



Helping Device OEMs Connect with Confidence

Active implantable image courtesy of CCC Medical Devices



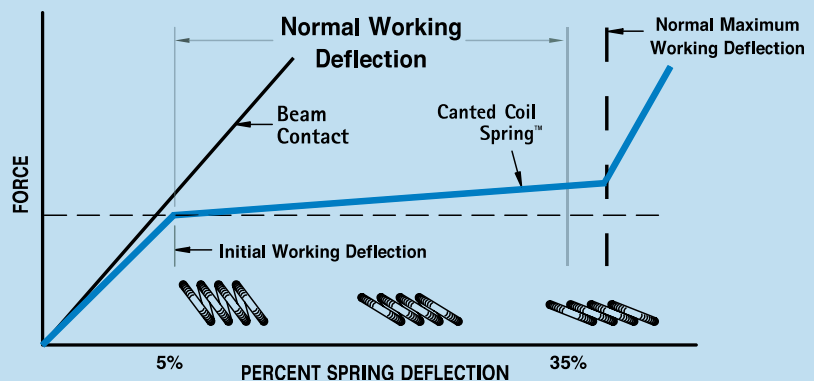
When manufacturers of active implantables need low-force, low resistance connecting solutions they can be confident about, they turn to Bal Seal Engineering. For more than 20 years, our electrical contact technology, based on the simple, robust Canted Coil Spring™, has been making and maintaining **reliable connections** in pacemakers, defibrillators, neurostimulators and many other critical electronic devices used to deliver life-improving therapies to the human body.

Precision-engineered and constructed 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 capability, while enabling surgeons to more simply and safely connect leads to header assemblies.

Already at work in more than 1 million implantables worldwide, our electrical connecting and conducting components are a proven solution to design challenges in both existing and emerging device technologies.

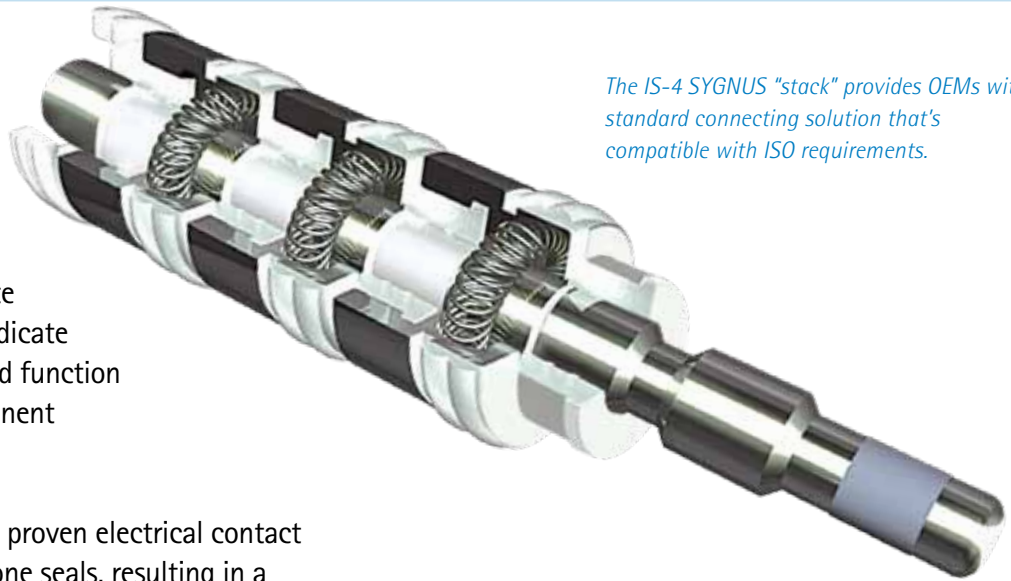
Technology at the Core

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



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 large and small device OEMs accelerate the development process and dedicate valuable resources to therapy and function improvements, instead of component procurement and testing.



The IS-4 SYGNUS "stack" provides OEMs with a standard connecting solution that's compatible with ISO requirements.

This innovative system combines proven electrical contact technology with pre-tested silicone seals, resulting in a densely-spaced connector "stack" that can accommodate leads with diameters ranging from 0.90mm to 3.20mm. The system's contact element consists of a housing made from medical-grade MP35N® and a Platinum-Iridium or MP35N® 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 implantable-grade silicone seals provide superior dielectric isolation for the prevention of signal leakage that can result in potential device malfunction. The combined stack exhibits excellent resistance to potential fatigue caused by multiple lead insertion cycles.

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, such as the IS-4 ISO Standard for cardiac health management devices. Regardless of configuration, the SYGNUS system's contact designs are subjected to comprehensive force testing, and its sealing components are packaged to "critical clean" standards.

The SYGNUS Difference

Proven

- Incorporates same proven electrical contact technology used in more than 1 million of today's IPGs
- Spring component's inherent multi-point conductivity reduces risk of failure due to connection loss

Compact

- Offers smallest pitch in the industry (approximately 2mm)
- Provides opportunity for greater connector density, resulting in more device functionality

Integrated Design

- Combines electrical contacts with fluid & electrical isolation components
- Eliminates need for dual sourcing and/or internal component development

Configurable

- Provides options for standard sizes in variable stack arrays
- Gives OEMs a basic technology platform for a wide range of size and design options

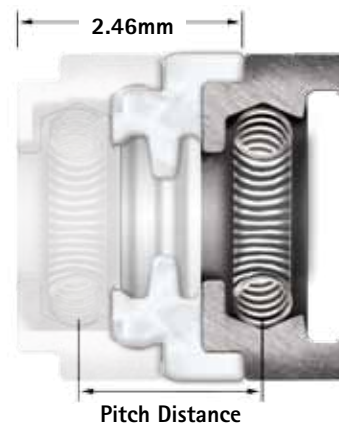
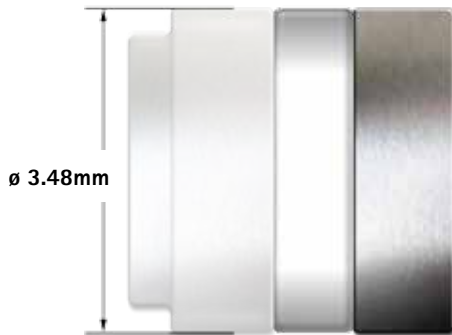
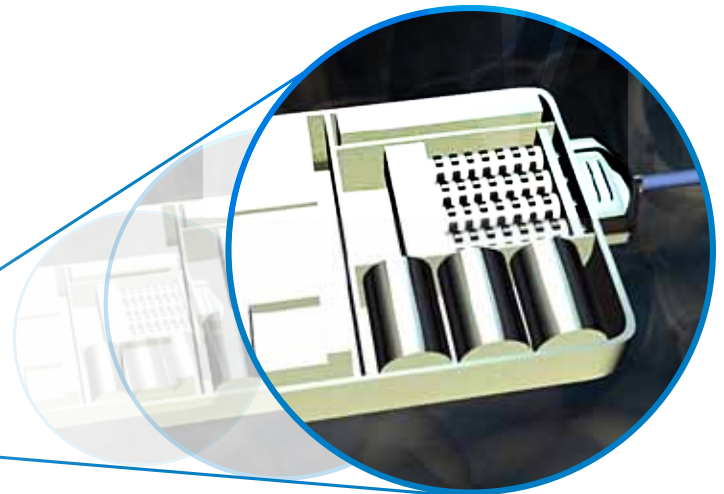
SYGNUS™ for Neuromodulation Applications

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 the industry's smallest pitch and combining both isolation seals and electrical contacts into a dense, configurable stack, SYGNUS allows for population of the IPG header with a greater number of connectors. The result is a decrease in overall device volume and an increase in functionality.



Typical Applications:

- Spinal cord stimulation (SCS)
- Deep brain stimulation (DBS)
- Functional electrical stimulation (FES)



Note: Unit consists of one seal, one spring and one housing.

Model	Functional Attributes					Physical Attributes			
	Lead Diameter	Sliding Insertion Force	Extraction Force	Electrical Isolation (kΩ)	Dry Static Contact Resistance (mΩ)	Materials			Pitch Distance
Neuro (Unit)	1.30mm	< .8N	< 1.4N	> 250	< 100	Housing	Spring	Seal	Pitch Distance
						MP35N®	Platinum Iridium	Implantable Silicone	2.01mm

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.

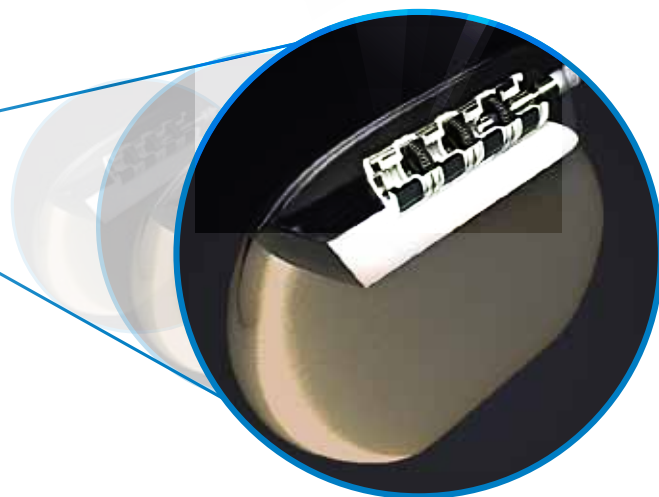
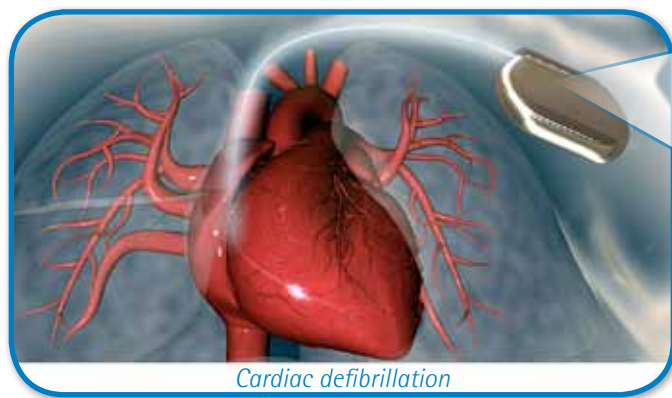
SYGNUS™ for Cardiac Health Management Applications

While reliability is always a primary concern for manufacturers of IPGs 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. For this reason, we've developed a standard four-pole configuration of the SYGNUS Implantable Contact System. The SYGNUS for IS-4 is compatible with ISO 27186 requirements for cardiac healthcare devices, and it offers OEMs a more efficient, plug-and-play option for integrating proven sealing and connecting technology into a standard platform.



Typical Applications:

- Cardiac resynchronization
- Cardiac defibrillation



Physical Attributes					
Materials			Pitch Distance	Number of Seals	Number of Electrical Contacts
Housing	Spring	Seal			
MP35N®	Platinum Iridium or MP35N®	Implantable Silicone	4.52mm	4	3

Model	Functional Attributes ¹					
IS-4	Lead Diameter	Insertion Force	Extraction Force	Electrical Isolation (kΩ)	Current Carrying Capacity	Dry Static Contact Resistance (mΩ)
	3.20mm	< 16	< 14	> 120	50A Pulse / 4µs	< 60

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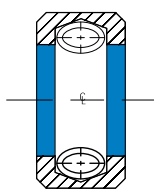
Bal Conn™: A Stand-alone Solution



The advanced technology behind the SYGNUS™ Implantable Contact System has its origins in the Bal Conn, an electrical contact component that remains the stand-alone solution of choice for OEMs seeking to ensure consistent, reliable connections in neuromodulation and cardiac IPGs. 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 lead wires to implantable electronic units across the therapy spectrum, shortening procedure times and reducing infection risk for patients. In addition to its very low electrical resistance, the Bal Conn offers redundant contact points, excellent resistance to fatigue and more design flexibility than any other IPG interconnect technology.

For Neuromodulation Applications

Bi-directional

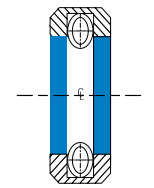
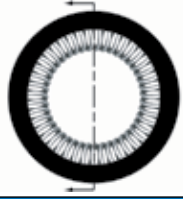


Key Points:

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. Ease of manufacturability
5. Compact size allows for increased connections in series

For IS-1 Cardiac Applications

Bi-directional

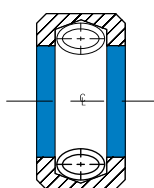


Key Points:

1. Proven to work with IS-1 seal elements
2. Axial design enables low contact resistance without noble metals
3. Potential for set screw replacement to reduce surgery time

For IS-4 Cardiac Applications

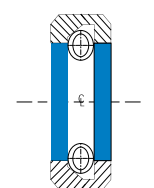
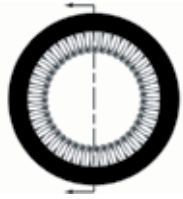
Bi-directional



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. Ease of manufacturability
5. Meets ISO requirements for force and contact resistance

Uni-directional



Key Points:

1. Consistent uni-directional insertion and removal force
2. Enables low contact resistance without the use of noble metals
3. Meets ISO requirements for force and contact resistance
4. Has larger OD requirements due to axial design configuration

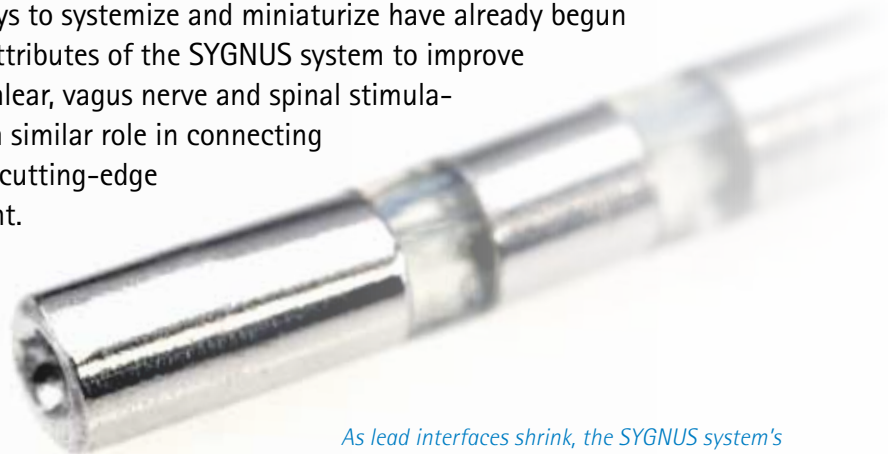


Application	Lead Diameter	Force Category	Breakout Force (N)	Running Force Range (N)		Housing Material	Spring Material	Static Dry Contact Resistance (mΩ)	
			Max	From	To			Nominal	Tolerance
Neuro (Bi-directional)	1.35mm	Medium	1.20	0.09	0.40	MP35N®	Platinum Iridium	70	± 20
		Light	0.70	0.07	0.30	316L	Platinum Iridium	600	± 200
						Titanium Grade 5	Platinum Iridium	350	± 150
						MP35N®	Platinum Iridium	80	± 30
						Platinum Iridium	Platinum Iridium	40	± 15
IS-1 (Bi-directional)	2.67mm	Medium	3.10	0.50	0.90	316L	MP35N®	100	± 60
IS-4 (Uni-directional)	3.20mm	Heavy	2.70	0.50	1.00	MP35N®	MP35N®	80	± 50
IS-4 (Bi-directional)	3.20mm	Medium	2.70	0.25	0.75	MP35N®	Platinum Iridium	40	± 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.

SYGNUS™ for Emerging Technologies

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 IPG technology. 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 deep brain, cochlear, vagus nerve and spinal stimulation therapies. 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.

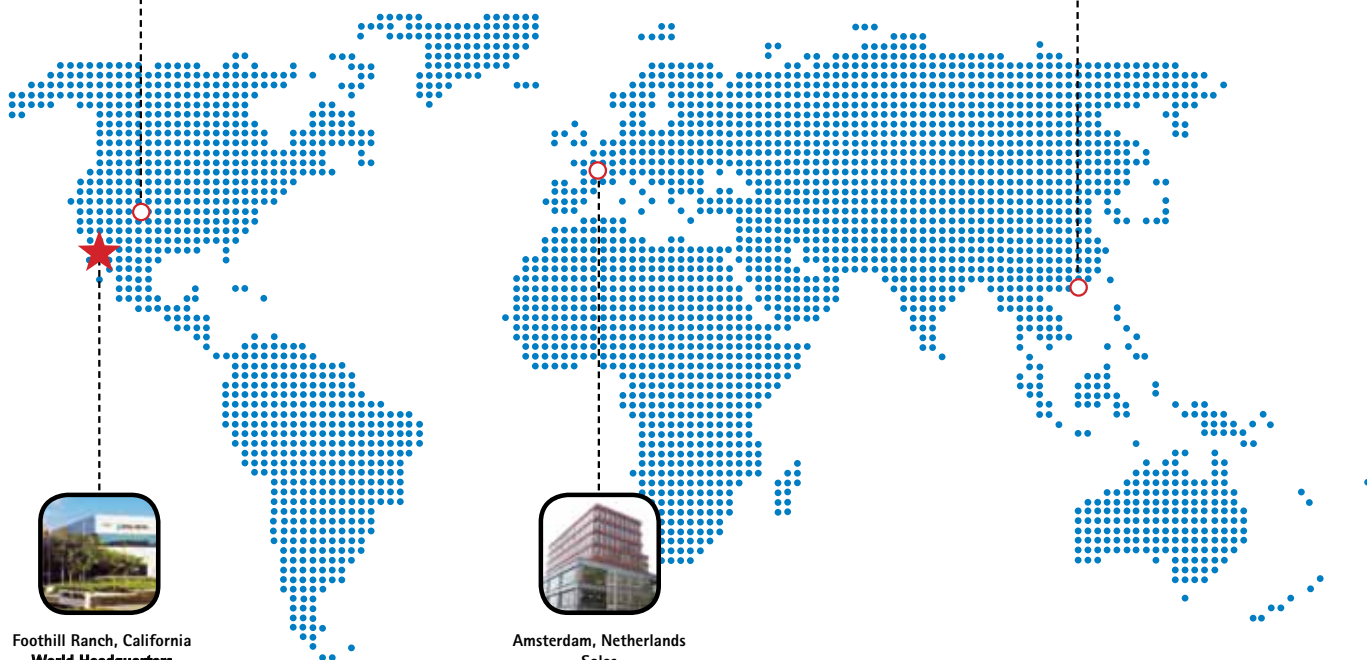


As lead interfaces shrink, the SYGNUS system's compact, flexible Canted Coil Spring™ technology will continue to help IPG developers make and maintain reliable connections.

Colorado Springs, Colorado
Manufacturing



Hong Kong, China
Sales



Foothill Ranch, California
World Headquarters
Manufacturing/Sales

Amsterdam, Netherlands
Sales

IMPORTANT: The SYGNUS™ Implantable Contact System is made from biocompatible materials and may require cleaning or other preparation processes prior to installation. The customer is solely responsible for selecting, testing and ensuring the appropriate use of the SYGNUS system in their medical device, and for assuring that all performance, safety and other requirements of the application are met.

www.balseal.com

Bal Seal Engineering, Inc. is certified to **ISO 9001**

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