PRE-MARKET APPLICATION

CFS™ FOR TREATMENT OF KNEE-LIGAMENT INJURIES

PLASTAFIL, INC.

VOLUME 1

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SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

Device Generic Name: Prosthesis, Knee Ligament, Anterior Cruciate, Carbon Fiber, Implanted with Specialized Fixation Devices

Device Trade Name: Plastafil CFS™ Carbon Fiber System

Applicant's Name and Address: Plastafil, Inc.
P.O. Box 268
Belcher, Louisiana 71004

Premarket Approval Application (PMA) Number:

Date of Panel Recommendation:

Date of Notice of Approval to Applicant:

II. Indications

The Plastafil CFS™ Carbon Fiber System (CFS™) is indicated for repair and reconstruction of the anterior cruciate ligament (ACL). If the ACL is repaired with the CFS™, the CFS™ may also be used to repair the posterior cruciate ligament, medial collateral ligament, and lateral collateral ligament, as needed. The CFS™ should be used only in patients who have not had previous surgery involving the ACL, and it should be used only in the absence of an intra-articular autologous tissue transfer.

III. Device Description

The CFS™ is a system consisting of an implant made of carbon fibers, two fixation devices used for attaching the implant to bone, a set of surgical instruments, and a specific surgical procedure for the cruciate and collateral ligaments of the knee. The implant is 48 centimeters long and 1.5 millimeters in diameter, and consists of a bundle of approximately 40,000 carbon fibers attached to a lead wire. The toggle is a rigid bar, 1 centimeter long, that accommodates one end of the carbon-fiber bundle, thereby permitting its attachment to bone. The bollard is an expanding rivet used for attaching carbon fibers to bone. The toggle and bollard are made of carbon-fiber-reinforced polysulfone. The implant and fixation devices are supplied sterile.

IV. Alternative Practices or Procedures

ACL insufficiency may be treated using conservative methods, or surgical procedures involving autogenous extra- or intra-articular reconstruction.

V. Potential Adverse Effects on Health of the Device

Presence of foreign particles in the knee joint has been observed. Adverse effects that have been observed are (1) failure of the implant or recurrent instability of the joint; (2) soft-tissue irritation associated with the fixation devices. Should a serious complication result, it may be necessary to perform a second operation to remove the device.

VI. Contraindications, Warnings, and Precautions

Contraindications:

The CFS™ is contraindicated in patients that have an incomplete closure of the tibial epiphyseal plate. The CFS™ is also contraindicated in patients who have an infection of the involved knee or who have had previous surgery involving the ACL in the involved knee.

Warnings:

The CFS™ is not designed, sold, or intended for use except as indicated. All other uses are investigational.

The CFS™ is not to be used for augmentation. It is to be used only as a total prosthesis; the efficacy of the CFS™ is dependent upon fibrous ingrowth into the implant. The portion of the implant within the joint capsule must be covered with synovial tissue.

Specialized instrumentation constitutes part of the CFS™, and failure to employ the instrumentation in the manner intended constitutes an experimental use of the CFS™.

Specialized fixation devices constitute part of the CFS™, and a failure to employ the fixation devices in the manner intended constitutes an experimental use of the CFS™.

A specific surgical procedure for the cruciate and collateral ligaments of the knee constitute part of the CFS™, and a failure to employ the specific surgical procedures described constitutes an experimental use of the CFS™. Further details are provided in the package insert (Attachment).

Precautions:

Only qualified surgeons who have received proper instruction may use the CFS™.

VII. History of Marketing

The complete CFS™ has not been marketed. Parts of the CFS™,

including the implant, fixation devices, and surgical instruments, and their prototypes, have been marketed in South Africa, England, France, Israel, and Australia, since 1980. No complications regarding parts of the CFS™ have been described in the literature or reported to Plastafil.

VIII. Summary of Preclinical Studies

A. Summary of In Vitro Studies

A limulus amebocyte lysate pyrogenicity test was performed to assess the fever-inducing potential of the CFS™. A sterile implant and fixation devices were immersed in 40 ml pyrogen-free water in a 125-ml pyrogen-free erlenmeyer flask. The flask was heated for 5 minutes in a boiling water bath with intermittent mixing. The extract was cooled to room temperature and tested. Less than 0.01 ng/ml endotoxin was found. The extract did not contain substances inhibitory to the LAL test.

The propensity of carbon fibers to support colonization by Staphylococcus epidermidis was compared to that of polyvinyl chloride (standard endotracheal tubes). Both materials were incubated in saturated bacterial cultures, and examined after 1-12 days of incubation. Throughout the time of observation, the carbon fibers were significantly more resistant to colonization and glycocalyx formation by S. epidermidis than was polyvinyl chloride.

B. Summary of Mechanical Testing

The bollard and toggle were loaded to failure in a manner that simulated the ordinary clinical use. The devices failed at average ultimate loads of 1495 newtons and 1154 newtons, respectively. The CFS™ failed at an average ultimate load of 307 newtons.

C. Summary of Animal Studies

Carbon fibers, 8 micrometers in diameter, were implanted in mice either adjacent to sciatic nerve, in axillary fat, or in quadriceps muscle. The tissue reactions to both intact fibers and fiber debris were studied at 1 and 5 weeks postoperatively. The implants elicited a thin encapsulating granulation tissue and a mild giant-cell reaction. Orientation of fibroblasts and new fibrous tissue occurred along the axis of the intact carbon fibers, out to a lateral distance of about 5 cell thicknesses. No histomorphological changes attributable to the carbon were seen in any of the host tissues studied. Transport of carbon particles to the lymph nodes was not observed.

The gastrocnemius and plantaris tendons of rabbits were removed and replaced with carbon fibers or nylon. The rabbits were sacrificed at various post-operative times up to 3 years, and the tissue associated with the implants was studied histologically. The regional lymph nodes were examined for the presence of carbon-fiber debris. Injury-induced fibrosis occurred in the carbon-fiber and nylon reconstructed rabbits; it did not differ between the groups in histological character or amount. Foreign-body fibrosis also occurred in both groups; it was histologically indistinguishable between the groups, but it differed markedly in amount -- significantly more foreign-body induced tissue occurred in the carbon-fiber implanted rabbits. In both groups, observations made after 1 year of implantation regarding histological character and amount of tissue were identical with those made 2 and 3 years after implantation. Transport of carbon particles to the iliac, inguinal, or popliteal nodes was not observed.

The anterior (cranial) cruciate ligament in goats was removed and replaced with carbon fibers; the implantation procedures and methods of fixation were similar to those used in patients. The carbon fibers were covered in the joint with either fascia lata or fat pad. The operated limb was not immobilized. The goats were sacrificed at 1.5, 3, and 18 months post-operatively, and the recovered tissues were examined grossly, and subjected to biomechanical and histological study. The implant broke near the bollard during the immediate post-operative period, but remained in place in the joint. Gross examination of each joint revealed no carbon-related changes in the articular cartilage, and no carbon-fiber debris in the local lymph nodes. The ultimate tensile load sustained by the implant at 18 months was (on average) 519 newtons; this value was significantly greater than the ultimate tensile load sustained at 1.5 or 3 months post-operatively. Progressive ingrowth of connective tissue into the intra-articular implant was observed, culminating in an induced ligament at 18 months having (on average) a diameter of about 5 mm.

Carbon fibers were implanted for up to 12 months in abdominal-wall defects in rats, and the tissue ingrowth was compared with that which occurred in polypropylene mesh. Carbon fibers induced significantly more tissue ingrowth than polypropylene mesh at 6-12 months post-operatively. The predominant tissue associated with carbon fibers and polypropylene mesh were dense connective tissue and fat, respectively. Fragmentation of the implants did not occur, and implant debris was not found in the regional lymph nodes.

The use of carbon fibers for treating bowed tendon (a common and debilitating form of tendinitis) was studied in Thoroughbred racehorses that had failed standard therapy, or were acutely injured. In the latter study, a historical control

group was used to evaluate the carbon-fiber treatment. Ability to return to the racetrack was the endpoint. Sixty-five percent of the horses that had suffered a single tendon injury and failed conventional therapy returned to the racetrack following treatment with carbon fibers. Among horses that suffered injuries to 2-3 tendons and failed conventional therapy, 45% of the horses returned to the racetrack after treatment. Among acutely-treated horses, 74% of the horses treated with carbon fibers returned to the racetrack, compared with 23% of the horses that were treated conventionally. Each of the differences was statistically significant.

D. Conclusion

Carbon fibers induced connective tissue both extra- and intra-articularly; the induced tissue could confer mechanical strength. Carbon fibers produced a clinical benefit in Thoroughbred racehorses. Carbon-fiber debris could not be detected in lymph nodes in mice, rats, rabbits, goats, or horses.

IX. Summary of Clinical Studies

A. Introduction

We conducted a randomized, prospective, controlled study. A total of 134 patients with injuries involving the anterior cruciate ligament (ACL) were entered, and randomized to either the carbon-fiber or control group. An additional group of 10 patients that were not randomized also received carbon fibers. Our rationale was that the tissue induced inside the carbon-fiber bundle would add mechanical strength at the anatomic location of the ACL. Thus, the carbon-fiber patients received carbon fibers but no intra-articular autologous tissue transfer, and the control patients received standard therapy (mostly, a patellar-tendon reconstruction).

The surgical procedure for implanting carbon fibers at the anatomic location of the ACL was standardized, and surgeons at each of the three Study Centers performed the same reconstruction. Surgical instruments required for handling the carbon fibers were designed and built, and were used by each study investigator. Specialized fixation devices required for attachment of carbon fibers to bone were designed, and incorporated in all carbon-fiber cases treated in the study. The follow-up instrument consisted of a standardized form that was completed at each follow-up visit. Predetermined weights were assigned to pertinent clinical observations regarding function, deformity, symptoms, laxity, and subjective evaluation. The statistical hypothesis involved comparison of total points achieved by patients in both groups at various post-operative times, using parametric statistics. Additionally, we considered various hypotheses involving the effect of type of treatment on distributions of patients

among classes of clinical parameters.

B. Study Methods

Patients that had a surgically significant injury to the ACL but not the posterior cruciate ligament (PCL) were randomized into carbon-fiber or control groups according to a plan intended to produce approximately 60% carbon-fiber patients and 40% control patients. Ten additional patients with injuries to both cruciate ligaments were treated with carbon fibers, but not randomized. In the randomized study, 31 patients were treated acutely with carbon fibers (surgery performed within 14 days of injury), and 43 patients were treated for chronic injuries. In the control group, 24 and 36 patients, respectively, were treated using standard therapy (mostly, patellar tendon transfer). In the non-randomized study, 7 patients were treated acutely with carbon fibers, and 3 patients were treated for chronic injuries.

In the carbon-fiber patients in the randomized study, the ACL was reconstructed using CFS™. If surgical treatment of the collateral ligaments or the PCL was needed, it was also performed using CFS™. This resulted in use of the CFS™ for repair of the collateral ligaments in 4 patients among the 43 chronic cases, and 12 patients among the 31 acute cases. In the non-randomized study, CFS™ was used to repair all injured ligaments in each of the 10 patients.

The plan in the Investigational Device Exemption required each patient to be examined at 3, 6, 9 and 12 months postoperatively; an overall evaluation of safety and efficacy was planned at 1 year postoperatively. The circumstances of the study, however, required a change in both the frequency and duration of the follow-up. It was not convenient for a significant majority of the patients in the study to be seen at follow-up 4 times in the year following surgery. The duration of the study was extended to 5 years postoperatively, and the procedure followed for obtaining follow-up was this. Each year following surgery, each patient was contacted and requested to appear for follow-up examination. If the patient refused (or if the examining physician could not see the patient at a time of the patient's choosing), the patient was not seen during the 12-month period. The process was repeated during the subsequent 12-month period, and if the patient had not been seen during the previous 12-month period, special efforts were made to encourage the patient to appear for follow-up examination. These efforts included repeated telephone calls, personal visits to the patient's home or place of employment, and offers to reimburse the patient. The effect of this procedure was to produce for follow-up examination a random sampling of the study patients. This procedure was carried out for 5 years. Of the 134 patients in the randomized study, and the 10 patients in the non-randomized study, we were unable to obtain follow-up beyond 24 months in 7 patients. One patient was killed in an automobile accident; the remaining 6 patients (2 carbon-fiber and 4

control patients) have consistently refused to consent to follow-up examination.

A standard follow-up form was used to record pertinent clinical indications for each patient at each follow-up visit. Points were assigned to the various classes for each clinical indication, and the points were combined according to a predetermined formula.

C. Results

The overall results of the randomized study are listed in Table 1. In the chronic category, 4 patients were treatment failures in each group; consequently, 39 and 32 patients were available for follow-up examination in the carbon-fiber and control groups, respectively. During the first postoperative year, we obtained one (or more) follow-ups on 89.7% of the carbon-fiber patients and 87.5% of the control patients in the chronic category. The average Scores in the two groups were essentially identical (Table 1, 65.6 and 64.8 for the carbon-fiber and control groups, respectively). During the second postoperative year, the follow-up in the chronic category consisted of 20 patients in the carbon-fiber group and 19 patients in the control group. Several of the patients in each group had not been followed during the first postoperative year; consequently, the cumulative percentage of patients seen at follow-up rose to 94.9% and 96.9% in the carbon-fiber and control groups, respectively. The pattern for reporting data has been followed consistently throughout Table 1. For example, in the chronic category during 4-5 years postoperatively, follow-up examination was obtained on 27 (of 39) carbon-fiber patients and 17 (of 32) control patients; the cumulative percentage of patients followed was 100% in each group.

Comparable data for patients in the acute category is presented in Table 1B; Table 1C contains the combined data from Tables 1A and B.

Table 2 contains the overall results from the 10 patients in the non-randomized study (3 chronic and 7 acute patients).

We found that for the chronic cases, the acute cases, the acute plus chronic cases (with and without inclusion of the 10 non-randomized patients), patients treated with carbon fibers fared as well as patients treated with control procedures, regardless of postoperative time.

The effect of carbon-fiber and control treatment on patient classification regarding specific clinical items is shown in Tables 3-38 for the randomized study and Tables 39-50 for the 10 patients in the non-randomized study. Carbon fibers produced the same results as control treatment in chronic patients, acute patients, and chronic plus acute patients,

with regard to the following items:

- Anterior drawer (30°)
- Anterior drawer (90°)
- Pivot shift
- Posterior drawer (90°)
- Giving way (normal activities)
- Giving way (sports activities)
- Pain (normal activities)
- Pain (sports activities)
- Swelling (normal activities)
- Swelling (sports activities)
- Performance (sports)
- Performance (normal activities)

Except as noted in the Tables, the respective pre-operative distributions were not different, both forms of treatment were associated with a beneficial effect, and at each post-operative time interval, the distributions were not different.

During their participation in the study, 8 patients required further surgery because of the failure of the initial surgery to control instability. Four were carbon-fiber patients, and 4 were control patients; all were in the chronic group. A fixation device was removed in two patients because of an irritation in the soft tissue, or infection. Implant infection did not occur.

D. Conclusion

The data shows that the CFS™ is safe and effective for the treatment of ACL instability in patients who have not undergone previous surgical treatment. The CFS™ is as good as standard intra-articular reconstructions using autologous tissue in patients having either acute or chronic injuries.

TABLE 1. Total Scores and Standard Deviations Observed in the Chronic, Acute, and Chronic + Acute Categories (highest score, 100). The numbers in parentheses are patients followed in the indicated time interval. Each group was sampled annually: the cumulative percentage of patients who were followed is shown for each group.

A. Chronic

	TIME (Years)					
	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	50.0 ± 15.4 (39[a])[d]	65.6 ± 15.2 (35)	78.0 ± 14.4 (20)	80.1 ± 12.3 (24[a])	72.9 ± 15.2 (17[a])	73.8 ± 15.1 (27[b])
		89.7%	94.9%	100%	100%	100%
CONTROL	49.4 ± 13.2 (32[b])[d]	64.8 ± 13.0 (29[a])	80.1 ± 10.9 (19[c])	84.2 ± 10.4 (14)	83.4*± 12.4 (17)	77.8 ± 14.6 (17[b])
		87.5%	96.9%	96.9%	100%	100%

[a] The Total Score was incomplete for one patient.
[b] The Total Score was incomplete for four patients.
[c] The Total Score was incomplete for two patients.
[d] Four patients were treatment failures; their Scores are not included.
* P = 0.04

B. Acute

	TIME (Years)					
	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	32.4 ± 10.4 (31[a])	71.6 ± 16.5 (26)	85.0 ± 9.6 (12)	87.2 ± 8.9 (17)	88.1 ± 8.1 (21[b])	84.5 ± 10.2 (11[b])
		83.9%	100%	100%	100%	100%
CONTROL	33.6 ± 9.0 (24[c])	72.5 ± 14.2 (18)	84.5 ± 5.4 (14[d])	80.7 ± 12.2 (12[d])	83.2 ± 9.9 (12[d])	78.2 ± 11.8 (9[b])
		75%	87.5%	95.8%	95.8%	100%

[a] The Total Score was incomplete for three patients.
[b] The Total Score was incomplete for two patients.
[c] The Total Score was incomplete for five patients.
[d] The Total Score was incomplete for one patient.

Table 1 (continued)

C. Chronic + Acute

	TIME (Years)					
	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	42.6 ± 16.0 (70[a])	68.2 ± 16.0 (61)	80.5 ± 13.2 (32)	83.0 ± 11.5 (41[c])	81.2 ± 14.0 (38[d])	76.8 ± 14.6 (38[e])
		87.1%	97.1%	100%	100%	100%
CONTROL	43.0 ± 14.0 (56[b])	67.8 ± 13.9 (47[c])	81.9 ± 9.3 (33[d])	82.6 ± 11.1 (26[c])	83.3 ± 11.3 (29[c])	77.9 ± 13.3 (26[e])
		82.1%	92.8%	96.4%	98.2%	100%

[a] The Total Score was incomplete for four patients.
[b] The Total Score was incomplete for nine patients.
[c] The Total Score was incomplete for one patient.
[d] The Total Score was incomplete for three patients.
[e] The Total Score was incomplete for six patients.

TABLE 2. Total Scores and Standard Deviations Observed in the Chronic, Acute, and Chronic + Acute Categories of the Non-Randomized Group (highest score, 100). The numbers in parentheses are patients followed in the indicated time interval. Each group was sampled annually: the cumulative percentage of patients who were followed is shown for each group.

A. Chronic

	TIME (Years)					
	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	46.8 ± 2.7 (2)	64.6 ± 1.3 (1)	61.5 ± 16.8 (2)	--- (1)[a]	62.9 ± 5.4 (2)	63.6 ± 16.4 (1)
		50.0%	100%	100%	100%	100%

[a] The Total Score was incomplete for one patient.

B. Acute

	TIME (Years)					
	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	11.0 ± 8.1 (7)[a]	71.6 ± 9.6 (5)[a]	71.9 ± 15.5 (6)	64.8 ± 15.2 (4)[a]	71.8 ± 14.8 (5)	--- (0)
		71.4%	100%	100%	100%	100%

[a] The Total Score was incomplete for one patient.

C. Chronic + Acute

	TIME (Years)					
	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	19.9 ± 18.0 (9)[a]	70.3 ± 9.0 (6)[a]	69.8 ± 15.4 (8)	64.8 ± 15.2 (5)[b]	69.2 ± 13.0 (7)	63.6 ± 16.4 (1)
		66.7%	100%	100%	100%	100%

[a] The Total Score was incomplete for one patient.
[b] The Total Score was incomplete for two patients.

TABLE 3. Anterior Drawer - 30°. Chronic patients. FDA designation, App. 6, Item 1. IDE designation, ST-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	22 /22.9%	9 /37.5%	9 /36.0%	2 /11.1%	6 /22.2%
	CLASS 2	14 /32.6%	56 /58.3%	10 /41.7%	8 /32.0%	14 /77.8%	14 /51.8%
	CLASS 3	23 /53.5%	18 /18.8%	3 /12.5%	7 /28.0%	2 /11.1%	2 /7.4%
	CLASS 4	6 /14.0%	0	2 /8.3%	1 /4.0%	0	5 /18.5%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /5.6%	35 /41.7%	10 /40.0%	9 /60.0%	5 /29.4%	4 /22.2%
	CLASS 2	13 /36.1%	36 /42.8%	13 /52.0%	2 /13.3%	12 /70.6%	11 /61.1%
	CLASS 3	17 /47.2%	13 /15.5%	1 /4.0%	3 /20.0%	0	2 /11.1%
	CLASS 4	4 /11.1%	0	1 /4.0%	1 /6.7%	0	1 /5.6%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 4. Anterior Drawer - 30°. Acute patients. FDA designation, App. 6, Item 1. IDE designation, ST-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	27 /39.7%	5 /38.5%	5 /29.4%	7 /33.3%	4 /36.4%
	CLASS 2	11 /35.5%	32 /47.0%	8 /61.5%	11 /64.7%	13 /61.9%	4 /36.4%
	CLASS 3	16 /51.6%	9 /13.2%	0	1 /5.9%	1 /4.8%	3 /27.3%
	CLASS 4	4 /12.9%	0	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /8.3%	24 /51.1%	5 /31.2%	3 /25.0%	7 /58.3%	3 /33.3%
	CLASS 2	14 /58.3%	17 /36.2%	9 /56.2%	6 /50.0%	2 /16.7%	2 /22.2%
	CLASS 3	8 /33.3%	6 /12.8%	2 /12.5%	3 /25.0%	2 /16.7%	3 /33.3%
	CLASS 4	0	0	0	0	1 /8.3%	1 /11.1%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were different. In the carbon-fiber group, 36% of the patients had an anterior drawer of less than 5 mm. In the control group, 67% of the patients had an anterior drawer of less than 5 mm ($P < 0.05$).
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 5. Anterior Drawer - 30°. Chronic + acute patients. FDA designation, App. 6, Item 1. IDE designation, ST-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	49 /29.9%	14 /37.8%	14 /33.3%	9 /23.1%	10 /26.3%
	CLASS 2	25 /33.8%	88 /53.6%	18 /48.6%	19 /45.2%	27 /69.2%	18 /47.4%
	CLASS 3	39 /52.7%	27 /16.5%	3 /8.1%	8 /19.0%	3 /7.7%	5 /13.2%
	CLASS 4	10 /13.5%	0	2 /5.4%	1 /2.4%	0	5 /13.2%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	4 /6.7%	59 /45.0%	15 /36.6%	12 /44.4%	12 /41.4%	7 /25.9%
	CLASS 2	27 /45.0%	53 /40.4%	22 /53.6%	8 /29.6%	14 /48.3%	13 /48.1%
	CLASS 3	25 /41.7%	19 /14.5%	3 /7.3%	6 /22.2%	2 /6.9%	5 /18.5%
	CLASS 4	4 /6.7%	0	1 /2.4%	1 /3.7%	1 /3.4%	2 /7.4%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different ($P < 0.056$).
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 6. Anterior Drawer - 9 °. Chronic patients. FDA designation, App. 6, Item 2. IDE designation, ST-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /2.3%	31 /32.3%	10 /41.7%	9 /36.0%	4 /22.2%	8 /28.6%
	CLASS 2	15 /34.9%	49 /51.0%	9 /37.5%	12 /48.0%	11 /61.1%	15 /53.6%
	CLASS 3	21 /48.8%	16 /16.7%	3 /12.5%	3 /12.0%	3 /16.7%	3 /10.7%
	CLASS 4	6 /14.0%	0	2 /8.3%	1 /4.0%	0	2 /7.1%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /5.7%	34 /40.5%	9 /36.0%	6 /40.0%	9 /52.9%	5 /27.8%
	CLASS 2	10 /28.6%	32 /38.1%	13 /52.0%	6 /40.0%	7 /41.2%	9 /50.0%
	CLASS 3	20 /57.1%	18 /21.4%	3 /12.0%	3 /20.0%	1 /5.9%	3 /16.7%
	CLASS 4	3 /8.6%	0	0	0	0	1 /5.5%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 7. Anterior Drawer - 90°. Acute patients. FDA designation, App. 6, Item 2. IDE designation, ST-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	5 /16.1%	28 /41.2%	3 /23.1%	6 /35.3%	7 /33.3%	3 /27.3%
	CLASS 2	9 /29.0%	29 /42.6%	8 /61.5%	10 /58.8%	11 /52.4%	4 /36.4%
	CLASS 3	15 /48.4%	11 /16.2%	1 /7.7%	1 /5.9%	3 /14.3%	4 /36.4%
	CLASS 4	2 /6.4%	0	1 /7.7%	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	8 /33.3%	22 /46.8%	6 /37.5%	3 /25.0%	7 /58.3%	2 /22.2%
	CLASS 2	9 /37.5%	21 /44.7%	8 /50.0%	9 /75.0%	3 /25.0%	3 /33.3%
	CLASS 3	7 /29.2%	4 /8.5%	2 /12.5%	0	1 /8.3%	3 /33.3%
	CLASS 4	0	0	0	0	1 /8.3%	1 /11.1%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 8. Anterior Drawer - 90°. Chronic + acute patients. FDA designation, App. 6, Item 2. IDE designation, ST-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	6 /8.1%	59 /36.0%	13 /35.1%	15 /35.7%	11 /28.2%	11 /28.2%
	CLASS 2	24 /32.4%	78 /47.6%	17 /45.9%	22 /52.4%	22 /56.4%	19 /48.7%
	CLASS 3	36 /48.6%	27 /16.5%	4 /10.8%	4 /9.5%	6 /15.4%	7 /17.9%
	CLASS 4	8 /10.8%	0	3 /8.1%	1 /2.4%	0	2 /5.1%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	10 /16.9%	56 /42.7%	15 /36.6%	9 /33.3%	16 /55.2%	7 /25.9%
	CLASS 2	19 /32.2%	53 /40.4%	21 /51.2%	15 /55.6%	10 /34.5%	12 /44.4%
	CLASS 3	27 /45.8%	22 /16.8%	5 /12.2%	3 /11.1%	2 /6.9%	6 /22.2%
	CLASS 4	3 /5.1%	0	0	0	1 /3.4%	2 /7.4%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 9. Pivot Shift. Chronic patients. FDA designation, App. 6, Item 3. IDE designation, ST-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years post-operatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	3 /7.0%	55 /57.3%	13 /54.2%	16 /64.0%	9 /50.0%	14 /50.0%
	CLASS 2	11 /25.6%	21 /21.9%	7 /29.2%	5 /20.0%	5 /27.8%	7 /25.0%
	CLASS 3	19 /44.2%	14 /14.6%	2 /8.3%	3 /12.0%	4 /22.2%	5 /17.9%
	CLASS 4	10 /23.2%	6 /6.2%	2 /8.3%	1 /4.0%	0	2 /7.1%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	1 /3.1%	63 /76.8%	15 /60.0%	8 /53.3%	15 /88.2%	10 /58.8%
	CLASS 2	7 /21.9%	14 /17.1%	9 /36.0%	5 /33.3%	2 /11.8%	6 /35.3%
	CLASS 3	20 /62.5%	5 /6.1%	1 /4.0%	2 /13.3%	0	1 /5.9%
	CLASS 4	4 /12.5%	0	0	0	0	0

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different, except at 3-4 years post-operatively.

TABLE 10. Pivot Shift. Acute patients. FDA designation, App. 6, Item 3. IDE designation, ST-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years post-operatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	5 /16.1%	49 /74.2%	9 /69.2%	12 /70.6%	16 /76.2%	6 /54.5%
	CLASS 2	2 /6.4%	12 /18.2%	4 /30.8%	4 /23.5%	4 /19.0%	4 /36.4%
	CLASS 3	17 /54.8%	3 /4.5%	0	1 /5.9%	1 /4.8%	1 /9.1%
	CLASS 4	7 /22.6%	2 /3.0%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	8 /33.3%	38 /80.8%	11 /68.8%	9 /81.8%	8 /66.7%	7 /77.8%
	CLASS 2	5 /20.8%	7 /14.9%	4 /25.0%	2 /18.2%	4 /33.3%	2 /22.2%
	CLASS 3	9 /37.5%	2 /4.2%	1 /6.2%	0	0	0
	CLASS 4	2 /8.3%	0	0	0	0	0

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 11. Pivot Shift. Chronic + acute patients. FDA designation, App. 6, Item 3. IDE designation, ST-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	8 /10.8%	104/ 64.2%	22 /59.4%	28 /66.7%	25 /64.1%	20 /51.3%
	CLASS 2	13 /17.6%	33 /20.4%	11 /29.7%	9 /21.4%	9 /23.1%	11 /28.2%
	CLASS 3	36 /48.6%	17 /10.5%	2 /5.4%	4 /9.5%	5 /12.8%	6 /15.4%
	CLASS 4	17 /23.0%	8 /4.9%	2 /5.4%	1 /2.4%	0	2 /5.1%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	9 /16.1%	101 /78.3%	26 /63.4%	17 /65.4%	23 /79.3%	17 /65.4%
	CLASS 2	12 /21.4%	21 /16.3%	13 /31.7%	7 /26.9%	6 /20.7%	8 /30.8%
	CLASS 3	29 /51.8%	7 /5.4%	2 /4.9%	2 /7.7%	0	1 /3.8%
	CLASS 4	6 /10.7%	0	0	0	0	0

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 12. Posterior Drawer - 90°. Chronic patients. FDA designation, App. 6, Item 8. IDE designation, ST-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	40 /93.0%	90 /93.8%	22 /91.7%	23 /92.0%	16 /88.9%	25 /92.6%
	CLASS 2	2 /4.6%	2 /2.1%	1 /4.2%	0	2 /11.1%	2 /7.4%
	CLASS 3	0	1 /1.0%	0	1 /4.0%	0	0
	CLASS 4	1 /2.3%	3 /3.1%	1 /4.2%	1 /4.0%	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	28 /80.0%	80 /95.2%	19 /76.0%	14 /93.3%	12 /70.6%	17 /94.4%
	CLASS 2	4 /11.4%	3 /3.6%	4 /16.0%	1 /6.7%	4 /23.5%	1 /5.6%
	CLASS 3	2 /5.7%	0	1 /4.0%	0	0	0
	CLASS 4	1 /2.8%	1 /1.2%	1 /4.0%	0	1 /5.9%	0

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was not associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 13. Posterior Drawer - 90°. Acute patients. FDA designation, App. 6, Item 8. IDE designation, ST-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	30 /96.8%	66 /97.0%	11 /84.6%	16 /94.1%	20 /95.2%	11 /100.0%
	CLASS 2	0	2 /2.9%	1 /7.7%	0	1 /4.8%	0
	CLASS 3	0	0	0	1 /5.9%	0	0
	CLASS 4	1 /3.2%	0	1 /7.7%	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	19 /79.2%	45 /95.7%	14 /87.5%	12 /100.0%	12 /100.0%	8 /88.9%
	CLASS 2	3 /12.5%	1 /2.1%	2 /12.5%	0	0	0
	CLASS 3	1 /4.2%	1 /2.1%	0	0	0	0
	CLASS 4	1 /4.2%	0	0	0	0	1 /11.1%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was not associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 14. Posterior Drawer - 90°. Chronic + acute patients. FDA designation, App. 6, Item 8. IDE designation, ST-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	70 /94.6%	156/95.1%	33 /89.2%	39 /92.8%	36 /92.3%	36 /94.7%
	CLASS 2	2 /2.7%	4 /2.4%	2 /5.4%	0	3 /7.7%	2 /5.3%
	CLASS 3	0	1 /0.6%	0	2 /4.8%	0	0
	CLASS 4	2 /2.7%	3 /1.8%	2 /5.4%	1 /2.4%	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	47 /79.7%	125/95.4%	33 /80.5%	26 /96.3%	24 /82.8%	25 /92.6%
	CLASS 2	7 /11.9%	4 /3.0%	6 /14.6%	1 /3.7%	4 /13.8%	1 /3.7%
	CLASS 3	3 /5.1%	1 /0.8%	1 /2.4%	0	0	0
	CLASS 4	2 /3.4%	1 /0.8%	1 /2.4%	0	1 /3.4%	1 /3.7%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was not associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 15. Giving way (normal activities). Chronic patients. FDA designation, App. 5, Item 4. IDE designation, S-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	12 /30.8%	65 /79.3%	17 /73.9%	22 /88.0%	10 /58.8%	17 /63.0%
	CLASS 2	14 /35.9%	14 /17.1%	5 /21.7%	3 /12.0%	7 /41.2%	8 /29.6%
	CLASS 3	13 /33.3%	3 /3.6%	1 /4.3%	0	0	2 /7.4%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	9 /28.1%	59 /85.5%	18 /75.0%	10 /71.4%	13 /76.5%	13 /76.5%
	CLASS 2	11 /34.4%	8 /11.6%	6 /25.0%	4 /28.6%	4 /23.5%	4 /23.5%
	CLASS 3	12 /37.5%	2 /2.9%	0	0	0	0

Class 1: None
Class 2: Occasional
Class 3: Chronic

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 16. Giving way (normal activities). Acute patients. FDA designation, App. 5, Item 4. IDE designation, S-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	3 /10.3%	57 /90.5%	13 /100.0%	15 /88.2%	19 /95.0%	8 /72.7%
	CLASS 2	2 /6.9%	3 /4.8%	0	2 /11.8%	1 /5.0%	3 /27.3%
	CLASS 3	24 /82.8%	3 /4.8%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /9.5%	37 /84.1%	15 /93.8%	8 /66.7%	7 /58.3%	5 /55.6%
	CLASS 2	3 /14.3%	7 /15.9%	1 /6.2%	4 /33.3%	5 /41.7%	4 /44.4%
	CLASS 3	16 /76.2%	0	0	0	0	0

Class 1: None
Class 2: Occasional
Class 3: Chronic

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different except at 3-4 years post-operatively.

TABLE 17. Giving way (normal activities). Chronic + acute patients. FDA designation, App. 5, Item 4. IDE designation, S-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	15 /22.1%	122/84.1%	30 /83.3%	37 /88.1%	29 /78.4%	25 /65.8%
	CLASS 2	16 /23.5%	17 /11.7%	5 /13.9%	5 /11.9%	8 /21.6%	11 /28.9%
	CLASS 3	37 /54.4%	6 /4.1%	1 /2.8%	0	0	2 /5.3%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	11 /20.8%	96 /85.0%	33 /82.5%	18 /69.2%	20 /69.0%	18 /69.2%
	CLASS 2	14 /26.4%	15 /13.3%	7 /17.5%	8 /30.8%	9 /31.0%	8 /30.8%
	CLASS 3	28 /52.8%	2 /1.8%	0	0	0	0

Class 1: None
Class 2: Occasional
Class 3: Chronic

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 18. Giving way (sports activities). Chronic patients. FDA designation, App. 5, Item 4. IDE designation, S-6. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	25 /86.2%	14 /73.7%	17 /70.8%	4 /28.6%	12 /50.0%
	CLASS 2	11 /31.4%	3 /10.3%	5 /26.3%	7 /29.2%	9 /64.3%	10 /41.7%
	CLASS 3	24 /68.6%	1 /3.4%	0	0	1 /7.1%	2 /8.3%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	1 /4.2%	18 /75.0%	15 /75.0%	9 /64.3%	12 /75.0%	12 /75.0%
	CLASS 2	4 /16.7%	2 /8.3%	5 /25.0%	3 /21.4%	4 /25.0%	3 /18.8%
	CLASS 3	19 /79.2%	4 /16.7%	0	2 /14.3%	0	1 /6.2%

Class 1: None
Class 2: Occasional
Class 3: Chronic

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval the distributions were not different except at 3-4 years post-operatively.

TABLE 19. Giving way (sports activities). Acute patients. FDA designation, App. 5, Item 4. IDE designation, S-6. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	> 4
CARBON FIBER	CLASS 1	1 /3.6%	25 /78.1%	11 /100.0%	13 /76.5%	18 /90.0%	6 /60.0%
	CLASS 2	2 /7.1%	4 /12.5%	0	3 /17.6%	2 /10.0%	4 /40.0%
	CLASS 3	25 /89.3%	3 /9.4%	0	1 /5.9%	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	> 4
CONTROL	CLASS 1	0	12 /54.5%	11 /78.6%	7 /63.6%	6 /50.0%	5 /55.6%
	CLASS 2	1 /5.9%	7 /31.8%	3 /21.4%	2 /18.2%	6 /50.0%	4 /44.4%
	CLASS 3	16 /94.1%	3 /13.6%	0	2 /18.2%	0	0

Class 1: None
Class 2: Occasional
Class 3: Chronic

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval the distributions were not different.

TABLE 20. Giving way (sports activities). Chronic + acute patients. FDA designation, App. 5, Item 4. IDE designation, S-6. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /1.6%	50 /82.0%	25 /83.3%	30 /73.2%	22 /64.7%	18 /52.9%
	CLASS 2	13 /20.6%	7 /11.5%	5 /16.7%	10 /24.4%	11 /32.4%	14 /41.2%
	CLASS 3	49 /77.8%	4 /6.6%	0	1 /2.4%	1 /2.9%	2 /5.9%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	1 /2.4%	30 /65.2%	26 /76.5%	16 /64.0%	18 /64.3%	17 /68.0%
	CLASS 2	5 /12.2%	9 /19.6%	8 /23.5%	5 /20.0%	10 /35.7%	7 /28.0%
	CLASS 3	35 /85.4%	7 /15.2%	0	4 /16.0%	0	1 /4.0%

Class 1: None
Class 2: Occasional
Class 3: Chronic

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 21. Pain (normal activities). Chronic patients. FDA designation, App. 5, Item 1. IDE designation, S-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	18 / 46%	74 / 87%	20 / 87%	25 / 100%	12 / 71%	23 / 85%
	CLASS 2	9 / 23%	4 / 5%	2 / 9%	0	2 / 12%	4 / 15%
	CLASS 3	12 / 31%	7 / 8%	1 / 4%	0	3 / 18%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	16 / 50%	61 / 87%	22 / 92%	14 / 100%	16 / 94%	16 / 94%
	CLASS 2	9 / 28%	6 / 9%	1 / 4%	0	1 / 6%	1 / 6%
	CLASS 3	7 / 22%	3 / 4%	1 / 4%	0	0	0

CLASS 1: No pain or mild occasional pain
CLASS 2: Mild chronic pain
CLASS 3: Severe pain

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 22. Pain (normal activities). Acute patients. FDA designation, App. 5, Item 1. IDE designation, S-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	5 / 17%	60 / 94%	13 / 100%	17 / 100%	19 / 95%	11 / 100%
	CLASS 2	0	2 / 3%	0	0	1 / 5%	0
	CLASS 3	25 / 83%	2 / 3%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	3 / 14%	43 / 98%	14 / 88%	7 / 58%	12 / 100%	9 / 100%
	CLASS 2	0	1 / 2%	1 / 6%	4 / 33%	0	0
	CLASS 3	18 / 86%	0	1 / 6%	1 / 8%	0	0

CLASS 1: No pain or mild occasional pain
CLASS 2: Mild chronic pain
CLASS 3: Severe pain

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different except at 2-3 years post-operatively.

TABLE 23. Pain (normal activities). Chronic + acute patients. FDA designation, App. 5, Item 1. IDE designation, S-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	23 / 33%	134/ 90%	33 / 92%	42 / 100%	31 / 84%	34 / 89%
	CLASS 2	9 / 13%	6 / 4%	2 / 6%	0	3 / 8%	4 / 10%
	CLASS 3	37 / 54%	9 / 6%	1 / 3%	0	3 / 8%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	19 / 36%	104/ 91%	36 / 90%	21 / 81%	28 / 96%	25 / 96%
	CLASS 2	9 / 17%	7 / 6%	2 / 5%	4 / 15%	1 / 4%	1 / 4%
	CLASS 3	25 / 47%	3 / 3%	2 / 5%	1 / 4%	0	0

CLASS 1: No pain or mild occasional pain
CLASS 2: Mild chronic pain
CLASS 3: Severe pain

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different except at 2-3 years post-operatively.

TABLE 24. Pain (sports activities). Chronic patients. FDA designation, App. 5, Item 1. IDE designation, S-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	5 / 15%	27 / 93%	16 / 84%	22 / 92%	10 / 71%	18 / 72%
	CLASS 2	4 / 12%	1 / 3%	1 / 5%	0	1 / 7%	2 / 8%
	CLASS 3	25 / 74%	1 / 3%	2 / 10%	2 / 8%	3 / 21%	5 / 20%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	5 / 21%	20 / 77%	18 / 90%	12 / 86%	14 / 88%	14 / 88%
	CLASS 2	2 / 8%	1 / 4%	1 / 5%	0	2 / 12%	0
	CLASS 3	17 / 71%	5 / 19%	1 / 5%	2 / 14%	0	2 / 12%

CLASS 1: No pain or mild occasional pain
CLASS 2: Mild chronic pain
CLASS 3: Severe pain

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 25. Pain (sports activities). Acute patients. FDA designation, App. 5, Item 1. IDE designation, S-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 / 4%	28 / 88%	10 / 91%	16 / 94%	19 / 95%	10 / 100%
	CLASS 2	0	0	0	1 / 6%	1 / 5%	0
	CLASS 3	26 / 96%	4 / 12%	1 / 9%	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	1 / 6%	18 / 82%	14 / 93%	7 / 64%	11 / 92%	8 / 89%
	CLASS 2	0	0	1 / 7%	2 / 18%	0	1 / 11%
	CLASS 3	15 / 94%	4 / 18%	0	2 / 18%	1 / 8%	0

CLASS 1: No pain or mild occasional pain
CLASS 2: Mild chronic pain
CLASS 3: Severe pain

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 26. Pain (sports activities). Chronic + acute patients. FDA designation, App. 5, Item 1. IDE designation, S-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	6 / 10%	55 / 90%	26 / 87%	38 / 93%	29 / 85%	28 / 80%
	CLASS 2	4 / 6%	1 / 2%	1 / 3%	1 / 2%	2 / 6%	2 / 6%
	CLASS 3	51 / 84%	5 / 8%	3 / 10%	2 / 5%	3 / 9%	5 / 14%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	6 / 15%	38 / 81%	32 / 91%	19 / 76%	25 / 89%	22 / 88%
	CLASS 2	2 / 5%	0	2 / 6%	2 / 8%	2 / 7%	1 / 4%
	CLASS 3	32 / 80%	9 / 19%	1 / 3%	4 / 16%	1 / 4%	2 / 8%

CLASS 1: No pain or mild occasional pain
CLASS 2: Mild chronic pain
CLASS 3: Severe pain

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 27. Swelling (normal activities). Chronic patients. FDA designation, App. 5, Item 5. IDE designation, S-3. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	22 /56.4%	71 /83.5%	21 /91.3%	25 /100.0%	15 /88.2%	23 /85.2%
	CLASS 2	4 /10.3%	7 /8.2%	1 /4.3%	0	0	3 /11.1%
	CLASS 3	13 /33.3%	7 /8.2%	1 /4.3%	0	2 /11.8%	1 /3.7%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	20 /62.5%	62 /88.6%	24 /100.0%	14 /100.0%	16 /94.1%	17 /100.0%
	CLASS 2	3 /9.4%	3 /4.3%	0	0	1 /5.9%	0
	CLASS 3	9 /28.1%	5 /7.1%	0	0	0	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 28. Swelling (normal activities). Acute patients. FDA designation, App. 5, Item 5. IDE designation, S-3. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /3.3%	56 /88.9%	13 /100.0%	17 /100.0%	20 /100.0%	11 /100.0%
	CLASS 2	4 /13.3%	5 /7.9%	0	0	0	0
	CLASS 3	25 /83.3%	2 /3.2%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /10.0%	39 /88.6%	16 /100.0%	12 /100.0%	12 /100.0%	9 /100.0%
	CLASS 2	0	3 /6.8%	0	0	0	0
	CLASS 3	18 /90.0%	2 /4.5%	0	0	0	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 29. Swelling (normal activities). Chronic + acute patients. FDA designation, App. 5, Item 5. IDE designation, S-3. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	23 /33.3%	127/85.8%	34 /94.4%	42 /100.0%	35 /94.6%	34 /89.5%
	CLASS 2	8 /11.6%	12 /8.1%	1 /2.8%	0	0	3 /7.9%
	CLASS 3	38 /55.1%	9 /6.1%	1 /2.8%	0	2 /5.4%	1 /2.6%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	22 /42.3%	101/88.6%	40 /100.0%	26 /100.0%	28 /96.6%	26 /100.0%
	CLASS 2	3 /5.8%	6 /5.3%	0	0	1 /3.4%	0
	CLASS 3	27 /51.9%	7 /6.1%	0	0	0	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 30. Swelling (sports activities). Chronic patients. FDA designation, App. 5, Item 5. IDE designation, S-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	13 /37.1%	26 /89.6%	17 /89.5%	22 /91.7%	12 /85.7%	18 /75.0%
	CLASS 2	3 /8.6%	0	1 /5.3%	0	1 /7.1%	1 /4.2%
	CLASS 3	19 /54.3%	3 /10.3%	1 /5.3%	2 /8.3%	1 /7.1%	5 /20.8%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	8 /33.3%	19 /79.2%	19 /95.0%	13 /92.8%	14 /87.5%	16 /100.0%
	CLASS 2	4 /16.7%	0	0	0	0	0
	CLASS 3	12 /50.0%	5 /20.8%	1 /5.0%	1 /7.1%	2 /12.5%	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 31. Swelling (sports activities). Acute patients. FDA designation, App. 5, Item 5. IDE designation, S-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	26 /81.2%	11 /100.0%	16 /94.1%	19 /95.0%	10 /100.0%
	CLASS 2	1 /3.7%	2 /6.2%	0	0	0	0
	CLASS 3	26 /96.3%	4 /12.5%	0	1 /5.9%	1 /5.0%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	21 /95.4%	14 /93.3%	7 /63.6%	10 /83.3%	8 /88.9%
	CLASS 2	0	0	1 /6.7%	2 /18.2%	1 /8.3%	1 /11.1%
	CLASS 3	15 /100.0%	1 /4.5%	0	2 /18.2%	1 /8.3%	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 32. Swelling (sports activities). Chronic + acute patients. FDA designation, App. 5, Item 5. IDE designation, S-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	13 /21.0%	52 /85.2%	28 /93.3%	38 /92.7%	31 /91.2%	28 /82.4%
	CLASS 2	4 /6.4%	2 /3.3%	1 /3.3%	0	1 /2.9%	1 /2.9%
	CLASS 3	45 /72.6%	7 /11.5%	1 /3.3%	3 /7.3%	2 /5.9%	5 /14.7%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	8 /20.5%	40 /87.0%	33 /94.3%	20 /80.0%	24 /85.7%	24 /96.0%
	CLASS 2	4 /10.2%	0	1 /2.8%	2 /8.0%	1 /3.6%	1 /4.0%
	CLASS 3	27 /69.2%	6 /13.0%	1 /2.8%	3 /12.0%	3 /10.7%	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 33. Performance Level (sports activities). Chronic patients. FDA designation, App. 5, Item 7. IDE designation, PE-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	6 /7.1%	4 /17.4%	5 /19.2%	3 /18.8%	3 /11.1%
	CLASS 2	1 /2.6%	3 /3.6%	5 /21.7%	3 /11.5%	5 /31.2%	4 /14.8%
	CLASS 3	4 /10.2%	11 /13.1%	1 /4.3%	8 /30.8%	2 /12.5%	4 /14.8%
	CLASS 4	3 /7.7%	3 /3.6%	3 /13.0%	2 /7.7%	0	2 /7.4%
	CLASS 5	31 /79.5%	61 /72.6%	10 /43.5%	8 /30.8%	6 /37.5%	14 /51.8%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	6 /8.4%	5 /20.8%	4 /28.6%	4 /23.5%	0
	CLASS 2	0	0	5 /20.8%	2 /14.3%	6 /35.3%	6 /40.0%
	CLASS 3	1 /3.1%	4 /5.6%	4 /16.7%	3 /21.4%	2 /11.8%	5 /33.3%
	CLASS 4	1 /3.1%	7 /9.8%	4 /16.7%	2 /14.3%	1 /5.9%	0
	CLASS 5	30 /93.8%	54 /76.1%	6 /25.0%	3 /21.4%	4 /23.5%	4 /26.7%

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 34. Performance Level (sports activities). Acute patients. FDA designation, App. 5, Item 7. IDE designation, PE-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	5 /7.7%	4 /30.8%	5 /29.4%	11 /52.4%	4 /36.4%
	CLASS 2	0	6 /9.2%	3 /23.1%	8 /47.0%	3 /14.3%	4 /36.4%
	CLASS 3	0	4 /6.2%	2 /15.4%	1 /5.9%	2 /9.5%	2 /18.2%
	CLASS 4	0	7 /10.8%	1 /7.7%	0	3 /14.3%	1 /9.1%
	CLASS 5	30 /100.0%	43 /66.2%	3 /23.1%	3 /17.6%	2 /9.5%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	0	5 /31.2%	3 /25.0%	2 /16.7%	0
	CLASS 2	0	8 /17.8%	3 /18.8%	2 /16.7%	3 /25.0%	4 /50.0%
	CLASS 3	0	3 /6.7%	2 /12.5%	4 /33.3%	4 /33.3%	1 /12.5%
	CLASS 4	0	7 /15.6%	2 /12.5%	0	3 /25.0%	0
	CLASS 5	24 /100.0%	27 /60.0%	4 /25.0%	3 /25.0%	0	3 /37.5%

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 35. Performance Level (sports activities). Chronic + acute patients. FDA designation, App. 5, Item 7. IDE designation, PE-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	11 /7.4%	8 /22.2%	10 /23.2%	14 /37.8%	7 /18.4%
	CLASS 2	1 /1.4%	9 /6.0%	8 /22.2%	11 /25.6%	8 /21.6%	8 /21.0%
	CLASS 3	4 /5.8%	15 /10.1%	3 /8.3%	9 /20.9%	4 /10.8%	6 /15.8%
	CLASS 4	3 /4.4%	10 /6.7%	4 /11.1%	2 /4.6%	3 /8.1%	3 /7.9%
	CLASS 5	61 /88.4%	104/69.8%	13 /36.1%	11 /25.6%	8 /21.6%	14 /36.8

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	6 /5.2%	10 /25.0%	7 /26.9%	6 /20.7%	0
	CLASS 2	0	8 /6.9%	8 /20.0%	4 /15.4%	9 /31.0%	10 /43.5%
	CLASS 3	1 /1.8%	7 /6.0%	6 /15.0%	7 /26.9%	6 /20.7%	6 /26.1%
	CLASS 4	1 /1.8%	14 /12.1%	6 /15.0%	2 /7.7%	4 /13.8%	0
	CLASS 5	54 /96.4%	81 /69.8%	10 /25.0%	6 /23.1%	4 /13.8%	7 /30.4%

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 36. Performance Level (normal activities). Chronic patients. FDA designation, App. 5, Item 7. IDE designation, PE-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	13 /15.5%	4 /17.4%	6 /23.1%	5 /31.2%	4 /14.8%
	CLASS 2	0	12 /14.3%	9 /39.1%	9 /34.6%	7 /43.8%	7 /25.9%
	CLASS 3	12 /30.8%	27 /32.1%	4 /17.4%	5 /19.2%	4 /25.0%	12 /44.4%
	CLASS 4	8 /20.5%	15 /17.9%	5 /21.7%	4 /15.4%	0	3 /11.1%
	CLASS 5	19 /48.7%	17 /20.2%	1 /4.3%	2 /7.7%	0	1 /3.7%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	10 /14.1%	6 /25.0%	6 /42.8%	6 /35.3%	3 /20.0%
	CLASS 2	0	4 /5.6%	8 /33.3%	4 /28.6%	7 /41.2%	4 /26.7%
	CLASS 3	3 /9.4%	20 /28.2%	9 /37.5%	4 /28.6%	2 /11.8%	7 /46.7%
	CLASS 4	12 /37.5%	14 /19.7%	1 /4.2%	0	1 /5.9%	0
	CLASS 5	17 /53.1%	23 /32.4%	0	0	1 /5.9%	1 /6.7%

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 37. Performance Level (normal activities). Acute patients. FDA designation, App. 5, Item 7. IDE designation, PE-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	6 /9.2%	5 /38.5%	7 /41.2%	10 /47.6%	3 /27.3%
	CLASS 2	0	19 /29.2%	5 /38.5%	8 /47.0%	4 /19.0%	5 /45.4%
	CLASS 3	0	14 /21.5%	3 /23.1%	2 /11.8%	7 /33.3%	3 /27.3%
	CLASS 4	3 /10.0%	12 /18.5%	0	0	0	0
	CLASS 5	27 /90.0%	14 /21.5%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	3 /6.7%	3 /18.8%	3 /25.0%	1 /8.3%	0
	CLASS 2	0	15 /33.3%	7 /43.8%	2 /16.7%	5 /41.7%	4 /50.0%
	CLASS 3	0	10 /22.2%	4 /25.0%	6 /50.0%	5 /41.7%	3 /37.5%
	CLASS 4	2 /8.3%	12 /26.7%	2 /12.5%	1 /8.3%	1 /8.3%	1 /12.5%
	CLASS 5	22 /91.7%	5 /11.1%	0	0	0	0

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 38. Performance Level (normal activities). Chronic + acute patients. FDA designation, App. 5, Item 7. IDE designation, PE-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	19 /12.8%	9 /25.0%	13 /30.2%	15 /40.5%	7 /18.4%
	CLASS 2	0	31 /20.8%	14 /38.9%	17 /39.5%	11 /29.7%	12 /31.6%
	CLASS 3	12 /17.4%	41 /27.5%	7 /19.4%	7 /16.3%	11 /29.7%	15 /39.5%
	CLASS 4	11 /15.9%	27 /18.1%	5 /13.9%	4 /9.3%	0	3 /7.9%
	CLASS 5	46 /66.7%	31 /20.8%	1 /2.8%	2 /4.6%	0	1 /2.6%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	13 /11.2%	9 /22.5%	9 /34.6%	7 /24.1%	3 /13.0%
	CLASS 2	0	19 /16.4%	15 /37.5%	6 /23.1%	12 /41.4%	8 /34.8%
	CLASS 3	3 /5.4%	30 /25.9%	13 /32.5%	10 /38.5%	7 /24.1%	10 /43.5%
	CLASS 4	14 /25.0%	26 /22.4%	3 /7.5%	1 /3.8%	2 /6.9%	1 /4.3%
	CLASS 5	39 /69.6%	28 /24.1%	0	0	1 /3.4%	1 /4.3%

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 39. Anterior Drawer - 30° (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 1. IDE designation, ST-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /12.5%	6 /46.2%	1 /10.0%	1 /25.0%	1 /14.3%	0
	CLASS 2	1 /12.5%	5 /38.5%	8 /80.0%	2 /50.0%	3 /42.9%	1 /33.3%
	CLASS 3	2 /25.0%	2 /15.4%	1 /10.0%	1 /25.0%	2 /28.6%	1 /33.3%
	CLASS 4	4 /50.0%	0	0	0	1 /14.3%	1 /33.3%

Class 1: 0 mm
Class 2: < 5 mm
Class 3: 5-10 mm
Class 4: > 10 mm

TABLE 40. Anterior Drawer - 90° (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 2. IDE designation, ST-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /12.5%	4 /30.8%	3 /30.0%	1 /20.0%	1 /14.3%	0
	CLASS 2	1 /12.5%	7 /53.8%	6 /60.0%	3 /60.0%	3 /42.9%	2 /66.7%
	CLASS 3	2 /25.0%	2 /15.4%	1 /10.0%	1 /20.0%	2 /28.6%	1 /33.3%
	CLASS 4	4 /50.0%	0	0	0	1 /14.3%	0

Class 1: 0 mm
Class 2: < 5 mm
Class 3: 5-10 mm
Class 4: > 10 mm

TABLE 41. Pivot Shift (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 3. IDE designation, ST-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /12.5%	12 /100.0%	9 /90.0%	4 /100.0%	4 /57.1%	2 /66.7%
	CLASS 2	0	0	1 /10.0%	0	1 /14.3%	0
	CLASS 3	2 /25.0%	0	0	0	1 /14.3%	1 /33.3%
	CLASS 4	5 /62.5%	0	0	0	1 /14.3%	0

Class 1: 0 mm
Class 2: < 5 mm
Class 3: 5-10 mm
Class 4: > 10 mm

TABLE 42. Posterior Drawer - 90° (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 8. IDE designation, ST-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	2 /25.0%	7 /53.8%	9 /90.0%	3 /60.0%	2 /28.6%	2 /66.7%
	CLASS 2	1 /12.5%	4 /30.8%	1 /10.0%	1 /20.0%	4 /57.1%	0
	CLASS 3	1 /12.5%	2 /15.4%	0	1 /20.0%	1 /14.3%	0
	CLASS 4	4 /50.0%	0	0	0	0	1 /33.3%

Class 1: 0 mm
Class 2: < 5 mm
Class 3: 5-10 mm
Class 4: > 10 mm

TABLE 43. Giving Way - Normal Activities (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 4. IDE designation, S-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	6 /46.2%	6 /60.0%	1 /20.0%	5 /71.4%	1 /33.3%
	CLASS 2	1 /12.5%	7 /53.8%	3 /30.0%	4 /80.0%	2 /28.6%	2 /66.7%
	CLASS 3	7 /87.5%	0	1 /10.0%	0	0	0

Class 1: None
Class 2: Occasional
Class 3: Chronic

TABLE 44. Giving Way - Sports Activities (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 4. IDE designation, S-6. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	3 /50.0%	2 /33.3%	1 /33.3%	4 /80.0%	2 /66.7%
	CLASS 2	0	2 /33.3%	2 /33.3%	2 /66.7%	0	1 /33.3%
	CLASS 3	7 /100.0%	1 /16.7%	2 /33.3%	0	1 /20.0%	0

Class 1: None
Class 2: Occasional
Class 3: Chronic

TABLE 45. Pain - Normal Activities (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 1. IDE designation, S-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	12 /92.3%	9 /90.0%	4 /80.0%	7 /100.0%	3 /100.0%
	CLASS 2	2 /22.2%	1 /7.7%	1 /10.0%	1 /20.0%	0	0
	CLASS 3	7 /77.8%	0	0	0	0	0

Class 1: No pain or mild occasional pain
Class 2: Mild chronic pain
Class 3: Severe pain

TABLE 46. Pain - Sports Activities (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 1. IDE designation, S-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	3 /50.0%	4 /66.7%	2 /66.7%	5 /100.0%	3 /100.0%
	CLASS 2	0	2 /33.3%	1 /16.7%	0	0	0
	CLASS 3	7 /100.0%	1 /16.7%	1 /16.7%	1 /33.3%	0	0

Class 1: No pain or mild occasional pain
Class 2: Mild chronic pain
Class 3: Severe pain

TABLE 47. Swelling - Normal Activities (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 5. IDE designation, S-3. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /11.1%	11 /84.6%	10 /100.0%	4 /80.0%	7 /100.0%	3 /100.0%
	CLASS 2	1 /11.1%	2 /15.4%	0	1 /20.0%	0	0
	CLASS 3	7 /77.8%	0	0	0	0	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

TABLE 48. Swelling - Sports Activities (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 5. IDE designation, S-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	4 /66.7%	5 /83.3%	3 /100.0%	5 /100.0%	3 /100.0%
	CLASS 2	0	2 /33.3%	0	0	0	0
	CLASS 3	7 /100.0%	0	1 /16.7%	0	0	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

TABLE 49. Performance Level - Sports (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 7. IDE designation, PE-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	0	0	0	2 /28.6%	1 /33.3%
	CLASS 2	0	3 /23.1%	3 /30.0%	2 /40.0%	2 /28.6%	1 /33.3%
	CLASS 3	0	2 /15.4%	2 /20.0%	0	0	0
	CLASS 4	0	0	0	0	0	1 /33.3%
	CLASS 5	9 /100.0%	8 /61.5%	5 /50.0%	3 /60.0%	3 /42.9%	0

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

TABLE 50. Performance Level - Normal (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 7. IDE designation, PE-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	0	1 /10.0%	0	1 /14.3%	1 /33.3%
	CLASS 2	0	6 /46.2%	2 /20.0%	2 /40.0%	2 /28.6%	0
	CLASS 3	0	4 /30.8%	4 /40.0%	3 /60.0%	1 /14.3%	2 /66.7%
	CLASS 4	1 /12.5%	2 /15.4%	3 /30.0%	0	3 /42.9%	0
	CLASS 5	7 /87.5%	1 /7.7%	0	0	0	0

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

ATTACHMENT: PROPOSED LABELING

PLASTAFIL CFS™
LIGAMENT REPAIR SYSTEM

DESCRIPTION

CFS™ is a system consisting of an implant made of carbon fibers, two fixation devices used for attaching the implant to bone, a set of surgical instruments, and a specific surgical procedure for the cruciate and collateral ligaments of the knee. The implant is 48 cm long and 1.5 mm in diameter, and consists of a bundle of carbon fibers attached to a lead wire. The toggle is a rigid bar, 1 cm long, that accommodates one end of the carbon-fiber bundle, thereby permitting its attachment to bone. The bollard is an expanding rivet used for attaching carbon fibers to bone. The toggle and bollard are made of carbon-fiber-reinforced polysulfone. The implant and fixation devices are supplied sterile.

INDICATIONS

CFS™ is indicated for repair and reconstruction of the anterior cruciate ligament (ACL). If the ACL is repaired with the CFS™, the CFS™ may also be used to repair the posterior cruciate ligament, medial collateral ligament, and lateral collateral ligament, as needed. CFS™ should be used only in patients who have not had previous surgery involving the ACL, and it should be used in the absence of an intra-articular autologous tissue transfer.

THE PERFORMANCE OF THE CFS™ IS DEPENDENT UPON IMPLANT TECHNIQUE. ONLY QUALIFIED SURGEONS WHO HAVE RECEIVED IMPLANTATION TRAINING SHOULD USE THIS DEVICE.

OVERVIEW OF IMPLANT METHOD

For the ACL, the implant is passed through a drill-hole in the tibia and routed retrosynovially over the lateral femoral condyle: The implant is attached on the medial tibia and the lateral femur.

SPECIAL INSTRUMENTS

The instruments required for use of the CFS™ system are:

1. Anterior Cruciate Drill Guide
2. Posterior Cruciate Drill Guide
3. Drill (4.8 mm)
4. Implant Hook

5. Over-The-Top Hook
6. Railroading Wire
7. Bollard Drill
8. Back Radius Cutter
9. Hole Probe
10. Tubular Guide
11. Semitubular Guide - Straight
12. Semitubular Guide - Curved
13. Bollard Punch
14. Mallet

CONTRAINDICATIONS

Use of the CFS™ is contraindicated in patients who have an incomplete closure of the epiphyseal plate and in patients who have infection in the involved knee.

WARNINGS

The CFS™ is not designed, sold, or intended for use except as indicated. All other uses are investigational.

The CFS™ is not to be used for augmentation. It is to be used only as a total prosthesis; the efficacy of the CFS™ is dependent upon fibrous ingrowth into the implant. The portion of the implant within the joint capsule must be covered with synovial tissue.

Specialized instrumentation constitutes part of the CFS™, and failure to employ the instrumentation in the manner intended constitutes an experimental use of the CFS™.

Specialized fixation devices constitute part of the CFS™, and a failure to employ the fixation devices in the manner intended constitutes an experimental use of the CFS™.

A specific surgical procedure for the cruciate and collateral ligaments of the knee constitute part of the CFS™, and a failure to employ the specific surgical procedures described constitutes an experimental use of the CFS™.

POTENTIAL ADVERSE EFFECTS

There may be an increased risk of infection due to the surgical implantation of the synthetic material. Should a serious complication result, it may be necessary to do a second operation to remove either the implant or the fixation devices. There is a possibility that the device or the surgery may fail and that the instability present in the knee before surgery could return.

STERILITY

The CFS™ implant and fixation devices are provided sterile and should be removed from their protective packaging only at the time of use. Cleaning and resterilization of an opened device should not be attempted.

SURGICAL PROCEDURE

Surgical Procedure: Anterior Cruciate Ligament

1. Using the anterior-cruciate drill guide, a 4.8-mm drill hole is made from the anteromedial surface of the tibia beginning about 4 cm distal to the joint surface and emerging within the tibial attachment of the anterior cruciate ligament in the intercondylar area of the tibial plateau. The proximal and distal openings of the drill hole are radiused using the bollard drill and the back radius cutter. The hole is cleansed of bony debris using a saline rinse.

2. Through a separate incision on the lateral side of the knee beginning above the level of the lateral epicondyle of the femur and extending proximally, a small area of bone is exposed through a longitudinal incision in the iliotibial tract. The purpose of this dissection is to identify the supracondylar triangle, a bare area of bone bordered anteriorly by the vastus lateralis as it runs from the lateral intermuscular septum to the extensor mechanism, posteriorly by the lateral intermuscular septum to which the posterior portion of the iliotibial tract is attached, and distally by the lateral superior genicular vessels. The vessels emerge from the popliteal fossa through a hiatus in the lateral intermuscular septum. Elsewhere, the septum is attached to the lateral supracondylar ridge where it forms a fibrous arch over the vessels. The triangle contains a variable amount of fat which must be pushed aside to expose the underlying bone and the genicular vessels. If a fold of synovium from the suprapatellar pouch is encountered during this procedure the dissection should be taken further posteriorly or proximally to avoid entry into the synovial cavity.

3. The over-the-top hook is introduced through the hiatus in the lateral intermuscular septum. Trauma to the geniculate vessels should be avoided, if possible. If not, the vessels should be cauterized. At this level the hook will be proximal to the capsule of the knee joint. The end of the hook is kept close to bone and advanced to the intercondylar area where it can be palpated by a finger in the joint. Then the capsule is penetrated and the joint is entered. A little pressure in the direction of the long axis of the instrument and some additional flexion of the knee beyond 90° may be necessary to

deliver the end of the hook to view. It is important to avoid the posterior cruciate ligament on the medial side of the intercondylar notch. Sharp dissection through the remnants of the anterior cruciate ligament may be required to visualize the end of the hook.

4. The CF Implant is threaded through the hole in the tibia using the semitubular guide to protect the Implant from abrasion and to prevent it from snagging on cancellous bone spicules, as well as to create a soft-tissue tunnel in the remains of the anterior cruciate ligament.

5. After emerging in the intercondylar notch, the wire loop on the end of the CF Implant is linked to the trailing loop of the railroading wire and the leading end of the railroading wire is passed through the hole in the end of the over-the-top hook until it locks. The hook is then withdrawn around the femoral condyle pulling the railroading wire and the CF Implant behind it. A toggle placed through the terminal loop of the CF Implant anchors it at the tibial end.

6. A drill hole is made a short distance proximal to the geniculars vessels using the bollard drill, and a bollard, with the CF Implant wound around it and mounted on the bollard punch tube, is introduced gently into the hole and held in place loosely by hand. This procedure allows the bollard to rotate in the drilled hole as the tension on the CF Implant is adjusted. The knee should now be gently extended to 180°, avoiding hyperextension, to ensure that there is no restriction of movement which may indicate that the CF Implant has been secured in an excessively tight position. The correct residual laxity of the joint should be the same as that in the opposite, uninvolved knee joint (which for comparison must have been examined preoperatively). With the knee extended, the bollard is seated firmly with the punch tube and mallet, and then expanded and locked by driving home the central pin.

7. The CF Implant is cut off about 1.5 cm from the bollard and the free end is sutured to deep tissue using interrupted sutures.

8. From this point on, the knee is held in flexion while hemostasis is secured and the wound is closed in layers.

9. The intercondylar area should now be examined. The entire CF Implant should be retrosynovial within the remnants of the ligament. If any of the CF Implant remains uncovered it should be buried by closing synovial tissue over it using fine interrupted sutures. If insufficient tissue is present in the notch to cover the implant, soft-tissue covering for the carbon fiber can be fashioned from the retro-patellar fat pad. This flap, based on a broad pedicle distally, is raised and pulled into the intercondylar notch.

Surgical Procedure: Posterior Cruciate Ligament

1. The synovium over the anterior part of the ligament is incised, dissected off the ligament, and retracted laterally into the intercondylar notch. A posterior passage through the soft tissues is opened by blunt dissection until the posterior rim of the tibial plateau is reached in the midline.

2. Using the over-the-top hook, a soft-tissue track is dissected on the posterior aspect of the tibia until a position is reached 2-3 cm distal to the tibial plateau.

3. The posterior cruciate drill guide is then introduced through the intercondylar area to reach the posterior aspect of the tibia. When correctly positioned for the drill hole, the connecting limb of the drill guide should be parallel to the tibial plateau.

4. A 4.8-mm drill hole is made from front to back at about the middle of the tibial origin of the posterior cruciate ligament. If desired, placement of the drill hole may be confirmed by x-ray. The hole is radiused front and back.

5. The wire-threading tube is now fitted into the guide and placed through the hole in the tibia. A palpable click is felt as the end of the tube touches the drill guide posteriorly. The absence of a click indicates the presence of tissue between the guide and the tube; the soft tissue may be cleared by the use of the drill bit.

6. With the threading tube in position, the leading loop of the railroading wire is pushed down the tube through the hole in the drill guide. The loop locks automatically and the threading tube is removed leaving the wire in situ. After removal of the drill guide, the wire is drawn through the intercondylar region (from posterior to anterior) completing a full loop through the bone and over the top of the tibial plateau.

7. A 4.8-mm hole is drilled through the medial femoral condyle from a position just posterior to the synovium medially to the middle of the femoral attachment of the posterior cruciate ligament. The hole is radiused, both front and back.

8. If the ligament has been avulsed from its tibial attachment, the remnants of the ligament are pulled forward through the intercondylar notch and two or three stay sutures are attached to the ends. Threading of the CF Implant begins from the medial surface of the femoral condyle. The leading loop of the railroading wire is bent to insure that its free end trails through the soft tissue without snagging, and it is attached to the introducing loop on the CF Implant. The stay sutures on the remnants of the posterior cruciate ligament are threaded through the loop in the introducing probe, and the implant and stay sutures are pulled through the hole in the

tibia following the railroading wire. If the femoral attachment of the ligament has been avulsed or detached, the threading begins from the tibial side by linking the introducing probe onto the trailing end of the railroading wire. Once again, interrupted sutures are placed on the avulsed end of the ligament, but in this situation, they may be brought through separate holes in the medial femoral condyle, and will secure the remnants of the ligament in position over the CF Implant at the end of the threading procedure. In either event, the CF Implant will be pulled in the direction which best replaces the remnants of the ligament in an anatomical position. The CF Implant is anchored by a toggle in its looped end and by a bollard at its other end, following the adjustment of tension.

9. The CF Implant is cut off about 1.5 cm from the bollard and the free end is sutured to periosteum or deep fascia. The bollard and toggle are buried under deep fascia, and the synovial covering in the intercondylar notch is repaired with interrupted sutures.

Surgical Procedure: Medial Collateral Ligament

1. The total ligament is dissected and displayed, except that portion under the pes anserinus. The distal attachment of the ligament can be exposed distal to the pes anserinus. The deep part of the ligament is distinguished by its attachment to the medial meniscus (posterior oblique ligament).

2. The aim of the repair is to stabilize a torn ligament by burying the CF Implant into its substance and by attaching the CF Implant to the tibial and femoral origins of the ligament. Burying is achieved by the use of the semitubular introducer or by splitting the ligament longitudinally and suturing it over the CF Implant using a round-bodied needle.

3. Anchorage is achieved via three bollards placed at the three points of attachment of the ligament. The CF Implant is attached to the posterior tibial bollard, passed upwards to and once around the femoral bollard, and then down to the anterior tibial bollard which is placed distal to the pes anserinus. The stability of the ligament is tested in various degrees of flexion. After checking to ensure that none of the carbon fibers remain superficial to the ligament, the wound is then closed in layers.

Surgical Procedure: Lateral Collateral Ligament

1. A lateral approach is made beginning about 2 cm proximal to the origin of the ligament on the lateral epicondyle of the femur and extending 1-2 cm distal to the subcutaneous prominence of the fibular head. The iliotibial tract should be

incised along its posterior margin. The following structures should be defined and positively identified:

(a) The biceps tendon towards the posterior part of the incision inserting on the head of the fibula.
(b) The popliteus tendon passing from behind the knee to its insertion on the lateral femoral condyle deep to the lateral collateral ligament.
(c) The common peroneal nerve which lies deep and posterior to the biceps tendon. It is advisable to mark this important structure with a tape.
(d) The retinaculum of the vastus lateralis which may appear in the proximal corner of the wound deep to the iliotibial tract.
(e) The remnants of the ruptured lateral collateral ligament which, in the acute case can be identified by an area of contusion which indicates the traumatized area. In the chronic case the lateral structures may be extensively scarred and adherent to one another, and they may have gained abnormal attachments. These scarified and malunited elements must be isolated and repositioned into their correct places.

2. After exposing the origin of the lateral collateral ligament on the lateral epicondyle of the femur, a bollard hole is drilled in this position at 90° to the surface of the bone.

3. The head of the fibula is cleared of soft tissue on its anterior surface and a 4.8-mm hole is drilled from anterior to posterior using the bollard drill, taking care to avoid the common peroneal nerve. The hole should traverse the head of the fibula at its widest part.

4. The posterior edge of the hole is rounded off using the back radius cutter.

5. To facilitate complete coverage of the CF Implant, the remnants of the lateral collateral ligament are now either split, by cutting along the ligament axis or pierced along their length using the semitubular guide.

6. The CF Implant is introduced through the hole in the fibula and anchored by a toggle (a bollard can also be used at each end). It is then passed through the remnants of the ligament via the semitubular guide (or laid into the prepared bed of ligamentous remnants) and fixed with a bollard on the lateral femoral condyle, after adjustment of tension.

Surgical Procedure: Combined Ligamentous Injuries

When more than one ligament is involved in acute injuries to the knee, a single anchorage point may be placed in a convenient position to work for two or more ligaments. The following is a

brief description of some typical combined repairs:

1. Ruptured Anterior Cruciate and Lateral Collateral Ligaments. The lateral collateral CF Implant may be anchored with a toggle placed at the posterior entrance to the hole through the head of the fibula (or with a bollard on the anterior surface), and a bollard inserted just proximal to the lateral epicondyle of the femur. Instead of cutting the CF Implant at this stage, it can be continued to make an over-the-top repair of the anterior cruciate, ending on the tibia with a bollard. If, because of the position of the rupture in the anterior cruciate, it is decided to insert the carbon in the opposite direction, then a toggle anchorage on the tibia and bollards on the lateral femoral condyle and the proximal fibular head are recommended.

2. Combined Anterior Cruciate and Posterior Cruciate Repair. Once again the CF Implant can be introduced in either direction but only one bollard is required on the tibia. The other two points of anchorage may be secured by two bollards or one bollard and one toggle. In combined repairs each ligament, although sharing a common anchorage, must be independently stable.

3. Combined Posterior Cruciate and Medial Collateral Repair. In this situation both ligaments may be approached by a long medial parapatellar incision in which the distal end of the incision is extended more medially than would normally be done for a posterior cruciate repair alone. Drill holes through the tibia and medial femoral condyle are made and the railroading wire is positioned in preparation for threading the CF Implant, as described for the posterior cruciate repair. The three bollard sites are now positioned for the repair of the medial collateral ligament taking care to accurately place the site on the femoral epicondyle just proximal to the anatomical origin of the ligament.

   Threading begins by passing the CF Implant directly through the hole in the medial femoral condyle into the intercondylar notch. The railroading wire is attached to the wire loop on the CF Implant. Then, having insured that the barbed end is bent so that it trails without snagging, the wire is pulled through the tibial side, railroading the CF Implant behind it. The looped end is anchored by a toggle at the femoral condylar side, and after adjusting the tension and testing the joint laxity, it is anchored to the tibia by a bollard placed distal to the pes anserinus (or under the proximal part, which must be exposed by cutting the proximal 2-3 cm of the pes anserinus) at the site for the repair of the superficial part of the medial collateral ligament without cutting the CF Implant by passing it upwards to the anchorage point on the medial femoral condyle and ending on the tibia at the bollard for the deep leaf of the ligament.

CAUTION

Federal law restricts this device to sale, distribution, and use by or on the order of a physician.