Oxiplex®

Absorbable Gel for Spine Surgery

CAUTION

Federal (US) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

Oxiplex® is a synthetic, absorbable, clear, flowable, viscoelastic gel that is comprised of sodium carboxymethylcellulose (CMC) and polyethylene oxide (PEO). In spinal surgery, Oxiplex gel is applied to the surface of adjacent tissues and nerve roots at the surgical site just prior to closure to reduce pain and improve patient outcomes. Oxiplex is for single use only and is provided sterile in a pre-filled syringe together with a sterile, flexible applicator for introduction of the gel during surgery. No mixing or other preparation is required. Oxiplex is non-pyrogenic and contains no human, animal, or bacterial components. No color additives are used in the device.

INDICATIONS FOR USE

Oxiplex® is a synthetic, absorbable gel intended as an adjunct to lumbar spinal surgery in adult patients with leg pain, back pain, and neurological symptoms undergoing discectomy to reduce leg pain and neurological symptoms.

CONTRAINDICATIONS

Oxiplex is contraindicated for use in the presence of active infection. Patients known to have a history of hypersensitivity to Oxiplex or its components should not be treated with Oxiplex.

WARNINGS

WARNING: *For single patient use only.*

Reuse of Oxiplex gel or applicator may compromise sterility and affect product handling, increasing the risk of infection or device failure. **Do not reuse or re-sterilize. Discard any unused contents.**

WARNING: *Risk during pregnancy.*

The effects of Oxiplex on fetal development are unknown. Women of childbearing potential should avoid becoming pregnant until after one complete menstrual cycle following application.

WARNING: *Use in nursing women has not been evaluated.*

It is unknown whether Oxiplex is excreted in human milk. Do not administer to breastfeeding patients.

WARNING: *Do not use Oxiplex as a drug delivery system.*

Introducing medications such as antibiotics or chemotherapeutics into Oxiplex may cause unintended pharmacological effects or compromise safety.

WARNING: *Do not inject Oxiplex into blood vessels.*

Intravascular injection may result in embolism or other serious complications. Ensure the product does not enter the vascular system.

WARNING: *Hemostasis must be achieved before application.*

Applying Oxiplex in the presence of active bleeding may reduce efficacy and increase risk of complications.

WARNING: *Repair any dural leaks before applying Oxiplex.*

Unsealed dural defects may alter product behavior and pose a risk of leakage into unintended spaces.

WARNING: *Unknown safety with certain surgical materials.*

The performance of Oxiplex has not been evaluated in procedures involving:

- Hemostatic agents
- Surgical drains

PRECAUTIONS

- Risk is inherent in the use of all medical devices. To minimize the risk associated with the use of this device, it is recommended that the information for use be read by the physician and discussed with the patient prior to use of the device.
- Oxiplex is supplied sterile. DO NOT USE IF STERILE PACKAGING IS OPENED OR DAMAGED. Discard or return damaged packaging and all contents.
- Do not use after the printed expiration date on the label.
- The safety and effectiveness of Oxiplex in patients who are not skeletally mature has not been established.
- The safety and effectiveness of Oxiplex in patients with metabolic bone disease has not been established.
- Oxiplex has not been studied at the site of bone fusion.
- Foreign body reaction may occur as with any implanted surgical device.

POTENTIAL ADVERSE EVENTS

Related to general use

Adverse events associated with surgery include fever (within 36 hours postop), chills, pain, redness, swelling, itching, bleeding, bruising, hemorrhage, hematoma, seroma, wound secretions/drainage, cellulitis, weakness, stiffness, spasms, tightness at the surgical site, and death.

Related to spine surgery

Adverse events associated with spine surgery include: atelectasis/pneumonia, adjacent level disease, arachnoiditis, cavernous malformation, deep vein thrombosis, pulmonary embolism, dural tear, spinal fluid leak, fibrosis, facet fracture, wound infection, myocardial infarction, nerve injury, neurological deterioration, vascular injury, delayed union/non-union of fusion, spinal cord injury, paresis, myelopathy, including paralysis, additional surgery, failure of the surgical procedure to improve symptoms and/or function, and death.

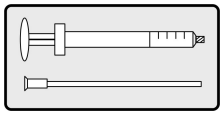
Adverse events related to lumbar spine surgery also include: cardiac disorders, visceral injury, gastrointestinal disorders, hepatobiliary disorders, cellulitis, hip fracture, incision site complication, musculoskeletal and connective tissue disorders, headache, migraine, syncope, psychiatric disorders, asthma, cholecystectomy, ileus, constipation, nausea, vomiting, chills, pyrexia, procedural pain, arthralgia, back pain, intervertebral disc protrusion, myalgia, pain in extremity, dizziness, hypoesthesia, hyporeflexia, sensory loss, insomnia, and pruritus.

Adverse events reported but not necessarily attributable to the use of Oxiplex include pain, headache, dizziness, inflammation, hematoma, wound issues, infection, neurological deterioration, and hypersensitivity reaction.

DIRECTIONS FOR USE

Oxiplex does not require refrigeration and should be stored at room temperature (2° C - 25° C / 36° F - 77° F).

This device includes:



1 – Pre-filled syringe 3mL or 1.5mL (luer lock)
1 – Applicator tip (luer lock)

Preparation

1. Remove packaging containing the pre-filled syringe and applicator from box.
2. Inspect packaging for any damage. Do not use if damaged or open. The exterior of the package is not sterile.
3. Using sterile technique, introduce syringe and applicator into sterile operating field.
4. Remove cap from luer lock end of syringe and connect the applicator to the luer lock end of the syringe; rotate until firmly attached.

Implantation

IMPORTANT: Oxiplex is to be used by physicians only. Use Oxiplex according to the instructions for use. Only up to 3 mL of Oxiplex should be used in a patient at a time.

Following the primary surgical procedure, and immediately prior to closing soft tissue incisions, use Oxiplex as follows:

1. Achieve hemostasis and repair any dural leaks.
2. Remove any hemostatic agents prior to applying Oxiplex.
3. Apply Oxiplex to the surface of adjacent tissues and nerve roots at the surgical site. Do not irrigate the site after application of Oxiplex. Surgical closure and the procedure are then concluded according to the standard technique of the surgeon.
4. Discard any opened or unused product. The used Oxiplex device may be a biohazard. Follow national, local, or institutional guidelines for disposal of biohazard material.

RESTRICTIONS

Oxiplex may only be sold, distributed, and used in accordance with the intended use. Only for professional use. The contents of this document may not be duplicated without written permission from Fziomed, Inc.

HOW SUPPLIED

Oxiplex is supplied sterile. Oxiplex is for single use only. Do not reuse. Do not re-sterilize.

MRI SAFETY INFORMATION

Oxiplex is MRI safe.

CLINICAL SUMMARY

Clinical evidence for the safety and effectiveness of Oxiplex is provided from a Confirmatory Clinical Study conducted in the United States to evaluate safety and effectiveness of Oxiplex as an adjunctive therapy during single-level discectomy at L4-L5 or L5-S1 in patients with primary leg pain of at least 60mm on a 100mm Visual Analog Scale (VAS) and back pain of at least 50mm on a 100mm VAS scale. This study was a prospective, randomized, patient-blinded, multi-center study. A 2:1 randomization was used to randomize subjects to receive either Standard of Care surgical intervention with Oxiplex or Standard of Care surgical intervention (without Oxiplex). A total of 134 subjects (87 Oxiplex, 47 control) were evaluated in Intent-to-Treat analyses that serve as the primary cohort for assessment of safety. Oxiplex subjects received an average of 2.1 mL (range 0.9 mL – 3.0 mL) of Oxiplex gel. After review by an independent Adjudication Committee, a total of 102 subjects (69 Oxiplex, 33 Control) were included in the Per Protocol cohort that served as the analysis data set for assessment of effectiveness. Follow-up visits were conducted at 6 Weeks, 3 Months, and 6 Months following the surgical procedure. The primary evaluation of effectiveness was conducted at 6 Months.

DEMOGRAPHICS

Evaluation of demographic and baseline continuous variable data for the Per Protocol cohort were balanced between the Oxiplex + Surgery and Surgery Alone control groups, except for SF-12 Physical Component Score (PCS) for which Oxiplex + Surgery had a higher mean score (p=0.023), as shown in Table 1.

Table 1: Demographics and Baseline Continuous Variable Data – Per Protocol Cohort

Demographic / Continuous Variable	Surgery + Oxiplex		Surgery Alone control		p-value[1]
	N	Mean ± SD	N	Mean ± SD	
ALL					
Age (years)	69	44.52 ± 13.41	33	47.09 ± 12.36	0.356
BMI (kg/m^2)	69	30.02 ± 5.48	33	29.52 ± 6.38	0.682
Height (inches)	69	68.33 ± 4.10	33	67.61 ± 3.87	0.399
Weight (lbs)	69	199.57 ± 41.97	33	191.64 ± 42.06	0.374
FEMALE					
Age (years)	38	43.49 ± 11.98	15	45.66 ± 13.20	0.567
BMI (kg/m^2)	38	30.03 ± 5.74	15	30.62 ± 8.23	0.769
Height (inches)	38	65.66 ± 2.57	15	64.74 ± 2.77	0.255
Weight (lbs)	38	183.75 ± 35.04	15	181.77 ± 46.65	0.867
MALE					
Age (years)	31	45.79 ± 15.09	18	48.29 ± 11.87	0.550
BMI (kg/m^2)	31	30.00 ± 5.24	18	28.59 ± 4.34	0.341
Height (inches)	31	71.60 ± 3.16	18	69.99 ± 2.93	0.085
Weight (lbs)	31	218.96 ± 42.12	18	199.86 ± 37.14	0.117
CLINICAL SCORES					
Oswestry Disability Index	69	58.13 ± 16.02	33	63.70 ± 14.26	0.092
VAS Back	69	77.91 ± 16.00	33	75.55 ± 14.99	0.477
VAS Ipsilateral Leg	69	85.13 ± 9.76	33	83.70 ± 12.48	0.528
VAS Contralateral Leg	69	8.30 ± 19.32	33	7.61 ± 18.04	0.862
Sciatica Bothersomeness Index (SBI)	69	18.64 ± 4.32	33	19.45 ± 3.29	0.339
SF12 PCS	69	30.10 ± 8.26	33	26.35 ± 6.20	0.023
SF12 MCS	69	43.50 ± 11.21	33	43.95 ± 12.60	0.854

[1]Two-sided t-test.

Evaluation of baseline categorical data for the Per Protocol cohort was balanced between the Oxiplex + Surgery and Surgery Alone control groups, as shown in Table 2.

Table 2: Demographics and Baseline Categorical Data – Per Protocol Cohort

Categorical Value	Surgery + Oxiplex N=69		Surgery Alone control N=33		p-value[1]
	N	%	N	%	
RACE					
American Indian or Alaska Native	0	0%	0	0%	>0.999
Asian	0	0%	0	0%	
Black or African American	8	12%	4	12%	
Native Hawaiian or Other Pacific Islander	0	0%	0	0%	
White	59	86%	29	88%	
Declined to specify	0	0%	0	0%	
Unknown	2	3%	0	0%	
ETHNICITY					
Hispanic or Latino	4	6%	1	3%	>0.999
Not Hispanic or Latino	65	94%	32	97%	
IPSILATERAL LEG					
Right	32	46%	14	42%	0.832
Left	37	54%	19	58%	
DURATION OF IPSILATERAL LEG PAIN					
Fewer than 6 months	28	41%	19	58%	0.292
6 months to 1 year	21	30%	8	24%	
More than 1 year	20	29%	6	18%	
Not applicable	0	0%	0	0%	
NICOTINE USE					
Current	12	17%	6	18%	0.896
Former	8	12%	5	15%	
None	49	71%	22	67%	

[1]Generalized Exact p-value.

EFFECTIVENESS SUMMARY

Evaluation of effectiveness was completed using the Per Protocol cohort, including subjects determined to meet all study inclusion/exclusion criteria aligned with the Oxiplex Indications for Use. The primary endpoint for the study was change in ipsilateral leg pain as measured by Visual Analog Scale (VAS) at the 6-month visit. The primary endpoint was not met as both Oxiplex + Surgery and Surgery Alone control groups achieved significant mean improvements in ipsilateral leg pain (-73.9 mm and -72.7 mm, respectively), but the difference between groups was not statistically significant (p=0.803).

Following the original analysis identified in the clinical study protocol, additional responder analysis was defined and conducted. A total of 5%, 11%, and 9% more Oxiplex + Surgery subjects had at least 100%, 90%, or 80% relief from ipsilateral leg pain at 6 Months, respectively, compared to Surgery Alone control subjects, as shown in Table 3.

Table 3: Ipsilateral Leg Pain High Responders at 6 Months – Per Protocol Cohort

VAS Ipsilateral Leg Pain Improvement	Surgery + Oxiplex N=68		Surgery Alone control N=32		Δ
	n	%	n	%	
100%	33	49%	14	44%	5%
Minimum 90% decrease	50	74%	20	63%	11%
Minimum 80% decrease	55	81%	23	72%	9%
Minimum 70% decrease	61	90%	29	91%	-1%
Minimum 60% decrease	63	93%	32	100%	-7%
Minimum 20% decrease	68	100%	32	100%	0%
Minimum 0% decrease	68	100%	32	100%	0%
Subjects who became worse	0	0%	0	0%	0%

VAS Ipsilateral Leg Pain was evaluated by degree of improvement, including high responder (minimum 68mm VAS improvement), moderate improvement (from 20mm to less than 68mm VAS improvement), and no improvement (less than 20mm VAS improvement). These data are shown in Table 4. An alternate presentation showing only those subjects meeting and not meeting the high responder threshold was also evaluated, as shown in Table 5, with associated pre-specified statistics following the table.

Table 4: VAS Ipsilateral Leg Pain Change by Response Threshold at 6 Months – Per Protocol Cohort

Study Group	High Responder Improvement (≤-68mm)	Moderate Improvement (-68mm < x ≤ -20mm)	No Improvement (>-20mm)	Total
Oxiplex + Surgery	51 (75.0%)	13 (19.1%)	4 (5.9%)	68
Surgery Alone	20 (62.5%)	12 (37.5%)	0 (0.0%)	32
Total	71	25	4	100

Table 5: 2x2 Table of VAS Ipsilateral Leg Pain Change by Response Threshold at 6 Months – Per Protocol Cohort

Study Group	High Responder Improvement (≤-68mm)	No Improvement (>-68mm)	Total
Oxiplex + Surgery	51 (75.0%)	17 25.0%	68
Surgery Alone	20 (62.5%)	12 37.5%	32
Total	71	29	100

Pre-specified statistics for Table 5:

- Sensitivity (SN): 0.718 [51/71] (0.614, 0.823)
- Specificity (SP): 0.414 [12/29] (0.235, 0.593)
- Positive Predictive Value (PPV): 0.750 [51/68] (0.647, 0.853)
- Negative Predictive Value (NPV): 0.414 [12/29] (0.207, 0.543)
- Risk Difference (RD): 0.125 (-0.071, 0.322)
- Odds Ratio (OR): 1.80 (0.73, 4.44)
- Chi-Squared (CS): 1.65 (p = 0.199)

More Surgery + Oxiplex subjects achieved complete or near complete improvement in their sciatica symptoms (as measured by SBI) at 6 Months, as shown in Table 6.

Table 6: Sciatica Bothersomeness Index Improvement at 6 Months – Per Protocol Cohort

Sciatica Bothersomeness Index Improvement at 6 Months	Surgery + Oxiplex N=67		Surgery Alone control N=32	
	n	%	n	%
100% decrease	20	30%	6	19%
Minimum 90% decrease	33	49%	8	25%
Minimum 80% decrease	45	67%	14	44%
Minimum 50% decrease	57	85%	26	81%
Minimum 30% decrease	60	90%	30	94%
Minimum 10% decrease	66	99%	32	100%
Minimum 0% decrease	66	99%	32	100%
Subjects who became worse	1	1%	0	0%

Effectiveness data interpretations were limited because the primary study endpoint (superiority in mean improvement of VAS Ipsilateral Leg Pain improvement over spinal surgery alone at 6 Months in the intention-to-treat data set) was not met with statistical significance. Following this, the effectiveness of Oxiplex was evaluated based on evaluation of a Per Protocol data set that was determined by an independent adjudication committee. Pain improvement data were evaluated based on observed outcomes, including post-hoc analyses with no p-values. The current clinical dataset does not specifically identify which patients will likely be high responders from using Oxiplex Gel based on their demographics and/or characteristics.

The available results indicate that the probable benefits from adjunctive use of Oxiplex during spinal surgery can include a more complete reduction in ipsilateral leg pain and reduced neurological symptoms at 6 Months.

SAFETY SUMMARY

Evaluation of safety was completed using the Intent-to-Treat cohort, including all subjects randomized in the Confirmatory Clinical Study. Safety measures evaluated included adverse events, secondary surgical interventions, and neurological status. Adverse events, secondary surgical interventions, and neurological status are summarized in Table 7, Table 8, and Table 9, respectively.

Table 7: Adverse Event Overview – Intent-to-Treat Cohort

AE Type	Surgery + Oxiplex (n=87)			Surgery Alone control (n=47)			p-value[2]
	Events	Subjs	%[1]	Events	Subjs	%[1]	
All Events	71	43	49.4%	40	24	51.1%	0.999
Cancer	1	1	1.1%	0	0	0.0%	0.999
Cardiac & Vascular	4	4	4.6%	5	4	8.5%	0.450
Dermatologic	2	2	2.3%	0	0	0.0%	0.541
Gastrointestinal	1	1	1.1%	1	1	2.1%	0.999
Genitourinary	4	4	4.6%	4	3	6.4%	0.696
Immunological	1	1	1.1%	0	0	0.0%	0.999
Infection	1	1	1.1%	1	1	2.1%	0.999
Musculoskeletal – Lumbar	1	1	1.1%	2	2	4.3%	0.281
Musculoskeletal – Non-Lumbar	3	3	3.4%	3	3	6.4%	0.423
Neurological – Lower Extremity	2	2	2.3%	4	3	6.4%	0.343
Neurological – Upper Extremity	1	1	1.1%	0	0	0.0%	0.999
Neurological – Central Nervous System	4	2	2.3%	0	0	0.0%	0.541
Pain – Spine	25	23	26.4%	12	12	25.5%	0.999
Pain – Extremity	7	6	6.9%	3	3	6.4%	0.999
Pain – Other	3	3	3.4%	3	3	6.4%	0.423
Psychosocial	1	1	1.1%	0	0	0.0%	0.999
Respiratory	2	2	2.3%	0	0	0.0%	0.541
Trauma	2	2	2.3%	0	0	0.0%	0.541
Wound Issue – Index Procedure	4	4	4.6%	2	2	4.3%	0.999
Other Primary Classification	2	2	2.3%	0	0	0.0%	0.541

[1]Percentage of subjects experiencing a specific event.

[2]Exact p-value.

Table 8: Secondary Surgical Interventions – Intent-to-Treat Cohort

Intervention Type	Surgery + Oxiplex (N=87)		Surgery Alone control (N=47)		p-value[1]
	n	%	n	%	
Reoperation	5	5.7%	2	4.3%	>0.999
Removal	0	0.0%	0	0.0%	>0.999
Supplemental Fixation	1	1.1%	2	4.3%	0.281
TOTAL	**6**	**6.9%**	**3**[**]	**6.4%**	**>0.999**
Surgery for Reherniation	4	4.6%	3	6.4%	0.670
Other Surgeries	2	2.3%	1	2.1%	>0.999

[1]Fisher's Exact Test. [**]One subject had two separate surgical interventions.

Table 9: Postoperative Neurological Status – Intent-to-Treat Cohort

Neurological status[1]	6 Months	
	Surgery + Oxiplex	Surgery Alone
Deteriorated [n (%)]	2 (2.5%)	0 (0.0%)
Not Deteriorated [n (%)]	77 (97.5%)	44 (100.0%)

[1]Neurological status as determined by the Clinical Events Committee.

The overall adverse event rate for the Surgery + Oxiplex group (49.4%) was not clinically or statistically different from the adverse event rate for the Surgery alone control group (51.1%; p=0.999, Exact). Although the incidence of device- or procedure-related adverse events was higher in the Surgery + Oxiplex group (14.9%) compared to the Surgery Alone control group (8.5%), this difference was not statistically significant (p=0.416, Exact). The study demonstrated a very low rate of device-related adverse events with zero (0) events (in 0.0% of Surgery + Oxiplex subjects) considered by the clinical events committee (CEC) to be definitely-related to the device and only two (2) events (in 2.3% of Surgery + Oxiplex subjects) considered by the CEC to be possibly-related to the device (severe hematoma and mild lumbar radiculopathy, both experienced on the day of procedure). No subject deaths or unanticipated adverse events occurred.

CONCLUSIONS FROM CLINICAL DATA

The clinical data support several adjunctive benefits from the use of Oxiplex with spinal surgery, including a more complete reduction in ipsilateral leg pain and reduced neurological symptoms. There is an increased likelihood of achieving high or complete resolution of ipsilateral leg pain at 6 Months (9% more Oxiplex subjects achieved at least 80% reduction, 11% more Oxiplex subjects achieved at least 90% reduction, 5% more Oxiplex subjects achieved 100% reduction).

Clinically meaningful improvements for Oxiplex subjects are demonstrated in total SBI score at 6 Months (4% more Oxiplex subjects achieved a minimum 9.0 point improvement in total SBI score, 23.4% more Oxiplex subjects achieved at least 80% reduction, 24.3% more Oxiplex

subjects achieved at least 90% reduction, 11% more Oxiplex subjects achieved 100% reduction).

The clinical data also support a very low incidence of Oxiplex device-related adverse events with no adverse events being definitely related to the device, and no significant differences in adverse event categories between groups. Overall, there was a similar rate of surgical interventions for both groups, a lower rate of secondary surgical interventions due to reherniation for Oxiplex subjects, and low rates of deterioration in neurological status for both groups.

MANUFACTURER

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Comments regarding the performance of this device in the USA can be directed to manufacturer above.

ORDERING INFORMATION

Item Description	Item Number
Oxiplex Absorbable Gel, 3mL	FPC-09010
Oxiplex Absorbable Gel, 1.5mL	FPC-09020

SYMBOL GLOSSARY

Symbol	Ref	Title	Symbol	Ref	Title
	5.1.1*	Manufacturer		21 CFR 801.109(b)(1)	For prescription use only
	5.1.4*	Use-by-date		5.3.7*	Temperature limit
	5.1.5*	Batch code		5.2.5*	Sterilized using steam or dry heat
	5.1.6*	Catalogue number		5.4.2*	Do not re-use
	5.2.11*	Single sterile barrier system		5.4.3*	Consult instructions for use
	5.7.7*	Medical device		6.4.4.1**	MR safe

**ISO 15223-1* ***ASTM F2503

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