BEAR® (Bridge-Enhanced ACL Restoration) Implant

Read this entire Instructions for Use (IFU) carefully prior to use.

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

DESCRIPTION
The BEAR Implant (22 mm in diameter and 45mm in length) is cylindrical in shape and comprised of collagen and extracellular matrix derived from bovine connective tissue, which has been cleaned, disinfected and processed by a proprietary manufacturing method. The implant has been terminally sterilized by electron-beam irradiation and is intended to be used with up to 10 ml of autologous blood drawn during the surgical implantation procedure. The BEAR Implant stabilizes the blood in the gap between the torn ligament ends. The BEAR Implant is resorbed within 8 weeks and replaced with a fibrovascular repair tissue.

INDICATIONS FOR USE
The BEAR® (Bridge-Enhanced ACL Restoration) Implant is a bovine extracellular matrix collagen-based implant for treatment of anterior cruciate ligament (ACL) injuries. The BEAR® Implant is indicated for skeletally-mature patients at least 14 years of age with a complete rupture of the ACL, as confirmed by MRI. Patients must have an ACL stump attached to the tibia to construct the repair.

CONTRAINDICATIONS
- The BEAR Implant is not designed, sold, or intended for use except as described in the indications for use.
- The BEAR Implant is contraindicated for use in any patient with a known allergy to bovine collagen, bovine gelatin or other bovine-derived products.

WARNINGS
- For single (patient) use only. Do not reuse, reprocess or re-sterilize this product. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the implant and/or create a risk of contamination of the device which could result in patient injury, illness or death. Cleaning, disinfection and re-sterilization may compromise the essential material and design characteristics of the implant leading to failure.
- Do not use the implant if either the outer foil pouch or the inner (Tyvek®/polyester) pouch is perforated or torn.
- The device is composed of bovine collagen. The potential for development of bovine collagen antibodies as a result of device implantation exists.
- If the implant becomes wet with saline or any fluid other than autologous blood on the surgical field, discard and use another BEAR Implant.

PRECAUTIONS
- The BEAR Implant should only be used by a licensed physician trained in knee surgery and the use of the device and the BEAR procedure.
- If the surgeon chooses to perform the BEAR procedure arthroscopically, he/she must be experienced in intraarticular arthroscopic techniques.
- Surgery to implant the BEAR device should be performed no later than 50 days after the ACL injury.
- Use the implant prior to the expiration date specified on the package.
- Do not cut, trim, shape or otherwise modify the BEAR Implant.

- In the BEAR II Study, the ACL re-tear rate following the BEAR procedure was numerically higher than following ACLR, the control treatment, in subjects who were 18 years of age or younger at the time of surgery. The re-tear rate for this age group in the BEAR arm was similar to the re-tear rate in patients of the same age who underwent ACLR using hamstring autograft in a historical control group (the MOON Cohort); only historical control patients in this age group who received a bone-patellar tendon-bone (BPTB) autograft had a lower re-tear rate than the BEAR arm of the BEAR II study. Individual patient benefit/risk should be considered when deciding whether to use the BEAR Implant for ACL repair in patients age 18 years and younger. Adherence to the appropriate rehabilitation protocol is thought to reduce the risk of re-tear.

SPECIAL PATIENT POPULATIONS
The safety and effectiveness of the BEAR Implant has not been established in the following patient populations:

- History of prior infection on affected knee
- Regular use of tobacco or nicotine in any form
- Use of corticosteroid within last 3 months
- Any history of chemotherapy treatment
- History of sickle cell disease
- Any condition that could affect healing or infection risk (diabetes, inflammatory arthritis, etc.)
- Diagnosis of posterolateral corner injury (LCL complete tear, biceps femoris tendon avulsion, tear of the arcuate ligament, tear of the popliteus ligament)
- Diagnosis of complete patellar dislocation

POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH
The same potential medical/surgical complications that apply to any orthopaedic surgical procedure, such as ACL reconstruction, may occur during or following implantation of the BEAR Implant. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. Additional surgery may be required to correct some of the adverse effects.

Below is a list of the potential adverse effects (e.g., complications) specifically associated with use of the BEAR Implant.

- Implant rejection or allergic reaction to the BEAR Implant
- As with any medical device derived from animal tissue, the potential for transmission of infectious agents, such as viruses or agents that transmit TSE, exists.

STORAGE REQUIREMENTS
Store the BEAR Implant at room temperature. Avoid excessive heat, humidity or exposure to sunlight.

STERILITY
The BEAR Implant has been terminally sterilized by exposure to electron beam irradiation. Do not re-sterilize the implant.

MR SAFETY
The BEAR Implant is MR Safe.
Note: This MRI safety designation applies only to the BEAR Implant itself. Refer to the instructions for use of any other devices that are implanted to construct the ACL repair for information on MR safety of those devices.

CLINICAL SUMMARY

Study Design

The BEAR Implant was studied in a randomized (2:1 ratio) controlled trial (the BEAR II Study) of 100 subjects with complete ACL rupture, performed at one U.S. site by three surgeons. Sixty-five (65) subjects were randomized to the BEAR Implant and 35 to the control treatment, ACL reconstruction (ACLR) with autograft (33 subjects received a hamstring graft and 2 received a bone-patellar-tendon-bone [BPTB] graft). Following surgery, subjects underwent a prescribed physical therapy regimen and were followed up at 1-2 and 6 weeks, and 3, 6, 12 and 24 months. Various outcomes were measured at the follow-up visits, including patient-reported outcomes, strength and functional measurements and imaging (x-ray, MRI). The primary endpoints, International Knee Documentation Committee (IKDC) Subjective Score, KT-instrumented AP knee laxity, and various safety parameters, were evaluated at 24 months (two years) post-surgery.

Patient Population and Baseline Demographics

The primary analysis population was the modified Intent-to-Treat (mITT) population, which consisted of all ITT patients who had the BEAR procedure attempted. This included 100 subjects, 65 in the BEAR group and 35 in the control group. Nine subjects were consented and randomized but did not undergo surgery, for various reasons. Thus, the ITT population was 109 subjects. The As-Treated (AT) population, analyzed for safety, was the same as the mITT population.

Baseline demographics are presented for the ITT population (Table 1). Subjects participating in the BEAR II study were young, with an overall mean age of 19.6±5.2 years and a median age of 17.5 years; overall 64.2% of subjects were 18 years and younger, and 35.8% were 19 years and older. To be eligible for the study, all patients had to have closed femoral and tibial physes and were therefore skeletally mature. More females than males were enrolled in the study (55.0% female, 45.0% male). Time from injury to surgery averaged 35.5±7.9 days, with a range of 12.0 to 46.0 days. There were no significant differences between the treatment groups at baseline.

Table 1: Key Subject Demographics at Baseline, ITT Population

	BEAR N=73	Control N=36	Total N=109	p-value [1]
Age (years) [2]				
Mean ± SD (N)	19.5 ± 5.2 (73)	19.8 ± 5.3 (36)	19.6 ± 5.2 (109)	0.784
Median (Min, Max)	17.4 (13.8, 35.6)	17.7 (14.1, 35.6)	17.5 (13.8, 35.6)	
Age Group % (n/N)				0.674
18 Years Old and Under	65.8% (48/73)	61.1% (22/36)	64.2% (70/109)	
19 Years Old and Over	34.2% (25/73)	38.9% (14/36)	35.8% (39/109)	
Gender % (n/N)				0.838
Female	56.2% (41/73)	52.8% (19/36)	55.0% (60/109)	
Male	43.8% (32/73)	47.2% (17/36)	45.0% (49/109)	
BMI (kg/m^2)				
Mean ± SD (N)	24.7 ± 3.8 (72)	23.5 ± 4.6 (36)	24.3 ± 4.1 (108)	0.147
Median (Min, Max)	24.5 (18.1, 36.9)	22.2 (17.2, 38.3)	24.0 (17.2, 38.3)	
Time from Injury to Surgery (days)				

	BEAR N=73	Control N=36	Total N=109	p-value [1]
Mean ± SD (N)	34.7 ± 8.1 (65)	36.9 ± 7.6 (35)	35.5 ± 7.9 (100)	0.189
Median (Min, Max)	36.0 (12.0, 46.0)	39.0 (15.0, 46.0)	37.5 (12.0, 46.0)	

[1] p-value from two-sample t-test or Fisher's Exact test comparing BEAR arm to Control arm.
[2] Age = (Date of informed consent - date of birth)/365.25.

Safety Results

Key safety parameters were evaluated throughout the 24 month follow-up period for the AT population (Table 2). There were no cases of deep joint infection or incision and drainage of deep surgical site infection and no evidence of graft/implant rejection in either group. Graft or repair failure occurred in nine BEAR subjects (13.8%) and two control subjects (5.7%), p=0.320. Additional surgical procedures (other than ACL surgery) were required on the study knee in eight BEAR subjects (12.3%) and four control subjects (11.4%), p=1.000. Neither comparison reached statistical significance. Bovine IgE antibody levels were positive at the 6-month follow-up in two BEAR subjects (3.1%) and no control subjects; both results were low positive (0.39 kU/L, just slightly above the threshold of 0.35 kU/L) and resolved at 15 months and two years post-surgery. Neither subject had any adverse events related to the transient antibody elevation.

Table 2: Safety Analysis Through 2 Years, AT Population

	BEAR N=65	Control N=35	p-value [1]
Deep Joint Infection/Incision and Drainage of Deep Surgical Site Infection	0% (0/65)	0% (0/35)	1.000
Evidence of Graft or Implant Rejection	0% (0/65)	0% (0/35)	1.000
Graft or Repair Failure	13.8% (9/65)	5.7% (2/35)	0.320
Additional Surgical Procedures Required on Study Knee [2]	12.3% (8/65)	11.4% (4/35)	1.000
Bovine IgE Antibody Levels >=0.35kU/L [3]	3.1% (2/64)	0% (0/33)	0.546
Bovine Antibody Level (kU/L)			
Mean ± SD (N)	0.39 ± 0.00 (2)		
Median (Min, Max)	0.39 (0.39, 0.39)		

[1] p-value from a two-sided Fisher's Exact Test, testing the null hypothesis that the true proportions are equal for the two treatments versus the alternative hypothesis that they are not equal.
[2] Not including subjects requiring a second ACL surgery.
[3] Subjects who tested positive resolved after 15 months and 2 years post procedure date.

Graft or repair failure was determined by positive pivot shift exam, Lachman exam with >6 mm side to side difference, absence of tissue in expected ACL location on MRI, MR evidence of graft or repair loss of continuity or symptomatic instability requiring revision ACL surgery. Of the nine BEAR subjects who experienced repair failure, five were non-compliant with post-operative requirements (physical therapy and/or brace use), returned to sports prior to surgeon clearance, had an accident or had a very high BMI, and three returned to sports prior to 9 months post-surgery. All subjects who re-tore the ACL, in both groups, were age 18 years or younger.

Results of the BEAR II study were compared to data from a historical control for which the manufacturer was able to access subject-level data and to data from a structured literature review. The analyses demonstrated that the rate of ACL re-tear with the BEAR Implant was similar to the historical control and was consistent with the published literature.

In conclusion, the BEAR Implant had a similar safety profile to ACLR, and repair failure was more likely to occur in younger subjects, which is consistent with the experience of ACLR as documented in the literature.

Effectiveness Results

Primary Endpoints
The BEAR II Study had two co-primary effectiveness endpoints, IKDC score and instrumented AP knee laxity, both at 24 months (two years) post-surgery (Table 3). In the primary analysis of the mITT population using multiple imputation for missing data, IKDC score for the BEAR group at 24 months was found to be non-inferior to control based on the null hypothesis that the true difference in the means between treatment groups was less than or equal to -11.5, which is considered a clinically significant difference and was the pre-specified non-inferiority delta. Mean IKDC score in the BEAR group was 88.6±13.4 and in the control group 84.6±13.3. The 95% confidence interval for the difference in the means was 4.03 (-1.55, 9.61) (p<0.001).

Instrumented AP knee laxity using the KT device at 24 months was found to be non-inferior to control based on the null hypothesis that the true difference in the means between treatment groups was greater than or equal to 2.0 mm, which is considered a clinically significant difference and was the pre-specified non-inferiority delta. Mean instrumented AP knee laxity in the BEAR group was 1.7±3.2 mm and in the control group 1.8±2.8 mm. The 95% confidence interval for the difference in the means was -0.10 (-1.45, 1.25) (p<0.001).

Both primary endpoints were confirmed by multiple sensitivity analyses, including a tipping point analysis.

Table 3: Primary Endpoints, mITT Population, Multiple Imputation [1]

	BEAR N=65	**Control N=35**	**Difference in Means BEAR - Control (95% CI) [2]**	**p-value**
IKDC Patient Reported Score at 24 Months [3]				
Mean ± SD	88.6 ± 13.4	84.6 ± 13.3	4.03 (-1.55, 9.61)	<0.001
Median (Min, Max) [4]	91.95 (35.63, 100.00)	89.08 (47.13, 100.00)		
KT Instrumented AP Knee Laxity (mm) at 24 Months (Injured Knee - Non-Injured Knee) [5]				
Mean ± SD	1.7 ± 3.2	1.8 ± 2.8	-0.10 (-1.45, 1.25)	0.001

	BEAR N=65	Control N=35	Difference in Means BEAR - Control (95% CI) [2]	p-value
Median (Min, Max) [4]	1.88 (-8.50, 7.00)	1.38 (-6.00, 6.00)		

[1] Analysis done on mITT population with multiple imputation used for missing data. In the BEAR group, 3 (4.6%) patients are missing IKDC and 7 (10.8%) patients are missing AP knee laxity at 24 months. In the control group, 1 (2.9%) patient is missing IKDC and 3 (8.6%) are missing AP knee laxity at 24 months.
[2] Confidence interval based on the t-distribution.
[3] p-value from a one-sided, two-sample t-test of the null hypothesis that the true difference in means is less than or equal to -11.5 versus the alternative hypothesis that it is greater than -11.5.
[4] Median, minimum and maximum values are shown for the observed data only, and do not include imputed values.
[5] p-value from a one-sided, two-sample t-test of the null hypothesis that the true difference in means is greater than or equal to 2.0 versus the alternative hypothesis that it is less than 2.0.

Secondary Endpoints

Twelve secondary effectiveness endpoints were statistically tested using multiple imputation for missing data and were tested hierarchically in the order specified below to control the Type I error rate and adjust for multiple testing, whereby further testing would stop if a result was not significant. These endpoints were:

- Hamstring strength, reported as percentage of the contralateral side, and as determined by hand-held dynamometer at 6 months post-surgery (superiority)
- Hamstring strength, reported as percentage of the contralateral side, as determined by hand-held dynamometer at 12 months post-surgery (superiority)
- Hamstring to quadriceps ratio for the operated knee at 6 months post-surgery (superiority)
- Hamstring to quadriceps ratio for the operated knee at 12 months post-surgery (superiority)
- ACL RSI score at 6 months post-surgery (superiority)
- Knee Injury and Osteoarthritis Outcome Score (KOOS) at 12 months post-surgery – Pain (non-inferiority)
- KOOS at 12 months post-surgery – Symptoms (non-inferiority)
- KOOS at 12 months post-surgery – Sports and Recreation (non-inferiority)
- KOOS at 12 months post-surgery –QOL (non-inferiority)
- KOOS at 12 months post-surgery – ADL (non-inferiority)
- KOOS at 12 months post-surgery – Pain (superiority)
- KOOS at 12 months post-surgery – Symptoms (superiority)

All 12 endpoints were statistically significant, either for non-inferiority or for superiority, as defined in the SAP. Prone hamstring strength and hamstring to quadriceps ratio, both tested for superiority at both 6 and 12 months post-surgery, were significantly better in the BEAR group than the control group. Mean prone hamstring strength, which is measured as the proportion of the strength of the injured knee to the non-injured knee, was more than (absolute) 30% higher in the BEAR group than control at 6 months (on average, 93.3% vs. 59.1%, respectively [$p<0.001$]), and this finding was sustained at 12 months (on average, 96.6% vs. 65.2%, respectively [$p<0.001$]). Similarly, mean hamstring to quadriceps ratio at 6 months was 0.5 ± 0.2 in the BEAR group vs. 0.3 ± 0.1 in the control group ($p<0.001$); at 12 months, the difference between treatment groups was slightly smaller but still statistically significant in favor of BEAR (0.4±0.1 vs. 0.3±0.1, $p<0.001$).

The mean ACL RSI in the BEAR group was superior to control by 12 points at 6 months post-surgery (71.5±19.5 compared to 58.9±24.1, $p=0.005$), the timepoint that was tested for this analysis.

All five KOOS domains, including pain, symptoms, sports and recreation, quality of life and activities of daily living, were tested for non-inferiority at 12 months; all were statistically significant for non-inferiority, and in all cases the BEAR value was numerically higher than the control value. KOOS-pain and KOOS-

symptoms were also tested for superiority at 12 months and found to be significantly better in the BEAR group than control.

The secondary endpoints were confirmed with sensitivity analysis.

Table 4: Secondary Endpoints Intended for Labeling, mITT Population [1], Multiple Imputation

	BEAR N=65	Control N=35	Difference in Means BEAR - Control (95% CI) [2]	p-value [3]
Prone Hamstring Strength at 6 Months (%) (100*(Injured Knee/Non-injured Knee)) (superiority) [4]				
Mean ± SD	93.3 ± 23.6	59.1 ± 21.3	34.21 (24.70, 43.72)	<0.001 [S]
Median (Min, Max) [5]	91.7 (29.6, 188.5)	56.4 (27.0, 124.0)		
Prone Hamstring Strength at 12 Months (%) (100*(Injured Knee/Non-injured Knee)) (superiority) [6]				
Mean ± SD	96.6 ± 16.7	65.2 ± 18.5	31.37 (24.08, 38.66)	<0.001 [S]
Median (Min, Max) [5]	96.8 (40.0, 164.0)	61.9 (36.0, 114.5)		
Hamstring to Quadriceps Ratio at 6 Months (Hamstring Strength/Quadriceps Strength) (superiority) [4]				
Mean ± SD	0.5 ± 0.2	0.3 ± 0.1	0.16 (0.10, 0.22)	<0.001 [S]
Median (Min, Max) [5]	0.4 (0.2, 1.2)	0.3 (0.1, 0.7)		
Hamstring to Quadriceps Ratio at 12 Months (Hamstring Strength/Quadriceps Strength) (superiority) [6]				
Mean ± SD	0.4 ± 0.1	0.3 ± 0.1	0.13 (0.09, 0.17)	<0.001 [S]
Median (Min, Max) [5]	0.4 (0.2, 0.7)	0.3 (0.2, 0.5)		
ACL RSI Score at 6 Months (superiority) [7]				
Mean ± SD	71.5 ± 19.5	58.9 ± 24.1	12.59 (3.74, 21.44)	0.005 [S]
Median (Min, Max) [5]	75.0 (0.8, 100.0)	64.2 (11.7, 95.0)		
KOOS at 12 months (Pain) (non-inferiority) [8]				
Mean ± SD	94.4 ± 6.6	91.2 ± 7.1	3.19 (0.37, 6.02)	<0.001 [N]
Median (Min, Max) [5]	97.2 (66.7, 100.0)	91.7 (77.8, 100.0)		
KOOS at 12 months (Symptoms) (non-inferiority) [8]				
Mean ± SD	88.3 ± 9.3	82.4 ± 12.0	5.87 (1.54, 10.19)	<0.001 [N]
Median (Min, Max) [5]	89.3 (57.1, 100.0)	85.7 (57.1, 100.0)		
KOOS at 12 months (Sports and Recreation) (non-inferiority) [8]				

	BEAR N=65	Control N=35	Difference in Means BEAR - Control (95% CI) [2]	p-value [3]
Mean ± SD	86.0 ± 15.7	83.0 ± 18.9	2.96 (-4.05, 9.98)	<0.001 [N]
Median (Min, Max) [5]	87.5 (15.0, 100.0)	85.0 (15.0, 100.0)		
KOOS at 12 months (Quality of Life) (non-inferiority) [8]				
Mean ± SD	69.4 ± 19.7	64.6 ± 17.5	4.76 (-3.19, 12.72)	<0.001 [N]
Median (Min, Max) [5]	68.8 (25.0, 100.0)	62.5 (37.5, 100.0)		
KOOS at 12 months (Activities of Daily Living) (non-inferiority) [8]				
Mean ± SD	98.8 ± 2.4	98.0 ± 4.2	0.74 (-0.59, 2.07)	<0.001 [N]
Median (Min, Max) [5]	100.0 (88.2, 100.0)	100.0 (77.9, 100.0)		
KOOS at 12 months (Pain) (superiority) [8]				
Mean ± SD	94.4 ± 6.6	91.2 ± 7.1	3.19 (0.37, 6.02)	0.027 [S]
Median (Min, Max) [5]	97.2 (66.7, 100.0)	91.7 (77.8, 100.0)		
KOOS at 12 months (Symptoms) (superiority) [8]				
Mean ± SD	88.3 ± 9.3	82.4 ± 12.0	5.87 (1.54, 10.19)	0.008 [S]
Median (Min, Max) [5]	89.3 (57.1, 100.0)	85.7 (57.1, 100.0)		

N=non-inferiority test; S=superiority test

[1] Analysis done on mITT population with multiple imputation used for missing data.
[2] Confidence interval based on the t-distribution.
[3] These are to be Tested in a hierarchical manner so that if a significant result is reached the next variable will be tested. If a result is not significant (p>0.05) then testing will not continue.
For tests of superiority, the p-value is from a two-sided, two-sample t-test, testing the null hypothesis that the true means are equal versus the alternative hypothesis that they are not equal.
For tests of non-inferiority, the p-value is from a one-sided, two-sample t-test of the null hypothesis that the true difference in means is less than or equal to -10 versus the alternative hypothesis that it is greater than -10.
[4] Data for prone hamstring strength and hamstring to quadriceps ratio at 6 months was imputed for 1 (1.5%) patient in the BEAR group, and 1 (2.9%) patient in the control group.
[5] Median, minimum and maximum values are shown for the observed data only, and do not include imputed values.
[6] Data for prone hamstring strength and hamstring to quadriceps ratio at 12 months was imputed for 3 (4.6%) patients in the BEAR group, and 3 (8.6%) patients in the control group.
[7] Data for ACL RSI Score at 6 months was imputed for 1 (1.5%) patient in the BEAR group, and 1 (2.9%) patient in the control group.
[8] Data for KOOS (all parts) at 12 months was imputed for 1 (1.5%) patient in the BEAR group, and 2 (5.7%) of patients in the control group.

Conclusion

In summary:

- The BEAR II study met its primary effectiveness endpoints, IKDC and instrumented AP knee laxity at two years, demonstrating that the BEAR Implant is non-inferior to ACLR.
- The BEAR Implant was shown to be superior to ACLR for seven secondary outcomes and non-inferior to ACLR for five other secondary endpoints.
- The safety of the BEAR Implant was demonstrated in this study; there were no serious device-related complications of deep joint infection, implant rejection, symptoms indicative of BSE, deep vein thrombosis, or allergic reaction, and safety was shown to be comparable to ACLR.

- The graft failure or re-tear rate for the BEAR Implant was numerically higher but not statistically different from the ACLR rate and was consistent with historical control results, as well as published literature.

In conclusion, the BEAR II study met its primary safety and effectiveness endpoints. This study demonstrates that the BEAR Implant is safe and effective for its intended purpose and has a favorable benefit/risk profile.

DIRECTIONS FOR USE

1. Access the ACL using standard surgical techniques.
2. Drill femoral and tibial tunnels within 2 mm of the footprint of the native ligament.
3. Attach an absorbable braided suture (referred to as the “docking stitch”) to the ACL tibial stump and loop the suture through a femoral fixation device (e.g., a cortical button).
4. Loop two non-absorbable braided sutures (referred to as the “suture stent”) through the same femoral fixation device.
5. Engage the femoral fixation device carrying the non-absorbable and absorbable sutures on the lateral femoral cortex.
6. Thread the non-absorbable braided sutures through the BEAR Implant.
7. Pass the free ends of the non-absorbable sutures through the tibial tunnel.
8. Hydrate the BEAR Implant with 5-10 mL of non-coagulated autologous blood.
9. Pass the BEAR Implant along the non-absorbable sutures into the intercondylar notch (where the ACL is anatomically located) between the two torn ends of the ACL tissue.
10. With the knee placed in extension, tighten the non-absorbable sutures and affix them to the second cortical fixation device (e.g., cortical button) secured on the anterior tibial cortex.
11. Use the absorbable sutures to pull the tibial ACL remnant toward the femoral attachment site and up into the blood-saturated BEAR Implant.

SYMBOLS USED ON LABELING


Consult Instructions for Use


Expiration Date


Do not reuse after opening


Do not use if package is damaged

Do not re-sterilize

Lot Number

Catalog Number

Method of Sterilization – Radiation (E-beam)


Pyrogen Free


Keep dry


Keep away from sunlight


Storage temperature limit


Manufacturer

Prescription use only

Manufactured exclusively for:
Miach Orthopaedics, Inc.
69 Milk Street, Suite 100, Westborough, MA 01581 USA

Manufactured by:
DSM Biomedical, Exton, PA 19341 USA

For further information on returns or to report a complaint or a potential adverse event, please contact Miach Orthopaedics Customer Service at 800-590-6995.

Miach Orthopaedics, Inc. warrants that reasonable care has been used in the design and manufacture of the BEAR Implant. Miach Orthopaedics excludes all warranties, expressed or implied, written or oral, by operation of law or otherwise, including fitness for a particular purpose since handling and storage as well as other factors relating to the patient, diagnosis, treatment, surgical procedure and other matters beyond the control of Miach Orthopaedics directly affect the BEAR Implant and the results obtained from its use. Miach Orthopaedics' obligation under this warranty is limited to the replacement of the BEAR Implant. Miach Orthopaedics shall not be liable for any incidental or consequential loss, damage, expense directly or indirectly arising from the use of the BEAR Implant. Miach Orthopaedics neither assumes, nor authorizes any other person to assume for it, any other liability or responsibility in connection with the BEAR Implant.