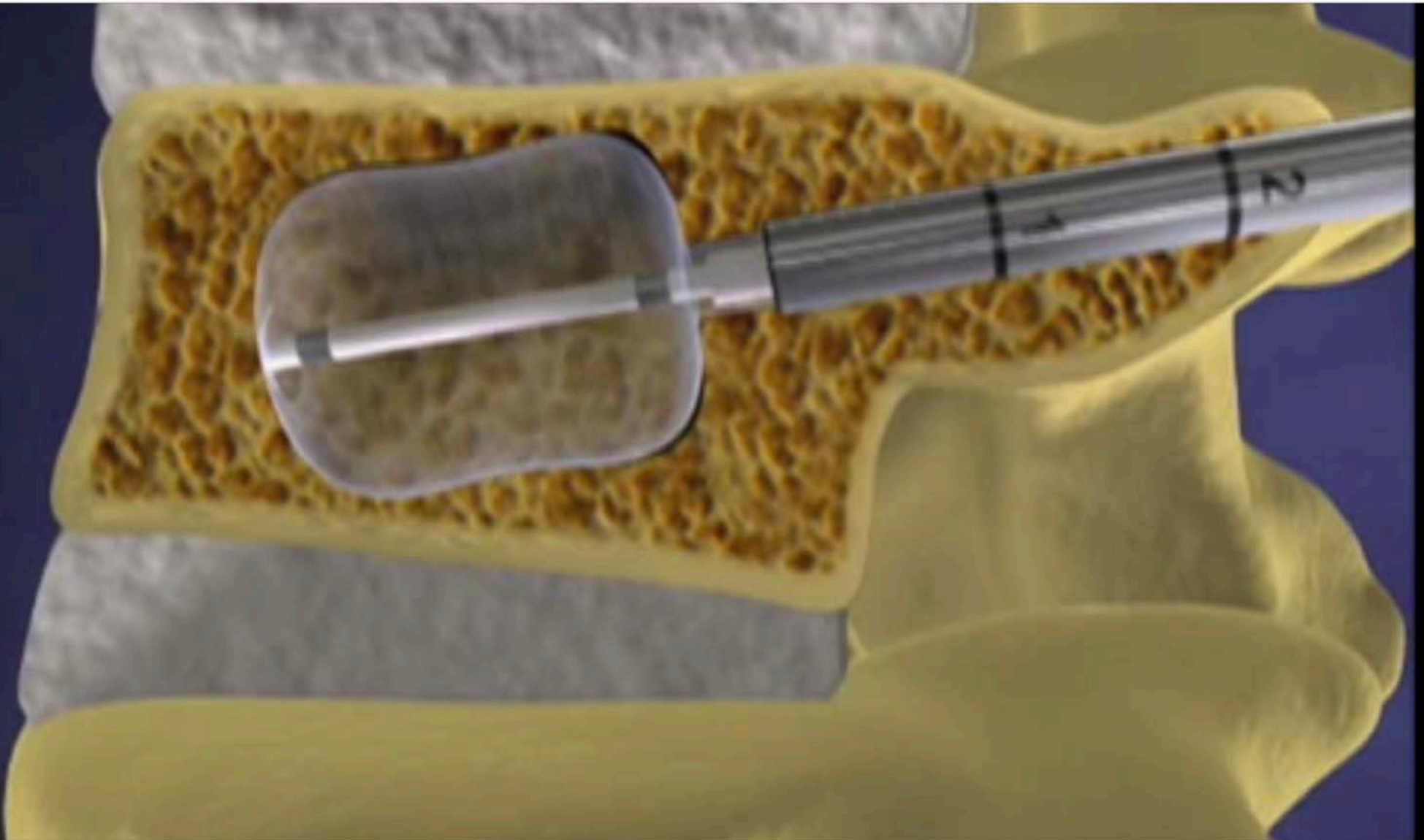


PATENT PROTECTION FOR SURGICAL METHODS AND INSTRUMENTS FOR CSFAPS

Richard Bennett Salles, Patent Attorney

“KYPHON Balloon Kyphoplasty”



<https://www.youtube.com/watch?v=WAGXUKIX>

LkU

The KYPHON Express(TM) II Balloon Kyphoplasty Platform features a maximum pressure rating of 700 psi, providing the treating physician a more powerful option for reducing fractures. The new system also gives physicians the option of using the cement resistant technique, which allows one balloon to remain inflated during contralateral cement fill, helping to maintain the goal of fracture reduction.¹ In addition, this system includes an expanded tools portfolio that is more versatile, allowing for the treatment of a variety of different levels of the spine¹.



The next-generation KYPHON[®] Cement Delivery System (CDS)

includes new features designed to increase the efficiency and precision of delivering bone cement into a vertebral body². The re-designed cement cartridges can be filled simultaneously with a provided T-adapter, increasing procedure efficiency. In addition, KYPHON[®] CDS now has longer shelf life for enhanced usability. The CDS continues to allow the physician to deliver highly viscous bone cement to the patient from up to 4 feet away from the radiation source while maintaining tactile feel. It also still includes a Quick Release



Button that provides the ability to halt the flow of bone cement on demand, giving the physician precise control over the amount of cement flow².

"KYPHON[®] BKP is a proven therapy that provides numerous benefits to patients suffering from vertebral compression fractures, including long-term maintenance of height restoration^{3,4,5,6}" said Dr. Doug Beall, Chief of Radiology Services for Clinical Radiology of Oklahoma. "With the introduction of the KYPHON Express(TM) II platform and improved tools like the next-generation KYPHON[®] Cement Delivery System, physicians can now treat more spine levels by choosing the sizes, length and volume most appropriate for the

Minimally Invasive Surgical Techniques

- Major Competitors
- ArthroCare Corporation www.arthrocare.com
- Boston Scientific www.bsci.com
- Clarus Medical www.clarus-medical.com
- ConMed Corp. www.conmed.com
- Covidien www.ussurg.com
- Ethicon Endo-Surgery, Inc. www.ethiconendo.com
- Gyrus ACMI was acquired by Olympus (Japan) in February 2008.
- www.gyrusgroup.com
- Intuitive Surgical Inc. (ISI) is the global leader in pioneering and developing robotic systems (da Vinci) for minimally invasive surgery.
- www.intuitivesurgical.com
- Karl Storz www.karlstorz.com
- Linvatec Corp. www.conmed.com/newdesign.php
- Medtronic ENT www.xomed.com
- Medtronic Kyphon www.kyphon.com/us/home.aspx?siteid=1
- Mentice Medical www.mentice.com
- ROBODOC www.robotdoc.com
- Smith & Nephew www.smith-nephew.com
- Stryker Corporation www.stryker.com
- Teleflex, Inc. www.teleflexmedical.com

Contract Manufacturers

More and more OEMs are focusing their efforts on R&D, design, regulatory issues, and marketing of new medical devices, and they are outsourcing a larger share of their manufacturing and assembly operations to contract manufacturers.

Approximately 50% of the contract manufacturing market for medical devices is controlled by no more than 12 firms, with leader Accellent Inc. (Wilmington, MA - www.accelent.com) controlling an estimated 12% of the market. Beyond the 12 leading firms, the other 50% of the contract manufacturing market is highly fragmented, comprised of firms that hold less than 1% market share each.

Other major contract manufacturers in the U.S. are:

- Analogic Corporation www.analogic.com
- C&J www.cjmedical.com
- Creganna TractX Medical www.cregannatactx.com
- CSI Medical www.csimed.com
- Group BIT www.group-bit.com
- Heraeus Medical Components www.heraeus-medicalcomponents.com
- Nortech Systems www.nortechsys.com
- Plexus Corp. www.plexus.com
- Ventrex Inc. www.ventrexinc.com

Drug-Device Combination Products

Combination products: e.g. drug-delivery systems (patches, transdermal /intradermal injections, inhalation devices, spays, drug-eluting disks), gene therapy systems, personalized medicine, nanotechnology, drug-enhanced devices (drug-eluting stents, coated catheters, anti-infective bone cements with antimicrobial agents), etc.

Major Players:

- Cordis (J&J) www.cordis.com
- Boston Scientific www.bostonscientific.com
- Abbott Laboratories www.abbott.com
- Medtronic www.medtronic.com
- Cook Medical, etc. www.cookmedical.com

Group Purchasing Organizations

Nearly all US hospitals buy through GPO's –also called Direct Purchasing Organizations-, which are cooperatives that increase the buying power of their healthcare provider members. GPO's save their members an average of 10% on supply costs.

Hospitals and nursing homes purchase about 80% of their supplies through GPO and integrated delivery network contacts: Amerinet (St Louis, MO), Consorta (Schaumburg, IL), etc.

Here is a select sample of such GPO's:

- Amerinet (*St Louis, MO*) www.amerinet-gpo.com
- Broadlane www.broadlane.com
- Consorta, Inc. (*Schaumburg, IL*) www.consorta.com
- HealthTrust Purchasing Group www.healthtrustpg.com
- Innovatix, LLC www.innovatix.com
- MedAssets www.medassets.com
- Novation/VHA/UHC www.novationco.com
- Premier www.premierinc.com

Margins

Medical device companies have an average margin of **14%** (more than the 8% for the overall healthcare industry)

For therapeutic and diagnostic products, market leaders (like Medtronic, St Jude, Boston Scientific, Zimmer, Stryker) reach a 25-30% range.

Mature market products like hospital supplies (considered a commodity) go by high volumes and low margins.

Patent License Agreement

This Patent License Agreement ("**Agreement**"), dated as of [DATE] [(the "**Effective Date**")], is by and between CLIENT, inventor, with offices located at [ADDRESS] ("**CLIENT**") and [LICENSEE NAME] a [STATE OF ORGANIZATION] [TYPE OF LEGAL ENTITY], offices located at [ADDRESS] ("**Licensee**").

WHEREAS, CLIENT is the [sole and exclusive] owner of and has the right to license to Licensee the Licensed Patents (as defined below); and

WHEREAS, Licensee wishes to [use/practice] the Licensed Patents [in the Field of Use (as defined below)] in the Territory (as defined below) in connection with the Licensed Products (as defined below) and CLIENT is willing to grant to Licensee a license to the Licensed Patents on the terms and conditions set out in this Agreement.

Thank You!