Why is the meniscus so important long-term?

The menisci are two crescent-shaped disks of fibrous cartilage located in the knee joint between the femur and the tibia (fig. 1). The menisci play an important role in knee function. In particular, they transfer the load from the upper to the lower leg and help stabilize the knee during bending, stretching, and torsional movements. In addition, the menisci distribute the load on the articular cartilage (fig. 2), act as shock absorbers, and help lubricate, nourish/feed, and protect the knee joint.

Fig. 1

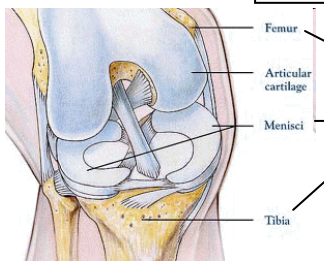
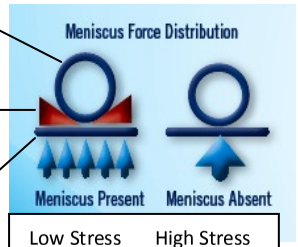


Fig. 2



A LACK OF MENISCAL TISSUE COULD RESULT IN DEVELOPMENT OF OSTEOARTHRITIS (OA) OF THE KNEE ASSOCIATED WITH CONSIDERABLE PAIN, LOSS OF MOTION, BONE SPURS, AND JOINT NARROWING (FIG.3). BECAUSE OF THESE IMPORTANT FUNCTIONS, EFFORTS SHOULD BE MADE TO KEEP THE MENISCI INTACT FOR AS LONG AS POSSIBLE TO PROTECT THE ARTICULAR CARTILAGE.

Fig. 3

30 y/o NFL player 7 yrs. post partial meniscectomy forced into early retirement

Common treatments for damaged menisci:
Partial Meniscectomy (90%)
Meniscus Repair (10%)
Meniscal Allograft (less 1%)

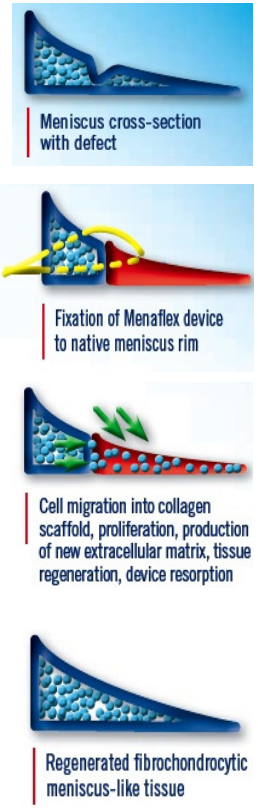
Note: late-stage OA may lead to Total Knee Replacement (TKR ~450,000/yr)

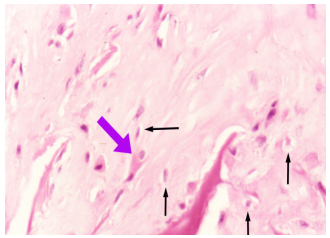
Introducing Menaflex… What is it?

Using Nature's way, Menaflex is a clinically proven biological method to safely replace lost or damaged meniscal tissue and to restore, as near as possible, the normal function of the meniscus. Menaflex is a resorbable natural implant with a spongy texture consisting of highly purified collagen, and its shape conforms to the human medial meniscus.

A Natural Biotech Advancement

- Menaflex uses the body's own healing capacity to regenerate tissue, as its porous structure serves as a tissue-engineering scaffold or template for ingrowth of new tissue.
- The body's own cells progressively migrate into the implant and produce new tissue.
- Menaflex is resorbed over time and replaced by new native tissue.





New tissue formed with body's own collagen cells

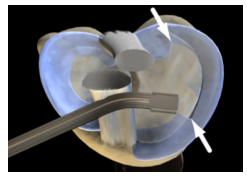
FACT: Clinical study* data show that Menaflex chronic patients gain 97% more tissue than they would have had with partial meniscectomy alone.

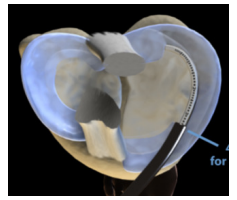
Who is a Menaflex candidate?

While your physician will determine the best care for you, identified below are a few examples highlighting Menaflex patient candidate qualifications for this arthroscopic procedure:

Indications (examples)

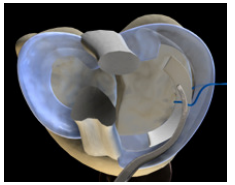
- Symptomatic knee who had a prior meniscectomy
- Acute tear (1st tissue resection) with significant tissue loss
- ACL surgery candidate with a loss of meniscus
- **Interest in joint preservation and ability to follow rehabilitation regimen**
  - **Young or Active**

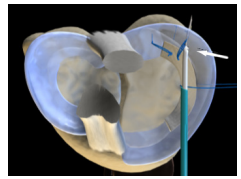




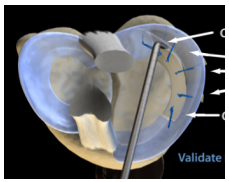
Contraindications (examples)

- Severe osteoarthritis
- Loss of the entire meniscus structure
- Uncorrected abnormal leg alignment
- Uncorrected ligamentous instability





Note: FDA cleared for use in the medial meniscus only.



What are the Rehabilitation expectations?

Short-Term effort for Long-Term results…

To maximize the success of Menaflex's regenerative process, it's extremely critical that patients fully understand and follow the recommended rehabilitation program throughout. It's important to remember that the newly formed tissue is undergoing a maturation process, so that even without pain, the tissue is still weak and should not be exposed to excessive stresses. Strict adherence to the rehabilitation regimen is of utmost importance.* Highlights of the rehabilitation regimen follow:

Weeks 1-4

- Sedentary activity- such as office work- can be resumed as early as the few days following the surgery…

Mos. 2-4

- Combination of weight-bearing, exercising, and strengthening ….

Mos. 5-6

- full-weight bearing and range of motion of the affected knee is possible, and specific training can begin for eventual return to usual sports or physically demanding activities.

***Please contact your physician's office for specific rehab protocols.**

Note: Extended rehab protocols are similar to other knee reconstructive procedures such as for ACL, articular cartilage deficiencies, and meniscal repairs.

New Hope in Meniscus injuries…

…Clinically proven Patient Benefits

*US Multi-Center Clinical Study **

"Menaflex vs. Partial Meniscectomy"

300+ Patients (1996-2003)

16 US Medical Centers

Greater than 5 year follow-up

Menaflex Patient Benefits:

Patients with Chronic or Acute Injuries:

- *Statistically significant improvements in pain, function and satisfaction from pre-op*

Patients with Chronic Injuries:

- *Regained more of their lost activity level than partial meniscectomy patients*
- *Fewer meniscus symptom related re-operations than partial meniscectomy patients*

*Rodkey WG, DeHaven KE, Montgomery WH, et al. Comparison of the collagen meniscus implant with partial meniscectomy: a prospective randomized trial. *J Bone Joint Surg AM*. July 2008;90:1413-1426.

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Quality of Life?

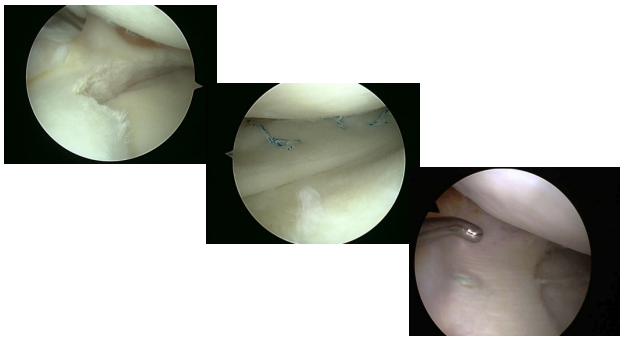
Partial Meniscectomy is not benign

Reduced Knee Pain?

Improved Knee Function?

Prevention Minded?

Joint Preservation: A common orthopedic goal in delaying the onset of Arthritis



"No longer do we remove, Now we repair…"