IMPULSE DYNAMICS

HFSA 2025
CCM PRESENTATIONS: HIGHLIGHTS

Effects of a Novel Cardiac Contractility Modulation-Defibrillator (CCM-D) on NYHA Functional Class in ICD-Indicated Patients: Post-Implant Results from the Integra-D Trial

Late-breaking Presentation By Nir Uriel, MD At HFSA Annual Scientific Meeting, September 28, 2025. Minneapolis, MN

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STUDY DESIGN & PATIENT CHARACTERISTICS

300 Patients

Stage C/D heart failure patients with EF ≤ 40% and Class I/II ICD indication

On GDMT

No CRT / pacing indication

No PR interval >375ms /AV block

75 US sites

Primary Efficacy Objective

100 Subjects

Evaluate device effectiveness in converting VF at implant

Completed: n = 101 across 24 sites

62.5 years	28.7%	30.0%	106.8 ms	52.5%
Mean Age	% Female	Mean LVEF	Mean QRS	Ischemic

Additional analysis: NYHA functional class change at 6-month in patients with paired data

SUMMARY OF STUDY CONCLUSIONS

CAUTION-CCM-D is an investigational medical device. It is not approved by the U.S. Food and Drug Administration (FDA) for commercial distribution.

100% Patients **Successfully defibrillated** with CCM-D (p<0.001, descriptive 95% CI [96.4%-100.0%])

No inappropriate CCM/ICD interaction occurred using novel hybridized circuits

Preliminary 6-month data shows that **HF symptoms improved or remained stable in majority (88%) of patients**

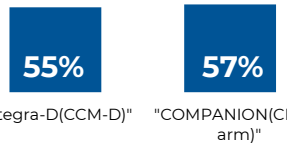
In progress

Safety objective evaluation in an additional 200 patients

Evaluate device-related complications and appropriateness of arrhythmia treatment through 6-month follow-up

55% of Class III/IV patients (N=44) improved - nearly identical to the **57%** improvement seen with CRT-D treatment arm in COMPANION*

Proportion of NYHA III/IV Patients with NYHA Improvement from Baseline at 6-Months



*Bristol et al. Cardiac-Resynchronization Therapy with or without an Implantable Defibrillator in Advanced Chronic Heart Failure. N Engl J Med 2004,350:2140-50