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## FLUID SILICONE IMPLANTATION OF THE FOOT

Independent study indicates injectable silicone is effective as an office treatment for corns and calluses. Since 1964, 1605 patients have received fluid silicone implants as an alternative to lifelong care or surgery for pressure-related foot disorders. This pamphlet answers questions on use of the fluid.

### WHAT IS FLUID SILICONE?

Fluid silicone is a clear, colorless, chemically inert synthetic oil that is classified as an injectable medical device by the Food and Drug Administration (FDA). Other silicones may be the consistency of water, gel or rubber, and are widely used in medicine and industry.

### WHAT ARE SOME OTHER MEDICAL USES OF SILICONE?

The silicone breast implant has had extensive media attention, however, a variety of surgical silicone devices are generally available, some for 45 years. These include:

- Hand and foot implants for arthritic joint reconstruction
- Hydrocephalus shunt for water on the brain
- Birth control implants
- Penile implants for male erectile dysfunction
- Testicular implants for poorly developed or diseased testes
- Artificial urethra
- Catheters, drains, and tubing
- Implants for paralyzed vocal cords
- Implants for cosmetic facial repair
- Silicone intraocular lenses for cataract surgery
- Fluid silicone has been used for 45 years as a lubricant to coat the outside of needles and inside of syringes. Yearly, billions of injections leave trace amounts of silicone fluid in the body, with no known tissue reaction. Injectable silicone oil was approved by the FDA in 1994 for treatment of detached retina.

### WHAT IS THE STATUS OF THIS TREATMENT?

Official studies in the United States to evaluate safety and efficacy have not been concluded, therefore its use in the foot is considered experimental and not FDA approved. However, injectable silicone for the foot (trademarked PodiSil) has been approved in Europe.

### FOR WHAT PROBLEMS IN THE FOOT HAS THE FLUID BEEN USED?

Silicone has been injected for corns, calluses, painful lack of fatty tissue, and prevention of painless diabetic foot ulcers.

**WHAT CAUSES CORNS AND CALLUSES?**

Friction and pressure. Considering we walk over 100,000 miles in a lifetime, mostly on hard surfaces in poorly designed, ill-fitting shoes, it is understandable why tissues wear out. Years of pressure results in a gradual loss of protective fat which explains why these problems worsen with age.

**HOW DOES THE SILICONE WORK?**

Injected silicone combines with existing fatty tissue and induces the formation of collagen fibers, the main supportive framework of skin and other tissues. The fluid is engulfed by cells and transformed into countless microscopic droplets that remain at or near the injected sites, serving as an internal soft tissue cushion at points of pressure.

**IS THE TREATMENT PAINFUL?**

Generally not. A skin freeze-spray or pressure-syringe without a needle permits the injection of local anesthesia and silicone with minimal or no discomfort.

**HOW MANY IMPLANTS ARE REQUIRED AND HOW OFTEN ARE THEY GIVEN?**

Three to 4 implants are needed to cushion a corn, and 4 to 8 for a callus on the bottom of the foot. Office calls may be spaced at 1 to 4 week intervals.

**HOW MUCH FLUID IS USED?**

The total amount needed for a typical callus equals about one-fifth teaspoonful, with only one-third that amount to treat a corn.

**IS THERE ANY DISABILITY FOLLOWING THE TREATMENT?**

No. Once the silicone has been implanted, regular activities can be resumed immediately.

**DOES THE SILICONE HARDEN?**

No. The fluid remains the consistency of fat with no awareness of the increased cushioning.

**CAN THE SILICONE BE REMOVED?**

Once injected, it becomes part of the soft tissue and can only be removed surgically.

**DOES THE SILICONE TRAVEL THROUGHOUT THE BODY?**

Autopsy studies show microscopic amounts can migrate from the foot to lymph nodes in the groin without symptoms or complaint. Most fluid, however, remains at or near the injected site.

**WHAT ARE THE RISKS?**

Rare skin discoloration and/or painless movement of the silicone have been observed. Very rarely, the fluid moves to form a skin tag or lump that may warrant surgical removal.

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**HOW EFFECTIVE IS THE TREATMENT?**

From 65% to 85% of painful corns and calluses are either eliminated or greatly improved.

**IS THERE A CONTINUING NEED FOR FUTURE INJECTIONS?**

Just as normal fat can thin out, so too may the silicone. Up to 50% of calluses and 20% of corns will need one or more "booster" implants several to many years later.

**WHAT ARE THE ALTERNATIVES IF THE SILICONE DOES NOT WORK?**

The same two choices that existed prior to implant therapy: either a continued trimming of the corn or callus, or surgery to remove or alter an underlying bony prominence.

**HOW SAFE IS FLUID SILICONE?**

In 41 years, over 25,000 silicone implants have been given for the treatment of several thousand corns and calluses without any serious complications. No infection, allergic reaction, or fluid rejection has been observed. The immune disorders, allegedly related to silicone gel-filled breast implants, such as joint or muscle pain, fatigue, fever, or connective tissue disease, have not been associated with foot injections. Multiple studies conclude there is no scientific evidence which shows silicone breast implants are related to any disease.

**WILL INSURANCE HELP COVER THIS TREATMENT?**

As this is not a government approved procedure, Medicare, most insurance companies, and Health Maintenance Organizations do not provide benefits.

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**FLUID SILICONE  
RESTORES CUSHIONING  
BETWEEN SKIN AND BONE**