Description

Title

Steerable Intracardiac Echocardiography and Pulsed-Field Ablation Fusion Catheter

Technical Field

The present invention relates to the field of cardiac electrophysiology medical devices, and more particularly to intracardiac catheters combining ultrasound imaging and pulsed-field ablation capabilities. The invention is applicable to catheter-based treatments of cardiac arrhythmias (such as atrial fibrillation) and other interventional cardiology procedures requiring integrated imaging and therapy.

Background

Catheter ablation has become a standard treatment for atrial fibrillation (AF) and other arrhythmias. In a typical AF ablation procedure, lesions are created in the left atrium (often around the pulmonary vein ostia) to isolate abnormal electrical foci. Traditionally, thermal ablation energy (radiofrequency or cryothermal) is used, which carries risks of collateral damage to adjacent structures such as the esophagus, phrenic nerve, and blood vessels. Intracardiac echocardiography (ICE) is frequently used during such procedures to visualize cardiac structures and monitor for complications in real time . ICE imaging from within the heart (usually via a separate ultrasound catheter in the right atrium) allows clinicians to guide transseptal punctures, position ablation catheters, and detect issues like pericardial effusion, thrombus, or esophageal heating early . However, current practice requires maneuvering at least two separate catheters – one for ablation and one for ICE imaging – which increases procedure complexity, adds extra venous access, and complicates real-time alignment of the ablation target with the imaging plane.

In recent years, pulsed-field ablation (PFA) has emerged as a non-thermal ablation modality for treating arrhythmias . PFA uses trains of high-voltage electrical pulses to induce irreversible electroporation in myocardial cells, creating lesions without significant heat generation. This technique can be made highly selective: the electric field parameters can be tuned to preferentially ablate cardiomyocytes while sparing surrounding tissues that have higher electroporation thresholds (such as nerves, blood vessels, and the esophagus) . Studies have

shown that PFA offers improved safety compared to thermal ablation, with substantially reduced risk of collateral damage . For example, one clinical analysis reported 0% incidence of esophageal lesions after PFA, versus 43% with conventional thermal ablation . Furthermore, PFA allows faster lesion creation and has shown excellent efficacy in achieving durable pulmonary vein isolation . In 2023, the first PFA catheter system received regulatory approval in the US , indicating the growing adoption of this technology.

Despite these advances, integrating real-time imaging with PFA delivery remains a challenge. Existing PFA catheter designs (often multi-electrode circular or lattice catheters) provide efficient lesion delivery but rely on separate imaging modalities for guidance. For instance, a recently developed 7.5-French circular PFA catheter ("lasso" design) with 10 irrigated electrodes (adjustable 25–35 mm diameter) achieved successful pulmonary vein isolation with no esophageal or phrenic nerve injury in preclinical testing . However, in use it still requires a separate ICE or fluoroscopic guidance to ensure correct placement relative to cardiac anatomy. The lack of integration means the operator must mentally register the ICE images (from a separate catheter) with the ablation catheter's position. This can be suboptimal when precision is needed near sensitive structures like the esophagus or phrenic nerve. Moreover, using multiple catheters can prolong procedure time and require additional transseptal punctures or vascular access.

There are technical hurdles to combining an ultrasound imaging transducer and high-voltage ablation electrodes on the same catheter. Electrical interference and safety isolation are primary concerns: the PFA pulses (hundreds to thousands of volts) could induce noise or even damage in the ultrasound transducer's sensitive electronics if not properly isolated. Additionally, the presence of metal electrodes near the ultrasound transducer can cause imaging artifacts (bright echoes) that degrade image quality. The catheter must also remain sufficiently flexible and steerable despite housing multiple functional components. These engineering challenges have so far prevented the fusion of ICE and ablation capabilities into a single device in mainstream clinical use.

Accordingly, there is a need for a single, integrated catheter that can provide intracardiac imaging and deliver pulsed-field ablation, enabling physicians to visualize target tissues and surrounding anatomy while performing ablation. Such a device would simplify AF ablation and other electrophysiology procedures by eliminating the need for a separate ICE catheter, reducing x-ray fluoroscopy reliance (through ICE visualization), and potentially improving precision and safety of lesion delivery. The present invention addresses these needs by providing a steerable ICE + PFA fusion catheter with specialized design features to ensure compatibility of the imaging and ablation functions.

Summary of the Invention

The invention provides a steerable intracardiac catheter system that integrates an ultrasound imaging assembly with a pulsed-field ablation electrode assembly on a single catheter shaft. In one aspect, the invention is a catheter apparatus comprising an elongated flexible shaft with a

proximal handle and a deflectable distal section. Mounted at or near the distal tip is an ultrasound transducer (for example, a phased-array or mechanical scanning transducer) capable of producing real-time intracardiac echocardiography (ICE) images. The distal section also includes one or more ablation electrodes configured to deliver pulsed electrical fields for irreversible electroporation (PFA) ablation of cardiac tissue. The catheter is connected to both an ultrasound imaging console and a PFA pulse generator, thereby enabling the operator to obtain ultrasound images and perform ablation using the same instrument.

Critically, the catheter's design incorporates electrical isolation and timing coordination such that the high-voltage ablation pulses do not compromise the imaging electronics. For example, the device may include isolation transformers, filtering circuits, or switching elements that decouple the ultrasound transducer and its signal lines during PFA pulse delivery. In some embodiments, the system's controller automatically blanks or pauses the ultrasound receiver for the millisecond duration of each ablation pulse, then rapidly resumes imaging. This prevents saturation or damage to the ultrasound electronics from the pulse-induced transients, while allowing near-instant return to imaging to visualize the post-ablation effect. The ultrasound and ablation functions can thus operate in an interleaved or simultaneous fashion without mutual interference.

The integrated catheter improves procedural workflow and patient safety. Using the invention, a single catheter insertion can accomplish both navigation/imaging and therapeutic ablation. For instance, during an atrial fibrillation ablation, the physician can visualize the left atrium and pulmonary vein ostia with ICE, identify the target tissue, and then immediately deliver PFA lesions through the same device – all under continuous guidance. Real-time ultrasound feedback helps confirm catheter contact and orientation, observe lesion formation (e.g., microbubble appearance or wall motion changes), and monitor adjacent structures. The PFA energy, being non-thermal, further reduces the risk of complications like char or steam pop; and any minor Joule heating that might occur is mitigated by design features such as irrigated electrodes or cooling channels. The result is an ablation system that is both highly selective and guided in real-time, a significant improvement over separate-catheter approaches.

From a structural standpoint, the catheter shaft is a multi-lumen construction that accommodates the necessary components: e.g., one lumen carries the cable bundle for the ultrasound transducer, another carries high-voltage leads for the electrodes, one or more lumens contain deflection pull-wires, and an optional lumen provides irrigation fluid to the electrode region. The shaft is preferably sized for cardiac use (in the range of 8–10 Fr outer diameter) and has sufficient torque control and flexibility to be steered through vasculature into the heart. A deflection mechanism in the handle (such as a rotatable knob or lever) allows the distal tip to be articulated (uni- or bi-directionally, or in some designs with four-way deflection) to facilitate imaging different angles and engaging specific ablation sites. The distal tip region is engineered to secure the ultrasound transducer and electrodes in close proximity while avoiding mutual interference: for example, the transducer may be located at the extreme tip with a clear acoustic window, and the ring electrodes positioned just proximal to it on the catheter shaft (or on a surrounding structure) such that they do not obstruct the ultrasound field of view.

The invention encompasses multiple embodiments and variations. The ultrasound imaging assembly may be realized by different technologies: in some embodiments a phased-array ultrasound transducer with multiple piezoelectric elements is used to provide a sector or volumetric image (with Doppler capabilities) – similar to current phased-array ICE catheters – whereas in other embodiments a mechanical ICE transducer (single element that rotates or oscillates) is employed for simplicity and high near-field resolution. The ultrasound may operate at frequencies suitable for intracardiac imaging (e.g. 5–10 MHz range). The ablation electrode configuration can also vary: one design uses a set of ring electrodes or a basket/loop of electrodes that can deliver circumferential PFA lesions (ideal for pulmonary vein isolation), while another design integrates a focal ablation tip electrode for point-by-point lesion creation. Electrodes can be monopolar or bipolar; they may be arranged on expandable structures (such as a balloon or “flower basket” that expands once in the chamber) to achieve a larger ablation footprint. An irrigation system can be incorporated to infuse saline through pores near the electrodes, cooling the tissue interface – this addresses the fact that while PFA is non-thermal in mechanism, some resistive heating can still occur with repeated high-current pulses , and irrigation helps dissipate heat and prevent microbubble formation .

The scope of the invention includes not only the catheter itself, but also a complete system and associated methods. A system according to the invention may comprise the integrated catheter along with an external ultrasound imaging unit (which could be a conventional ultrasound machine or a specialized intracardiac echo console) and a PFA pulse generator, coordinated via a control interface. The system may incorporate safety interlocks and user controls to seamlessly switch between imaging and ablation modes. Also encompassed are methods of using the catheter for cardiac ablation procedures, which include steps of introducing the catheter to the heart, visualizing target structures in real-time, and delivering PFA energy under imaging guidance. Example methods cover pulmonary vein isolation for AF, ablation near the atrioventricular valves or septum, or any situation where real-time intracardiac imaging can improve ablation accuracy (such as avoiding phrenic nerve injury by monitoring diaphragmatic motion, or visualizing the esophagus to avoid it during posterior wall ablation).

Additionally, the invention anticipates modular and alternative configurations. In some embodiments, the imaging component and ablation component may be designed as modular units that can be separably combined – for instance, a removable ultrasound probe that mates with an ablation catheter – providing flexibility in upgrading or replacing one component without entire device replacement. Variations also include integration of location sensing technology (e.g., magnetic sensor or impedance-based localization) on the catheter to allow mapping system visualization, and inclusion of surface ECG or intracardiac electrogram sensing through the ablation electrodes (so they double as mapping electrodes when not firing pulses). The claims are intended to cover the catheter device itself, the system of catheter plus auxiliary equipment, and methods of treatment, with broad coverage of the inventive concept and specific dependent claims directed to particular features (such as phased-array vs. mechanical ultrasound, balloon vs. basket electrode structure, irrigation, energy isolation means, etc.).

In summary, the present invention provides a unified ICE + PFA catheter that significantly streamlines electrophysiology procedures by combining two critical functions into one tool. This

fusion catheter improves ease of use, enhances safety by keeping critical structures in view during energy delivery, and expands the capabilities of pulsed-field ablation with direct intraprocedural imaging feedback.

Brief Description of the Drawings

- FIG. 1 is an overview schematic of an embodiment of the integrated ICE-PFA catheter system. The catheter is shown inserted into a patient's heart, with the distal tip in the left atrium and the proximal handle and connectors attached to an imaging console and PFA generator (schematically illustrated). FIG. 1 depicts the single steerable catheter (100) performing both imaging and ablation functions within the heart.

- FIG. 2 is a cross-sectional diagram of the distal portion of the catheter shaft, illustrating an example multi-lumen construction. The figure shows an ultrasound transducer (110) at the tip, ablation electrodes (160) on the catheter circumference, a pull-wire (180) for deflection, an irrigation lumen (154) with an outlet port, and cable wiring (152) running through the shaft. Structural features for electrical isolation (such as insulation and shielding between the ultrasound cable and electrode conductors) are also schematically indicated.

- FIG. 3A and FIG. 3B show two alternative embodiments of the ultrasound imaging assembly at the catheter tip. FIG. 3A illustrates a phased-array ICE transducer (110A) with multiple piezoelectric elements (111) arranged to provide a sector imaging field (P). FIG. 3B illustrates a mechanical ICE transducer (110B) with a single element that rotates about an axis (via a micro motor 113 or drive shaft) to sweep an imaging plane. These figures also show example placements of ablation electrodes (160) relative to the transducer in each configuration.

- FIG. 4A and FIG. 4B illustrate two variations of the ablation electrode deployment mechanism. FIG. 4A shows an embodiment with a balloon-mounted electrode array: an inflatable balloon (170) at the distal tip is expanded at the target site, and multiple electrodes (172) on the balloon surface contact the tissue to deliver PFA. FIG. 4B shows an embodiment with a flower-basket (expandable spline) electrode array: a set of flexible splines (174) carrying electrodes expands from a collapsed state (within a sheath) to an open "basket" configuration in the chamber, conforming to the tissue (e.g., encircling a pulmonary vein ostium) for ablation. Both FIG. 4A and FIG. 4B show the ultrasound transducer (110) positioned centrally so that imaging can be performed with the structures deployed.

- FIG. 5A and FIG. 5B are schematic illustrations of example clinical use-cases leveraging the invention's capabilities. FIG. 5A shows the catheter tip (100) positioned in the left atrium (LA) at a pulmonary vein (PV) ostium near the posterior wall, with the ultrasound imaging field (P) visualizing the adjacent esophagus (E) running behind the heart. This demonstrates how an operator can monitor esophageal location and avoid injury while

delivering PFA lesions. FIG. 5B shows a scenario of real-time lesion monitoring, where the ultrasound image detects indicators of effective ablation – for instance, microbubbles (B) or changes in tissue echogenicity – immediately after a PFA pulse near the phrenic nerve region. The diaphragm (D) motion can also be observed to ensure phrenic nerve function is preserved during ablation.

Detailed Description of Preferred Embodiments

Overall Catheter Structure (FIG. 1 & FIG. 2): Referring to FIG. 1, the integrated ICE-PFA catheter 100 includes an elongated flexible shaft 120 with a distal section 130 that is steerable/deflectable and a proximal handle 140 for user control. In this embodiment, the catheter 100 is inserted through a sheath 50 (for example, via the femoral vein and through a transseptal puncture into the left atrium). The proximal handle 140 houses steering controls – for instance, one or two pull-wire actuation knobs 142 that deflect the distal section 130 in one or two planes. By manipulating the handle 140, the operator can navigate the distal tip within the heart chambers and maintain contact with target tissues. The catheter shaft 120 is constructed with a multi-lumen design as shown in FIG. 2. In FIG. 2, a cross-section of the distal shaft illustrates an arrangement with an ultrasound transducer cable bundle 152 running through a central lumen, one or more high-voltage electrode conductors 153 (connected to ablation electrodes 160 on the exterior), a dedicated irrigation lumen 154 ending in an outlet port 155 near the electrodes, and steering pull-wires 180 in opposite lumens (for bidirectional bending). The shaft's body is made of a biocompatible polymer (e.g., Pebax® or polyurethane) with embedded braided reinforcement for torque control. Each lumen is lined with appropriate insulation to prevent electrical cross-talk between the PFA conductors and the ultrasound cable. The ultrasound transducer 110 is located at the distal tip (in this example, it's a side-looking phased array, see FIG. 3A), and just behind it on the shaft are a series of ring electrodes 160 that serve as the PFA ablation electrodes. The ring electrodes 160 are electrically isolated from the transducer 110 by an insulating spacer 115 and by shielding layers on the transducer, to reduce ultrasonic imaging interference and protect the imaging electronics from high-voltage surges.

To further ensure energy isolation, the catheter includes features such as choke inductors or ferrite beads on the electrode conductors 153 and possibly transient voltage suppressor diodes on the transducer cable 152 (located, for example, in the handle 140 or connector) to shunt any induced spikes. The handle or connector also contains a multiplexed interface that splits into an imaging connector (to the ultrasound console 200) and an ablation connector (to the PFA generator 300). In some embodiments, the handle 140 houses an electronic control circuit that coordinates these functions, whereas in other embodiments the coordination is managed by the external systems (with the catheter simply providing the hardware channels). The steerability of the catheter is comparable to standard ablation catheters – e.g., the distal 5–15 cm can be deflected up to 90–180° via a pull-wire 180. The catheter 100 may also be rotated as a whole via the handle to sweep the imaging sector or reposition electrodes circumferentially.

Ultrasound Imaging Assembly (FIG. 3A & 3B): FIG. 3A illustrates an embodiment where the catheter tip carries a phased-array ultrasound transducer 110A. This transducer 110A consists of multiple small piezoelectric elements (111) arranged, for example, in a linear or slightly curved array at the tip. The array produces a 2D sector-shaped ultrasound beam (P in FIG. 3A) that can image the surrounding cardiac structures in real time. Modern ICE phased arrays typically have 64 elements and operate at 5–10 MHz, providing up to a 90° imaging sector . In this design, the array 110A is oriented such that its imaging plane covers the region where the ablation will occur. For instance, if ring electrodes 160 are just behind the transducer, the array can be oriented to image lateral and forward of the catheter tip, so that tissue being ablated by the electrodes is visible. The elements 111 are connected via micro-coaxial cables in cable bundle 152 that run through the shaft to the ultrasound console 200. Optionally, an ASIC (application-specific integrated circuit) in the tip can multiplex the signals to reduce the number of wires. The phased-array can perform not only B-mode imaging but also Doppler flow imaging and other modalities if connected to a suitable console, similar to existing phased-array ICE catheters .

FIG. 3B shows an alternative embodiment with a mechanical ultrasound transducer 110B. Here, a single piezoelectric crystal or a small number of elements are mounted on a rotating or swiveling platform at the tip. A miniature motor or torque wire 113 spins the transducer to sweep an ultrasound beam in a 360° radial plane (perpendicular to the catheter) or in a forward arc, depending on design. Mechanical ICE catheters (such as rotational ICE) typically use ~9 MHz single crystals and produce high-resolution images in the near field . In this design, the transducer 110B's rotation can be controlled via the handle (e.g., a spinner mechanism or automatically by the console). Mechanical transducers are advantageous for their simplicity and smaller footprint, at the cost of lacking Doppler and requiring moving parts. In FIG. 3B, the ablation electrodes 160 are again located on the shaft proximal to the transducer window. To avoid image artifacts from the electrodes, the transducer 110B can be oriented so that the electrodes lie outside of the primary imaging plane. Additionally or alternatively, the electrodes 160 may have an acoustically dampening coating to reduce their echogenicity. The catheter's imaging assembly can be positioned to view forward (distal end) or sideways (lateral), or even a combination if a 3D phased array is used – various orientations are possible and can be chosen based on the target anatomy.

In both FIG. 3A and 3B embodiments, the ultrasound imaging function is tightly integrated but electrically and electronically isolated from the ablation function. During PFA energy delivery, the system may implement a brief imaging pause or blanking. For example, the ultrasound console 200 can be signaled (via the catheter's interface or by detection of the ablation trigger) to stop transmitting pulses and ignore received signals during the ~5–50 ms window of a PFA pulse train. This prevents the front-end amplifiers from saturating due to any residual noise. Immediately after the PFA pulse, imaging can resume to assess results. In some embodiments, rather than fully pausing, the console might employ a high dynamic range filter to continue imaging and subtract out the pulse artifact. The temporal coordination ensures that the operator effectively sees a near-continuous image except for perhaps a flicker during each ablation burst. Because PFA is delivered in very short bursts (on the order of milliseconds) , the interruption to imaging is negligible.

Ablation Electrode Assembly (FIG. 4A & 4B): The catheter's ablation component can be configured in different ways to best create the desired lesions. In the embodiment of FIG. 1–3, we described ring electrodes 160 on the distal shaft that could be used in pairs or groups to create focal or linear lesions. For example, to perform a pulmonary vein isolation, the clinician could maneuver the catheter tip around the vein ostium, delivering PFA via the ring electrodes at each position to create a contiguous circle. Alternatively, larger structures can simplify this process. FIG. 4A shows an embodiment with a balloon 170 at the tip. The balloon 170 is inflatable via the irrigation lumen (which doubles as a balloon inflation lumen in this design). Electrodes 172 (which could be wire mesh, patches, or an array of spots) are distributed on the balloon's surface. In use, the balloon 170 is positioned at the pulmonary vein opening and inflated to conform to the tissue; then a PFA pulse is delivered between the electrodes 172 (which could be arranged as alternating polarity pairs) to achieve a circumferential lesion in one application. After ablation, the balloon is deflated for removal. The ultrasound transducer 110 in this embodiment may be located at the tip inside the balloon or immediately behind the balloon. If inside, the balloon material is selected to be ultrasonically transparent (e.g., a thin urethane) and filled with saline to facilitate sound transmission, so the ICE can image through the balloon. The real-time imaging helps verify balloon contact with the PV ostium and monitor for complications like impedance rises or gap in contact.

FIG. 4B depicts a flower-basket electrode array 174, which is another "single-shot" ablation structure. The basket consists of multiple flexible splines that expand outward when deployed from the sheath. The splines 174 carry a series of electrodes 172 that, when expanded, form a circumferential arrangement. This design, akin to a pentaspline PFA catheter, allows one to position the collapsed basket through a small sheath and then expand it in the atrium to encircle a vein or create a larger lesion area . The basket can also conform to irregular shapes (useful for anatomical variations). The ultrasound transducer 110 in FIG. 4B is shown at the center of the basket. In practice, it could be at the tip of a central shaft with the splines around it, giving a hub-and-spoke arrangement. This central location of the imaging transducer is ideal because it provides a 360° view of the expanding splines and the tissue interface. The operator can see, for example, whether all electrode splines have made contact with the endocardial wall (poor contact might appear as gaps on the ICE image). The basket's electrodes 172 can be energized in various biphasic combinations by the PFA generator to create a homogeneous lesion. After ablation, the splines collapse back for withdrawal. Both the balloon and basket embodiments demonstrate how the invention supports alternative electrode geometries. Importantly, in all these variations, the integration of ICE imaging means the clinician has direct visualization of the ablation structure's position and the surrounding anatomy while energy is delivered, which is a significant safety improvement.

It should be noted that while PFA is largely non-thermal, some thermal effects can occur if high-current pulses are applied repeatedly, due to resistive (Joule) heating in tissue . The invention addresses this in two ways: (1) using PFA protocols that minimize thermal load (for example, short pulse bursts and biphasic waveforms to reduce ion accumulation and muscle contraction, as known in PFA research), and (2) including irrigation to cool the electrode-tissue interface. In embodiments with irrigation (either through a balloon inner volume or via perfusion holes on electrodes), saline is infused at a rate (e.g., 2–10 mL/min) to dissipate heat and also to

wash away any blood that could form microbubbles or thrombus around the electrode. Experimental data has shown that irrigation of PFA electrodes can mitigate temperature rise and prevent heat stacking over multiple pulse applications . Thus, the catheter may be connected to a standard EP irrigation pump, and the fluid can exit through small pores around each electrode 160 or through the inflation/irrigation lumen in balloon-based designs.

Energy Isolation and Signal Management: A core aspect of this invention is managing the coexistence of high-voltage ablation signals with low-voltage imaging signals. The catheter and system implement multiple layers of isolation. Physically, as mentioned, the wiring for the ultrasound transducer is routed separately from the electrode conductors and is shielded. The transducer elements and front-end may be referenced to a different ground than the ablation electrodes. During ablation, the ultrasound front-end can be momentarily grounded or isolated. In one embodiment, the catheter handle 140 contains a miniature relay or solid-state switch that disconnects the transducer cable 152 from the console input during a PFA pulse (the timing controlled either by the generator or a foot pedal that triggers both imaging pause and pulse). Additionally, band-stop filters can be placed on the ultrasound cable to block the specific frequency content of the PFA pulse (which is usually in the kilohertz range), while passing the megahertz-range ultrasound signals – effectively preventing saturation. Conversely, the ablation leads may include RF chokes to block any high-frequency coupling from the ultrasound side. The goal is to ensure the operator and patient do not experience any unintended consequences of energy coupling: the imaging hardware is protected from burnout, the image display is not overwhelmed by noise, and the ablation waveform is not distorted by any loading from the imaging side. All these measures are contained within the catheter system design in a manner that is invisible to the user – from the physician's perspective, they simply see stable images and deliver pulses as needed.

Use-Case Example – PFA near the Esophagus (FIG. 5A): One of the most critical scenarios in AF ablation is lesion creation on the posterior left atrium, where the esophagus lies just behind the heart wall. Thermal ablation here risks esophageal injury, potentially leading to atrio-esophageal fistula, a rare but often fatal complication. With the present invention, this risk is dramatically reduced. FIG. 5A shows the catheter 100 in the left atrium, with the ultrasound transducer 110 imaging the posterior wall. The esophagus E is visible in the ICE image as an echo-lucent (dark) tubular structure posterior to the atrial wall. Using ICE, the operator can continuously monitor the esophagus position and even measure the real-time distance between the ablation electrode and the esophageal wall. Because PFA is used, the risk of esophageal damage is intrinsically lower – as noted, electroporation can spare esophageal tissue due to its higher threshold for injury . Indeed, clinical data reported zero esophageal lesions with PFA in contrast to significant lesion rates with RF or cryo . Nonetheless, the physician can take additional precautions with the integrated ICE: for example, they might hold off on energy delivery if the esophagus appears particularly close or if they see unexpected swelling; or they might adjust the catheter position slightly under visualization. The catheter could also be used to visualize any tenting of the atrial wall or early signs of edema. After delivering a PFA lesion set around the pulmonary vein, the ICE transducer can be used to scan for complications – e.g., pericardial effusion (fluid in the pericardial space) can be seen by imaging through the septum or from the right atrium. This eliminates the need to withdraw the ablation catheter and insert an

ICE catheter for complication monitoring, since our device does both in one. Thus, FIG. 5A exemplifies how real-time lesion guidance and safety monitoring is achieved near a vulnerable structure like the esophagus.

Use-Case Example – Phrenic Nerve Monitoring (FIG. 5B): Another concern during certain cardiac ablations (especially around the right-side pulmonary veins or the superior vena cava) is phrenic nerve injury. The right phrenic nerve descends along the superior vena cava (SVC) and right atrium, and ablation too close to it can cause diaphragmatic paralysis. PFA's selectivity partially helps here – nerves generally have a higher injury threshold than myocardium, so PFA tends to spare nerves when properly dosed . Indeed, studies have noted that no permanent phrenic nerve palsies occurred in PFA trials, whereas thermal ablations can sometimes cause phrenic injury . However, transient phrenic nerve capture can occur with PFA if the nerve is within the electric field, causing diaphragmatic twitching during energy delivery . FIG. 5B illustrates a scenario in which the catheter 100 is ablating near the right superior pulmonary vein (RSPV) and SVC junction – a location where the phrenic nerve runs nearby. The ICE transducer 110 is aimed toward the diaphragm (D) and the right lung base. By pacing the phrenic nerve (typically done by pacing the right diaphragm or phrenic nerve via a separate catheter in the SVC), the operator can use ICE to observe the motion of the diaphragm. In practice, before delivering each ablation pulse near the RSPV, the physician might stimulate the phrenic nerve (using, e.g., a pacing electrode on the catheter or a separate lead) and confirm diaphragmatic motion on ICE. If loss of capture or movement is seen, it's a warning to reposition to avoid nerve damage. During PFA delivery, any diaphragmatic contractions triggered by the pulses could also be visualized in real time on ICE – as a contracting motion of the muscle. The integrated catheter thus allows immediate detection if the phrenic nerve is being affected, and because ICE is on the ablation catheter, one can precisely know the catheter's location relative to where the nerve likely is. Moreover, since PFA is used, even if the nerve is within range, the non-thermal mechanism means the risk of lasting damage is low . The physician can proceed with more confidence, or modulate the pulse amplitude if needed. This kind of functional monitoring (seeing the moving diaphragm) is not feasible with fluoroscopy and would be difficult with a separate ICE catheter due to alignment issues – but is made practical by our integrated design.

Modular and Alternative Embodiments: While the detailed embodiments above describe a fully integrated single catheter, the invention also covers modular configurations. In one variation, the catheter could be composed of two interfacing parts: an ultrasound imaging module and an ablation module. For example, a small ICE catheter (perhaps a 5–7 Fr ultrasound probe with deflection) could be inserted through the lumen of a larger ablation catheter or sheath. The probe could lock in place such that its tip aligns with the ablation electrode assembly. This modular approach would allow the ultrasound probe to be removed or exchanged (for instance, to use a higher frequency probe for detailed imaging, or to remove it if only ablation is needed at some stage). In another alternative, the ablation electrode assembly itself could be detachable, such as clip-on rings or an expandable array that attaches to the catheter tip on demand. However, a permanently integrated assembly as described in the preferred embodiment provides the most seamless user experience.

Yet another variation involves adding electrophysiological mapping capability. Since the ablation electrodes are electrodes after all, they can double as sensing electrodes for cardiac electrical signals. The system could be configured so that prior to (or between) ablation pulses, the electrodes 160 are connected to a mapping system or EP recording system to record intracardiac electrograms or to perform pacing. For instance, the electrodes could be used to verify conduction block around a pulmonary vein by sensing potentials or pacing the tissue. This could obviate the need for a separate mapping catheter. Some current PFA systems use their multi-electrode arrays for both ablation and sensing , and the same principle is applied here, now with the added benefit of co-located ICE imaging.

Additionally, the catheter may incorporate a position sensor (like a magnetic sensor for Carto® or other mapping systems) to allow the catheter to be visualized on an anatomical map. Integration with electroanatomical mapping systems can further enhance guidance, especially if the ultrasound images are registered to the map. Prior work has shown the feasibility of registering ICE images to 3D maps by using the catheter's location and known geometry . In our system, because the catheter already has both imaging and ablation functions, such registration could allow creation of real-time lesion maps with confirmed imaging of gaps, etc.

Variations in Size and Use Cases: The embodiments described are generally for intracardiac use via venous access (e.g., for left atrial procedures). The invention can also be applied in other contexts. A smaller diameter version could be used in pediatric cases or in smaller chambers. A longer version could be used via a retrograde aortic approach for ventricular ablation, where intracardiac imaging could guide ablation in the ventricle or septum. The principles of combining imaging and electroporation are equally applicable to treating ventricular tachycardia substrates, for example, allowing identification of scar tissue via ICE and then targeted PFA ablation of that region. Because PFA is inherently less tissue-type-specific (it can ablate myocardium but spare nerves and vessels if threshold differences are exploited), one could even use this for ablating areas near coronary arteries (where thermal ablation risk injuring the artery, PFA might spare it). The ICE would in that scenario help visualize the wall and possibly the artery location (ICE can visualize larger coronary arteries as echogenic structures with Doppler flow).

Finally, it is contemplated that the catheter could support dual-energy operation – for example, combining PFA with radiofrequency (RF) ablation capabilities in one catheter (similar to some lattice-tip designs that can do both). This could be useful if a specific lesion benefits from a small RF touch-up (since PFA lesions can sometimes spare certain muscle fibers or have gaps if contact was poor). In such embodiments, the electrodes 160 would be connected to a generator capable of delivering both modalities, and the catheter's cooling irrigation would serve both purposes (PFA cooling and RF cooling). The ICE imaging would allow one to see phenomena like microbubble generation or tissue char that are more relevant in RF, providing an extra layer of safety.

Throughout all these variations, the unique advantage of this invention is maintained: the union of real-time intracardiac visualization with therapeutic ablation in one instrument, improving procedural efficiency and patient safety. Those skilled in the art will appreciate that various

changes can be made to the device's form and function without departing from the spirit of the invention. The following claims are intended to cover such modifications and alternative embodiments within the scope of the inventive concept.

Variations and Alternative Embodiments

To highlight the flexibility of the invention, several specific variations and alternative embodiments are described here:

- Ultrasound Transducer Types: The catheter can employ either a phased-array ICE transducer or a mechanical ICE transducer. A phased-array (typically 8–10 Fr) provides electronic steering, Doppler, and potentially 3D imaging , which is advantageous for comprehensive visualization. A mechanical transducer, on the other hand, offers high-resolution single-plane images and can be made in smaller sizes or lower cost. Both types are within the scope of the invention, and the catheter design can accommodate either by adjusting the distal tip configuration (FIG. 3A vs FIG. 3B). In some embodiments, the ultrasound assembly could even be a forward-looking array (e.g., a 2D matrix array giving a volumetric image straight ahead of the catheter), which could be useful for certain applications like visualizing a ventricular apex.

- Ablation Electrode Configurations: The PFA electrodes on the catheter may be configured in numerous ways. In one variation, the catheter has a focal ablation tip electrode (or a small cluster of electrodes at the tip) for delivering focal lesions. This is analogous to a standard RF ablation catheter tip but used with PFA energy. In another variation, the catheter employs a multi-electrode ring assembly – multiple ring electrodes along ~1–2 cm of the distal shaft – which can be used to create linear lesions or circumferential lesions by sequential or simultaneous activation. Yet other embodiments use expandable structures as illustrated in FIG. 4A and 4B: a balloon-mounted array or a multi-spline basket. These single-shot configurations are particularly useful for pulmonary vein isolation; for example, a 25–35 mm diameter expandable loop with 10 electrodes (as in the VARIPULSE™ design) could be integrated . The system could optionally support replaceable electrode attachments – e.g., a catheter could have a detachable tip where one tip is a balloon and another is a focal tip, allowing the operator to switch based on lesion set required. All such configurations are considered part of this invention, as they all involve the co-location of imaging and ablation on one shaft.

- Modularity and Component Exchange: In some embodiments, the catheter's imaging core is modular. For instance, the ultrasound transducer and associated wiring might be contained in a removable cartridge or core wire that runs inside the catheter. This could allow the imaging unit to be retracted or replaced. A use-case for this might be to insert the catheter and perform initial mapping with ICE; if extensive ablation is then done, one might remove the imaging core to make the catheter even more maneuverable, then reinsert it to check lesions. Alternatively, modular design could facilitate using the imaging probe independently as a diagnostic ICE catheter, then attaching it to the

ablation shaft when therapy is needed. The claims cover such modular arrangements, including a system of two interlocking catheters (an imaging catheter and an ablation catheter) that together perform the described function.

- Irrigation Options: The catheter may include an irrigation channel for saline infusion. In one embodiment, each electrode is irrigated through small holes (like porous electrodes). In another, a single distal irrigation port flushes the area. Irrigation flow rates can be controlled (e.g., 2–4 mL/min during PFA as per one study) to balance cooling and avoid volume overload. Some variations might omit irrigation if it's deemed unnecessary (for example, if the PFA pulse protocol is very short and produces negligible heating, a dry electrode could be used to simplify design). However, given evidence that even PFA can cause some temperature rise with multiple bursts , the irrigated approach is a preferred embodiment for safety.

- Energy and Signal Isolation Techniques: Various alternative techniques can be used to isolate the imaging and ablation energies. Instead of purely electrical isolation, one embodiment uses optical signal transmission for the ultrasound: the transducer signals could be converted to optical signals at the catheter (using an opto-electronic module in the handle) and sent via fiber-optic cable to the console. Optical fibers are immune to electromagnetic interference from the PFA pulses. Conversely, the ablation pulses themselves could be delivered via optical means (e.g., an optical PFA system with photovoltaic electrodes), though that is more speculative. Within the electronic domain, the use of differential signaling on the ultrasound lines and heavy shielding can effectively cancel out induced noise, and modern ultrasound front-ends often include protection circuits for high-voltage pulses (since ultrasound transducers are themselves driven by ~50–100 V transmit pulses, their electronics are designed to handle that, which bodes well for handling external pulses). The catheter leverages such existing technology and extends it to cover the much higher voltage and lower frequency content of PFA pulses.

- Mapping and Navigation Integration: As a variation, the catheter can integrate with 3D navigation systems. For example, a small electromagnetic sensor embedded near the tip can provide real-time 3D coordinates of the catheter (within a magnetic field generator in the lab). This can allow the system to display the catheter on an electroanatomical map. If the ultrasound imaging plane is known relative to this sensor, the ICE images could be overlaid on the map, creating an augmented reality view for the operator . This could also facilitate the creation of lesion maps – after PFA delivery, the region of electroporation as seen on ICE (or inferred from electrode positions) could be marked on the map. These are additional features that, while not necessary to practice the core invention, demonstrate its compatibility with advanced lab integrations.

- Use in Various Regions and Adjacent Structure Monitoring: The specification has focused on atrial fibrillation ablation as an example, but the invention is not limited to that. Variations of the catheter could be tailored for ventricular tachycardia ablation,

where intracardiac echo could help visualize papillary muscles or thick scar tissue in the ventricles while PFA ablates it (potentially PFA is advantageous in ventricular scar due to better penetration). Another use-case is AV node ablation for AV nodal reentrant tachycardia or for creating complete heart block intentionally – ICE could ensure the catheter is properly positioned at the compact AV node (near Koch's triangle) while delivering a very focal PFA lesion that might avoid collateral damage to surrounding atrial tissue more than RF would. Furthermore, when ablating near valves, ICE can show the valve structures, reducing the risk of damaging them. Adjacent structure monitoring via ICE can be done not only for esophagus and phrenic nerve as discussed, but also for the aorta (when ablating the septum, one could see the aortic root and avoid it) and for the coronary arteries (ICE can see bright spots of catheters in coronary sinus or even visualize the left main artery if oriented well). These variations underscore the broad applicability of having imaging on the ablation tool.

Each of the above variations can be combined with others. For example, one could have a balloon PFA catheter with a phased-array ICE transducer and irrigation – all in one. The intention of listing these alternatives is to make clear that the claim scope should not be limited to one narrow implementation. The invention generally covers any catheter or system where intracardiac ultrasound imaging means and pulsed-field ablation means are integrated on a single steerable platform to work in tandem.

1. Introduction

This supplemental specification is intended to be read in conjunction with the above description of the intracardiac echocardiography (ICE)-integrated pulsed-field ablation (PFA) catheter system. Unless expressly contradicted herein, all definitions, reference numerals, and functional relationships disclosed in the above specification are incorporated by reference.

> **Inventive focus**: Providing real-time intracardiac imaging that is spatially and temporally coincident with PFA energy delivery so that lesion formation, electrode–tissue contact, and collateral-structure motion can be monitored without repositioning the catheter.

For clarity, "distal" refers to the end of the catheter closest to the patient's heart, while "proximal" refers to the handle end.

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2. Common Structural Framework

All embodiments share the following elements (numbers correspond to those in the parent drawings):

- **100** steerable catheter shaft (6–12 Fr) with at least one pull-wire lumen.

- **110** high-voltage conductors for delivering PFA pulses (0.8–2 kV).
- **120** imaging signal conductors or optical fibers, as appropriate.
- **130** basket-type electrode assembly comprising 4–10 splines (131) carrying ablation electrodes (132).
- **140** electrical and/or acoustic isolation members separating the PFA pathway from the ICE circuitry.

Each alternative embodiment modifies only the **imaging transducer assembly 150** and its placement relative to the basket.

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3. Embodiment A – Hub-Mounted Side-Looking Phased-Array ICE (FIG. 5B-A)

- **Structure**: A rectangular phased-array transducer (152) comprising 64–128 piezoceramic elements is recessed in a window (153) formed in the catheter hub immediately proximal to the basket origin. The active face is oriented perpendicular to the catheter's longitudinal axis.
- **Imaging volume**: Electronic sector steering produces a 120-degree fan (155) intersecting the electrode plane (E) and extending to at least 25 mm beyond the atrial wall.
- **Advantages**: No moving parts, low profile, minimal incremental length.

4. Embodiment B – Distal Spherical 3-D Matrix ("Ball") Array (FIG. 5B-B)

- **Structure**: A geodesic dome housing (160) with a 1024-element 2-D matrix array (162) is affixed at the extreme distal tip, with the basket assembly (130) immediately proximal.
- **Imaging volume**: Omni-directional cone with ≥300° solid-angle coverage (165).
- **Advantages**: Continuous panoramic visualization without catheter rotation; captures full circumference of lesion and adjacent structures.

5. Embodiment C – Annular (Ring) Co-Axial Array (FIG. 5B-C)

- **Structure**: A stack of thin annular piezoceramic rings (170) encircle the catheter shaft at the exact axial location of the basket hub. Each ring can be driven individually or in groups.
- **Imaging volume**: Cylindrical sheet (172) orthogonal to the shaft, yielding a "bullseye" cross-section of electrode contact.
- **Advantages**: True 360° radial slice; perfect co-registration with ablation plane.

6. Embodiment D – Cylindrical Sleeve Micro-Array (FIG. 5B-D)

- **Structure**: A flexible PCB (180) bearing 256 micro-elements (182) wraps around the shaft just proximal to the basket. A thin acoustic window (183) is formed by removing metal braid directly under the array.
- **Imaging volume**: Electronic arc steering provides a selectable angular sector (0–360°) with adjustable focal depth.
- **Advantages**: Keeps distal tip free for anchoring or irrigation; single PCB simplifies assembly.

7. Embodiment E – Mechanical Rotational Single-Crystal (FIG. 5B-E)

- **Structure**: A 9-MHz single piezoelectric crystal (190) is mounted on a micro-motor shaft (191) within the lumen, spinning at 600–1,200 rpm. The basket is located 2–3 mm distal to the crystal's center.
- **Imaging volume**: Continuous 360° radial B-mode slice (192).
- **Advantages**: Cost-effective; proven technology; smaller cable count.

8. Embodiment F – Spline-Integrated Micro-Transducers (FIG. 5B-F)

- **Structure**: Each spline (131) carries one or more miniature piezoceramic patches (200) bonded adjacent to its electrode segment (132). Signals are multiplexed through a switching ASIC (202) in the hub.
- **Imaging volume**: Individual narrow beams converge inward to a common focal region (205). Software mosaics the beams into a circumferential image.
- **Advantages**: Measures electrode-specific contact; no separate array; minimal shaft diameter increase.

9. Embodiment G – Fiber-Optic CMUT Halo (FIG. 5B-G)

- **Structure**: Twelve capacitive micromachined ultrasonic transducer tiles (210) are powered and interrogated optically via fiber bundle (212) that runs alongside the HV conductors. The halo (211) sits distal to the basket.
- **Imaging volume**: 270° fan with optical – electrical isolation inherently immune to high-voltage PFA interference.
- **Advantages**: No copper leads in the distal tip; compatible with kilo-volt pulses; inherently MR-safe.

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10. Timing & Control (All Embodiments)

In all versions, imaging frames may be acquired **(i)** immediately before a PFA pulse to verify electrode–tissue contact, **(ii)**inter-leaved between pulse trains, or **(iii)** immediately after ablation to document lesion formation. Interleaving is achieved by gating the imaging controller such that

the transducer firing is suspended ~5 µs before each PFA burst and resumes ~20 µs after the burst terminates.

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11. Alternative Electrode Geometries

While the basket is shown as looped splines, the same imaging configurations apply to umbrella-type, balloon-mounted, or C-shaped electrode arrays, provided that the imaging beam intersects the electrode–tissue interface.

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12. Conclusion

These alternative embodiments illustrate that the inventive concept—real-time ICE imaging spatially and temporally coincident with pulsed-field ablation—is **not limited to a single transducer geometry or location**. Any of the above imaging assemblies may be substituted, combined, or interchanged without departing from the scope of the invention as defined by the appended claims.