

Ultra-High Density Packaging Technology for Injectable Medical Devices

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Abstract— Future implantable medical devices will be highly miniaturized and almost certainly leverage die-level electronics miniaturization and packaging. Here, an integrated ultra-high density packaging platform is proposed to enable a new class of medical devices. Dense modules are obtained by interconnecting existing ASICs and discrete components using a process which achieves the highest packaging densities available.

I. INTRODUCTION

Medical implants are generally positioned inside small cavities in the human body using invasive surgical procedures, and the total implant volume must be minimized. As shown in Figure 1, the x-ray image of a Cyberonics Vagus Nerve Stimulator Demipulse™ Model 103 [1] reveals that approximately 33% of the implant area is consumed by a printed circuit board (PCB), surface mount components (SMC), and discrettes. However, while the battery dominates the small size, such implants are not fully miniaturized. It is believed that future medical implants should be packaged at the wafer rather than PCB level to reduce size and increase functionality and lifetime.

Draper's integrated Ultra High Density (iUHD) electronics packaging technology [2] could immediately eliminate much of the circuitry volume in implants. By interconnecting application-specific integrated circuit (ASICs) die, other semi-conductor die, and discrete components at the wafer rather than PCB level, miniaturized modules are realized. Compared to the incremental improvements in battery energy density, dense packaging technologies such as iUHD could immediately reduce circuitry volume while incorporating features such as inductive re-charge and telemetry coils. Furthermore, the technology provides a pathway to medical implant manufacturing at the wafer level enabling a new class of highly miniaturized, integrated and injectable devices. With further work, the modules will be hermetically sealed using Titanium or ceramic deposition at the wafer/module level with high-density hermetic feedthroughs.

II. ELECTRONICS PACKAGING AND MEDICAL IMPLANTS

An implantable device is typically a hermetic titanium can with some combination of battery, capacitors, hermetic feed-throughs, wireless re-charging coil, printed circuit board (with ASIC, discrete components, and micro-controller). High end applications reduce volume by

integrating functionality into one custom designed application-specific integrated chip (ASIC). However, the power efficiency and chip performance (Q factor, linearity, etc) are traded off when active and passives are locked to a single process. Furthermore, the volume efficiency of ASIC [3] is lost when the semiconductor die are encapsulated and packaged as SMCs.

Volume-efficient designs would leverage a variety of integrated chip manufacturing processes to combine, for example, state of the art flash memory and microprocessors. Draper's iUHD technology allows this component selection in an extremely volume-efficient package by embedding and interconnecting die from disparate fabrication processes into hybrid silicon-epoxy module.

iUHD is the next generation of Draper's MCM-D technology, which has a proven track record over 1000 deployed systems and qualified to 0-70°C against military reliability standards (MIL-STD 883C Method 1011 thermal shock, 36-inch drop shock, and MIL-STD-810E Method 514.4 vibration). No fielded MCM-D system has experienced a failure to date. For many years, Draper's multi-chip module fabrication process has delivered systems with radio-frequency and mixed-signal functions. The iUHD platform delivers higher density and lower-cost modules, shown in Figure 2.

While describing the details of the iUHD process lies outside the scope of this paper, the key features include bare die embedded a hybrid silicon-polymer substrate, photolithographically-defined electrical interconnect built up on the top and bottom of the substrate, and electrical connection through the substrate. This allows traces to completely envelop the die/module. Additionally, the iUHD platform is "die agnostic" such that a wide variety of chip technologies can be integrated into the same module (standard CMOS, III-V materials, micromachined silicon (MEMS), quartz, ferrites, etc) at nearly the same footprint as a single monolithic ASIC.

Volume minimization requirements vary by clinical application. As such, Table 2 compares the total volume of commonly implanted devices, procedure cost, and the projected volume reduction if the implant PCBs were replaced with die-level packaged circuits. The Medtronic Reveal® DX insertable cardiac monitor is among the smallest implants and is positioned in the subcutaneous space using a minimally invasive procedure.

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Injectable devices represent the future of implanted recording and stimulation by facilitating a less invasive procedure, and potentially removing the requirement for long electrical leads which are prone to failure. Though injectables may be inexpensively inserted using a needle or catheter, and despite the myriad of clinical potential, they are not commercially available. Advanced Bionics' RFBion® is likely to be the first injectable device, which is only beginning to find application. Wafer-scale packaging techniques and interconnected ASICs are essential to achieve the tiny volumes required for injection ($<0.032 \text{ cm}^3$). [4] Other implantable challenges include the micro-watt operating power constraints which demand high energy density sources. Micro-battery, super-capacitor, harvesting, and wireless energy sources are promising only at small duty cycles and load responses.

Draper's iUHD platform provides a pathway towards future, densely packaged implantable and injectable medical devices. Smaller device volumes reduce the surgical load for implantation and improve patient acceptance. Increased battery life or wireless power for implants translates to fewer surgeries for device replacement. Finally, iUHD leverages the use of commercially available components which minimizes the development needed for an ASIC at the beginning of new device designs.

III. A NOVEL INTEGRATED CIRCUIT AND PACKAGING TECHNOLOGY

High density circuit board-like packaging [5] includes ceramic-based multi-chip modules (MCM), polyimide-based flexible substrates, and high-end epoxy-fiber organics. Solutions such as through-silicon via (TSV) technology are emerging and represent the extreme in double-sided interconnect density. [6] Table 2 compares iUHD to these foot-print limited technologies—devices are mounted in a planar fashion on substrate faces and integrated into the package itself.

Alternatively, system-on-packages (SOP) stack multifunctional chips from disparate fabrication technologies, wire-bond to pads on the offsets of the chips, and encapsulate them in a discrete package. [7] SOPs are generally limited to wire bond or flip chip connections which greatly limits between-layer interconnect flexibility, in comparison to through-substrate connections.

Draper's iUHD platform eliminates space-inefficient leaded plastic packages and PCBs by embedding bare die semiconductor devices (ASICs, etc) plus discrete components in a silicon-encapsulant package as shown in Figure 3. The package also serves as a protective fixture that is a miniature analogue of a plastic molded part, but provides a planar substrate upon which layers of electrical interconnect can be built-up. The resultant hybrid substrate wafer can be treated in subsequent processes as a silicon wafer. Novel through-substrate via technology allows back-to-front connectivity for two-sided modules at low-cost. Dielectric layers consist of spin-coated, photodefinable epoxy for patterning of microvias to die and between layers. With additional processing, the technology also permits

multi-layer construction of 3D electronic modules. Table 2 shows that iUHD features are the smallest and densest commercial methods, and rival even TSVs at potentially lower cost and better mechanical properties. As an example, a typical iUHD transceiver module contains TI MSP430, FPGA, RF transceiver, NAND flash, A/D converters, and various discrete passives. The PCB volume was 722 mm^3 while the iUHD module was 75 mm^3 – a 10x volume reduction with equivalent functionality. As an aside, the associated volume and complexity of this example was significantly greater than most medical implants.

iUHD modules have been successfully tested for thermal, electrical, and mechanical robustness to the relevant military specifications (MIL-STD). The materials chosen for the silicon-encapsulant package and the new dielectric layers have also passed cellular toxicity testing (Nelson Labs, Salt Lake City, UT) which completes a step towards preparing for implantation. For some medical implant applications such as ASIC functionality within an electrode lead, the modules must be made to be biocompatible with a hermetic seal. Figure 4 shows a Titanium sputtered coating and the challenges associated with step coverage of features of the substrate. The authors are investigating iUHD metallization techniques and coatings that facilitate chronic stability in-vivo, as well as hermetic interconnects to external sensors. As per Figure 4, the hermetic connector and associated PCB space occupies a non-negligible portion of the implant area.

IV. FUTURE DIRECTIONS

State-of-the art semi-conductor packaging techniques have been reviewed in the context of implantable medical device electronics miniaturization. We have presented a novel and reliable iUHD electronics packaging technology that could immediately be used to reduce existing implant volumes. More interestingly, iUHD could enable a new class of highly-miniaturized implantable and injectable medical implants.

ACKNOWLEDGMENT

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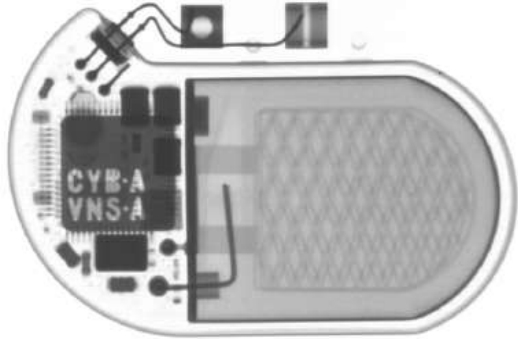


Figure 1: Figure 1: An x-ray image of a Cyberonics Vagus Nerve Stimulator Demipulse (TM) 103. [1] The circuitry, which is the darker shaded objects, occupies about one-third of the device footprint on the left while the battery occupies the remaining space and is shaded light gray.



Figure 2: A mixed-signal iUHD module constructed of semi-conductor die and die-level interconnects.

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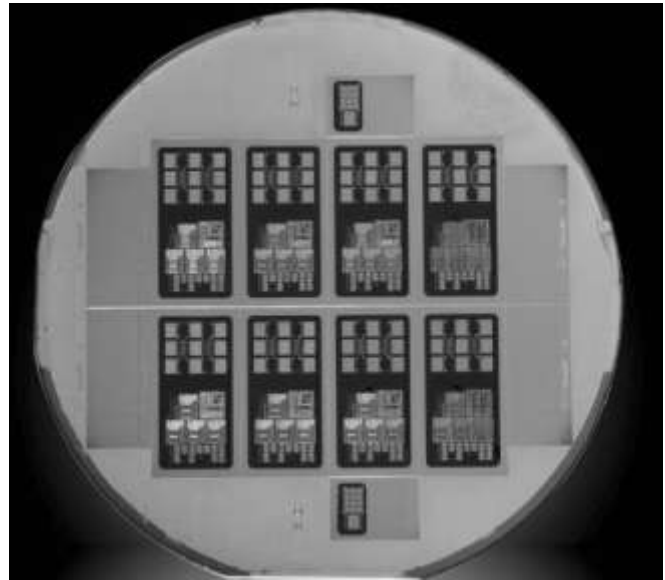


Figure 3: iUHD modules in 4 inch wafer form before interconnect buildup and dicing, showing typical embedded components.

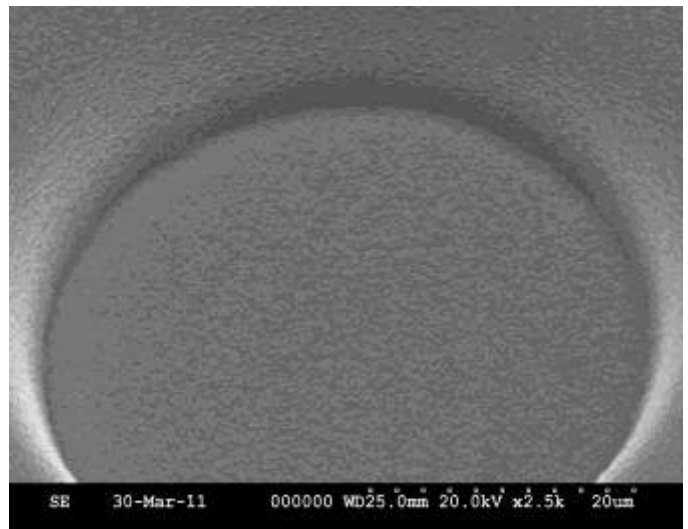


Figure 4: SEM image of a titanium sputtered coating of step features on an iUHD substrate.

Table 1: Comparison of medical device size and volume. The expected volume shows what is achievable if implant PCBs were replaced with die-level packaged electronics.

Device	Medical Procedure Cost	Dimensions (mm)	Device Volume (cm ³)	Expected volume after <u>iUHD</u> miniaturization (cm ³)
Activa [®] RC (Medtronic)	High	53.3 x 53.3 x 10.2	22	15.4
Demipulse [™] 103 (Cyberonics)	High	45 x 32 x 6.9	10	7.0
Reveal [®] DX (Medtronic)	Moderate	62 x 19 x 8	9	6.3
RF Bion [®] (Boston Scientific)	Low	28 x 3 (diam.)	0.2	-
HiRes 90K [™] (Advanced Bionics)	High	28 x 56 x 3	5	3.5

Table 2: Comparison of IC Feature Size and Packaging Densities

<i>*All values in micro-meters</i>	Layer thickness*	Minimum line thickness/spacing*	Minimum hole/via*	Minimum pad over via*
i-UHD	6 (routing); 150 (die)	10-25	20	50
Polyimide Flex	12-75	10-25	20	50
Multilayer Ceramic**	25-90	30	75	N/A
Organic (PCB) ***	60-85	75	150	225