



Corporate Fact Sheet
Baxano, Inc.

Year Founded	2005
Founder	Jeffrey Bleich, MD
CEO	Tony Recupero
Location	San Jose, CA
Website	www.baxano.com
Employees	40
Industry	Medical Device Manufacturing
Facility	21,000 ft ² , including 1,400 ft ² Class 100k Cleanroom
Intellectual Property	Approximately 70 patents issued and/or pending
Ownership	Privately-held and VC-backed
Investors	CMEA Capital, Kaiser Permanente Ventures, Affinity Capital Management, Athenian Venture Partners, Prospect Venture Partners, Three Arch Partners, Kearny Venture Partners
Business model	The Baxano iO-Flex™ System is sold through direct sales representatives in the US to hospitals and hospital systems
Regulatory status	FDA 510(k) cleared instrument set
Indication statement	The Baxano™ MicroBlade Shaver™ instrument and accessories are designed for accessing, cutting, and biting soft tissue and bone during surgery involving the spinal column (K100958). The Baxano™ Neuro Check™ device is designed for use with Baxano™ cutting and biting devices for localization of motor nerves in settings where visualization is compromised (K092729). For complete information regarding precautions and methods of use, please refer to individual device Instructions for Use.

Press contact

Eileen McCullough
Baxano, Inc.
emccullough@baxano.com
(408) 514-2247

Notes: Baxano™ and iO-Flex™, MicroBlade Shaver™ and Neuro Check™ are trademarks and service marks of Baxano, Inc.

There are risks associated with any type of surgery. Your doctor will help explain the risks associated with lumbar decompression surgery using the iO-Flex™ System. For more information on spinal decompression and the iO-Flex™ System, please talk with your doctor.



Company and Product Backgrounder

Baxano, Inc.

Mission

Baxano’s mission is to develop innovative tools that restore spine function, preserve healthy tissue, and enable a better quality of life for the patients we serve. Along with our dedication to advanced technology development, Baxano™ is focused on providing exceptional value to patients, customers, investors and employees.

Products

Baxano, Inc. is the developer of the iO-Flex™ System which is an advancement in surgical technology for central, lateral recess and foraminal lumbar stenosis. This unique technology uses thin, flexible instruments through an open exposure or a minimally invasive tube to provide precision lumbar decompression from the “inside out” (“iO”). This “over the wire” approach allows surgeons to address targeted impinging tissue with a nonimplant, direct decompression, while preserving facet joint integrity. Up to four nerve roots may be decompressed through a single-point access using this system.

Indication statement

The Baxano™ MicroBlade Shaver™ instrument and accessories are designed for accessing, cutting, and biting soft tissue and bone during surgery involving the spinal column (K100958). The Baxano™ Neuro Check™ device is designed for use with Baxano™ cutting and biting devices for localization of motor nerves in settings where visualization is compromised (K092729). For complete information regarding precautions and methods of use, please refer to individual device Instructions for Use.

Large Market Opportunity

- Over 3 million patients diagnosed with Lumbar Spinal Stenosis¹
- 250,000 lumbar decompression procedures annually¹
- 70,000 lumbar spinal fusion procedures for Lumbar Spinal Stenosis¹ in the US annually
- Inadequate treatment of foraminal stenosis is the most common structural cause of failed back surgery syndrome (up to 58% of cases)²
- Compelling clinical advantages relative to current care:

Data set	OR Time	Average Length of Stay
SPORT trial ³	148 minutes	3.5 days
iO-Flex System pilot study ⁴	124 minutes	1.4 days
Computed Benefit	24 minutes	2.1 days

Press contact

Eileen McCullough
Baxano, Inc.
emccullough@baxano.com
(408) 514-2247

Sources:

1. Millennium Research Group. “US Markets for Spinal Implants 2007.” All data for the US, annually.
2. Jenis and An. Spine 2000 reporting on Burton R, et al. Causes of failure of surgery on the lumbar spine. Clin Orthop 1981;157:191–7.
3. Personal communication 2010, Dartmouth Department of Orthopedics, SPORT trial, patient subset with foraminal stenosis.
4. Baxano U.S. pilot study data on file.

Notes: Baxano™ and iO-Flex™, MicroBlade Shaver™ and Neuro Check™ are trademarks and service marks of Baxano, Inc.

There are risks associated with any type of surgery. Your doctor will help explain the risks associated with lumbar decompression surgery using the iO-Flex™ System. For more information on spinal decompression and the iO-Flex™ System, please talk with your doctor.



Executive Biographies

Tony Recupero
President and CEO

Tony brings over 20 years of experience in the medical device industry to Baxano, Inc. Tony served as Vice President of Sales for Kyphon, Inc., joining the company at commercial inception and spearheading Kyphon's significant revenue growth over a period of five years. At Kyphon, Tony led one of the largest and most effective direct sales forces in the spine market. Prior to Kyphon, Tony was the National Sales Manager for Sulzer Spine-Tech, Inc., where he was responsible for revenue growth of the BAK fusion cage and other spinal hardware. Tony started his medical device career in sales and sales management with United States Surgical Corporation.

Tony is a graduate of The General Management Program at Harvard Business School and holds a B.A. in Communications from State University of New York at Albany. Tony serves on the Board of Directors at Aragon Surgical, Inc.

Mike Wallace
Senior Vice
President, Research,
Development and
Operations

Mike brings more than 18 years of research and development experience in the medical device industry to Baxano, Inc. Previously, Mike held executive positions at BARRX Medical, Boston Scientific and Target Therapeutics managing research and development, engineering, advanced research, new business development and operations. During his tenure, Mike led several product development programs to successful multi-million dollar launches. Prior to BARRX Medical, Boston Scientific and Target Therapeutics, Mike was an orthopedic research engineer for the University of California, Davis and also a process development/manufacturing engineer for W.L. Gore & Associates.

Mike holds an M.S. in Mechanical Engineering with a bioengineering emphasis from the University of California, Davis and a B.S. in Mechanical Engineering from the University of Delaware. He has co-authored six articles published in peer-reviewed technical journals and is an inventor on over 80 issued or pending U.S. patents.

Todd Clearwater
Vice President of
Sales

Todd has almost 20 years of experience in spine sales. Prior to joining Baxano, Inc., Todd was National Vice President of Sales at Apatech, Inc., which was acquired by Baxter, Inc. Prior to Apatech, Todd held roles of increasing sales management responsibility, including serving as Sr. Vice President, Sales at Interventional Spine, Inc. and Director of Sales/Spine Education at Kyphon, Inc. (acquired by Medtronic, Inc.) Todd graduated from Eastern Illinois University with a B.A. in Political Science.

Ed Sinclair
Vice President,
Regulatory and
Quality

Ed has over 25 years of medical device industry experience at market-leading corporations as well as early phase ventures. Prior to joining Baxano, Inc., Ed held a wide variety of positions in clinical research, regulatory affairs, operations and quality assurance. Ed was a Vice President at CardioKinetix, Conceptus, Prolifix Medical, and PercuSurge (Medtronic). Other management positions were held at Cardiac Pathways (Boston Scientific) and Advanced Cardiovascular Systems (Guidant).

Ed has a B.S. in Biological Sciences from the University of California, Irvine and an M.A. in Management from the University of Redlands.

Amie Borgstrom
Vice President,
Marketing

Amie brings over 15 years of medical device experience to the Baxano, Inc. team. Prior to joining Baxano, Amie held roles in marketing and product development at companies including Abbott and DePuy Spine, a Johnson & Johnson company. She has worked closely with leading physicians to develop and successfully launch seven new implant and instrument systems and is an inventor on over 30 issued or pending US patents.

Amie holds an M.B.A. from the Stanford Graduate School of Business, M.S.E. from Columbia University, and B.S.E. from the University of Pennsylvania.

Greg Welsh
Senior Director,
Operations

Greg has more than 20 years of operations and engineering experience in the medical device industry. He has held various management positions at a variety of companies from start-up ventures to global Fortune 500 corporations including Baxter Healthcare, Target Therapeutics, Boston Scientific, Cierra, and Avantis Medical Systems.

Greg holds a B.S. degree in Mechanical Engineering from Cal Poly San Luis Obispo.



Frequently Asked Questions

Baxano, Inc.

When was Baxano founded? The company was incorporated in 2005; first patents filed prior to 2005.

Where does the company's name come from? The company's name comes from a combination of "sano" (health) and "back" with an "x" in the middle to indicate "precision."

Who founded Baxano? Baxano was founded by Jeff Bleich, MD, a pain management specialist who identified the need for a new surgical tool because he saw patients in his clinic who did not get relief from the symptoms of lumbar spinal stenosis through traditional decompression surgery.

What is Lumbar Spinal Stenosis? Lumbar spinal stenosis is the overgrowth of bone and ligament into the space where the spinal nerves exit between the vertebrae in the low back (lumbar spine), which can put pressure on the nerves, resulting in pain, weakness, numbness and/or tingling that are felt in a patient's back and legs.

How big of a problem is Lumbar Spinal Stenosis? Each year, approximately 1.5 million people will seek medical care for symptoms of lumbar spinal stenosis. Over 300,000 people will have a surgical procedure.

What is traditional decompression surgery? In traditional decompression surgery, surgery is performed using rigid instruments to remove the bone and tissue in the way until pressure on the nerve is relieved. Because the nerves lie behind the facet joints that link one vertebra to another in your back, occasionally some or all of the facet joint will have to be removed in order to access the bone and ligament that's pressing on the nerve and causing the symptoms of lumbar spinal stenosis.

What are the benefits of using the iO-Flex™ System? The iO-Flex System provides surgeons with thin, flexible instruments to easily access and remove tissue from the "inside out" (or "iO".) The iO-Flex system instruments allow a surgeon to remove tissue crowding spinal nerves without removing the facet joint. This can help surgeons achieve a more complete decompression from the inside-Out.¹

Where did the iO-Flex™ System get its name? The iO-Flex System is designed to provide precision lumbar decompression from the "inside out" ("iO") using thin, flexible ("Flex") tools designed as a "System."

What is minimally-invasive surgery? Minimally-invasive surgery (or "MIS") utilizes special methods, such as smaller incisions and microscopes, with the goal of imparting less trauma in the surgical field.

What is over-the-wire? Over-the-wire means using a wire to thread larger tools and instruments into a surgical site. By utilizing a wire to establish the trajectory for the MicroBlade Shaver™ Instrument, the iO-Flex System can be part of minimally-invasive surgery for decompression of lumbar spinal stenosis.

Where is the product available? The iO-Flex System is 510(k) cleared and is used by surgeons in both academic medical centers and community hospitals across the United States.

Who uses the iO-Flex™ System? The iO-Flex System is used in surgical procedures by surgeons including orthopedic spine surgeons and neurosurgeons in lumbar spinal surgery procedures called "decompression" surgery.

Is the iO-Flex™ System technology patented? There are over 70 patents applied for and/or granted for the technology utilized in the iO-Flex System.

Does using the iO-Flex™ System change the procedure? No. The surgeon performs a standard lumbar decompression procedure. The only difference is the cutting tool that is utilized to cut and bite away the bone and soft tissue causing symptoms of lumbar spinal stenosis.

Who is a candidate for the iO-Flex™ System? Any patient who is a candidate for decompression of lumbar spinal stenosis is a candidate for having the iO-Flex System incorporated as a part of their procedure.

What are the risks and benefits of the iO-Flex™ System? There are risks with any type of surgery. Please speak to a doctor to help explain the risks associated with lumbar decompression surgery using the iO-Flex System.

1. Data on file.

Glossary
Baxano, Inc.

Access: Medical definition, point of entry/direction into the body tissue.

ALIF: Anterior Lumbar Interbody Fusion – a spine fusion surgery procedure where the spine is approached from the front of the body.

Anatomical position: position of the human body used for anatomical reference, in which the subject is standing upright with the limbs extended, face to the front, palms facing outward and feet together.

Anterior: In human anatomy, referring to the front surface of the body or the position of one structure relative to another. Opposite of posterior.

Axial plane: the plane dividing the body into upper and lower parts; also called the transverse plane.

Biomechanical stability: A joint is considered to have biomechanical stability if it can carry its intended load.

Cauda equina: The bundle of spinal nerve roots extending from the conus medullaris into the vertebral canal below L1.

Caudad / caudal: in the direction toward the tail. Opposite of cephalad / cephalic / cranial.

Central canal: encloses and protects the spinal cord and cauda equina.

Cephalad / cephalic / cranial / rostral: In the direction of the head. Opposite of caudad / caudal.

Chronic pain: Long-lasting or frequently occurring.

Congenital: From birth

Contralateral: On or relating to the opposite side of the body. Opposite of ipsilateral.

Coronal plane: The plane dividing the body into front and back parts. Also called the frontal plane.

Degenerative disc disease (DDD): A progressive disorder that produces clinical symptoms (such as loss of cushioning between the vertebrae) and signs (pain and/or deformity changes).

Dissection: Separation by cutting away or apart.

Distal: Away from or further from a point of reference. Opposite of proximal.

Dorsal: Pertaining to the back, often used to indicate the position of one structure relative to another. Opposite of ventral.

Dorsal root ganglion / dorsal root ganglia (plural): The accumulation of cell bodies on the dorsal roots that are the control centers of the sensory nerves. These are located outside but close to the spinal cord.

Dura mater: The tough, fibrous membrane covering of the central nervous system. Adj: dural.

Epidural space: The space surrounding the spinal cord, filled with fatty tissue, veins and arteries.

Extension: The act of straightening or backward bending. Opposite of flexion.

Facet joint: A synovial joint formed by the inferior articular process of one vertebra and the superior articular process of the adjacent vertebra where two vertebrae meet and articulate or move. Also called the zygapophyseal joint or z-joint.

Facetectomy: To remove part of the facet joint.

Flexion: The act of flexing or forward bending. Opposite of extension.

Fluoroscopy / fluoro image: Real-time x-ray imaging.

Foramen / foramina (plural): A natural hole or opening through which blood vessels and nerves pass.

Foraminotomy: To make the foramen larger.

Frontal plane: The plane dividing the body into front and back parts. Also called coronal plane.

Fusion, spinal: To permanently join two adjacent vertebrae together.

Hemi: Half. Also called semi.

Herniated disc: A rupture of the disc between two vertebrae, occurring most often in the lumbar region.

When a disc ruptures, there is a lack of cushioning between the vertebrae, resulting in pressure on spinal nerves, often causing pain.

Hypertrophic: A nontumorous enlargement of body tissue.

Inferior: Located below or beneath a point of reference, nearer the soles of the feet. Opposite of superior.

Inferior Articular Process: The half of the facet joint projecting downward from the superior vertebra. Also called IAP.

Interspinous ligament: Ligament connecting each adjacent spinous process with fibers extending from the base to the tip of each spinous process.

Intervertebral disc: Fibrocartilaginous structure located between the concave articular surfaces of the vertebral body endplates, permitting slight motion at each vertebral level.

Glossary (cont'd, 2/3)

Baxano, Inc.

- Intervertebral foramen:** The openings into the vertebral canal bounded by the pedicles of adjacent vertebrae above and below, the vertebral bodies anteriorly and the articular processes posteriorly.
- Ipsilateral:** On or relating to the same side of the body. Opposite of contralateral.
- Joint:** The place of union, usually somewhat moveable, between two or more bones. Joints are classified into three general morphological types: fibrous, cartilaginous, and synovial.
- Kerrison Rongeur:** A double-action rongeur used in neurosurgery.
- Lamina / laminae (plural):** The two flattened plates of bone extending medially from the pedicles.
- Laminectomy:** To remove the lamina.
- Laminotomy:** To remove part of the lamina.
- Lateral:** Relating to the middle or center; farther from the median plane. Opposite of medial.
- Lateral recess:** The space in the spinal column adjacent to the exit of the nerve root, between the posterior edge of the disc and the anterior edge of the facet joint.
- Ligament:** A band or sheet of tough, fibrous tissue connecting two or more bones or other structures in a joint.
- Ligamentum flavum:** Strong longitudinal ligament connecting the laminae of each vertebra from C2 to sacrum.
- Lumbar decompression:** Removal of lumbar bone, ligament, or disc to relieve pressure on spinal nerves or the spinal cord.
- Lumbar:** Relating to the loins or the section of the back and sides between the ribs and the pelvis. In the spinal column, the last five vertebrae.
- Lumbar Spinal Stenosis:** Degenerative spinal disease that causes narrowing of the spinal canal causing back pain and/or numbness, tingling or weakness down their legs.
- Lumbar spine:** Composed of the five vertebrae above the sacrum, below the ribs and above the hip bones.
- Medial:** relating to the middle or center; nearer to the median plane. Opposite of lateral.
- Median plane:** The plane dividing the body into left and right parts. Also called sagittal plane.
- Minimally invasive surgery (MIS):** surgery utilizing special methods, such as smaller incisions and microscopes, with the goal of imparting less trauma in the surgical field. Opposite of open exposure.
- Motion segment:** The intervertebral disc and facet joints connecting any two adjacent vertebrae. The “functional unit of the spine” because a combination of adjacent motion segments allows spinal movement in six degrees of freedom.
- Nerve root:** The bundle of the motor and sensory branches which join to form a spinal nerve leaving the spinal cord or cauda equina. Two nerves leave at each spinal motion segment, one on the right and one on the left.
- Nerves:** Fibers with nerve cells that send messages between the brain and the body.
- Nerve impingement:** Abnormal pressure on a nerve, causing compression, which can lead to nerve damage and muscle weakness.
- Neurolocalization / neural localization:** To determine the location of a nerve.
- Neurosurgeon:** A physician trained in surgery of the nervous system and who specializes in surgery on the brain and other parts of the nervous system.
- Osteophyte:** An overgrowth of bone.
- Open exposure:** Making a wide enough incision that all structures to be operated on can be seen directly with the eye. Opposite of minimally invasive surgery.
- Orthopedic spine surgeon:** A surgeon trained to treat problems developing in the spine and its component bones and joints.
- Over the wire:** Using a wire to thread larger tools and instruments into a surgical site.
- Plane:** A real or imaginary flat surface made by “cutting” through the body, then turning the part so as to view the flat surface of the cut. The cut is usually made vertically or horizontally.
- PLIF:** Posterior Lumbar Interbody Fusion – a spine fusion surgery procedure where the spine is approached from the back of the body.
- Posterior:** In human anatomy, denoting the back surface of the body, indicating the position of one structure relative to another. Opposite of anterior.
- Proximal:** Nearer or closer to a point of reference. Opposite of distal.
- Radiating pain:** Pain spreading from a focus or point of origin.

Glossary (cont'd, 3/3)

Baxano, Inc.

Radiculopathy: Pain referring into extremities, usually radiating down the arms or legs.

Retraction: Pulling away or holding apart.

Retractor: The surgical instrument that performs retraction.

Rongeur: a strongly constructed instrument with a sharp-edged, scoop-shaped tip, used for gouging out bone. An instrument for removing small amount of tissue, particularly bone. A ronguer is a spring loaded forceps with a sharp blade that may be either end cutting or side cutting.

Sagittal plane: The plane dividing the body into left and right parts.

Sciatica: Pain along the sciatic nerve.

Scoliosis: An abnormal lateral curvature of the spinal column.

Spinal canal: Bony channel that contains the spinal cord, a large foramen (opening) formed by the anterior and posterior vertebral arches through which the spinal cord passes. When the vertebrae are stacked on top of each other, the vertebral foramina form the spinal canal.

Spinal cord: The bundle of nerves that carries messages between the brain and the body as part of the central nervous system. A firm but delicate cord of gray and white nerve tissue extending from the medulla oblongata of the brain, through the vertebral canal, and terminating as the conus medullaris. At each vertebral level, nerves branch off the spinal cord to various parts of the body.

Spinal instability: The loss of the spinal ligaments, muscles and disks' ability to maintain control in reaction to physiological loads or stresses.

Spinal fusion: A surgical procedure where disc and bone material is removed and an implant or other fixation devices are placed between two vertebrae in an effort to cause bone to form and fuse together.

Spine: The vertebral column, consisting of seven cervical, twelve thoracic, and five lumbar vertebrae.

Spinous process: The projection of bony tissue located on the posterior arch midline of a vertebra at the junction of the laminae serving as an insertion point for ligaments.

Spondylolisthesis: Condition when vertebra slips forward in relation to the vertebra below it.

Spondylolysis: A vertebral defect (stress/pars fracture).

Spondylosis: Degenerative osteoarthritis of the facet joints.

Subdural space: The small space between the dura mater and the arachnoid layers of tissue covering the spinal cord.

Superior: Located above a point of reference or directed upward, situated nearer the head in relation to a specific reference point. Opposite of inferior.

Superior articular process: The half of the facet joint projecting superiorly from the inferior vertebra. Also called SAP.

Synovial joint: A joint with articulating surfaces that are lined with a layer of hyaline cartilage. The entire joint is contained in a fibrous capsule lined with synovial membrane and containing synovial fluid. Synovial fluid acts as a lubricant between the articular surfaces.

Tissue sparing surgery (TSS): Surgery methods with the goal of imparting less trauma on tissue that is not intended for removal. See also minimally invasive surgery.

TLIF: Transforminal Lumbar Interbody Fusion. A spinal fusion surgery procedure where the spine is approached from one side of the back of the body.

Transverse plane: See axial plane.

Transverse processes: The left and right vertebral processes extending laterally on each side of the pedicle.

Tube / Tubular retractor: Retraction performed by a minimally invasive surgical technique that permits the surgeon to operate down a very narrow opening.

Ventral: Pertaining to the belly or anterior surface of a body or structure. Often used to indicate the position of one structure relative to another. Opposite of dorsal.

Vertebra / vertebrae (plural): One of the thirty-three bones forming the spine or vertebral column.

Vertebral body: The weight-bearing portion of the vertebra, cylindrical in shape, and located anterior to the spinal cord.

XLIF: Cross Lumbar Interbody Fusion. A spinal fusion surgery procedure where the spine is approached from the side of the body (laterally) as opposed to the front (anteriorly) or back (posteriorly).