sheath and a pump error). Three of the procedures were able to be completed with an additional MAGiC Catheter, 1 was completed with a different catheter. None of the device deficiencies caused an adverse event to the subject, the user or others involved in the case.

Subgroup analysis – congenital subjects

Six subjects enrolled were treated for various arrhythmias and were categorized as having complex congenital heart disease (CHD) with structural heart modifications. Below is an analysis of this population of subjects.

Disposition Of CHD Subjects

A total of 7 subjects at 2 centers signed an Informed Consent Form. The accounting of subject participation in the study is shown below.

Table 17. Subject Disposition (Congenital Sub-Group) – ITT & PP

Study Status	**MAGIC (N=6)**
Consent Signed	7 (100%)
Screen Failure Prior to MAGiC Insertion	0 (0%)
Treated	7 (100%)
Still in Follow-Up	2 (29%)
Completed	5 (71%)
Withdrawn	0 (%)
Subject requested to be withdrawn after treatment	0 (0%)
Subject lost to follow-up / moved	0 (0%)
Subject Expired	0 (0%)
Subject withdrawn based on investigator decision	0 (0%)
Screen Failure after MAGiC inserted	0 (0%)
Other reason	0 (0%)

Subject Demographics

The gender and ethnic breakdown for the Intent to Treat (ITT) population of the congenital heart sub-group is presented in Table 18. Age, height and weight data for this sub-group is presented in Table 19.

Table 18. Subject Gender and Ethnic Group (Congenital Sub-Group)

Variable	**Category**	**MAGiC (N=6)**
Gender	Male	5 (71%)
	Female	2 (29%)
Ethnicity	Caucasian	7 (100%)
	Asian	0 (%)
	Black	0 (0%)
	Other	0 (0%)

Table 19. Subject Age, Height, Weight (Congenital Sub-Group)

Variable	**Mean**	**Std Dev**	**n**	**Min**	**Max**	**Median**
Age (years)	40.86	10.56	7	28	58	41
Baseline Height (cm)	175.57	9.32	7	158	185	180
Baseline Weight (kg)	86.07	25.38	7	52	128.5	86

Table 20. Medical History (Congenital Sub-Group)

Medical Condition	**N**	**%**
Atrial septal defect	1	14.3 %
Cancer, breast	1	14.3 %
Cardiomyopathy	1	14.3 %
Congestive Heart Failure (CHF)	4	57.1 %
Heart Block	4	57.1 %
Right Bundle Branch Block (RBBB)	3	42.9 %
AV Block	1	14.3 %
Heart Valve Disease	4	57.1 %
Hypercholesterolemia	1	14.3 %
Hypertension	1	14.3 %
Kidney Disease	1	14.3 %
Pleural Effusion	1	14.3 %
Structural Heart Disease	7	100.0 %
Other	9	
Aortic stenosis	1	14.3 %
Aneurysm, Rt ventricle	1	14.3 %
Cardiac Arrest	1	14.3 %
Hyperthyroidism	1	14.3 %
ICD	1	14.3 %
Pacemaker	1	14.3 %
Transposition vasorum complete	1	14.3 %
Vena cava superior syndrome	1	14.3 %
Ventricular Septum defect	1	14.3 %

**Table categories to be added until enrollment is completed*

Table 21. – Arrhythmia Treated (Congenital Sub-Group)

Arrhythmia	**N**	**%**

Atrial Flutter	5	71.5 %
Atrial Fibrillation	0	0 %
AVNRT	1	14.3 %
AVRT	0	0 %
Focal AT	0	0 %
PVC	0	0 %
VT	0	0 %
WPW	1	14.3 %

There were 2 subjects that had 1 previous ablation prior to the current one that was performed for the investigation.

Primary Endpoint - Acute Performance

A primary clinical endpoint in this sub-analysis was to document the acute procedural success across a range of treated arrhythmias for patients with a history of congenital heart defects and to assess the acute safety of MAGiC by the freedom from major adverse events (MAE) related to MAGiC.

Table 22. Acute Procedural Success (Congenital Sub-Group)

Arrhythmia	N	% Success
Atrial Flutter (AFL)	5	100%
Atrial Fibrillation (AF)	0	100%
AV Node Reentry Tachycardia (AVNRT)	1	100%
AV Node Ablation	0	-
AV Reentry Tachycardia (AVRT)	0	-
Focal Atrial Tachycardia (FAT)	0	0%
Premature Ventricular Contractions (PVCs)	0	-
Ventricular Tachycardia (VT)	0	-
Wolff Parkinson White Syndrome (WPW)	1	100%

Primary Endpoint - Acute Safety

There have been no adverse events reported in the sub-study of the congenital subjects.

Table 23. Acute Safety - Freedom from MAE related to MAGiC (Congenital Sub-Group)

MAE	N	%
Atrioesophageal fistula	0	0 %
Cardiac Perforation/tamponade	0	0 %
Cerebral Infarct	0	0 %
Death	0	0 %

MAE	N	%
Major bleeding which requires transfusion of blood products	0	0 %
Myocardial Infarct	0	0 %
Phrenic nerve damage causing permanent diaphragmatic paralysis	0	0 %
Pulmonary vein stenosis, if symptomatic	0	0 %
Systemic embolism	0	0 %
Unintentional persistent conduction AV Block	0	0 %
Valvular damage (mitral, tricuspid)	0	0 %

Secondary Endpoints - Chronic Success

Estimate the percentage of subjects free from the treated index arrhythmia at the relevant chronic timepoint. To be counted as recurrence, the recurrent arrhythmia must be the same arrhythmia as primary index arrhythmia and must last at least 30 seconds. The data have been analyzed, and chronic success presented by arrhythmia.

Table 24. Chronic Success: (Congenital Sub-Group)

Freedom from treated index arrhythmia	Visits to date	Free from index arrythmia	%
1 Month	7	7	100%
3 Month (AVNRT, AVRT, FAT and WPW)	7	7	100%
6 Month (A Flutter)	4	4	100%
12 Month (VT and Atrial Fib only)	None Required	None Required	--

Secondary Endpoints - Safety Events

The portion of subjects experiencing investigational device-related adverse events and procedure-related adverse events. All Safety Events have been presented as a percentage of subjects experiencing the Event. All AEs have been recorded as assessed for severity, relatedness, and outcome. No Safety Events were reported in the congenital subject subgroup.

Secondary Endpoints - Procedure Efficiency

To characterize procedure efficiency, the following variables have been recorded and presented:

- Procedure time (insertion of first sheath to removal of last sheath);
- Fluoroscopy duration and dose (DAP);
- Total ablation time (measured as the sum of all application durations);

Table 25. Procedure Efficiency (Congenital Sub-Group)

Variable	Mean	Std Dev	n	Min	Max	Median
Procedure time (minutes)	150.1	38.76	7	119	230	133
Fluoroscopy Duration (minutes)	14.4	9.35	7	4.7	33.1	11
Total ablation time (seconds)	840.3	683.95	7	216	1914	452

Observed Device Deficiencies

There were no device deficiencies observed in the congenital subjects sub-group.

Conclusions for Congenital Sub-Group

The sub-analysis of patients with complex congenital heart disease (CHD) with structural heart modifications has shown that the MAGiC catheter is safe and effective for this sub-group of patients, and that the MAGiC catheter offers unique capabilities to the procedure. The procedures addressed a range of complex anatomies and arrhythmias challenges: lack of IVC access to the heart, transposition of the Great Arteries with either Senning or Mustard surgical modifications, Ebstein's Anomaly, Mahaim Fiber Accessory Pathway, and Tetralogy of Fallot. The physician operators found that use of the MAGiC catheter provided advantages over manually navigated devices, including the ability to successfully navigate challenging access pathways that would not be possible for manual catheters, stability on the cardiac substrate even in high blood flow areas, and avoiding having to puncture the surgical baffle. Physicians were able reach the location for ablation treatment and delivers lesions that successfully restored sinus rhythm in each of the cases.

Overall Conclusions

All of the procedures have been performed following the clinical investigation protocol and there have not been any SAE's reported to date attributed to a problem or failure of the investigational device. The procedures conducted with the investigational device have shown high rates of acute and chronic success. The study thus far supports the safety and efficacy of the MAGiC ablation catheter for a range of arrythmias with a potential significant safety and efficacy benefit for subjects with complex anatomical challenges due to a history of congenital heart defects and surgical modifications.

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.