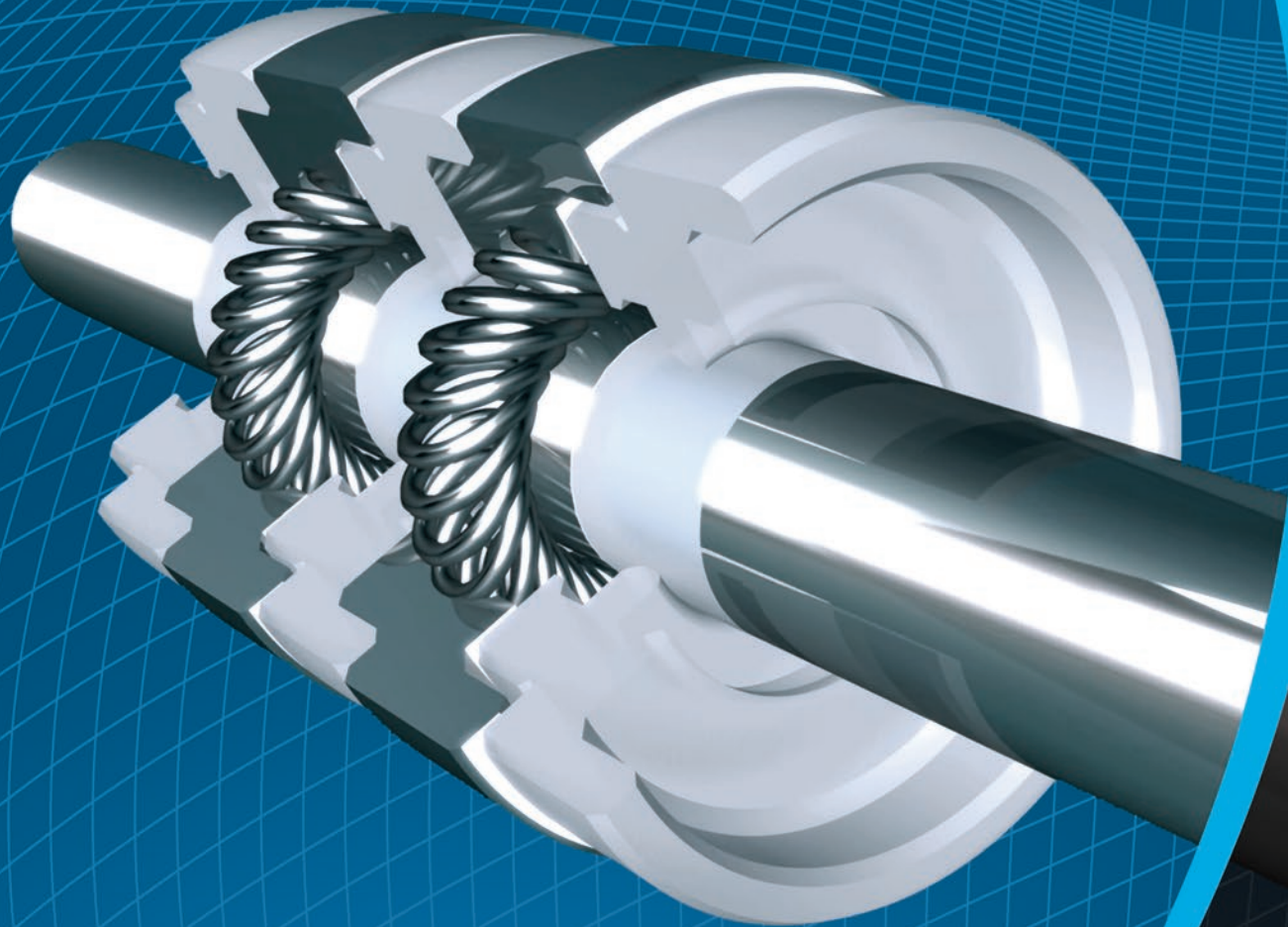


IMPLANTABLE
DEVICES

TMB-10



Electrical Contact Solutions for Medical Active Implantables

CUSTOM COMPONENTS THAT DRIVE TOMORROW'S TECHNOLOGIES.

BAL SEAL
ENGINEERING, INC.



Helping Device OEMs Connect with Confidence

When manufacturers of active implantables need low-force, low-resistance connecting solutions they can be confident about, they turn to Bal Seal Engineering.

For more than 20 years, our electrical contact technology, based on our proven, robust Bal Spring™ canted coil spring, has been making reliable connections in pacemakers, defibrillators, neurostimulators, and many other active implantable devices used to deliver life-improving therapies to the human body.



Already at work in more than a million implantables worldwide, our electrical connecting and conducting components are a proven solution for both existing and emerging therapies.

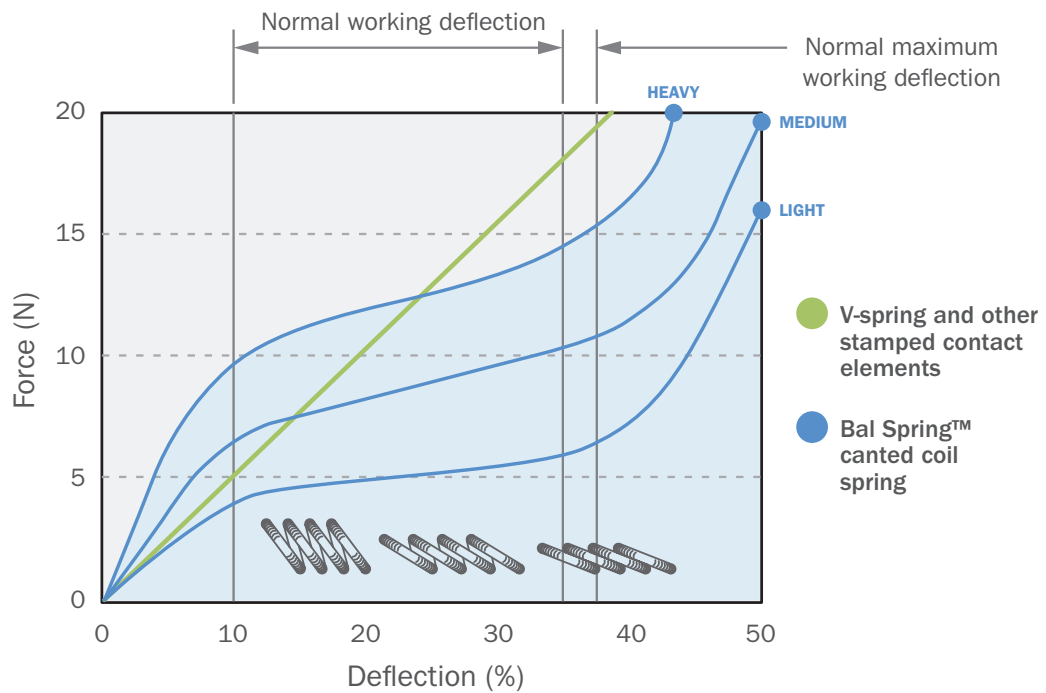
Precision-engineered and manufactured from biocompatible materials, our customizable solutions offer high performance and superior conductivity in a compact footprint that gives OEMs the ability to advance technology and increase device functionality, while enabling surgeons to more simply and safely connect leads to implantable devices. Our two manufacturing locations enable us to mitigate risk and ensure on-time delivery.



Technology at the Core

At Bal Seal Engineering, the solutions we develop are centered on our Bal Spring™ canted coil spring technology. In electrical connecting applications, the spring's individual coils provide multi-point contact, and multiple coils provide further redundancy. Their controllable force compensates for irregularities in mating surfaces that might otherwise compromise performance. The Bal Spring can be customized to meet application-specific insertion/extraction force requirements, and their unique design gives them superior resistance to compression set.

Typical Force Deflection Curves





Bal Conn™ Electrical Contact



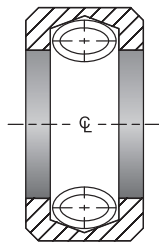
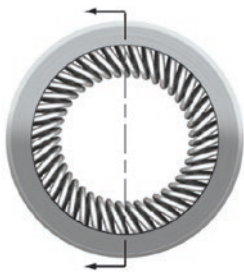
The Bal Conn™ is an electrical contact component that remains the stand-alone solution of choice for OEMs seeking to ensure consistent, reliable connections in implantable devices used for neuromodulation and cardiac health. For over two decades, the Bal Conn has been helping manufacturers improve device performance and push the technology envelope. It has also dramatically simplified the process surgeons use to connect leads to implantables across the therapy spectrum, shortening procedure times. Due to its redundant contact points, the Bal Conn offers low contact resistance. Its canted coils provide excellent resistance to fatigue and more design flexibility than any other implantable device interconnect technology. With its ability to offer low insertion force and uncompromising electrical conductivity, the Bal Conn is ideal for use in devices with high connection counts.

Bal Conn™ Technical Specifications

Application	Lead Diameter (mm)	Force Category	Breakout Force (N)	Running Force Range (N)		Housing Material	Spring Material	Static Dry Contact Resistance (mΩ)	
			Max	From	To			Nominal	Tolerance
Neuro (Bi-directional)	1.35	Medium	1.20	0.09	0.40	MP35N®	Platinum Iridium	70	±20
		Light	0.70	0.07	0.30	316L	Platinum Iridium	600	±200
						Medical-Grade Titanium	Platinum Iridium	350	±150
						MP35N®	Platinum Iridium	80	±30
						Platinum Iridium	Platinum Iridium	40	±15
IS-1 (Bi-directional)	2.67	Medium	3.10	0.50	0.90	316L	MP35N®	100	±60
IS-4/DF-4 (Uni-directional)	3.20	Heavy	2.70	0.50	1.00	MP35N®	MP35N®	80	±50
IS-4/DF-4 (Bi-directional)	3.20	Medium	2.70	0.25	0.75	MP35N®	Platinum Iridium	40	±20
VAD	3.20	Medium	2.70	0.25	0.75	Platinum Iridium	Platinum Iridium	30	±20

This data is presented for comparative purposes only, and it represents the performance of the Bal Conn electrical contact under specific design parameters. Customer results may vary depending upon application requirements and other factors.

Applications

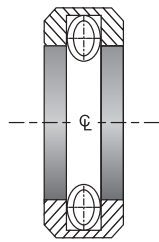
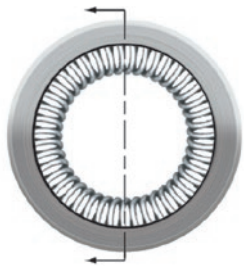


For Neuromodulation Applications

Bi-directional

KEY POINTS

1. Creates consistent force during insertion and removal by limiting spring movement
2. Reduces contact resistance due to more points of contact
3. Supports minimized insertion forces without compromising performance
4. Compact size allows for increased connections in series

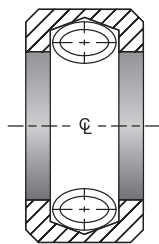
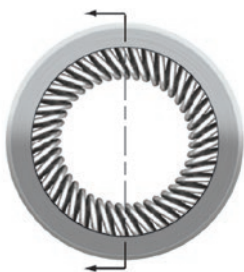


For IS-1 Cardiac Applications

Bi-directional

KEY POINTS

1. Proven to work with IS-1 seal elements
2. Axial spring design enables low contact resistance without noble metals
3. Potential replacement for set screw to reduce duration of surgery and eliminate leak path

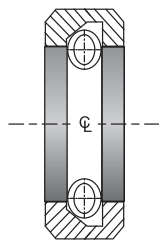
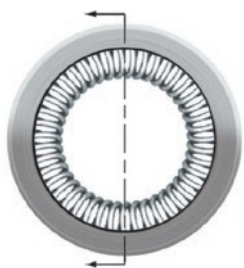


For IS-4/DF-4/VAD Cardiac Applications

Bi-directional

KEY POINTS

1. Creates consistent force during Insertion and removal by limiting spring movement
2. Reduces contact resistance due to more points of contact
3. Supports minimized insertion forces without compromising performance
4. Meets ISO 27186 requirements for force and contact resistance
5. Noble metals required to achieve optimal contact performance



Uni-directional

KEY POINTS

1. Consistent uni-directional Insertion and removal force
2. Axial spring design enables low contact resistance
3. Meets ISO 27186 requirements for force and contact resistance
4. Achieves optimal contact performance without use of noble metals

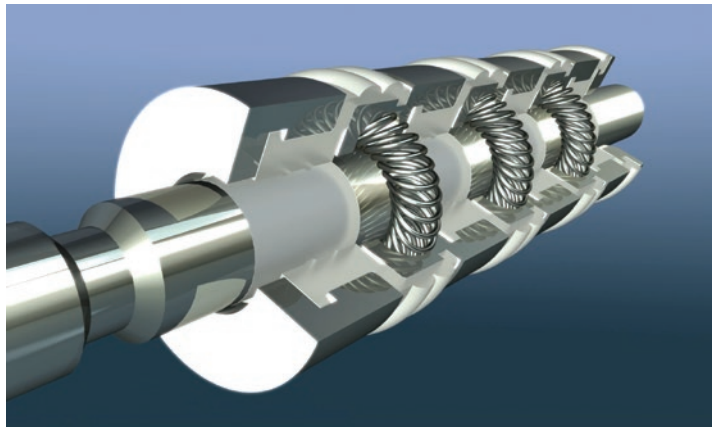


The SYGNUS® Implantable Contact System

The SYGNUS® Implantable Contact System

SYGNUS is the world's first integrated seal and electrical contact system for active implantable devices. It is engineered to help device OEMs accelerate time to market and dedicate valuable resources to therapy and function improvements, instead of component development and testing.

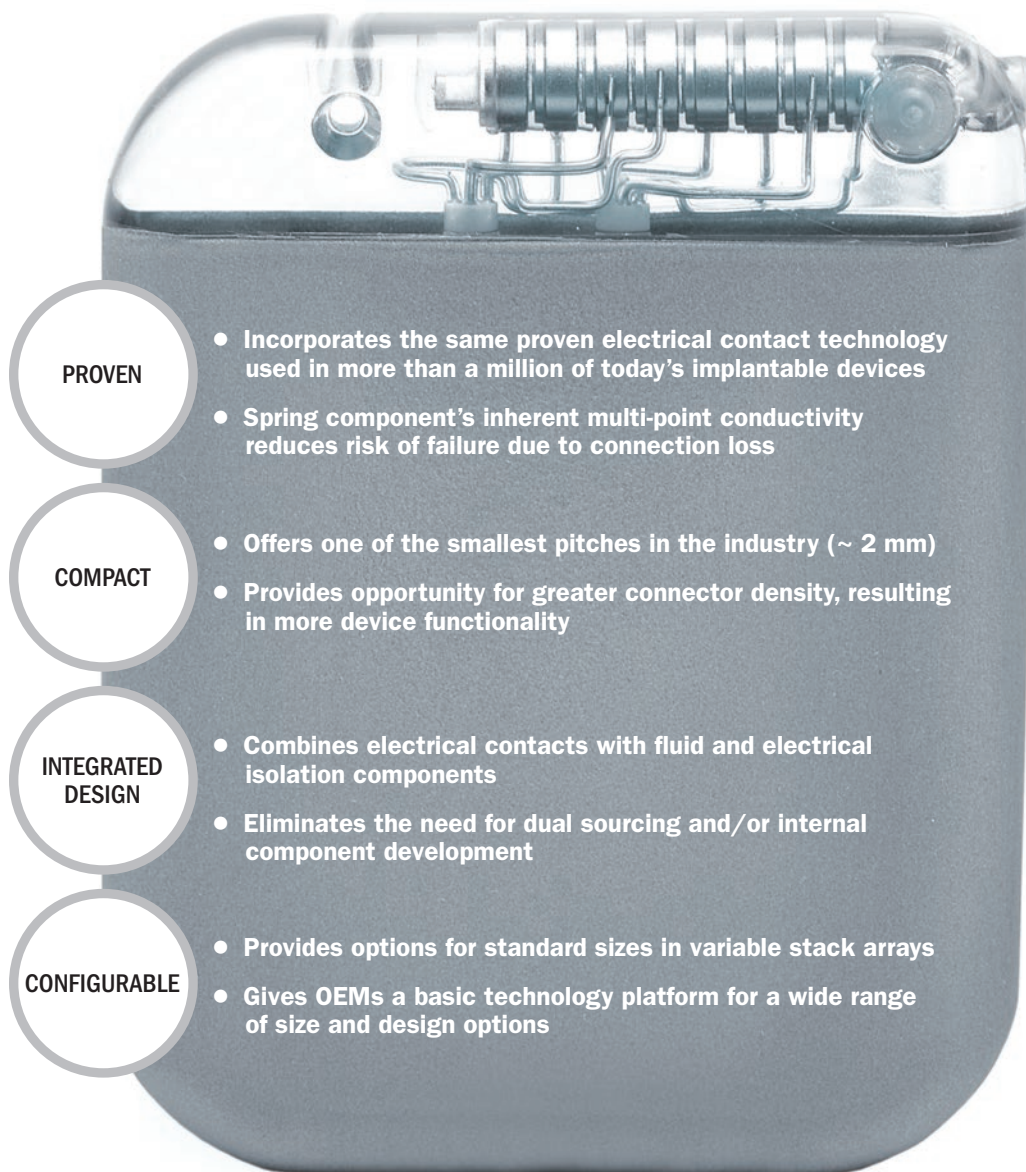
This innovative system combines reliable Bal Conn™ electrical contact technology with proven implantable-grade silicone isolation seals, resulting in a densely spaced connector “stack” that can accommodate leads with diameters down to 0.7 mm. The system's contact element consists of a housing made from medical-grade MP35N® and a platinum-iridium or MP35N® Bal Spring™ canted coil spring. The spring contact offers low insertion force, provides multi-point conductivity, and compensates for both misalignment and mating surface irregularities.



SYGNUS precision-engineered silicone seals provide superior dielectric isolation for the prevention of signal leakage that can result in potential device malfunction.

SYGNUS is scalable and completely configurable—the number of contacts and seals in the system can be specified to support unique application and industry requirements. Regardless of configuration, the SYGNUS system's contact designs are subjected to comprehensive force testing. Its proven sealing components are packaged to critical clean standards.

The SYGNUS® Difference

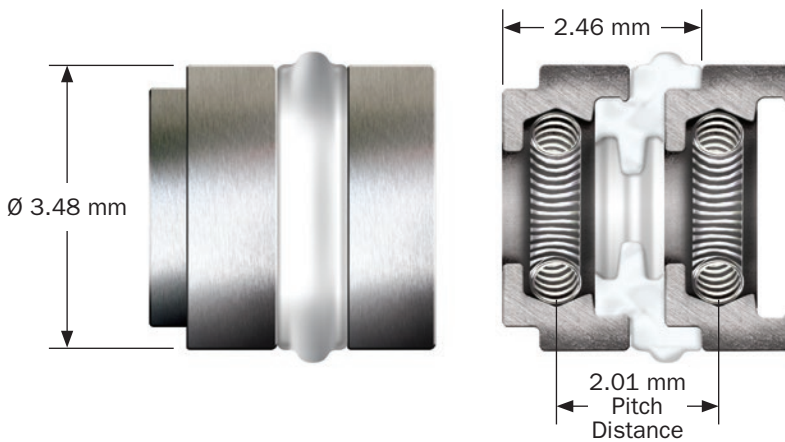
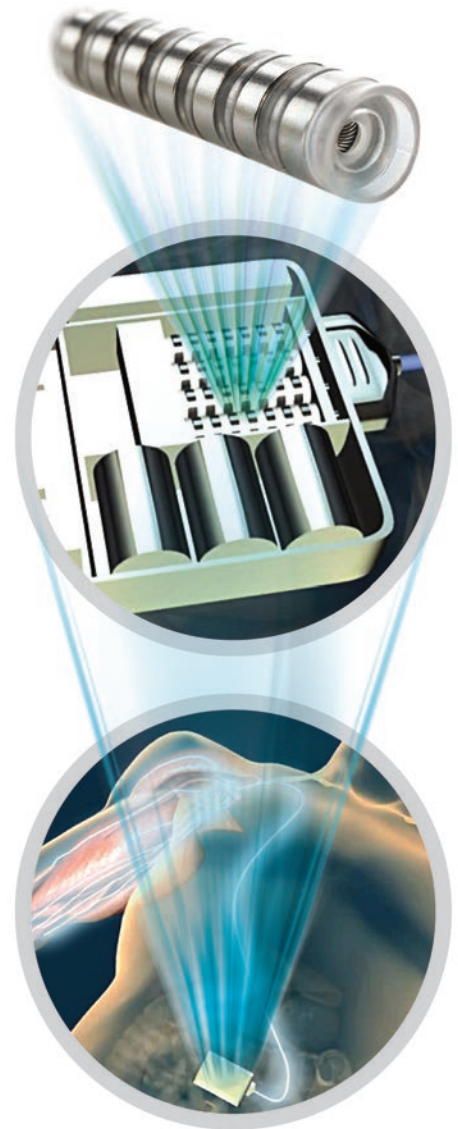




The SYGNUS[®] Implantable Contact System

SYGNUS[®] for Neuromodulation Applications

For manufacturers of devices used to deliver neuromodulation therapies, package size reduction is a constant challenge. The compact design of our SYGNUS implantable contact system lets OEMs conserve space without compromising performance. By offering one of the industry's smallest pitches and combining both isolation seals and electrical contacts into a dense, configurable stack, SYGNUS allows for a greater number of contacts to be used. The result is a decrease in overall device volume and an increase in functionality.



Model	Functional Attributes					Physical Attributes			
	Lead Diameter (mm)	Insertion Force (N)	Extraction Force (N)	Electrical Isolation (kΩ)	Dry Static Contact Resistance (mΩ)	Housing	Materials Spring	Seal	Pitch Distance (mm)
Neuro (Unit)	1.30	<0.8	<1.4	>250	<100	MP35N [®]	Platinum Iridium	Implantable Silicone	2.01

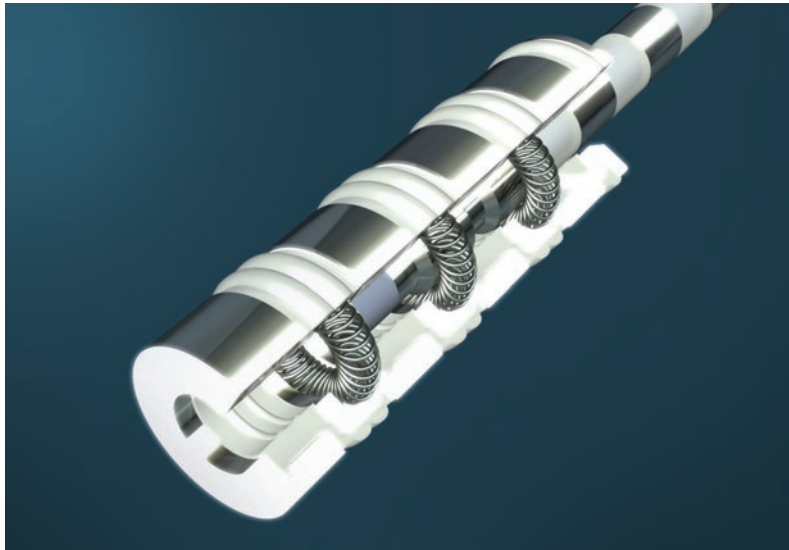
This data is presented for comparative purposes only, and it represents the performance of the SYGNUS[®] implantable contact system under specific design parameters. Customer results may vary depending upon application requirements and other factors.

SYGNUS® for Cardiac Health Management Applications

While reliability is always a primary concern for manufacturers of implantable devices used in cardiac healthcare management therapies, integration and ease of use have become equally important factors in choosing components that form the critical lead/connector interface. The SYGNUS implantable contact system offers OEMs a more efficient, plug-and-play option for integrating proven sealing and connecting technology into a standard platform.

SYGNUS® for Emerging Therapies

The SYGNUS implantable contact system's integrated design and proven performance, coupled with its ability to stack a greater number of contacts in a smaller space, makes it ideal for use in the development of breakthrough implantable device technologies. OEMs seeking ways to systemize and miniaturize have already begun to leverage the unique physical and functional attributes of the SYGNUS system to improve the capability of devices used in therapies such as deep brain, cochlear, vagus nerve, spinal stimulation, and others. Soon, the system will be playing a similar role in connecting patients through even smaller lead interfaces to cutting-edge treatments for hearing loss and vision impairment.



As lead interfaces shrink, the SYGNUS system's compact, flexible Bal Spring™ canted coil spring technology will continue to help implantable device developers make and maintain reliable connections.

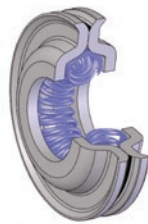


Pushing the Technology Envelope

We share your passion for developing technologies that help shape industry standards and dramatically improve quality of life. That's why our research and development team creates and evaluates new electrical contact alternatives designed to meet your unique requirements for performance, size, and efficiency.

Micro-Welded Contacts

Our latest advancement, the micro-welded contact, is a small electrical component consisting of two precision formed and micro-welded halves. Engineered to offer performance characteristics comparable to those of our Bal Conn™ product in an alternative form factor, the contact represents a new option for device manufacturers seeking to integrate high-quality, ultra-reliable components that carry current from battery to lead in medical active implantables. The micro-welded contact provides reduced axial pitch, and it employs our proven Bal Spring™ canted coil spring technology. Its construction supports high-volume production. Several different groove configurations accommodate a range of design and performance requirements.



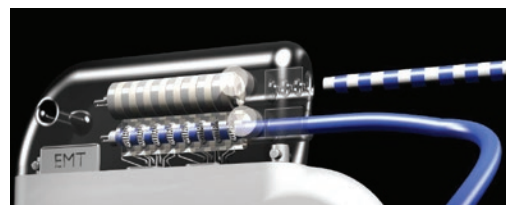
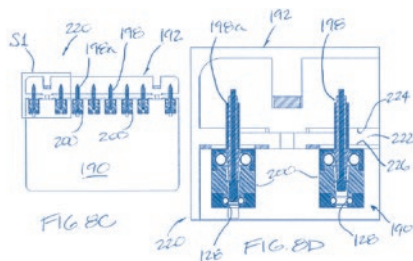
design, uses vertically positioned pins or rods of varying diameters to double or triple the amount of connections available to the device lead. It is engineered to minimize insertion force issues that can present challenges in serial arrays with small leads, and it offers designers new opportunities for improved contact density.

Encompass™ Lead-Interconnect System

The Encompass Lead-Interconnect System, offered by Evergreen Medical Technologies, is the first pretested integrated lead-interconnect system designed for medical active implantable devices. Enabled by the SYGNUS® implantable contact system and built around premolded 16-channel header technology, Encompass saves development time and costs for neurostimulation devices. It provides OEMs with a means to integrate the header, connector, sealing components, and lead into a single system.

High Density Vertical Array

In order to help engineers dramatically improve device functionality while reducing overall package size, we've also developed a high density vertical array design that can be incorporated into new and emerging therapy platforms. The design is based on the creation of a subassembly consisting of one or more small Bal Conn electrical contacts, a non-conductive polymer interface and an implantable-grade silicone seal. The subassembly, which can incorporate a cap or cover



Because the Encompass is pretested and already incorporates both the header and the interconnect system including lead, it eliminates the roadblocks associated with design, development, sourcing, and testing of a final product. In addition, the system reduces the package size needed for different therapy options for implantable device developers.

Important Information

It is essential the end user run evaluation testing under actual service conditions with a sufficient safety factor to determine if the proposed, supplied, or purchased Bal Seal Engineering products are suitable for the intended purpose. Welded springs have an increased probability of breaking or failing at or adjacent to the weld as opposed to other areas of the spring. This probability is increased further if the spring is used in an application involving extension of the spring. Temperature affects the properties (i.e. tensile strength, elongation, etc.) of the spring. Failure of Bal Seal Engineering, Inc. products can cause greater leakage, equipment failure, property damage, personal injury, and/or death. Equipment containing Bal Seal Engineering products must be designed to provide for the safe handling of any eventuality that may result from a partial or total failure of said Bal Seal Engineering products. Bal Seal Engineering products must be tested with a sufficient safety factor after installation. A program of regular maintenance and inspection must be performed. The user, through their own analysis and testing, is solely responsible for making the final selection of the products and for assuring that all performance, safety, and warning requirements of the application are met.

CLEANING

Customer/end user is advised that Bal Seal Engineering products may require cleaning and/or sterilization prior to usage, depending on the application.

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Bal Seal Engineering is more than a component manufacturer. By applying our canted coil spring technology and material science expertise, we provide OEMs and tier suppliers everywhere with innovative, custom-engineered sealing, connecting, conducting and EMI shielding and grounding solutions.



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