Agili-C™ Benefits and Risks

Possible benefits from taking part in this study

Using the Agili-C™ implant may help repair your cartilage and bone.
However, it is possible that you will receive no direct health benefit from being in this study. Information collected during this study will increase medical knowledge and help treat diseases of cartilage and bone and in the future, may help other patients like you.

General procedure related risks – applicable for both SSOC and Agili-C™

In any surgical procedure, there are risks involved. Some of these risks, if occur, may necessitate additional surgery, prolonged hospitalization, and/or extended outpatient therapy to permit adequate treatment. Rarely may they lead to severe health deterioration, up to death.
It is possible, though unusual, to experience a bleeding episode during or after surgery.
Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood (hematoma). The need for blood transfusion is extremely rare.
Although strokes, blood clots, blood clots going to the lungs and heart attacks (myocardial infarction) caused by complications within the circulation are extremely rare in young and fit patients, they can be more common in those with underlying medical conditions.
You may experience a heart attack or stroke; blood clots may accumulate in the veins or lungs. This complication might necessitate other treatments and might lead to significant disability or even death.
As cartilage repair procedures focus on the joints, the risk of accidental damage to major organs or blood vessels during surgery is minimal, however, there is some risk of damage to surrounding structures, including vessels, nerves, or adjacent joint tissue.
Tobacco use increases the risk of infection and other complications, and has a serious negative effect on the outcome of any type of cartilage repair. There are inherent risks of anaesthesia, including drug reactions, damage to airway if endotracheal intubation is used, infection if local or regional anaesthesia is used and nerve damage if regional anaesthesia is used.
Extremely rare instances of severe allergic reaction have been reported, and death is reported in approximately 1 in 100,000 patients undergoing general anaesthesia.
In cartilage repair procedures, there is also the possibility that despite the best efforts of the healthcare team, the procedure does not achieve the desired outcome.
In such cases, the patient and the doctor will discuss future options and the potential for further treatments or procedures.

Risks that may occur during arthrotomy (opening of the knee joint) or mini-arthrotomy

An operative incision is expected to leave a scar that might be numb, painful or associated with surrounding skin numbness. In rare cases the scar might become hypertrophic or discoloured. The scar should be protected from sun exposure for a year after surgery especially in dark skinned individuals.

Surgical approach to a joint might lead to local infection that might be early or late in occurrence, necessitating antibiotic treatment or repeat surgery with wound lavage (washing). Surgical arthrotomy (opening of the knee joint) or even arthroscopy might lead to worsening of the arthritic process with pain and limitation of function. In some cases, an intra articular-scar (arthrofibrosis) might develop limiting joint motion. There may be temporary or permanent stiffness, swelling, and pain after the procedure.
There may be damage to the surrounding nerves, which could lead to tingling, numbness, pain, and weakness in the affected area. Use of a tourniquet device to limit blood flow to the limb during surgery helps prevent blood loss and improves structure visualization. In some cases tourniquet use might lead to nerve injury including decreased sensation in the foot, or even muscle weakness in the foot. There may be damage to the surrounding tendons. You may develop fluid collection in the joint, necessitating fluid removal through a needle. You may develop an allergic reaction to tape, suture material, or topical preparations. Systemic reactions that are more serious may result from drugs used during surgery and prescription medicines. Allergic reaction may require additional treatment. The surgery may fail to achieve the intended result, your condition may worsen, necessitating a reoperation.

Risks associated with the SSOC Group
The treatment in the SSOC group may include microfracture and / or debridement. Either of these treatments may lead to worsening of the joint degradation process, requiring pain medication or even repeated surgery. Cartilage lesions are associated with the development of knee arthritis over the long term. In some rare cases, following these treatments avascular necrosis of the treated condyle might occur (decreased or lack of blood supply to the bone), a painful process though often reversible. Rarely additional surgery is needed due to bone collapse. Such surgery might eventually require total or partial joint replacement (joint arthroplasty).
Rarely a device used for microfracture or debridement might break inside the joint. Fragments of metal might flake off the device. Most often these complications do not lead to adverse results.
Microfracture might accelerate the degenerative (osteoarthritic) process, leading to worsening of pain and function, and might shorten the period until joint arthroplasty (implantation of a total joint replacement device) is required. Smoking and non-compliance with the suggested rehabilitation regimen might compromise the chances for success.

Agili-C™ specific risks
Following are risks that may occur if you receive the Agili-C™:
- Improper placement of the implant, which might lead to poor surgical results
- Implant breakage, instability or implant loosening leading to failure of the procedure which might require a repeated procedure
- Bone breakage

- Damage to nerves which might cause problems in sensation and motion of the foot and ankle Problem to blood supply to the foot
- Bone cyst formation
- Particulate debris may cause an inflammatory response - joint swelling, fluid accumulation, pain and limitation of joint function. Occasionally the joint might feel warm or assume a reddish tint
- Idiosyncratic rejection reaction – such as fluid accumulation in the joint, pain and decreased range of motion, inflammation of the membrane lining of the joint. This is a rare reaction that is patient specific and might be caused by the device or its related instruments.
- Effusion – painful accumulation of fluid in the knee
- Pain
- Synovitis – inflammation of the membrane lining of the joint
- Fever
- Inflammation might lead to degeneration of other articular surfaces, as well as ligament laxity and joint deformity
- Bone edema - a situation observed on MRI in which there is abnormal MRI signal indicating water accumulation in the bone. Such water accumulation is often painful and can limit joint function. Sometimes it resolves spontaneously and sometimes it requires surgical intervention such as drilling or even joint arthroplasty
- Undesired tissue growth in the defect: e.g. partial ingrowth, overgrowth, fibrous tissue ingrowth or partial coverage of the implant
- Muscle atrophy - weak muscles who lost tissue volume and cannot develop sufficient strength, may lead to pain and joint instability

There are other risks to Agili-C™ implantation procedure that are currently unforeseeable.

Possibility of a repeat arthroscopy

The need for arthroscopy is determined by your doctor. This procedure may occur for either study group. There is a possibility that a repeat arthroscopy will be necessary due to currently unknown clinical circumstances. During this procedure, your doctor may need to remove pieces of tissue or pieces of the implant. Any tissue or implant that is removed (called a biopsy sample) will be collected and evaluated.