

BEAR® Implant

Public Relations Toolkit

Miach Orthopaedics, Inc. is pleased to share with you this public relations toolkit, which provides customizable materials to help you increase patient awareness of your use of the BEAR[®] Implant – the first new innovation in ACL tear treatment in 30+ years.¹ Please note that the use of these materials is strictly voluntary, and you are not obligated to purchase Miach Orthopaedics, Inc.'s products. The kit includes:

- <u>Press Release Template</u> Send to local media once you begin performing the procedure at your practice or hospital. Within the release, there are placeholder sections for you to add your information. Please also feel free to update the physician and/or patient quote as desired and send to your local media outlets.
- <u>Bylined Article Authored by Physician</u> Send to local newspapers and magazines that do not have staff to write an original piece.
- <u>Patient Newsletter Article</u> Include in your patient newsletter. If possible, the article would be richer if you are able to insert one of your patient's stories in the designated sections (only with the patient's consent, of course).
- Hospital Medical Staff Newsletter Article Include in your hospital's medical staff newsletter.
- <u>Social Media Posts</u> Use for your Facebook and/or Twitter accounts to help people discover your practice or hospital and drive traffic to your website. We recommend posting them to your accounts after you've posted the BEAR Implant copy to your website and/or published the patient newsletter article.
- <u>Media Interview Background & Tips</u> Prepare for media interviews about the BEAR Implant and patient experience.
- <u>Website Copy</u> Add information about the BEAR Implant procedure to your website.
- <u>Referring Physician Letter/Email</u> Send to your referral base.
- <u>Physical Therapist Letter/Email</u> Send to affiliated PT groups regarding unique rehab protocol for the BEAR Implant.
- <u>Banner Ad Copy</u> Use when designing banner ads to promote the BEAR Implant on hospital or physician websites.

If you have any questions or suggestions for other materials that might help generate awareness about the BEAR procedure, we are here to support you. Please contact your sales rep to discuss your needs.

¹ Mascarenhas R, MacDonald PB. Anterior cruciate ligament reconstruction: a look at prosthetics--past, present and possible future. Mcgill J Med. 2008;11(1):29-37.

[Hospital/Physician Practice] First in [City/State] to Offer Innovative BEAR[®] Implant to Treat ACL Tears

Implant First Innovation in ACL Tear Treatment in 30+ Years; Enables Injured ACL to Heal Itself

[CITY, State] – [Date] – [Hospital Name] is the first in [city/state] to offer the BEAR[®] Implant for treatment of anterior cruciate ligament (ACL) tears, one of the most common knee injuries in the U.S. The BEAR Implant is the first medical advancement to enable the body to heal its own torn ACL. This new approach is a paradigm shift from the current standard of care – reconstruction that replaces the ACL with a graft – and is the first innovation in ACL tear treatment in more than 30 years.

Every year, approximately 400,000 ACL injuries occur in the U.S. A torn ACL does not heal without treatment, resulting in ACL reconstruction being one of the most common orthopedic procedures in the U.S. Yet the procedure has drawbacks; some procedures require two separate incisions, and some people who undergo reconstruction are unable to return to the same level of daily activities or sports.

SAMPLE QUOTE: "There are a number of advantages to restoring a ligament instead of replacing it, and the BEAR Implant is an exciting medical technology that is the first to clinically demonstrate that it enables healing of the patient's torn ACL while maintaining the natural knee anatomy," said Dr. [Name, title]. "Encouraging clinical studies have shown faster recovery of muscle strength and higher patient satisfaction with regard to readiness to return to sport than traditional ACL reconstruction – the standard of care today."

During an ACL reconstruction, the surgeon completely removes the remaining torn ACL and reconstructs it with either a tendon from the patient's own leg (called an autograft) or a deceased donor (called an allograft). As with any surgery, ACL reconstruction has certain risks. About half of people who receive patellar tendon grafts experience pain while kneeling, and those who receive hamstring grafts have persistent weakness – as much as a 50% deficit at two years after surgery.

Unlike reconstruction, the BEAR Implant does not require a second surgical wound site to remove a healthy tendon from another part of the leg or the use of a donor tendon. The BEAR Implant acts as a bridge to help ends of the torn ACL heal together. The surgeon injects a small amount of the patient's own blood into the implant and inserts it between the torn ends of the ACL in a minimally invasive procedure. The combination of the BEAR Implant and the patient's blood enables the body to heal the torn ends of the ACL back together while maintaining the ACL's original attachments to the femur and tibia. As the ACL heals, the BEAR Implant is resorbed by the body, within approximately eight weeks.

SAMPLE PATIENT QUOTE (if available): "After tearing my ACL during a game, I was devastated – but I was optimistic when I learned about the BEAR Implant," said [Patient Name]. "It was a relief knowing I didn't have to worry about a second incision or donor graft. As weeks pass, every step of progress is more exciting than the last, and my doctor is confident I'll be back to my regular activities soon."

The BEAR Implant was granted De Novo Approval from the U.S. Food and Drug Administration and 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 facilitate the restoration. The BEAR device must be implanted within 50 days of injury. Patients should discuss their individual symptoms, diagnosis and treatment with their surgeon. The BEAR Implant has the same potential medical/surgical complications as other orthopedic surgical procedures, including ACL reconstruction. These include the risk of re-tear, infection, knee pain, meniscus injury and limited range of motion.

About [Hospital] [Insert Boilerplate]

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[Media Contact Information]

Physician Byline Article

Breakthrough Technology Enables Injured ACL to Heal

BEAR® Implant First New Innovation in ACL Tear Treatment in 30+ Years

By Dr. [Name]

Orthopedic Surgeon at [Practice/Hospital]

Every year, approximately 400,000 ACL injuries occur in the U.S. A torn ACL does not heal without treatment, resulting in ACL reconstruction being one of the most common orthopedic procedures in the U.S. Yet the procedure has drawbacks; some people are unable to return to the same level of daily activities or sports.

Historically, orthopedic surgeons have had limited options in treating a torn ACL. With ACL reconstruction, today's standard of care, the surgeon completely removes the remaining torn ACL and reconstructs it with either a tendon from the patient's own leg (called an autograft) or a deceased donor (called an allograft).

At [Hospital], we are now offering a new technology called the BEAR[®] Implant. The BEAR Implant is the first medical advancement granted approval from the U.S. Food and Drug Administration (FDA) that enables the body to heal its own torn ACL. This new approach is a paradigm shift from ACL reconstruction and is the first innovation in ACL tear treatment in more than 30 years.

Unlike reconstruction, the BEAR Implant does not require a second surgical wound site to remove a healthy tendon from another part of the leg or the use of a donor tendon. The BEAR Implant acts as a bridge to help ends of the torn ACL heal together. The surgeon injects a small amount of the patient's own blood into the implant and inserts it between the torn ends of the ACL in a minimally invasive procedure. The combination of the BEAR Implant and the patient's blood enables the body to heal the torn ends of the ACL back together while maintaining the ACL's original attachments to the femur and tibia. As the ACL heals, the BEAR Implant is resorbed by the body, within approximately eight weeks.

Preserving a patient's native ACL instead of replacing it with a graft has long been a goal of surgeons, as there are a number of advantages to restoring a ligament instead of replacing it. First, both ACL reconstruction approaches have an ACL re-tear rate as high as 20% for teens and as high as 9% for adults. And, following ACL reconstruction, a large number of athletes (more than 55%) can't return to the same level of sport.

As with any surgery, ACL reconstruction has certain risks. Depending on the type of graft used, there can also be clinical complications. About half of people who receive patellar tendon grafts experience pain while kneeling, and those who receive hamstring grafts have persistent weakness – as much as a 50% deficit at two years. In addition, if the ACL is re-injured, revisions with the BEAR Implant are easier. Revisions to traditional ACL reconstruction can be complicated and can require multiple surgeries.

Clinical studies have demonstrated that the BEAR Implant restores torn ACL quality and size similar to a patient's non-injured ACL. Compared with autograft ACL reconstruction, it also has shown faster recovery of muscle strength and higher patient satisfaction with regard to readiness to return to sport.

Patients should discuss their individual symptoms, diagnosis and treatment with their surgeon. The BEAR Implant has the same potential medical/surgical complications as other orthopedic surgical procedures, including ACL reconstruction. These include the risk of re-tear, infection, knee pain, meniscus injury and limited range of motion.

We started using this breakthrough technology at [Hospital] in [month year]. If you are at least 14 years of age, have a complete rupture of the ACL (as confirmed by MRI) and can undergo the surgery within 50 days of the injury, call [phone number] to schedule a consultation to see if you might be a good candidate for the BEAR Implant, or visit [website] for more information.

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[Insert physician bio, if available. If you have a headshot photo, please also supply to the publication.]

Patient Newsletter Article

Game-Changing Technology for Torn ACL:

New Implant Enables Injured ACL to Heal

SAMPLE PATIENT STORY: During the last 10 seconds of a soccer game during her senior year, [Name, age], slipped and fell. "I planted my foot wrong and just slipped. I was going for the ball when my knee went one way and my body went the other," she said. "I just knew something terrible had happened."

Sure enough, [Name] had torn her anterior cruciate ligament (ACL) – one of the key ligaments that help stabilize the knee joint. With approximately 400,000 ACL injuries occurring in the U.S., it is one of the most common sports injuries that involve sudden stops and changes in direction, such as while playing soccer, basketball, tennis and football.

Unfortunately, the ACL does not heal without treatment, resulting in ACL reconstruction surgery being one of the most common orthopedic procedures in the U.S. While ACL reconstruction historically has been a successful procedure, there are drawbacks.

"During an ACL reconstruction, the surgeon removes the remaining torn ACL and replaces it with either a tendon from the patient's own leg, called an autograft, or a graft from a deceased donor, called an allograft," said Dr. [Name, title]. "This has been the standard of care for many years; however, both ACL reconstruction approaches have an ACL re-tear rate as high as 9% for adults and 20% for teens."

In addition to the chance of a re-tear and possible clinical complications such as pain while kneeling or persistent weakness, a large number of athletes (more than 55%) can't return to the same level of sport following ACL reconstruction. For a young athlete like [Name], that news can be scary and devastating.

[Hospital/Practice Name] is one of the first in [City/State] to offer a new technology granted approval from the U.S. Food and Drug Administration (FDA) called the BEAR[®] Implant. The BEAR Implant is the first medical advancement to enable the body to heal its own torn ACL. This new approach is a paradigm shift from ACL reconstruction and is the first innovation in ACL tear treatment in more than 30 years.

Unlike reconstruction, the BEAR Implant does not require a second surgical wound site to remove a healthy tendon from another part of the leg or using a deceased donor's tendon. The BEAR Implant acts as a bridge to help ends of the torn ACL heal together. The surgeon injects a small amount of the patient's own blood into the implant and inserts it between the torn ends of the ACL in a minimally invasive procedure.

"The combination of the BEAR Implant and the patient's blood enables the body to heal the torn ends of the ACL back together while maintaining the ACL's original attachments to the femur and tibia," said Dr. [Name, title]. "As the ACL heals, the BEAR Implant is resorbed by the body, usually within eight weeks."

Clinical studies have demonstrated that the BEAR Implant restores torn ACL quality and size similar to a patient's non-injured ACL. Compared with autograft ACL reconstruction, it also has shown faster recovery of muscle strength and higher patient satisfaction with regard to readiness to return to sport.

Patients should discuss their individual symptoms, diagnosis and treatment with their surgeon. The BEAR Implant has the same potential medical/surgical complications as other orthopedic surgical procedures, including ACL reconstruction. These include the risk of re-tear, infection, knee pain, meniscus injury and limited range of motion.

SAMPLE PATIENT QUOTE: "After my injury, I was scared I wouldn't be able to play soccer at the same level I was before," said [Name]. "But so far, my recovery has been smooth, and my doctor is confident I'll be back on the field soon and able to play soccer at college. I feel really good about choosing the BEAR Implant."

[Hospital/Practice Name] started using this breakthrough technology in [month year]. If you are at least 14 years of age, have a complete rupture of the ACL (as confirmed by MRI) and can undergo the surgery within 50 days of the injury, call [phone number] to schedule a consultation to see if you might be a good candidate for the BEAR Implant, or visit [website] for more information.

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[Include patient photo, if available.]

Medical Staff Newsletter Article

New Treatment at [Hospital] for Torn ACL

BEAR[®] Implant First Innovation in ACL Tear Treatment in 30+ Years

Orthopedic surgeons at [Hospital] are performing a new procedure to treat anterior cruciate ligament (ACL) tears using the BEAR[®] Implant – first medical technology to clinically demonstrate that it enables healing of the patient's torn ACL while maintaining the natural knee anatomy. This new approach is a paradigm shift from reconstruction and is the first innovation in ACL tear treatment in more than 30 years.¹

The BEAR Implant has been studied extensively and received De Novo marketing approval from the U.S. Food and Drug Administration in December 2020. The BEAR I and BEAR II clinical studies demonstrated that the BEAR Implant enables healing of the patient's torn ACL and restores torn ACL quality and size similar to a patient's non-injured ACL. Two-year follow-up data showed BEAR Implant was non-inferior to autograft ACL reconstruction in young, active athletes.² Based on these clinical trials, the procedure offers several advantages:

- **Restores natural anatomy and function of the knee.** The BEAR Implant acts as a bridge to help ends of the torn ACL heal together. We inject a small amount of the patient's own blood into the implant and insert it between the torn ends of the ACL in a minimally invasive procedure. The combination of the BEAR Implant and the patient's own blood enables the body to heal the torn ends of the ACL back together while maintaining the ACL's original attachments to the femur and tibia. As the ACL heals, the BEAR Implant is resorbed by the body, usually within eight weeks.
- Less invasive. Unlike reconstruction with a graft, the BEAR Implant does not require a second surgical wound site to remove a healthy tendon from another part of the leg or using a cadaver tendon.
- **Higher patient satisfaction.** Compared with autograft ACL reconstruction, the BEAR Implant showed faster recovery of muscle strength and higher patient satisfaction with regard to readiness to return to sports.

SAMPLE PHYSICIAN QUOTE: "Preserving a patient's native ACL instead of replacing it with a graft has long been a goal," [Name] said. "The BEAR Implant represents the first substantial advancement in the treatment of ACL tears in decades and has the potential to change the standard of care."

The BEAR Implant was pioneered by Martha Murray, M.D., founder of Miach Orthopaedics, at the Boston Children's Hospital Department of Orthopaedic Surgery with initial research funding provided by the NFL Players Association, Boston Children's Hospital and the National Institutes of Health. It 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 facilitate the restoration.

¹ Mascarenhas R, MacDonald PB. Anterior cruciate ligament reconstruction: a look at prosthetics--past, present and possible future. Mcgill J Med. 2008;11(1):29-37.

² Murray MM, Fleming BC. Use of a bioactive scaffold to stimulate anterior cruciate ligament healing also minimizes posttraumatic osteoarthritis after surgery. Am J Sports Med. 2013;41(8):1762-1770.

The BEAR device must be implanted within 50 days of injury. The BEAR Implant has the same potential medical/surgical complications as other orthopedic surgical procedures, including ACL reconstruction. These include the risk of re-tear, infection, knee pain, meniscus injury and limited range of motion.

To refer a patient for consultation, contact Dr. [Name] at [Phone].

Social Media Posts

Bridge-Enhanced® ACL Restoration (BEAR®) Implant Social Media Posts

Facebook

- Every year, approximately 400,000 ACL injuries occur in the U.S. A torn ACL does not heal without treatment, resulting in ACL reconstruction being one of the most common orthopedic procedures in the U.S. [Hospital] is one of the first in [City/State] to use a new, less-invasive procedure called the BEAR[®] Implant the first medical advancement to enable the body to heal its own torn ACL. [attach photo] [link to hospital website or animation]
- ACL injuries can be tough and usually require surgery. A new technology at [Hospital] provides patients with an option other than ACL reconstruction. The BEAR[®] Implant facilitates healing of the torn ACL and does not require a second surgical wound site to remove a healthy tendon from another part of the leg. [attach photo] [link to hospital website or animation]
- [Hospital] is thrilled to offer a new treatment option for adults and teens who suffer a torn ACL. As an alternative to ACL reconstruction, the BEAR[®] Implant has been approved by the FDA and enables the body to heal the torn ends of the ACL back together while maintaining the ACL's original attachments to the femur and tibia. [attach photo] [link to hospital website or animation]
- For patients like [Name] who suffer from an ACL injury, there's a worry that after reconstruction surgery they won't be able to return to the same level of activity. Dr. [Name] is using a new, less-invasive technology called the BEAR[®] Implant that has shown higher patient satisfaction in terms of readiness to return to sport. [link to newsletter patient story]

Twitter

- New approach to surgery for #ACLtears at [@Hospital] enables healing of the patient's #ACL while maintaining natural knee anatomy. #BEARImplant #ACLsurgery [link to hospital website]
- With 400,000 #ACL injuries every year in the U.S., Dr. [@Name] at [@Hospital] is helping patients safely heal their ACL using a new technology called #BEARImplant. [link to animation]
- .[@Hospital] offers new procedure for #ACLtears that restores the natural anatomy and function of the knee. #BEARImplant #ACLsurgery [link to hospital website]
- Patient [Name] is one of the first in the area to be treated at [@Hospital] with a new, less-invasive technology for #ACLtears. [link to newsletter patient story]

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[If you would like to include an animation video of the procedure, it can be linked from <u>YouTube</u>.]

BEAR® Implant Background & Media Interview Tips

To help you prepare for media interviews regarding the BEAR[®] Implant, this tip sheet has been developed to provide background on ACL injury and current treatment options.

Key Messages

Following are questions you may be asked, along with sample language you can use to create key messages in your own words. Please refer any questions about development of the BEAR Implant, cost, FDA approval, etc. to Miach Orthopaedics for response.

Question	Suggested Key Messages	
How common are ACL injuries?	 Every year, approximately 400,000 ACL injuries occur in the U.S., making them one of the most common knee injuries. 	
	 Without treatment, the ACL does not heal, resulting in ACL reconstruction surgery being one of the most common orthopedic procedures in the U.S. 	
What is the standard treatment for ACL injuries today?	 Today, the standard of care is to reconstruct the ACL. During an ACL reconstruction, the surgeon completely removes the remaining torn ACL and reconstructs it with either a tendon from the patient's own leg (called an autograft) or a graft from a deceased donor (called an allograft). 	
What are the drawbacks to ACL reconstruction?	 Both standard-of-care ACL reconstruction approaches have drawbacks that the less-invasive BEAR Implant overcomes. ACL reconstruction using an autograft stabilizes the knee, but it requires harvesting a graft of tendon from a previously healthy part of the leg, so patients will need to heal two surgical wounds. As with any surgery, ACL reconstruction has certain risks. About half of people who receive patellar tendon grafts experience pain while kneeling, and those who receive hamstring grafts have persistent weakness – as much as a 50% deficit at two years. ACL reconstruction using an allograft has been reported to have a lower success rate among younger, more active patients. There can also be variable quality of the donor grafts, as well as a risk of disease transmission. 	
How effective is ACL reconstruction?	 Both autograft and allograft ACL reconstruction approaches are effective, but they have an ACL re-tear rate as high as 20% for teens and as high as 9% for adults. A large number of athletes (more than 55%) can't return to the same level of sport. If the ACL is re-injured, revisions can also be complicated, often requiring multiple surgeries. 	

What is the BEAR Implant?	 The BEAR Implant acts as a bridge to help ends of the torn ACL heal together. The BEAR Implant represents a paradigm shift in the treatment of ACL tears from reconstruction to restoration. It is the first medical advancement to enable the body to heal its own torn ACL while maintaining the natural knee anatomy. Please do not refer to the BEAR Implant as a "scaffold" or "sponge." The preferred terminology is "implant."
What is the procedure process?	 Unlike reconstruction that uses a graft and is the current standard of care, the BEAR implant does not require a second surgical wound site to remove a healthy tendon from another part of the leg or using a deceased donor's tendon. The BEAR Implant acts as a bridge to help ends of the torn ACL heal together. The surgeon injects a small amount of the patient's own blood into the implant and inserts it between the torn ends of the ACL in a minimally invasive procedure. The combination of the BEAR Implant and the patient's blood enables the body to heal the torn ends of the ACL back together while maintaining the ACL's original attachments to the femur and tibia. As the ACL heals, the BEAR Implant is resorbed by the body, usually within eight weeks.
Is the BEAR Implant an effective treatment for ACL injuries?	 Clinical studies have demonstrated that the BEAR Implant restores torn ACL quality and size similar to a patient's non-injured ACL. Compared with autograft ACL reconstruction, it also has shown faster recovery of muscle strength and higher patient satisfaction with regard to readiness to return to sport. It is hoped that by providing more normal anatomy and function of the knee, a higher percentage of BEAR Implant patients will be able to return to the level of activities they enjoy.
What is the current length of recovery from an ACL-tear reconstruction surgery, and could this technology help athletes return to play sooner?	 Current length of recovery from traditional ACL reconstruction surgery is typically seven to nine months, and only about 55% of patients can return to their sport at the same level. While the return to sport is similar with the BEAR Implant, it is hoped that by providing more normal anatomy and function of the knee, a higher percentage of patients will be able to return to the level of activities they enjoy.

Tips for Controlling the Media Interview

There are techniques you can use to control the flow of an interview with a reporter. These include:

- 1. Repeat the Reporter's Question in Your Answer By repeating your answer in the question, it provides a complete "soundbite" that can be used by the media.
 - **Question:** What is the BEAR Implant?
 - Answer: The BEAR Implant is...
- 2. Repeat Your Key Messages Use one of the statements below to transition to your key message.
 - The most important point is...
 - Again, as you recall, what is really important is...
 - As a matter of fact...
 - The fact is...
 - Actually
- **3.** Manage Pregnant Pauses When a reporter is silent, don't feel like you have to keep talking. Instead, you can ask simple questions like the following, which put the ball back in the reporter's court.
 - Did I answer your question?
 - Is that clear?
- 4. Block and Bridge If a reporter asks a question you can't or don't want to answer, you can use the "block and bridge" technique to return to your key messages. Following are samples of blocking and bridging statements.

Block:	Bridge:
I can't speak to	What I can speak to is
I can't speculate on	What I do know is
That's not my area of expertise	What I can tell you is

5. Wrap up the Interview – At the interview close, if the reporter asks if there's anything else you want to say, repeat your key messages. Do NOT say "No, I think we've covered it," or anything to decline the opportunity to repeat your key messages! If the reporter wraps up the interview, feel free to add "The last thought I want to leave everyone with is..." and repeat your key messages!

Website Copy

BEAR® Implant

[Hospital/Physician Practice] is pioneering the use of a breakthrough technology called the BEAR[®] Implant for treatment of anterior cruciate ligament (ACL) tears, one of the most common knee injuries in the U.S.

The BEAR Implant is the first innovation in ACL tear treatment in more than 30 years. It is the first FDAapproved medical technology to enable healing of a torn ACL. This new approach is a shift from the current standard of care, reconstruction, which replaces the ACL with a graft.

Every year, approximately 400,000 ACL injuries occur in the U.S. A torn ACL does not heal without treatment, resulting in ACL reconstruction being one of the most common orthopedic procedures in the U.S. Yet the procedure has drawbacks; some procedures require two separate incisions, and some people who undergo reconstruction are unable to return to the same level of daily activities or sports.

There are a number of advantages to restoring a ligament instead of replacing it, and this exciting medical technology is the first to enable the body to heal its own torn ACL while maintaining the natural knee anatomy.

What does the procedure entail?

Unlike reconstruction, the BEAR Implant does not require a second surgical wound site to remove a healthy tendon from another part of the leg or using a deceased donor's tendon. Instead, the implant acts as a bridge to help ends of the torn ACL heal together.

The surgeon injects a small amount of your own blood into the implant and inserts it between the torn ends of the ACL in a minimally invasive procedure. The combination of the BEAR Implant and your blood enables the body to heal the torn ends of the ACL back together while maintaining the ACL's original attachments to the femur and tibia. As the ACL heals, the BEAR Implant is resorbed by the body, usually within eight weeks.

[can link to/embed animation]

Who is the procedure for?

Your physician may recommend the BEAR Implant if you are at least 14 years of age, skeletally mature, with a complete rupture of the ACL, as confirmed by MRI. You must have an ACL stump attached to the tibia to facilitate the restoration. The BEAR device must be implanted within 50 days of injury.

What are the benefits?

About half of people who receive patellar tendon grafts experience pain while kneeling, and those who receive hamstring grafts have persistent weakness – as much as a 50% deficit at two years. Since the BEAR Implant doesn't involve a graft, these types of complications don't occur.

Additionally, both ACL reconstruction approaches have an ACL re-tear rate as high as 20% for teens and as high as 9% for adults. If the ACL is re-injured, revisions to traditional ACL reconstruction can be complicated and can require multiple surgeries. Conversely, revisions with the BEAR Implant are easier and more predictive.

Unlike reconstruction, the BEAR implant does not require a second surgical wound site to remove a healthy tendon from another part of the leg or use of a deceased donor's tendon.

The BEAR Implant has the same potential medical/surgical complications as other orthopedic surgical procedures, including ACL reconstruction. These include the risk of re-tear, infection, knee pain, meniscus injury and limited range of motion. You should discuss your individual symptoms, diagnosis and treatment with their surgeon.

If you've injured your ACL, speak to your physician today to see if you might be a good candidate for BEAR Implant.

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[If you would like to include an animation video of the procedure, it can be embedded from <u>YouTube</u>.]

Referring Physician Letter/Email

Dear Dr. [Name],

I am now performing a new surgery at [Hospital] using the BEAR[®] Implant for treatment of anterior cruciate ligament (ACL) tears. The implant is the first medical technology to clinically demonstrate that it enables restoration of the patient's torn ACL. This new approach is a paradigm shift from ACL reconstruction and is the first innovation in ACL tear treatment in more than 30 years.¹

The BEAR Implant has been studied extensively and received De Novo marketing approval from the U.S. Food and Drug Administration in December 2020. The BEAR I and BEAR II clinical studies demonstrated that the BEAR Implant enables healing of the patient's torn ACL and restores torn ACL quality and size similar to a patient's non-injured ACL. Two-year follow-up data showed BEAR Implant was non-inferior to autograft ACL reconstruction in young, active athletes.² Based on these clinical trials, the procedure offers several advantages:

- **Restores natural anatomy and function of the knee.** The BEAR Implant acts as a bridge to help ends of the torn ACL heal together. We inject a small amount of the patient's own blood into the implant and insert it between the torn ends of the ACL in a minimally invasive procedure. The combination of the BEAR Implant and the patient's blood enables the body to heal the torn ends of the ACL back together while maintaining the ACL's original attachments to the femur and tibia. As the ACL heals, the BEAR Implant is resorbed by the body, usually within eight weeks.
- Less invasive. Unlike reconstruction with a graft, the BEAR Implant does not require a second surgical wound site to remove a healthy tendon from another part of the leg or using a cadaver tendon.
- **Higher patient satisfaction.** Compared with autograft ACL reconstruction, the BEAR Implant showed faster recovery of muscle strength and higher patient satisfaction with regard to readiness to return to sports.

Based on my own experience performing the BEAR Implant procedure and our results thus far, I believe this is procedure has the potential to become the standard of care for ACL injuries. If you have patients who are at least 14 years of age, are skeletally mature, have a complete rupture of the ACL (as confirmed by MRI) and would be able to complete the surgery within 50 days of the injury, we would be happy to see and evaluate them for the BEAR Implant. Complete information concerning the BEAR Implant, including indications, contra-indications, warnings and precautions is available here.

Please contact our office, [name] at [phone].

Sincerely, [Doctor name]

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¹ Mascarenhas R, MacDonald PB. Anterior cruciate ligament reconstruction: a look at prosthetics--past, present and possible future. Mcgill J Med. 2008;11(1):29-37.

² Murray MM, Fleming BC. Use of a bioactive scaffold to stimulate anterior cruciate ligament healing also minimizes posttraumatic osteoarthritis after surgery. Am J Sports Med. 2013;41(8):1762-1770.

Physical Therapist Letter/Email

Dear Dr. [Name],

I am now performing a new surgery at [Hospital] using the BEAR[®] Implant for treatment of anterior cruciate ligament (ACL) tears. This new approach is a paradigm shift from ACL reconstruction and is the first innovation in ACL tear treatment in more than 30 years.

The implant is a completely different approach to treating ACL tears and requires a unique physical therapy approach. Instead of reconstructing the ACL with a graft, the BEAR Implant acts as a bridge to help ends of the torn ACL heal together. The rehabilitation protocol for the BEAR Implant has been carefully designed to help protect the ACL during the healing process.

Here is the <u>link</u> for you to access the BEAR Implant Rehabilitation Protocol. If you have any questions, please contact our office at [phone].

Sincerely,

[Doctor name]

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Banner Ad Copy

BEAR® Implant Banner Ad Copy

[Link to BEAR Implant web copy on your hospital/practice website.]

New Technology Enables Injured ACL to Heal Itself

[Hospital/Physician Practice] now offering BEAR[®] Implant – first innovation in ACL tear treatment in 30+ years. Click to learn more.

[Hospital/Physician Practice] Now Offering BEAR[®] Implant

New technology enables injured ACL to heal itself. Click to learn more.

Do you have an ACL Injury?

New procedure at [Hospital/Practice] enables injured ACL to heal itself. Click to learn more.