CASE STUDY

Glass Encapsulation: How it Aids in Implant Miniaturization and RF Communication

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Glass Encapsulation: How it Aids in Implant Miniaturization and RF Communication

Challenge: Package and encapsulate a wireless electronic module for an implantable limb lengthening device.

Solution: A hermitically sealed glass encapsulated coil assembly which is 7.5 x L: 27.5mm in size

SYNOSTE partnered with GlencaTec to develop an advanced implantable limb lengthening system which is patient and surgeon friendly. The limb lengthening system, named Nitinail is being developed with strong bio-compatible shape memory alloys which allows for control of the lengthening process using a unique heating and cooling technology. The Nitinail distraction process provides controlled lengthening progression of the treatment.

Figure 1 SYNOSTE System

For patients and doctors the SYNOSTE Nitinail provides lengthening control and convenience resulting in better patient and cost outcomes. The implantable Nitinail guarantees patients safer treatment, less infections, and pain. The systemôs accurate control also lowers the complication rate leaving less room for error.

GlencaTec provides expertise in microfabrication. Their room temperature patent pending laser micro welding process for advanced hermetic glass encapsulation provides a novel solution for sealing implants which contain electronics**.** For this project, GlencaTecôs role was to be the process, development and assembly partner for the glass encapsulated electronic system used in the implantable part of the SYNOSTE device. This embedded module aids the surgeon during surgery and provides the patient improved home care.

Todayôs limb lengthening devices offer two choices, external fixators and implantable nails. External fixators are decades old technology however they offer flexibility especially for significant deformities with the major downside being their negative effect on quality of life in the distraction phase. Alternatively, implantable nails offer a quicker recovery and are more patient friendly however there is risk of breakage, blockage, runaways and unwanted retraction. They are generally best suited for cases with low-grade complexity.

There is still plenty of room for improvement as current implantable nails cannot support full weight-bearing load following surgery leading to muscle weakness and longer recovery periods. The process of limb lengthening has many potential complications, including a surgeonôs experience not only in the performance of limb lengthening surgery, but also in the prevention and treatment of complications which are integral to the process.

Third Generation Limb Lengthening

SYNOSTEôs implantable nail lengthening system is addressing these issues with its revolutionary use of shape memory alloys.

The key to the system is an implanted electronic capsule, which contains a Nitinol wire that can heat and cool the implant itself and precisely control the lengthening process with a revolutionary RF induced thermal elongation principle.

GlencaTecôs responsibility was the design and development of the glass encapsulation for the electronics and later also included the process development of the assembly. It was imperative that the capsule would not allow liquids to penetrate due to risk of substance diffusion from the internal components. Additionally, the glass for the encapsulation needed to be bio-compatible since it was to be implanted in the body.

The implanted electronic components had to remain stable for three months after implantation. The capsule itself would not be powered by battery instead through induction from an external magnetic field.

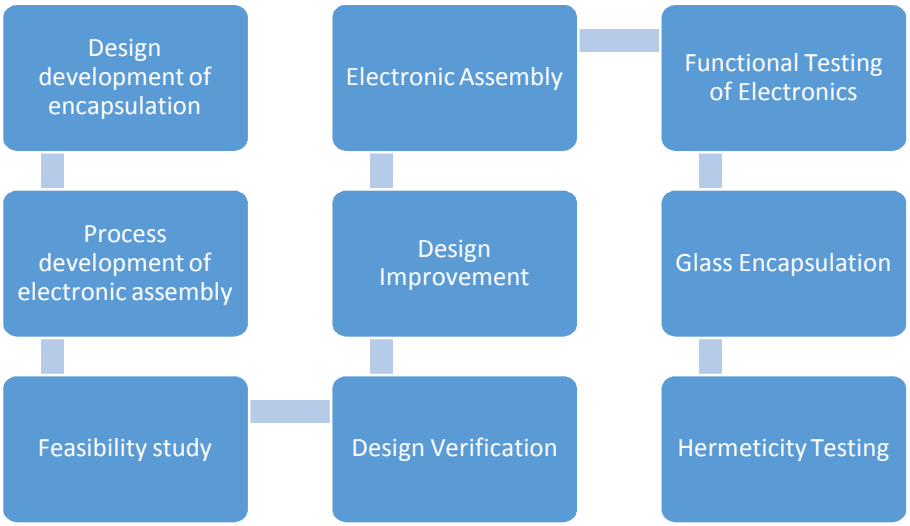

Figure 2 GlencaTec Process

SYNOSTE provided GlencaTec with the capsule components which consisted of a ceramic compound, a copper coil, a capacitor and PEEK frame. GlencaTec needed to assembly and package these into a capsule that was D: 7.5 x L: 27.5mm in size. These combined components perform power management for the expandable nail that carries out the physical part of the distraction. There were also strict requirements on the electrical performance of the assembled electronic circuit.

Cylindrical Glass Encapsulation

GlencaTec originally considered using Planar Glass Encapsulation for the electronic implant however due to the design of the electronics, they turned to Cylindrical Gas Encapsulation (CGE) which was

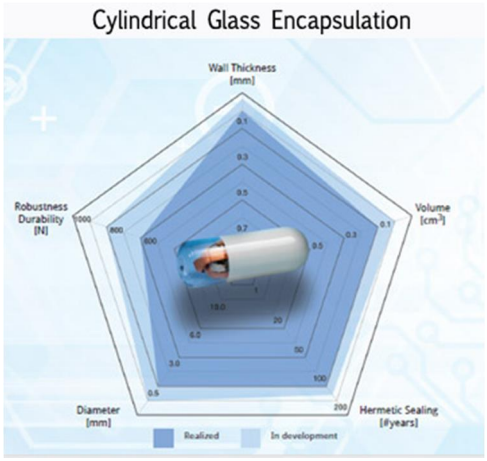

Figure 3 CGE Performance Capability

able to meet the customer's requirement of 1.4 bar mechanical load of saline testing. CGE itself is a tubular glass component that surrounds the electronics and it provides a complete hermetic seal through a laser weld which does not harm the electronics. There are no additives in this process which helps in preserving biocompatibility. The CGE system uses a CO_2 laser welding machine which can also encapsulate using an inert gas. It has a cycle time of approximately 5 seconds.

Based on prior experience the glass material chosen for the CGE process is Borosilicate with Fiolax, a type of glass that is very suitable to GlencaTec's laser welding. Its properties include: excellent biocompatibility, high hydrolytic resistance, good mechanical strength as well as a low melting point. This glass is a Type I glass and meets ASTM E438 standards as well.

Once the glass encapsulation welding is completed it was essential to verify 100% hermeticity as this is vital in protecting patients from the effects of the breakdown of components and material inside the implant. Helium leak testing was done according MIL STD 883 for verification.

The third generation limb lengthening system provides advancement in nail technology through its use of super alloys. It offers improved outcomes through its high precision mechanism and a better experience for patients with the wireless energy transfer, made possible by cutting edge glass encapsulation technology. If all goes according to plan and the Nitinail is market approved expect to see this technology address other bone malformities as well.

Contact

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