IntraOsseous BioPlasty® (IOBP®) Procedure

Restore Subchondral Bone and Improve Knee Pain[1] With Your Own Cells

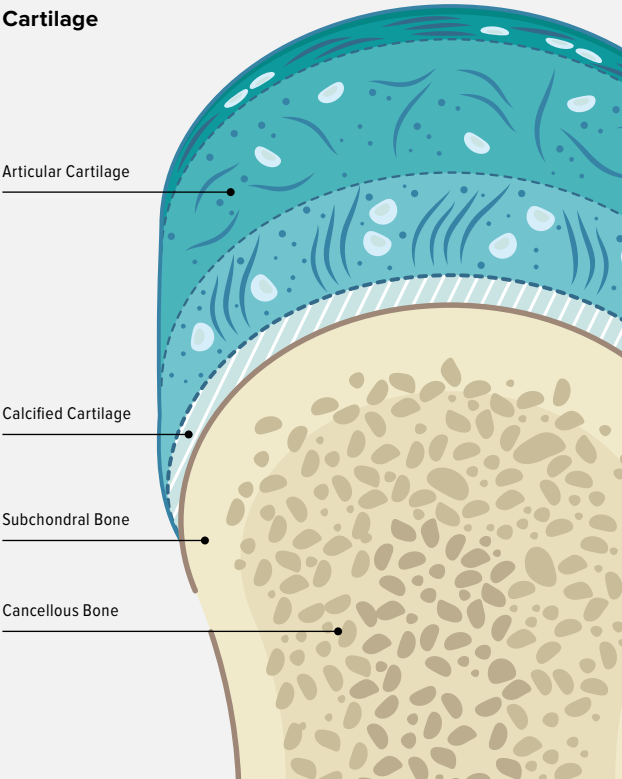
Arthrex®

About Subchondral Bone

The knee joint contains articular cartilage, calcified cartilage, and subchondral bone.[2] These structures are highly responsive to the forces placed on the joint that allow for normal movement within the joint.[3]

Knee pain can result from cartilage wear and tear as well as damage to the subchondral bone.[2] When the subchondral bone is damaged, this can result in bone marrow lesions (BMLs). Persistent BMLs are the result of both acute and chronic injuries, including insufficiency fractures, osteoarthritis, persistent bone bruises, and osteonecrosis. When conservative treatments do not help address the pain from BMLs, you may benefit from the IntraOsseous BioPlasty® (IOBP®) technique.

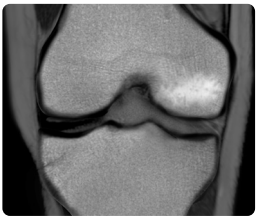
Left untreated, osteoarthritis in conjunction with a BML can rapidly progress and lead to a total knee arthroplasty.[4]



A Biologic Solution to a Biologic Problem

The IOBP® procedure is simple with a low complication rate[4] and may be performed in a doctor's office as a same-day outpatient procedure. Your doctor will visualize your knee, then use a biologic solution to fill your BML. It can also be performed at the same time as other procedures if you have additional injuries your doctor is treating.

What Is Being Injected?
Your doctor will inject bone marrow and bone graft concentrated using the Angel® cPRP and bone marrow processing system to stimulate your body's healing response.[5]

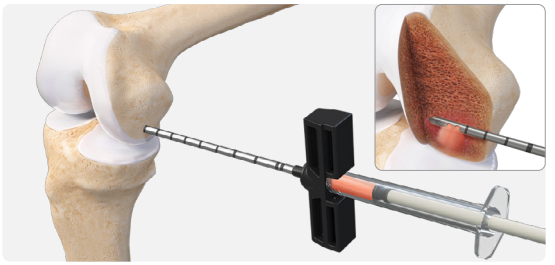


1

An MRI is used to identify the site of a BML. During the procedure, an x-ray or ultrasound is used to pinpoint the location of the BML and the respective injection.

2

Bone marrow aspirate is harvested then concentrated with the Angel system.



3

The biologic bone graft is delivered into the BML site to support bone healing and remodeling.

About the IOBP® Procedure

- Intended to relieve pressure in a joint and stimulate your body's natural healing response[5]
- Designed for injuries to the underlying bone (called subchondral bone) resulting from acute or chronic injuries[6]
- Can help restore blood flow and reduce pressure in the joint[6]
- Promotes bone repair and amplifies healing[7] using your own cells

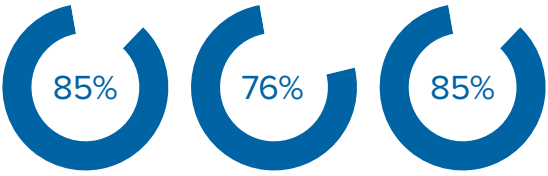
Benefits of IOBP Treatment

- Studies have shown reduced pain[8]
- May quickly return patients to activities of daily living, sports, and recreational activities[4,6]

IOBP Treatment Recovery

This same-day, outpatient procedure may allow patients to bear weight as tolerated, meaning an early return to function and activities of daily living.[4,6] Ask your doctor about any further recommendations or recovery information.

Treating subchondral bone pathologies with the IOBP procedure shows:



Improvement of pain within the first 6 months after the procedure[1]

Improvement of function during sports and recreational activities[1]

Improvement in pain, function, and daily activities[7]

Talk With Your Doctor

To see if the IOBP procedure is right for you, here are some potential questions to ask:

- How quickly can I get back to work?
- When can I return to physical activities?
- How much pain will I be in after my joint preservation procedure?
- Will insurance cover this procedure?
- What can I do to prepare for my recovery?

Important Safety Information

Angel® cPRP System With Aspiration Kit and Aspirate Kit

Indications

The Arthrex Angel System Kits are intended to be used intraoperatively at the point-of-care for the safe and rapid preparation of platelet-poor plasma and platelet concentrate (platelet-rich plasma) from a small sample of peripheral blood or a small sample of a mixture of peripheral blood and bone marrow. The platelet-poor plasma and platelet-rich plasma are mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

Contraindications

This system should not be used if you have blood supply limitations and previous infections, which may retard healing; any active infection or blood supply limitations; conditions that tend to limit your ability or willingness to restrict activities or follow directions during the healing period.

Adverse Effects

Possible side effects include infections, both deep and superficial; foreign body reactions; and hematoma.

Warnings

This system can only be sold by or on the order of a physician. It should be used by trained medical professionals. Do not resterilize this device. Do not reuse this device or any of its components. Using this device in a way that differs from the provided instructions may cause the device to fail, prevent it from working as intended, or negatively affect the surgical procedure. Following proper preoperative and surgical procedures, including using the correct surgical techniques and choosing and positioning the device appropriately, is important for the device to be used safely and effectively. Devices labeled for single use must never be reused. Reuse can create serious health and safety risks, including infection, device breakage with fragments left in the body, reduced mechanical performance from wear, malfunction or loss of function, and the inability to ensure proper cleaning or sterilization. Biohazard materials, such as removed devices, needles, and contaminated surgical instruments, should be disposed of safely according to the health care facility's policies. Report serious incidents to Arthrex, Inc., or its authorized representative, as well as to the appropriate health authority.

AlloSync™ Allograft

Indications

Demineralized bone fibers are made entirely from donated human tissue and are regulated by the U.S. Food and Drug Administration. They are intended only to be used in the body for purposes that match their natural function, specifically to help repair, replace, or rebuild areas of damaged or missing bone.

Adverse Effects

Any side effects or unexpected outcomes related to this tissue should be reported promptly to Arthrex, Inc., at 800-933-7001 ext. 78718 or Complaints@Arthrex.com.

Warnings

This tissue is intended for use in one patient during a single procedure only. Do not use this tissue if the packaging has been damaged or opened. Once the seal on the innermost package is broken, the tissue graft must be transplanted or discarded. This tissue must not be sterilized or resterilized by the health care facility. This tissue is intended to be used only by qualified health care professionals, such as physicians, dentists, or podiatrists. Although this tissue has been screened and tested for human pathogens and processed under sterile conditions, tissue derived from human donors may still carry a risk of transmitting infectious agents. It is the responsibility of the tissue provider, distributor, and/or the clinician using the tissue to ensure that it is stored under appropriate conditions before distribution or transplantation. If you have any questions or concerns, please discuss them with your health care provider.

The information contained in this brochure is not medical advice and is not meant to be a substitute for the advice provided by a surgeon or other qualified medical professional on the use of these products. You should talk with your physician or health care provider for more information about your health condition and whether Arthrex products might be appropriate for you. The surgeon who performs any surgical procedure is responsible for determining and using the appropriate techniques for surgical procedures on each individual patient. Arthrex recommends that surgeons be trained on the use of any particular product before using it in surgery. A surgeon must always rely on their own professional medical judgment when deciding whether to use a particular product when treating a particular patient. A surgeon must always refer to the package insert, product label, and/or directions for use before using any Arthrex product. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes. Products may not be available in all markets because product availability is subject to the regulatory approvals and medical practices in individual markets. Please contact Arthrex if you have questions about the availability of products in your area.

References

1. Sánchez M, Delgado D, Sánchez P, et al. *Biomed Res Int.* 2016;2016:4868613. doi:10.1155/2016/4868613 **2.** Stewart HL, Kawcak CE. *Front Vet Sci.* 2018;5:178. doi:10.3389/fvets.2018.00178 **3.** Lepage SIM, Robson N, Gilmore H, et al. *Tissue Eng Part B Rev.* 2019;25(2):114-125. doi:10.1089/ten.TEB.2018.0122 **4.** Tanamas SK, Wluka AE, Pelletier JP, et al. *Rheumatology (Oxford).* 2010;49(12):2413-2419. doi:10.1093/rheumatology/keq286 **5.** Hernigou P, Poignard A, Beaujean F, Rouard H. *J Bone Joint Surg Am.* 2005;87(7):1430-1437. doi:10.2106/JBJS.D.02215 **6.** Martin JR, Houdek MT, Sierra RJ. *Croat Med J.* 2013;54(3):219-224. doi:10.3325/cmj.2013.54.219 **7.** Hernigou P, Mathieu G, Poignard A, Manicom O, Beaujean F, Rouard H. *J Bone Joint Surg Am.* 2006;88 Suppl 1 Pt 2:322-327. doi:10.2106/JBJS.F.00203 **8.** Kasik CS, Martinkovich S, Mosier B, Akhavan S. *Arthrosc Sports Med Rehabil.* 2019;1(1):e7-e14. doi:10.1016/j.asmr.2019.07.001

Learn more about the IOBP® technique

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