UltiSynq™ Defibrillation Lead

Precise Positioning Solution for Left Bundle Branch Pacing (LBBP) Capture[Φ], Without Compromising ICD Function[1,2]



Controlled torque transmission for consistent, confident LBBP Capture[1,3]

<1 Mean repositioning attempts observed[1]

Engineered to address challenging anatomy often encountered in ICD and CRT-D patients[1,3]

Built on a proven ICD lead coil design[+,1]

100% Defibrillation success **without** lead repositioning[1]

97.5% complication free rate at 3 months, exceeding the pre-specified performance goal[1]

True bipolar design delivers accurate sensing[1]

Zero inappropriate shocks due to P- or T- wave oversensing[1]

True bipolar sensing simplifies lead slack management and device programming[Ω,4]

All clinical data shown are based on results from the ASCEND CSP clinical trial.[1]
[Φ]86% of patients achieved LBBP or likely LBBP capture.[1]
[+]The UltiSynq Defibrillation Lead coil design is based on commercially available and established Abbott defibrillation leads.
[Ω]Compared to additional lead slack management and programming steps observed with integrated bipolar leads.[4]

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Demonstrated success in left bundle branch area pacing implant procedures[1]



CPS Locator™ 3D Plus Delivery Catheters

The CPS Locator 3D Plus Delivery Catheters are available in 3 unique distal curves and 3 lengths for **use across a range** of anatomies.

For more information, please scan here or visit **cardiovascular.abbott/ultisynq**

MR Conditional. Allows patients to safely undergo an MRI scan when used in combination with an MRI-Ready device.*

*For additional information about specific MR Conditional systems and lead model numbers, including warnings, precautions, adverse conditions to MRI scanning and potential adverse events, please refer to the MRI-Ready Systems Manual at manuals.eifu.abbott or check our MRI-Ready resources at medical.abbott/manuals.

References:

1. Schaller RD, Sanders P, Joza J, Zimetbaum P, Birgersdotter-Green U, Tung R, Singh B, Tam MTK, Thomaides A, Nair D, Leclercq C, Vijayaraman P, Hadadi CA, Wiley J, Ganz L, Feng L, Johnson G, Ryu K, Shaw R, Charan V, Lee K, Burri H; ASCEND CSP Investigators. Safety and performance of a novel ICD lead for left bundle branch area pacing: Results from the ASCEND CSP trial. Heart Rhythm. 2026 Apr 25:S1547-5271(26)02194-6. doi: 10.1016/j.hrthm.2026.03.1939. Epub ahead of print. PMID: 42033435.
2. J. Requena-Carrion, J. Vaisanen, F. Alonso-Atienza, J. L. Rojo-Alvarez, J. Hyttinen and A. Garcia-Alberola, "Comparison of the scope of true and integrated bipolar leads in implantable cardioverter defibrillators," 2007 Computers in Cardiology, Durham, NC, USA, 2007, pp. 233-236, doi: 10.1109/CIC.2007.4745464.
3. Data on File (Torque Transmission Assessment for UltiSynq and UltiPace Leads (91190757 Rev A))
4. Medtronic Left bundle brancharea pacing (LBBAP) Implant procedure reference guide (US-CV-2600638 v1.0)

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

UltiSynq™ Defibrillation Leads

Indications for Use: The UltiSynq™ defibrillation lead is indicated for use in combination with implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy-defibrillators (CRT-D) to provide sensing, pacing, and cardioversion/defibrillation therapy in patients who are at risk of sudden cardiac death due to bradyarrhythmias or life-threatening tachyarrhythmias. The lead may be implanted transvenously in either the left bundle branch area or the right ventricle.

Intended Use: The UltiSynq™ defibrillation lead is intended for use with a compatible pulse generator to provide long-term cardiac pacing and sensing in the right ventricle or the left bundle branch area, cardioversion/defibrillation therapy to treat life-threatening ventricular arrhythmias, and biventricular pacing when used with a coronary sinus lead.

Contraindications: UltiSynq™ defibrillation lead, is contraindicated:

- in the presence of tricuspid atresia and significant tricuspid stenosis
- for patients with mechanical tricuspid valves
- for patients with a history of ventricular septal defect, repair, or both
- in patients who are expected to be hypersensitive to device material components or a single dose of 1.0 milligram of dexamethasone sodium phosphates
- in the presence of any condition that precludes adequate vascular access
- for patients with active systemic infection

For contraindications of the ICD/CRT-D device used with the UltiSynq defibrillation lead, please refer to the applicable pulse generator manual.

Adverse Events: Potential adverse events and their categories as applicable when using an UltiSynq™ defibrillation lead include: Arrhythmia (Accelerated arrhythmia, Induced atrial ectopy or arrhythmias, Induced ventricular ectopy or asystole, Myocardial irritability), Damage to the Conduction System (Complete heart block, Right bundle branch block), Coronary sinus or coronary vein perforation/dissection, coronary artery perforation, Coronary vessel fistula, Cardiac perforation (Cardiac tamponade, Pericardial Effusion, Pericarditis, Septal perforation), Death, Embolism (Air embolus, Thromboembolism, Foreign body), Device related thrombus, Extra-cardiac stimulation, Heart failure (HF decompensation, Cardiogenic shock), Pacing-induced cardiomyopathy, Tricuspid valve dysfunction/insufficiency (Tricuspid regurgitation), Tricuspid valve injury, Hypersensitivity, including local tissue reaction or allergic reaction, Infection (Endocarditis), Lead dislodgement, Hemothorax, Pneumothorax, Pulmonary edema, Respiratory compromise, Septal hematoma, Vascular injury (Vascular perforation, Dissection, Arteriovenous fistula), Hemorrhage/ Hematoma at access site, Vascular thrombosis, Lead revision resulting from, but not limited to, loss of pacing and/ or sensing (Electrical malfunction of the lead, Lead dysfunction with no clear electrical and mechanical cause, Oversensing, Undersensing, Capture threshold elevation, Mechanical malfunction of the lead), Inappropriate defibrillation therapy, Loss of capture, Loss of defibrillation therapy, Prolonged exposure to fluoroscopic radiation, Contrast media, Anesthesia risks.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

CPS Locator™ 3D Plus Delivery Catheters

Indications for Use: The Delivery Catheter is indicated for the introduction of various types of pacing or defibrillator leads to the right heart, inclusive of the Left Bundle Branch Area.

Contraindications:

- Obstructed or inadequate vasculature for venous access
- Review contraindications associated with ancillary devices used with the Delivery Catheter

Complications: Possible complications associated with the Delivery Catheter include: Delay in procedure, Vessel trauma, Endocardial trauma, Air ingress, Blood loss, Lead Dislodgement, Embolization (material, air), Allergic reaction, Infection, Device incompatibility, Incomplete therapy. Possible complications associated with the use of ancillary devices with the Delivery Catheter include: Air embolism, Bleeding, Bradycardia, Cardiac perforation, Cardiac tamponade, Chronic nerve damage, Death, Extracardiac stimulation (muscle/nerve stimulation), Hematoma, Heart block, Hemothorax, Incisional pain, Infection including endocarditis, Lead dislodgement, Myocardial infarction, Myocardial trauma, Pericardial effusion, Pericarditis, Pneumothorax, Stroke, Tachyarrhythmias, Thrombosis/thromboemboli, Valve damage, Venous occlusion, Venous trauma (e.g., perforation, dissection, erosion).

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions, and potential adverse events.

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