**For Release March 6th at 8:30 a.m. CT**

Contact
[Insert Name]

 [Insert phone]

**DRAFT**

**[Institution] participates in GLOBAL PIVOTAL TRIAL dEMONSTRATING IMPRESSIVE RESULTS OF PFA treatment for atrial fibrillation**

**[CITY/STATE] – Month day, 2023 –** [INSTITUTION] participated in a global clinical trial whose results were released [today/this week/recently]. The landmark trial exceeded its safety and efficacy performance goals for the PulseSelect System that uses PFA – a novel, breakthrough technology that uses pulsed electric fields to treat atrial fibrillation (AF) – for the treatment of patients with paroxysmal or persistent AF. The study demonstrated the system achieved one of the lowest adverse event rates of any prior U.S. FDA Investigational Device Exemption (IDE) trial for AF ablation or any multi-center PFA study – and exceeded the threshold for its efficacy performance goal in the global clinical trial.

Findings from the PULSED AF Pivotal Trial were presented as a late-breaking trial [today] at the American College of Cardiology’s Annual Scientific Session Together with World Congress of Cardiology (ACC.23/WCC) and simultaneously published in *Circulation.*

**[Insert quote from investigating physician. Consider addressing 1) the institution’s role in generating robust clinical data for PFA; and/or 2) how PFA can potentially help advance treatment of AF forward and provide additional tools for performing ablation safety and effectively [PHYSICIAN NAME, TITLE].**

**[INSTITUTION] enrolled [xxx] patients into the trial.**

The primary effectiveness endpoint was achieved in 66% of paroxysmal AF patients and 55% of persistent AF patients (p<0.001).Additionally, clinical success, freedom from recurrence of any symptomatic atrial arrhythmias, was 80% for paroxysmal and 81% for the persistent cohort.

The study exceeded its performance goal of freedom from a composite of serious procedure and device-related adverse events with a 0.7% (p=0.002) rate of primary adverse events in both patient cohorts. There were no esophageal events, instances of pulmonary vein stenosis, or phrenic nerve injury – common procedural complications associated with ablation.
 **About the PULSED AF Pivotal Study**

PULSED AF is the first and only completed, global, and multi-center clinical study with IDE approval to evaluate the safety and effectiveness of PFA technology for AF ablation. PULSED AF is designed to evaluate the safety and efficacy of the PulseSelect System for the treatment of AF in adult patients with a history of drug refractory, recurrent and symptomatic paroxysmal or persistent AF. The trial is a prospective, single arm, multi-center clinical that treated 300 patients (150 with paroxysmal AF and 150 with persistent AF). Patients were enrolled across 41 sites in nine countries with 67 operators throughout the United States, Canada, Europe, Australia, and Japan.

Patients underwent rigorous arrythmia monitoring with assessments at six and 12 months and weekly and symptomatic trans-telephonic monitoring.

The trial was sponsored by Medtronic.

**About the Medtronic PulseSelect System**

The single-shot PulseSelect System delivers pulsed electric fields through an ablation catheter designed specifically to interrupt irregular electrical pathways in the heart that trigger AF. However, unlike traditional methods of ablation that heat (radiofrequency ablation) or cool (cryoablation) the atrial tissue, the PulseSelect System uses a non-thermal approach and preferentially targets heart tissue with the goal of avoiding unwanted injury to surrounding structures, a risk of current ablation technologies.

Worldwide, the PulseSelect System is investigational and not approved for sale or distribution. For more information on PULSED AF, visit [Medtronic.com/PFA.](http://medtronic.com/pfa)

[INSERT INSTITUTION BOILERPLATE PARAGRAPH]

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4 Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the Framingham Study. Stroke 1991;22:983-8.

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8 Andrade JG, Wells GA, Deyell MW, et al. Cryoablation or Drug Therapy for Initial Treatment of Atrial Fibrillation. N Engl J Med. January 28, 2021;384(4):305-315.