

FASCIAN INJECTION CONSENT ADDENDUM

In addition to any other potential risks and complications that Dr. _____ has explained to me. I am aware that after injection of the particulate fascia, known as FASCIAN, the following may occur.

Allergic Reactions: An allergic reaction would be considered extremely rare. Were it to occur, it could be as varied from a rash to a severe hypersensitivity reaction. Anti-inflammatory medications or additional medical treatment may be required.

Scarring: This can occur in two possible ways
(1) A scar may occur at any external puncture site. This is an extremely uncommon occurrence and usually would resolve with time.
(2) Scarring in the tissue underneath the skin occurs frequently. This is the normal tissue response to the injected fascia. Scarring is the process of replacing the graft with the body's own collagen.

Deformity: This is a term for any cosmetic irregularities that may occur after an injection. FASCIAN typically spreads evenly and smoothly through the tissue. The exact cosmetic configuration cannot always be achieved. Sometimes, touch-up procedures are required.

Revision Procedures: These are typically smaller procedures to correct any problems with the original procedure and are rarely necessary.

Numbness: Occurs from cutting across the sensation nerves in the area of the skin elevation. Since the injection site is a small area, a significantly large numb area would be rare. Although, it is not a functional problem, it can be an annoyance. Nerves are very slow to heal and it may be many months before sensation fully returns. Some areas of numbness may be permanent.

Discoloration: Persistent redness or bruising after injection is rare but it can occur. This typically goes away without further treatment but may occur over months.

Persistent Folds, Depressions or Wrinkles: FASCIAN injection typically improves skin irregularities in the area of injection. However, some folds, depressions or wrinkles may persist. There are no promises or guarantees regarding the degree of improvement.

The practice of medicine and surgery is not an exact science. Although good results are expected, there cannot be any guarantee or warranty expressed or implied by anyone as to the results that may be obtained with the use of FASCIAN. All complications may result in additional procedures and additional expenses to you.

PATIENT INITIALS:

"I certify that I have read and understand all of the above information on this consent addendum"

PATIENT SIGNATURE: _____

DATE: _____

PHYSICIAN SIGNATURE: _____

DATE: _____

STAFF SIGNATURE: _____

DATE: _____