

ORTHOPEDIC MEDICAL CHANNELS

Developer and Distributor of Latest Patented Bone-Screw Technology Used in Orthopedic, Dental and Veterinary Surgical Markets

> Confidential Business Plan April 2014

Mr. Wayne Willert Inventor, Founder & CEO (516) 767-8801

Orthopedic Introduction

According to data from the American Academy of Orthopedic Surgery the future holds many twists and turns for those in the orthopedic community. The aging of America, the controversy of less invasive surgical procedures, new devices and technologies and the potential for reimbursement reductions will all contribute to the changing face of orthopedic medicine. Reviewing the U.S. Census Bureau historical procedure rates from 1990 through 2003, the American Academy of Orthopedic Surgery has calculated increases which were well over 100 percent. In the near future, increases will be more than the 100 percent range. Current statistics by the Center for Disease Control say that a total number of 51.4 million procedures are performed each year in the United States and over 4 million of them are for first time orthopedic surgerys. For a second corrective orthopedic surgery known as a revisit add a staggering 6.8 million and you will have a total of 10.8 million annual orthopedic operations in United States hospitals. According to the American Federation for Clinical Research, there are over 68 thousand complications from orthopedic surgical site infections.

Currently, the problems with predicate bone screw are well known, and without a technology change, the mechanic results will worsen. Orthopedic Medical Channels, LLC has mechanically improved in six areas that needed improvements for reducing bone screw failure and infection occurrences.

Wayne Willert, Inventor, Principle of Orthopedic Medical Channels LLC, has patented bone screw implant technology which addresses six current mechanical problems resulting in bone screw failure and infection.

Wayne A. Willert Bone Screw Failure Specialist Infection Control Systems

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Orthopedic Medical Channels™ LLC

Medical Screw Implants

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AN INTRODUCTION TO THE ORTHOPEDIC BONE-SCREW INDUSTRY

Demand for surgical bone-screws is expected to rise due to the aging and extended life of world populations and a mandate for improved medical technology that contributes to reducing costs and better patient outcomes. The Orthopedic Medical Channel's patents will dynamically contribute to these marketplace demands and are poised for immediate high-margin monetization across several medical sectors.

Bone-screws are specialized devices designed for use in orthopedic surgery. These bone-screws are made from nonreactive materials which can be safely used inside a patient's body and are driven through the bone with the assistance of specialized tools.

There are a number of surgical conditions in which bone-screws are utilized and a wide range of sizes that are manufactured by a large number of medical device companies of which 20-40 produce approximately 80% of bone-screws used today in trauma and spinal-related procedures. There are an estimated 15,000 different bone-screw variations used in orthopedic, dental and veterinary surgeries to stabilize fractures, reinforce implants, support deteriorating bones and serve other medical treatments, including neurosurgical and cardiac procedures.

The spinal devices market is expected to reach the value of \$13.5 billion by 2016 with a CAGR of 9.3% from 2011 to 2016. This is mainly due to increasing incidence of spinal deformities such as disc compression amongst the aging population and popularity of non-fusion devices such as artificial spinal disc and nucleus. The increasing market demand by an aging population and advancement in medical technologies (minimally invasive techniques and biologics) boost the need for joint reconstruction. This market is expected to reach \$19.2 billion by 2016 at a CAGR of 5.8% from 2011 to 2016.

The trauma fixation market can generally be segmented into two categories of high-energy fractures from the young patient under age 45, or the elderly population above age 65 that experiences low-energy fractures. For the aging, osteoarthritis has become a global public health concern with no cure. This is an indication that is growing rapidly, afflicting all joints. As hip fixation continues to be up to 20% of the trauma market, this segment is expected to continue to grow. The extremities segment also continues to drive growth, which consists of approximately another 20% of the market. Sporting injuries, vehicular accidents, violence and falls are the primary factors that make this trauma fixation market grow at a rate of 6.8%, far higher than that of the joint replacement markets within the hip and knee space. Generally, fixation devices such as plates, screws, intramedullary nails and external fixation are far cheaper than joint replacement, and are thus a preferred treatment methodology when clinically feasible.

Companies in the orthopedic devices market are employing number of strategies to gain a competitive advantage including new product developments, mergers and acquisitions, and partnerships/collaborations/agreements. The key growth strategy followed by most of the companies is frequent product launches. New product launches accounted for almost 70% of strategic developments. Agreements, collaborations, and strategic partnerships accounted for almost 20% of the total strategic developments in the industry from 2008 to September 2011 and the trend continues through 2013.

MARKET OUTLOOK

Industry research validates a growth trend in trauma-related surgical fixations that require multiple surgical bone-screws. These procedures are an essential component of the OMC business model because they represent the single largest segment of bone-screw utilization in the US and abroad.

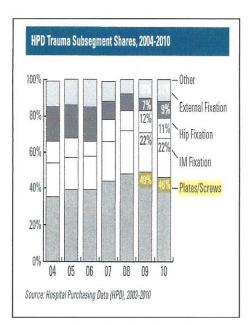
Surgical bone-screws play an important role in trauma treatment, and new technologies like the OMC patents are ripe for exploitation by a global market of healthcare practitioners and institutions.

As a result of an aging global population, an increasing number of hip and back surgeries that are being performed creating a high growth rate in the industry for hardware used in these (and other trauma) procedures.

The overall number of hospitalized fractures increased about

2.9% between 2007 and 2008 (the most recent data available) to 1.89 million, the number of internal fixation procedures was about 635,000 and there were about 42,000 hospitalized external fixation procedures in 2008.

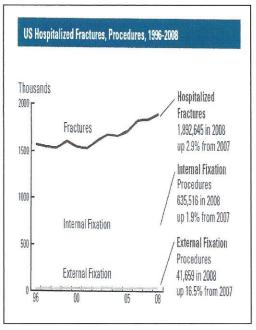
This data collected uses elderly inpatient data from over 5,000 hospitals in 42 states with in the US but does not include any outpatient data for trauma treatment. The market size and growth trend would



likely be significantly greater if data from fractures of small bones that are treated in emergency departments, ambulatory surgery centers, urgent care centers, and physician offices were included. Accordingly, OMC anticipates annual growth of approximately 3.5% in the market sectors in which it participates, of which internal (surgical) fixation (using bonescrews such as those manufactured and licensed by OMC) is the largest segment.

Distribution of Trauma Sales By Segment

Market outlook data does not include almost \$1 billion in dental implant procedures, another segment that is expected to rise as a result of aging populations and better access to dental care.



Long Bone Stim

Craniofacial 6%

External

Fix

14%

Source, Orthopedic Network News estimates

Other 4%

Internal

Fixation

HOW THE ORTHOPEDIC MEDICAL CHANNELS, LLC PATENTS WILL IMPROVE SURGICAL BONE-SCREWS

OMC bone-screw implant technology and patents were designed to address six current mechanical problems resulting in bone-screw failure and infection:

1) Currently, insertion torque creates friction, heating and burning of bone causing complications responsible for bone-screw loosening, rejection, infection and crippling or death.

In OMC's testing of its patented technology against the current predicated bone-screw, the insertion torque is reduced by over fifty percent resulting in less heating and burning of the bone.

2) Exceeding the limit of compression pressure between metal screw and bone can choke and deprive bone of its life sustaining living metabolism. Current predicated bone-screw threads and core are completely solid shapes only relying on chance to not exceed bone killing compression needed to anchor the screw.

OMC's patented technology contains depth shapes within the bone-screw thread and core. It allows for rebounding or bone growth as the compression pressure relief area naturally anchors the bone-screw implant.

3) From the beginning, OMC's patented technology revealed successful osterio integration.

The OMC bone-screw implant is the strongest section compared to current predicated bone-screw implants which make it the weakest section of bone.

4) The current bone-screws used today cut into hard and soft bone, dragging and trapping bone residue throughout bone creating an environment for possible infection.

OMC's patented Medical Channels allow flexing of bone around a bone-screw implant, tremendously reducing the trapping of cut bone residue within bone.

5) When current predicate bone-screws are affected by any loss of tightening compression, a continuing, loosening cycle begins resulting in the potential of the bone-screw falling out requiring surgery to re-tighten and or replace.

If there is a loosening occurrence, OMC's Medical Channel technology will assist the bone to naturally grow bone and re-anchor itself within the patented Channels, eliminating the need for physical retightening and or surgery to replace it.

6) Predicate bone-screws do not provide any type of effective medicine delivery system.

OMC's Medical Channels patent has a medicine delivery system allowing for the placement of antiinfection bone healing medicine for short or long term disbursement anywhere within the bone.

COMPETITION

Because of its patents, OMC, LLC is in a unique position that enables the company to directly manufacture bone-screws that will be totally unique in the marketplace and distribute them through a large network of existing medical device resellers.

Alternatively, the company can license its patents to existing surgical bone-screw manufacturers that can re-tool their existing products to take advantage of the unique OMC features and manufacture new products using the patent and pay OMC a royalty and/or license fee.

Due to its innovative patent strategy, the traditional competitive dynamics that would challenge OMC's entry into the surgical bone-screw marketplace have been mitigated and the company is poised to be able to do business with every existing manufacturer and distributor now and in the future.

There are an estimated 15,000 different orthopedic bone-screw variations (and multiple sizes for each screw) used in orthopedic, dental and veterinary surgeries that are manufactured by an estimated 1,000 specialized companies around the world. The largest of these companies are the biggest distributors of medical bone-screws globally, one of them with a near 50% market domination.

OMC management is confident that its patents will be highly desirable for integration with product strategies of every segment of the bone-screw industry. As more and more manufacturers apply the patent to their existing screw designs, the OMC will acquire FDA approvals that will facilitate adoption by an increasing number of manufacturers, enabling OMC to piggyback on existing and successful lines produced by manufacturers of every size.

Company	2010 Share	2009 Share	Change
Synthes	48.1%	42.9%	+ 5.2
Stryker	13.0	13.7	- 0.7
DePuy	9.7	8.1	+1.6
Smith Nephew	7.7	5.6	+2.1
Acumed	7.7	13.1	- 5.4
Wright Medical	3.9	7.3	- 3.4
Zimmer	1.7	2.8	-1,1
Others	8.2	6.4	+1.8
Total	100.0	100.0	

MANUFACTURING & DISTRIBUTION

OMC's strategy is to develop production and licensing relationships with ISO certified small medical screw manufacturers that can produce (and, in some cases distribute) a large percentage of 15,000 different sized bone-screws used in orthopedic, dental and veterinary surgeries.

Initially, OMC plans to retain 2-5 entrepreneurial and certified manufacturers that operate a FDA-approved facility compliant with the Journal of Biomedical Engineering to perform 100-piece test production runs using the OMC patent. Test facilities must be able to provide the highest quality sterilization, electro polishing, FDA-approved packaging/labeling, material validation, and quality control procedures. Engineering drawings and pre-production tooling will be required and OMC plans to absorb this expense.

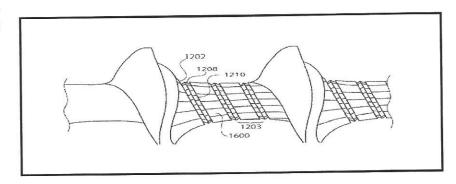
The manufacturing tests will be used to perfect the process, measure the time required for each bone-screw and secure FDA approval, which should be obtained in substantially less time than a new product application because an existing FDA-approved bone-screw is being modified using the OMC patent, so the certification process is technically a modification to an existing approval. Production time tests are extremely important because they will help the company establish the number of manufacturers required to meet the 15,000 different sized bone-screw implants that presently exist in the marketplace.

Secondary tests will be conducted by Orthopedic Test Lab Centers over a 30-60 day period during which comparison to predicated bone-screws will be conducted as well as testing using fresh sheep tibia bone. These tests will also be compliant with standards of the Journal of Biomedical Engineering and include ASTM test method for axle pullout, screw toggle, strength of medical channel bone-screws and the generation of printed test results and charts, written reports including a formal opinion and other documentation required for FDA approval and successful marketing of the patent.

Immediately following secondary testing, OMC will undertake a 3-month period to identify ISO-certified manufacturers with approved industrial qualifications and negotiate terms of a potential business relationship.

A second round of orthopedic testing will be conducted in parallel with manufacturer qualification, enabling OMC to confirm that its testing was performed with all protocols in place and to organize

classified devices for FDA testing. Further testing will be conducted on human, fresh cadavers and small animals, after which the form 510K will be filed with the FDA. The company anticipates rapid approval from the FDA on all devices to which the patent has been successfully applied.



OMC, LLC Patented Bone- Screw Technology

MANAGEMENT & OPERATIONS

Mr. Wayne Willert – Inventor, Founder & CEO has extensive hands-on experienced in the usage, design and manufacturing of medical bone-screws. In addition, Wayne has successfully participated in obtaining over 2,696 FDA approved medical fasteners over the years. Mr. Willert will be involved in the selection of the following team members that are expected to join OMC, LLC over its initial 3-year launch and growth phase:

Position Y	ear 1	Year 2	Year 3
EO			
VP Operations			
Dir. Operations			
VP Manufacturing			
Dir. Quality Control			
Field QC Manager			
Field QC Manager			
Field QC Manager			
VP Legal Services			
Staff Lawyer			
Paralegal			
CFO			
Controller			
Dir. Human Resources			
Admin			
Admin			
Admin			
VP Sales			
Sales Region 1		8.0	
Sales Region 2			
Sales Region 3			
Sales Support			E.I.
Sales Admin		1 1 2 3 4 5 5 6 5 6 5 6 5 6 5 6 6 6 6 6 6 6 6 6	
VP Marketing			
Dir. Marketing			
Marketing Manager			
Admin			
Admin			

Mr. Willert's vision for the company will be implemented through an accomplished management team composed of finance, legal, quality control, sales, marketing and customer service professionals working from offices in Metropolitan New York City and eventually, leading global cities.

Due to the significant number of manufacturing contracts, worldwide patent applications and complex business affairs of the company, OMC plans to operate an in-house legal department that will significantly reduce the cost of outside counsel.

An in-house sales and marketing organization will create lucrative relationships with a global network of manufacturers and a highly-skilled quality control team will insure that each manufacturer observes the highest standards of production.

The company's marketing programs will be focused to commercial users via extensive trade media promotion and consumers through an educational website that promotes the benefits of the patents. The company anticipates being one of the most recognized brands in the medical bone-screw industry.

Orthopedic Medical Channels LLC Patents

Patent Filing Date February 9, 2012, Patent issued August 17, 2013, and Utility Patent # US8535358B2

January 14, 2013 filed two patent divisional applications

September 9, 2013 filed one patent continuation in part

Proceeding

In conjunction with the US patent already secured, OMC will be filing for additional patents worldwide with over 143 countries, no later than August 2014

Orthopedic Medical Channels, LLC Business Direction

Orthopedic Medical Channels will established a completely new orthopedic bone-screw market to service the tens of millions of patients worldwide affected by the medical failures of the current bone-screw market. Those failures have opened the door for OMC, LLC to aggressively capitalize on the \$100 billion a year bone-screw failure market. OMC, LLC has received an excellent early-stage response from researchers and manufacturers, with independent field representative's participation. Conservative projections estimate that within a 3 to 5 year period, OMC, LLC products will become the primary bone-screw devices requested and purchased-not just as replacements for existing bone-screw implant failures, but for *all* bone-screw implants.

Orthopedic Medical Channels, LLC Established Value

Based on the written analysis posted on www.orthopedicnetworknews.com, a quarterly publication and on-line information service on cost & quality issues in orthopedics, volume 20, number 4, October 2009 Issue found on page 5, a very clear summary is presented. Review of financial statistics chart for SPINAL ONLY, a segment of Implant Company's investment for Research and Development (R&D) is over \$9.8 billion dollars in 2008. Orthopedic Medical Channel's has completed the Implant Company's R&D phase, saving these companies an average of \$818 million dollars on Spinal Implant R&D costs. This estimate has been taken into consideration as part of OMC, LLC value calculation.

Orthopedic Medical Channels, LLC Private Financial Opportunity

Based on the \$818 million dollar spinal R&D expenses incurred by Implant Companies in 2008, and the 144 worldwide patents available (including the US patent), OMC, LLC has conservatively calculated 144,000 units for the company at a value at \$5,000 per unit. With terms, OMC, LLC convertible promissory note OMC, LLC's offer is 14,400 units; the cost per unit is \$5,000. In return, the investor's 14,400 unit value will equal approximately 1% of the company's gross sales that would be paid out to participating investor on a quarterly basis.

NON-DISCLOSURE AGREEMENT

This Agreement is made and entered into by and between ORTHOPEDIC MEDICAL CHANNELS, LLC having its principal offices at 22 Second Avenue, Port Washington, New York 11050, its parent, subsidiaries and affiliates (collectively "ORTHOPEDIC MEDICAL CHANNELS") and having its principal office at , and its parent, subsidiaries and affiliates (collectively "")(each being a "party" or collective "parties").

- 1. <u>Disclosure.</u> The parties intend to engage in discussions concerning a potential business relationship (the "Proposed Relationship"). In connection with such discussions and any resulting relationship, ORTHOPEDIC MEDICAL CHANNELS and may disclose to each other technical, financial and/or other information, material, or data which is written, oral or in any other form, electronic or otherwise (collectively "Data") which is considered confidential and proprietary.
- 2. Confidential Data. "Confidential Data" means (a) any Data disclosed by or on behalf of a party ("disclosing party") to the other party ("receiving party"), including, without limitation, (i) any materials, trade secrets, business models, know-how, inventions, data, proprietary information, business and marketing plans, financial and operational information and all other non-public information, material or data relating to the current and/or future business and operations of the disclosing party, and (ii) any information, material or data provided by third party vendors of the disclosing party; and (b) any analyses, compilations, studies, summaries, extracts or other documentation prepared by the receiving party based on the Data disclosed by the disclosing party.
- 3. Public Data. Notwithstanding any other provision of this Agreement, Data shall not be, or shall cease to be, Confidential Data hereunder: (a) if such Data is known to the receiving party prior to disclosure thereof by the disclosing party; (b) after such Data is published or becomes available to others, without restriction and without breach of this Agreement by the receiving party; (c) after such Data becomes available to the receiving party from others having no obligation to hold such Data in confidence; or (d) if such Data is developed by the receiving party independently of any disclosure of such Data by the disclosing party.
- 4. Non-Disclosure Obligation. Unless otherwise agreed to in writing by the disclosing party, the receiving party agrees (a) not to disclose the Confidential Data; (b) use the same degree of care and diligence to protect such Confidential Data from disclosure to others as such party employs or should reasonably employ to so protect its own information of like importance (but in no event less than reasonable care); and (c) not to reproduce or copy the Confidential Data, in whole or in part, except as necessary



for the evaluation or conduct of the Proposed Relationship. Notwithstanding the foregoing, the receiving party may disclose the Confidential Data to such of the receiving party's consultants, agents and affiliates (collectively "receiving party representative") which the receiving party reasonably and in good faith believes should be involved in the evaluation or performance of the Proposed Relationship, provided such receiving party representative is informed of this Agreement and agrees to be bound by the terms hereof, and the receiving party uses best efforts to cause the receiving party representative to observe the terms of this Agreement. The receiving party agrees that a breach of this Agreement by a receiving party representative shall constitute a breach by the receiving party. In the event that the receiving party is required by applicable law, rule, regulation or lawful order or ruling of any court, government agency or regulatory commission to disclose any Confidential Data, the receiving party agrees that it will provide the disclosing party with prompt notice of such requests(s) to enable the disclosing party to seek an appropriate protective order or to take steps to protect the confidentiality of such Confidential Data.

- No Additional Rights. The receiving party shall not have any rights or obligations respecting the Confidential Data other than those specifically set forth in this Agreement. Without limiting the generality of any other provision of this Agreement: (a) no license is hereby or otherwise granted, directly or indirectly, under any patent, copyright or other proprietary right of the disclosing party or its third party vendors; and (b) neither party shall be obligated to disclose Data to the other party or to enter into any further agreements relating to the Proposed Relationship or Data. A party may terminate discussions regarding the Proposed Relationship at any time. The receiving party shall, upon written request of the disclosing party, return to the disclosing party all Confidential Data, including all copies thereof, disclosed hereunder. The receiving party's obligations under this Agreement respecting the Confidential Data shall survive termination of said discussions.
- 6. <u>Injunctive Relief.</u> Both parties acknowledge and agree that the disclosing party and/or its third party vendors (as the case may be) own all rights, title and interest in the Confidential Data. Both parties further acknowledge and agree that the unauthorized disclosure of the Confidential Data will cause irreparable harm to the disclosing party. As a result of the unique nature of the Confidential Data, in addition to all other remedies available, the disclosing party shall be entitled to seek injunctive and other extraordinary relief in a court of competent jurisdiction in order to enforce the disclosing party's obligations hereunder.
- 7. Other Provisions. The parties further agree that: (a) this Agreement shall be governed by the laws of the State of New York; (b) this Agreement sets forth the entire agreement and understanding between the parties with respect to the subject matter hereof, and none of the terms of this Agreement may be amended or modified except by a written instrument signed by both parties; (c) a party may waive any rights under this Agreement only by written waiver duly signed by such party, and no failure to exercise or delay in exercising a right under this Agreement shall constitute a waiver of such right; (d) this Agreement shall inure only to the benefit of the parties hereto, and the rights and obligations of each party under this Agreement may not be assigned or delegated without the consent of the other party; (e) no provision of this Agreement shall affect, limit or restrict either party's right to engage in any business in any place at any time, whatsoever, provided the receiving party does not disclose the Confidential Data in violation of this Agreement; (f) each party agrees not to



advertise or otherwise make known to others, any information regarding this Agreement or the Proposed Relationship except as may be required by law; (g) neither party makes any representations or warranties as to the accuracy or completeness of any Data disclosed hereunder; (h) the invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement; (i) all notices under this Agreement must be in writing and shall be deemed to have been delivered to and received by a party, and will otherwise become effective, on the date of actual delivery thereof (by personal delivery, express delivery service or certified mail) to the Notice Address of such party set forth below; (j) this Agreement may be executed in counterparts; and (k) this Agreement is dated for all reference purposes

ORTHOPEDIC MEDICAL CHANNELS, LLC

By:			By:	
Name: WAYNE	Waver	MES.	Name:	

Notice Address: 22 Second Avenue

Port Washington, New York 11050

Notice Address: