

HIGHLIGHTS

- **JointRep™ is the first CE-Marked directly injectable implant in the lesion of the cartilage for the repair of traumatic or arthrosis chondropathy, to restore hyalin cartilage, substantially and rapidly reduce pain, and delay or avoid joint replacement where possible.**
- Innovative & easy-to-use, it is administered through **arthroscopy**.
- **IT'S NOT A VISCOSUPPLEMENT, IT REPAIRS DIRECTLY THE AFFECTED CARTILAGE**
- Isotonic with neutral PH, it is non-toxic and safe, and is compatible with living cells (e.g. stem cells, PRP or chondrocytes).
- Can be premixed with bone marrow extracts or PRPs while maintaining its injectability and thermogelling properties.
- **Can be used alone or with microfracture technique in case of significant loss of articular cartilage.**
- Initial clinical experience (first-in-man) in Canada (2010) and Clinical post-market studies in Switzerland, Italy and France.
- **By the end of 2015, JointRep™ has been used in more than 1500 patients in different countries. There has been no incident or complaint of any kind.**
- **Rehab:** Following arthroscopy, patients are allowed for total load ambulation with the use of a contralateral cane for 5 days. At 15 days post-op, patients are allowed quadractic electro stimulation, leg extensions, swimming, stationary bike for 20 days.



Defect in intercondylar notch prepared for JointRep™ Defect filled with material Defect one year after

1 Healthy Cartilage
2 Defect



Interested in our innovative technology
**Watch JointRep™ Surgery without microfracture
 (symptomatic lesions grade I & II)**

www-oligomedic.com/surgery-video



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JointRep™

**CARTILAGE PRESERVATION AND REPAIR
 TECHNOLOGY**

A New Paradigm in reducing Articular Pain

JointRep™



BUSINESS SUMMARY

OligoMedic is based on a platform technology, which is the first approved injectable implant to repair traumatic and arthrosis chondropathy, preserve or repair cartilage, fast and effectively reduce pain, and delay or avoid joint replacement, where possible. First commercialization milestone has been attained, OligoMedic has CE-Marked JointRep™ (2012) for use in all body joints.

UNMET CLINICAL NEEDS

Osteoarthritis (OA) is the most common joint disease and estimated to affect more than 27 million people in the US alone. Overtime, the cumulative wear leads to an end-state joint failure, and if left untreated would require a total joint replacement. For patients, quality of life reduced due to loss in mobility and joint pain, which progresses to continuous discomfort, even at rest. Initial treatments focus on pain relief via analgesic drugs to reduce the pain, but they are noncurative. Both patients and physicians are faced with a large unmet clinical need, in which OA prevalence is significant, and current treatment options cannot halt or slow disease progression.

TECHNOLOGY PLATFORM

OligoMedic has developed a family of injectable bioadhesive implants that has mechanical properties of a liquid at room temperature but solidifies within minutes when exposed to body temperature. Its composition is mainly water (>90%) and polysaccharide ingredient. OligoMedic technology is applicable to cartilage joint preservation and restoration, plastic surgery, and veterinary.

LEADING PRODUCT

OligoMedic has developed JointRep™ as a simple biocompatible bioadhesive, and easy-to-use matrix to fill small and large chondropathy defects. JointRep™ is designed to reduce joint pain, restore hyalin cartilage and improve patient mobility. Product administration is through arthroscopy.

TARGET MARKET

Osteoarthristis market has reached \$7+ billion by 2015 and is forecasted to grow steadily, driven by an aging population, obesity and increasing healthcare costs.

COMPETITIVE ADVANTAGE

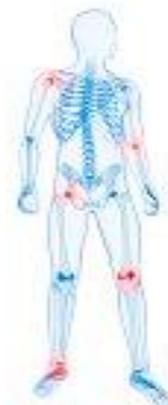
JointRep™ is a device that provides a practical benefit to the patient whilst minimizing the cost and risk related to its administration. Highly marketable and marginal procedural-time addition (few minutes) than arthroscopy alone, JointRep™ offers a clinical outcome superior to current technologies, since it “plugs” focal defects and bridges between deteriorated cartilage and healthy one.

INTELLECTUAL PROPERTY

OligoMedic has a foundational patent granted in almost all countries of the world.. Additional patents are also granted or pending.

REGULATORY PATH

Currently JointRep™ has achieved CE-Mark and is distributed in Europe. In 2015, JointRep™ is marketed and distributed in 15 countries worldwide, and still will expand its regulatory submissions in Latin America including Brazil, Asia: Malaysia (China in progress), and Middle East including Iran markets. OligoMedic is planning to file with Health Canada in Spring 2016, and since there is no predicate to JointRep™, the company is seeking US FDA approval via 510(k) deNovo first then PMA as a second option.



JointRep™:

A Controlled Post-Market Clinical Study with JointRep™ (Italy)

A Controlled Post-Market Study, conducted by Pr. Pipino, full professor of orthopedic surgery at University of Lugano in Switzerland and also practicing in Italy, compares arthroscopic microfracture with JointRep™ procedure (Test group) versus conventional microfracture procedure alone (Control group) for the treatment of Chondropathies (grade III-IV) in knee joints.

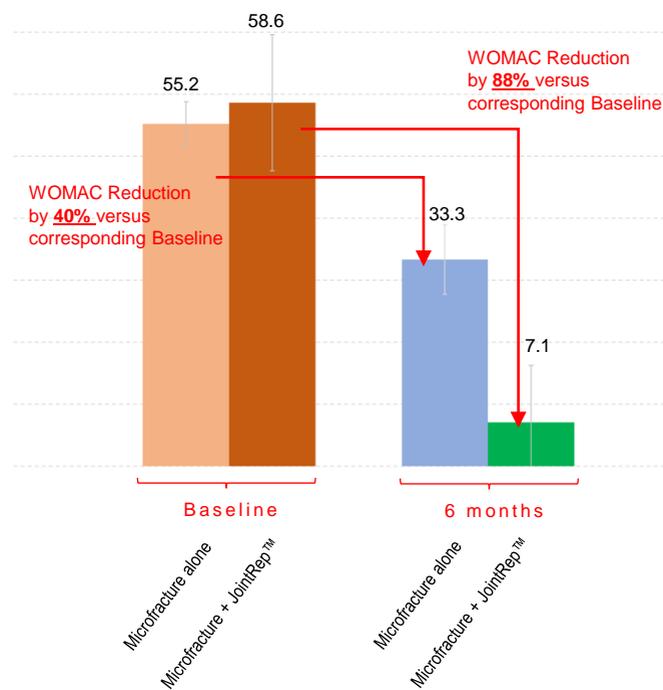
The Controlled Post-Market Study compares two independent groups (Control: Microfracture alone; Test Group: Microfracture + JointRep™) and incorporates more than 70 patients (for the 2 groups). Selected patients were both males and females, aged from 18 to 75 years old, having grade III or IV knee joint cartilage damage defects (cartilage defects with associated knee joint lesions were included). Patients in both Control and Test groups were treated under normal arthroscopic procedures. Following arthroscopy, patients were allowed for total load ambulation with the use of a contralateral cane for 5 days. At 15 days post-op, patients were allowed quadratic electro stimulation, leg extensions, swimming, stationary bike for 20 days. Post-op evaluation of patients in both groups was done by using WOMAC and IRM imaging at 6 months, 1 year, then annually.

At 6 months post-op in Microfracture + JointRep™ group, all WOMAC scores (total, pain, stiffness, physical) were significantly reduced by 85-90% in comparison to WOMAC baseline scores (t=0). In the Control group (Microfracture alone), the WOMAC scores at 6 months post-op were reduced by 12-55% in comparison to WOMAC baseline scores. No adverse events were reported in both groups.

Short-term clinical outcomes demonstrated that the arthroscopic treatment of Microfracture + JointRep™ is highly effective and significantly improves all WOMAC scores, showing superior 6-month results than the Microfracture alone control treatment.

Post-Market Controlled Study of JointRep™ (Microfracture + JointRep™ vs Microfracture alone)

WOMAC Total Score



As soon as 6 months post-op, Treatments with Microfracture plus JointRep™ significantly improve all WOMAC scores

Pre-Clinical Results

STATUS	TEST DESCRIPTION	CONCLUSION
PASS	In-vitro Cytotoxicity test of JointRep™ in L929 Mouse Fibroblast cells	JointRep™ did not exhibit reactivity (Grade 0) and therefore the sample was considered not cytotoxic under the conditions of this experiment.
PASS	Acute systemicToxicity of JointRep™	Under the conditions of the study, extracts of the test sample, JointRep™, did not cause systemic toxicity and therefore met the requirements of the test.
PASS	Intracutaneous Reactivity test of JointRep™ in Rabbits	Under the conditions of this study, the test article, JointRep™, extracted in 0.9% Sodium Chloride and Cottonseed Oil met the requirements of the test since the difference between each test extract and the corresponding control mean score was less than 1.0.
PASS	Skin Sensitization test of JointRep™ in Guinea pigs	An evaluation of irritancy was carried out at 24 ± 2 hours and 48 ± 2 hours after removal of the patches. Under the conditions of this study, extracts of the test sample, JointRep™, showed no evidence of sensitization.
PASS	Mutagenicity – Bacterial Reverse Mutation of JointRep™	JointRep™ was not mutagenic to <i>S. typhimurium</i> strains TA98, TA100, TA1535, TA1537 and <i>E. coli</i> strain, WP2 <i>uvrA</i> , under the test conditions.
SAFE	Implantation study of JointRep™ for femoral condylar cartilage using an ovine model (time points 14d & 56d)	All animals maintained a general good health status throughout the study. As such, there was no bias introduced in the study and all samples were acceptable for histopathological evaluation. The Study pathologist concluded that at day 56, the test material exhibited excellent biocompatibility as evidenced by the minimal tissue reaction. Synovial changes were minor and relatively similar in both groups. Systemic effects of the implantation of the test material was not seen in the organs (heart, kidney, lungs, liver and spleen) examined.

