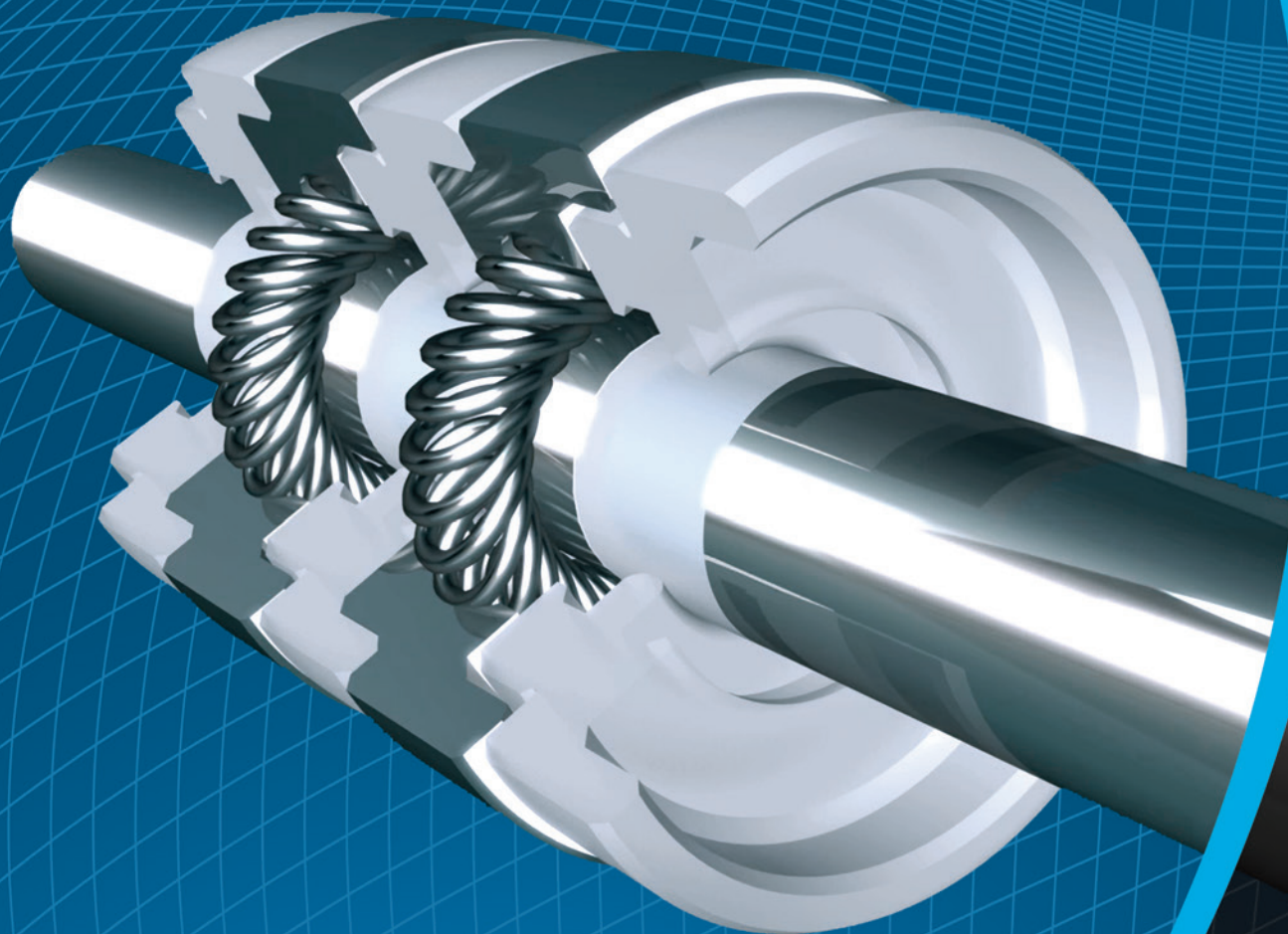


NEUROMODULATION
CARDIAC RHYTHM
MANAGEMENT

TMB-10



Electrical Contact Solutions for Medical Active Implantables

Custom components that drive tomorrow's technologies.®

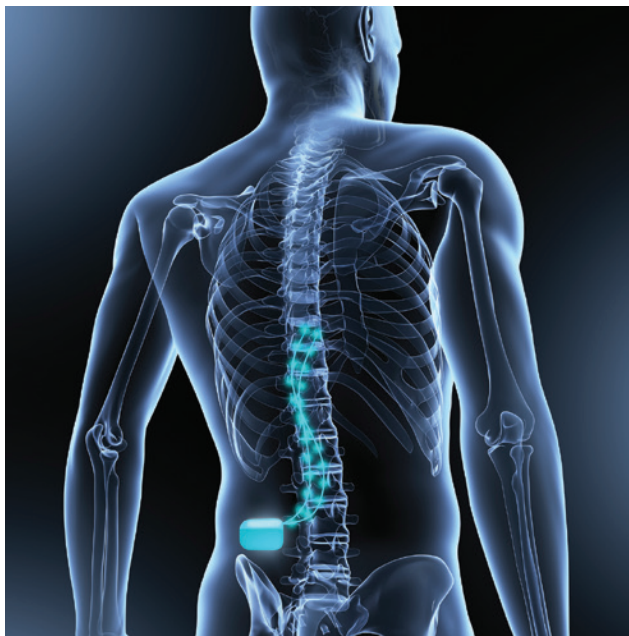
BAL SEAL
ENGINEERING, INC.



Helping Device Makers 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 the 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 millions of implantables worldwide, our electrical connecting and conducting components are a proven solution for both existing and emerging therapies.

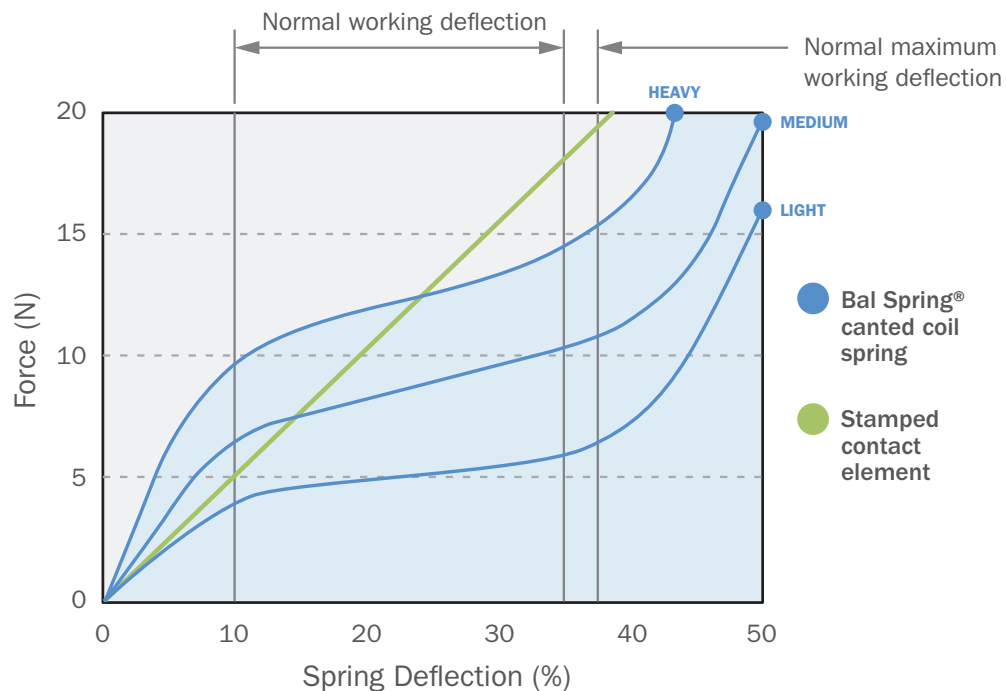
Precision-engineered and manufactured from biocompatible materials, our customizable contact solutions offer high performance and superior conductivity in a compact footprint. They give OEMs the ability to advance technology and increase device functionality, while enabling surgeons to more simply and safely connect leads to implantable devices.



Technology at the Core

The solutions we develop are based on our Bal Spring® canted coil spring technology. In electrical connecting applications, the spring's individual coils provide multi-point contact and redundancy. They also compensate for irregularities in mating surfaces that might otherwise compromise performance. The Bal Spring can be customized to meet application-specific insertion and removal force requirements, and its unique design gives it superior resistance to compression set.

Typical Force Deflection Curves





Bal Conn® Electrical Contact



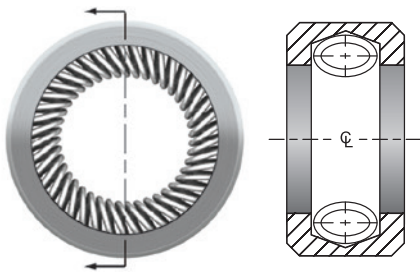
Our Bal Conn® electrical contact remains the stand-alone solution of choice for designers who need to ensure consistent, reliable connectivity in implantable devices used to deliver neuromodulation and cardiac therapies. For over two decades, the Bal Conn has been helping manufacturers improve device performance and push the technology envelope. It has also shortened procedure times by dramatically simplifying the process surgeons use to connect leads to implantables across the therapy spectrum. Due to its redundant contact points, the Bal Conn offers very 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 in a space-efficient design, 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 on application requirements and other factors.

Bal Conn® Configurations

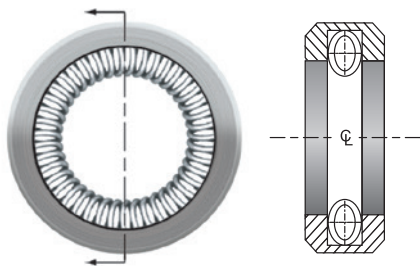


For Neuromodulation Applications

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

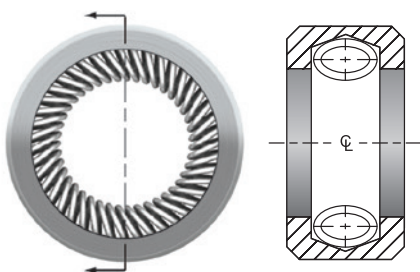


For IS-1 Cardiac Applications

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

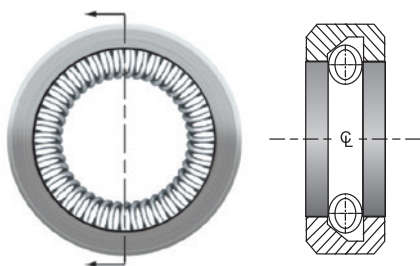


For IS-4/DF-4/VAD Cardiac Applications

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

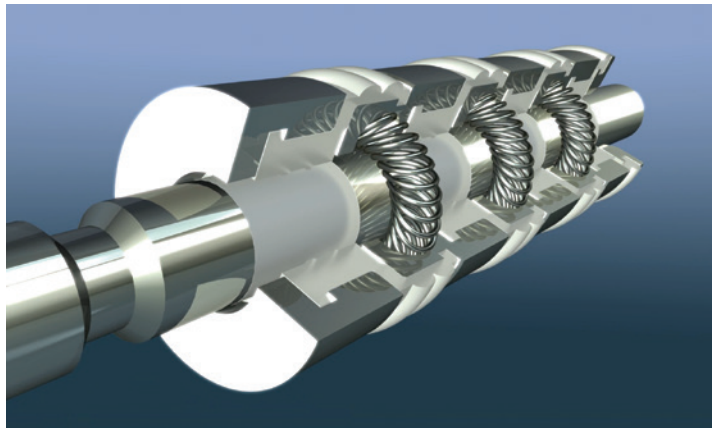


The SYGNUS® Implantable Contact System

The SYGNUS® Implantable Contact System

SYGNUS® is the world's first integrated seal and electrical contact system for active implantable devices. It's engineered to help device designers improve speed to market and focus on therapy and functional improvements, instead of component development and testing.

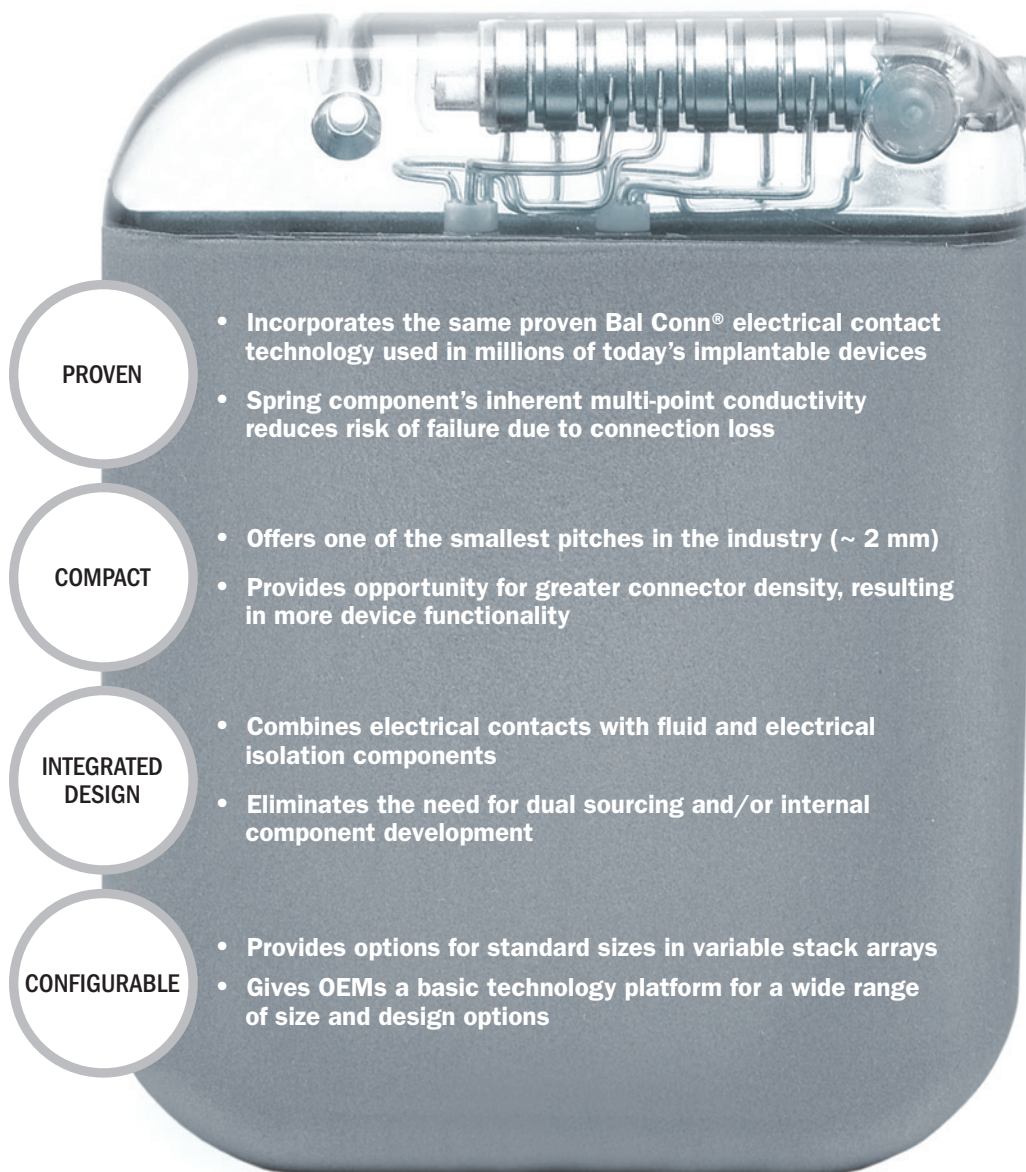
This innovative system combines reliable Bal Conn® electrical contact technology with proven implantable-grade silicone isolation seals, resulting in a densely spaced connector "stack" that can accommodate leads with diameters down to 0.7 mm. The system's contact element consists of a housing made from 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

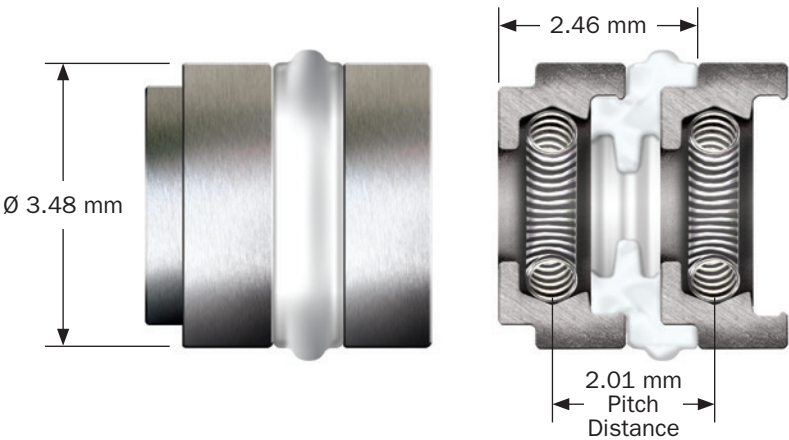
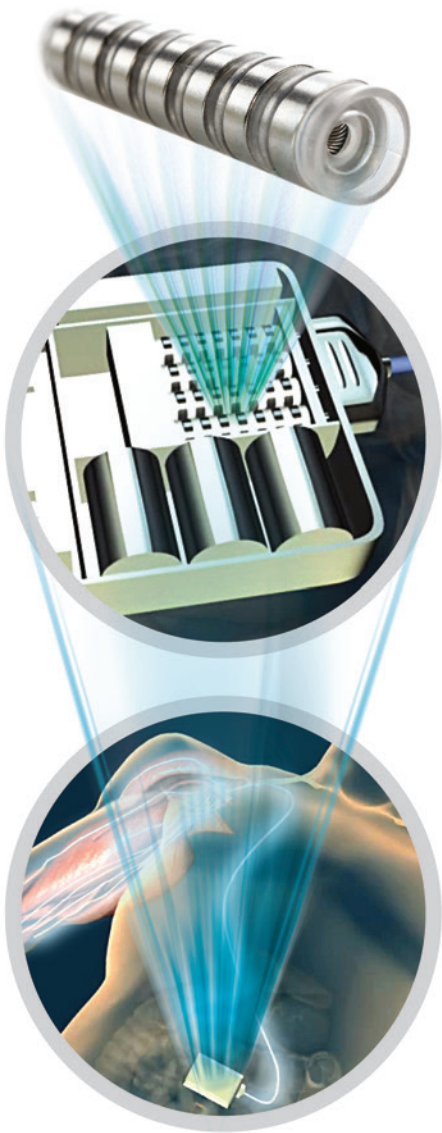




The SYGNUS® Implantable Contact System

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

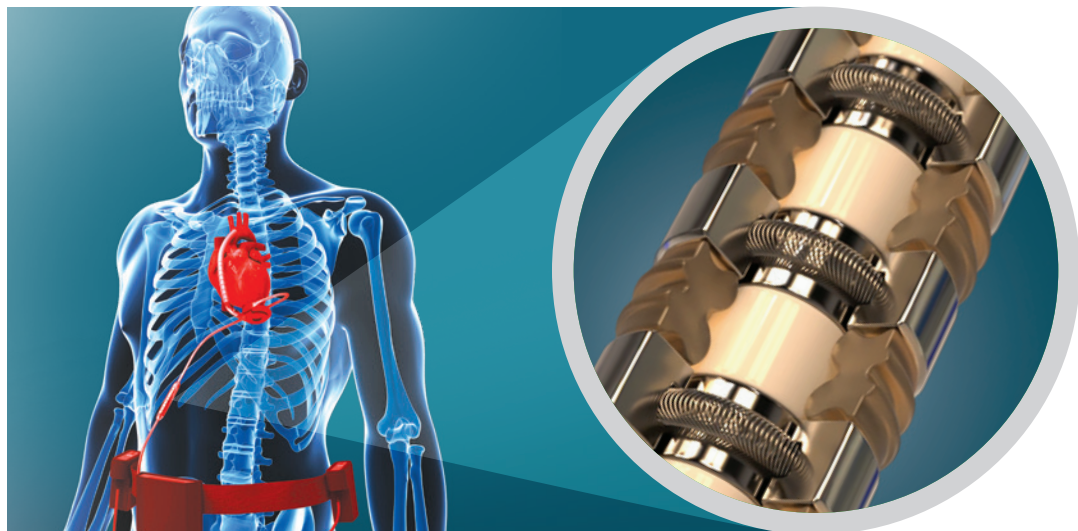
This data is presented for comparative purposes only, and it represents the performance of the SYGNUS® implantable contact system under specific design parameters. Customer results may vary depending upon application requirements and other factors.

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, make it ideal for use in the development of breakthrough implantable device technologies. Device makers seeking 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 VAD, deep brain, cochlear, vagus nerve, spinal stimulation, and others. The system is playing a similar role in connecting patients through even smaller lead interfaces to developing treatments for hearing loss and vision impairment.



The SYGNUS® implantable contact system facilitates ultra-reliable inline connection of the VAD pump to power source, providing device makers with a proven contact and seal solution, and allowing replacement of lead segments with lower patient risk.

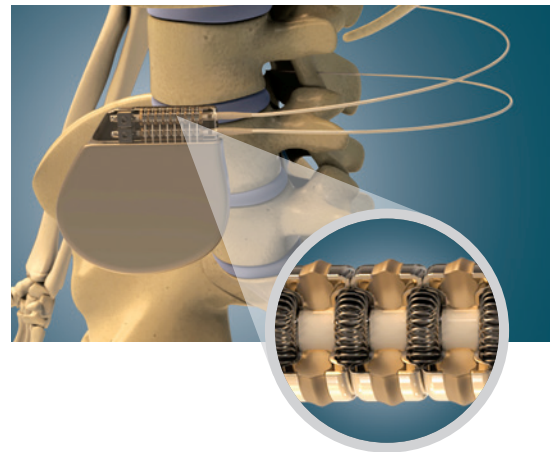


Pushing the Technology Envelope

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 options designed to meet your unique requirements for performance, size, and efficiency.

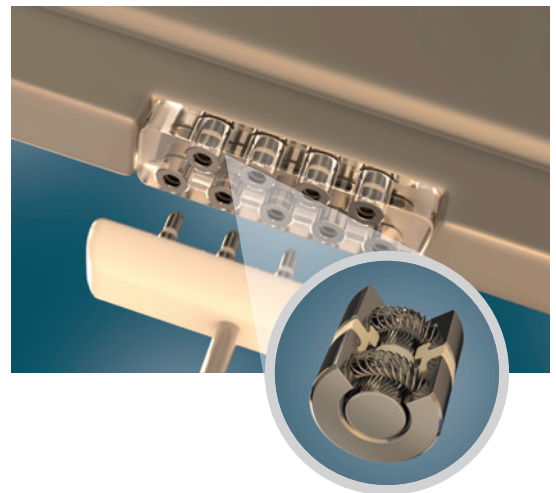
Next-generation Bal Conn® Electrical Contacts

Engineered to offer performance characteristics comparable to those of our standard Bal Conn® product in an alternative form factor, the next-generation Bal Conn 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 next-generation Bal Conn allows for reduced axial pitch, and exhibits lower electrical impedance. It employs our proven Bal Spring® canted coil spring technology, and its construction supports high-volume production. Several groove configurations are available to accommodate a range of design and performance requirements.



Bal Conn® 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 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.



Important Information

CLEANING

Bal Seal Engineering products may require cleaning and/or sterilization before use, depending on the application.

TESTING

It is essential that the customer run evaluation tests to determine if the proposed, supplied, or purchased Bal Seal Engineering products are suitable for the intended purpose. Tests should be run under actual service conditions with an adequate safety factor.

Welded springs have an increased probability of breaking or failing at or near the weld. This probability is magnified if the spring is used in an application involving extension of the spring. In addition, temperature affects the properties of the spring (i.e., tensile strength, elongation, etc.) Failure of Bal Seal Engineering products can cause equipment failure, property damage, personal injury, or death. Equipment containing Bal Seal Engineering products must be designed to provide for any eventuality that may result from a partial or total failure of Bal Seal Engineering products.

Bal Seal Engineering products must be tested with a sufficient safety factor after installation and they must be subjected to a program of regular maintenance and inspection. The customer, through analysis and testing, is solely responsible for making the final selection of the products and for ensuring that all performance, safety, and other requirements of the application are met.

All information and recommendations contained herein are based on tests Bal Seal Engineering believes to be reliable, but the accuracy or completeness is not guaranteed. Any such information or recommendation is given solely for purposes of illustration and is not to be construed as a warranty that any goods will conform to such information or recommendation. No one, including Bal Seal Engineering employees, salespersons, representatives, wholesalers, or distributors is authorized to make any warranty or representation, and no customer or other user may rely on any such warranty or representation. Bal Seal Engineering reserves the right to make any changes to its products and to the contents of this document (such as dimensional data, force, torque, materials, pressures, temperatures, surface finishes, surface speed, etc.) without notice.

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The liability of Bal Seal Engineering, whether as a result of breach of any warranty, failure to provide timely delivery of products, product malfunction, negligence or otherwise, shall be limited to repairing or replacing the non-conforming products or any part thereof, or, at Bal Seal Engineering's option, to the repayment to the customer all sums paid by the customer upon return to Bal Seal Engineering of the non-conforming products or part thereof. It is expressly agreed that the customer's remedy, as stated above, shall be exclusive and that under no circumstances shall Bal Seal Engineering be liable for any other damages, including direct, indirect, incidental, or consequential damages (LE-173-5 Rev. 0).

PATENTS

The products described herein include those which are the subject of pending and issued patents, both foreign and domestic, including patents 9,011,169; 8,167,660; (LE-173 Rev. 0) (Report #621-7).

Copyright 2019, Bal Seal Engineering, Inc.

We're more than just a component maker. In early development or existing product improvement stages, we combine our proven seals, springs, and electrical contacts with engineering, material science, and precision manufacturing expertise to produce solutions that break down performance barriers.



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*Registered manufacturing facilities in California and Colorado enable us to ensure on-time product delivery, and help you mitigate risk.



Custom components that drive tomorrow's technologies.®

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