



Autologous Stem Cell Therapy for
Cartilage Lesions

OVERVIEW AND OPTIONS

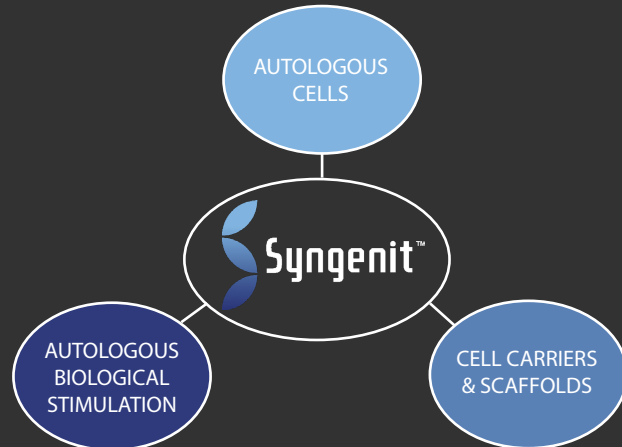
WHAT IS SYNGENIT?

Syngenit™ provides patients with a choice of injection-based or surgical treatments for cartilage damage. Syngenit uses Bone Marrow Aspirate Concentrate (BMAC) as a source of concentrated stem cells. These cells are obtained from bone marrow aspirated from the patient which is normally performed under a General Anaesthetic (GA). The clinician may offer a local anaesthetic if appropriate. Bone marrow aspiration takes a few minutes to complete and is typically from the pelvis or tibia (shin bone). Depending on the procedure, the total clinical time is 30 to 60 minutes for Syngenit Injectables or Injectables Plus. Syngenit Surgical is normally completed in 60 to 90 minutes. A review of the first 100 patients (2016-2019) demonstrates a significant improvement in patient outcomes using the Syngenit Surgical procedure.



MRI example of a patient who underwent syngenit surgical procedure for a knee cartilage defect.

THE PRINCIPALS OF REGENERATIVE MEDICINE IN ORTHOPAEDIC CONDITIONS



Autologous (definition): Cells or tissues obtained from the same individual.

The principal of Syngenit is to use materials from the patient (such as stem cells) where possible and to re-implant them in a biologically optimal environment enabling regeneration and healing. This is a single clinical intervention completed within the operating room. It does not involve removing autologous materials for laboratory manipulation and/or expansion and the need for a second procedure at a later date.

IS THERE ANY EVIDENCE THIS WORKS?

There have been multiple peer-reviewed publications evidencing the use of BMAC in the regeneration of cartilage defects from 2009 to date.

Current clinical results are more supportive for surgical intervention than injections.

WHY IS PATIENT BONE MARROW USED?

Bone Marrow Aspirate is used because it is a source of stem cells and is relatively easy to obtain from the patient. Stem cells have the potential to differentiate into different types of cells including cartilage.

Depending on the condition being treated, the stem cell concentrate may be reintroduced into the patient using the following options:



The BMAC is suspended in Sodium Hyaluronate and injected back into the patient.



The BMAC is used in conjunction with a fibrin glue. This combination may be given by injection or through a small surgical incision for certain defects.



This is for larger cartilage defects requiring surgery. The BMAC is applied to a pad which is placed into the defect through a small incision and retained with fibrin glue.



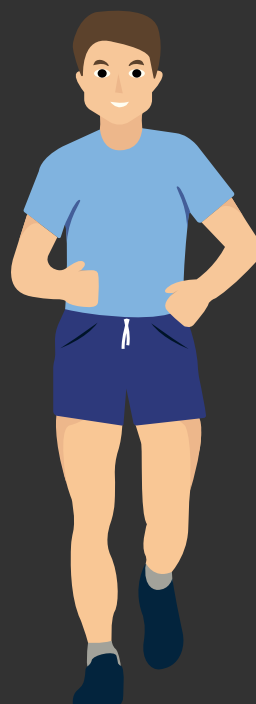
Syngenit Adipose offers a system for the aspiration and processing of adipose tissue in the operating room. The system uses saline solution and a variable filter membrane to refine the source material ready for patient use. - *Please enquire for availability.*

PATIENT SUITABILITY

Clinicians familiar with treating cartilage damage can advise on the most appropriate options.

Patients should ideally meet the optimal selection criteria because clinical evidence suggests improved outcomes when factoring patient age, previous interventions, an appropriate weight (BMI) and being a non-smoker.

The current analysis of patient outcomes suggests certain criteria will give a more satisfactory result. Here is a patient that fits these criteria.



This will be my first cartilage regeneration surgery on this knee. Previous surgeries can impact results.

I have a BMI under 35 and I am in good shape.

I have an otherwise healthy knee. This is not a solution for osteoarthritis

I am aged 55 or less.

I am a non-smoker. Smoking is detrimental to cell health and healing

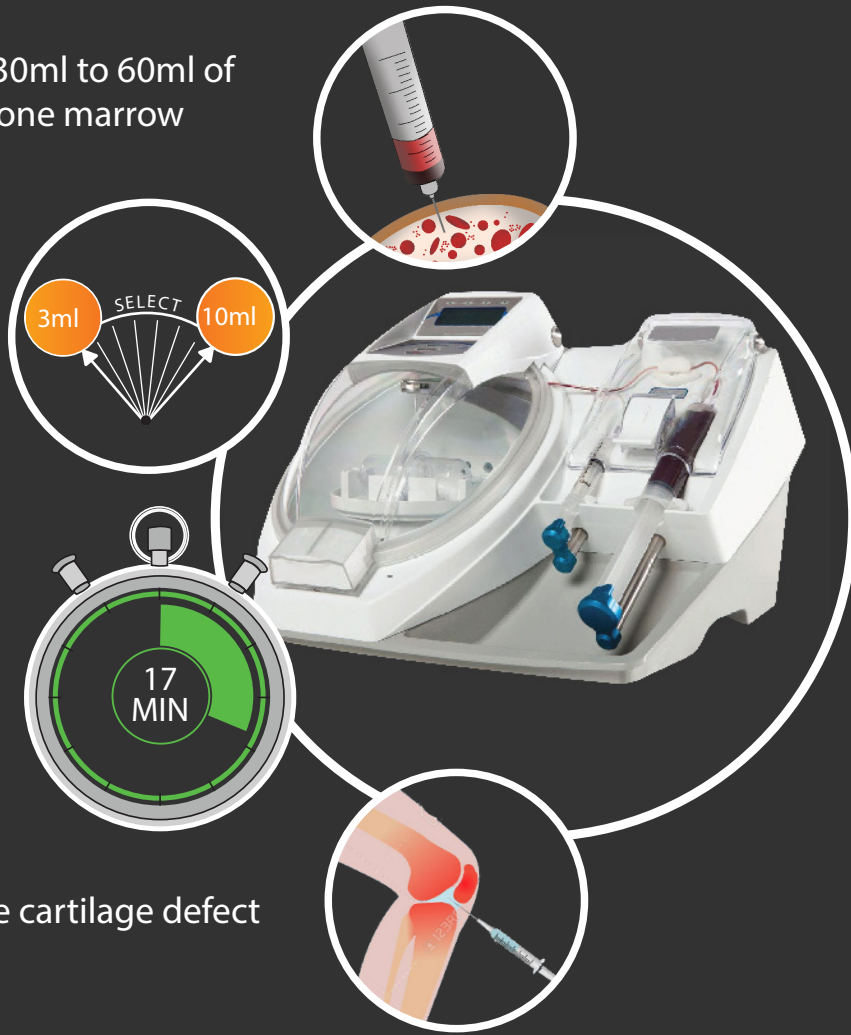
OVERVIEW

Aspirate 30ml to 60ml of patient bone marrow

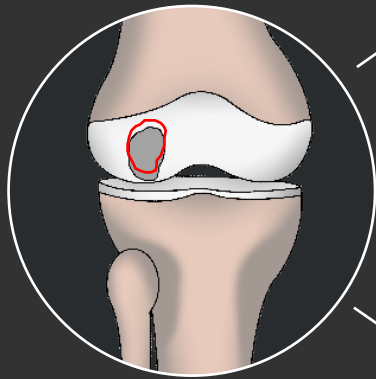
Select 3ml to 10ml of bone marrow aspirate concentrate (BMAC)

BMAC processing time

Implant into the cartilage defect



Defect Sizes and their solutions.



0-6mm
19mm²

Syngenit[™]
INJECTABLES

6-8mm
19-25mm²

Syngenit[™]
INJECTABLES
PLUS **+**

>8mm
>25mm²

Syngenit[™]
SURGICAL



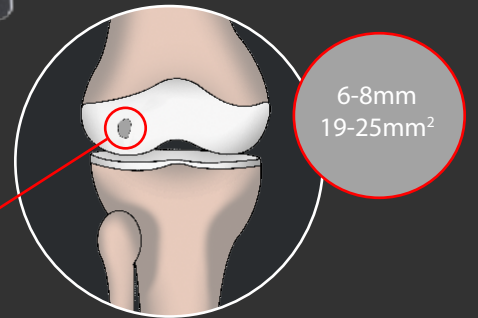
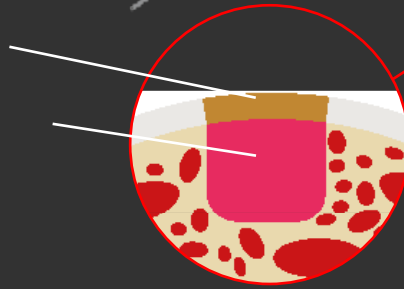
BMAC + Sodium Hyaluronate



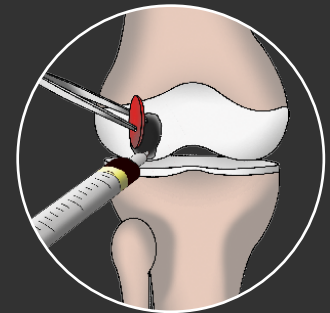
BMAC + fibrin glue

fibrin glue 'Cap'

BMAC+ fibrin glue



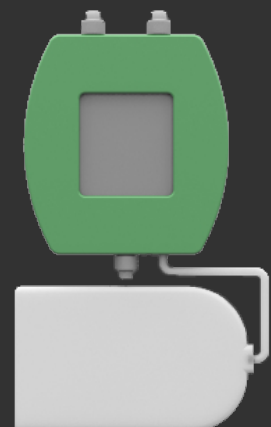
Surgical application of BMAC in conjunction with fibrin glue for defects 6 to 8mm



This is for larger cartilage defects requiring surgery. The BMAC is applied to a pad which is placed into the defect through a small incision and retained with the fibrin glue.

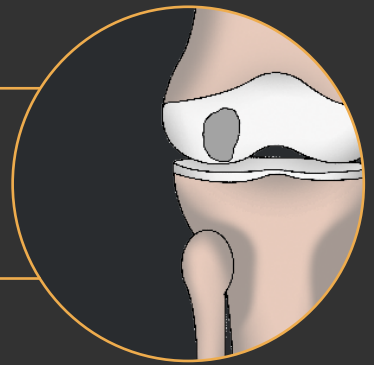


Syngenit Adipose offers a system for the aspiration and processing of adipose tissue in the operating room. The system uses saline solution and a variable filter membrane to refine the source material ready for patient use.
- Please enquire for availability.



PROCEDURE OVERVIEW

The cartilage defect is identified prior to the surgery using MRI. An arthroscopy may also be used to verify the defect is suitable for this treatment.



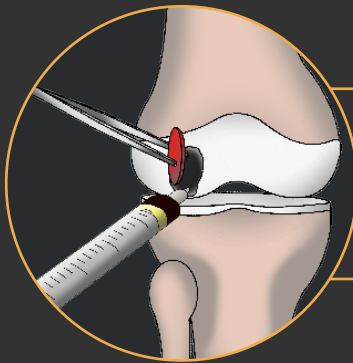
Bone marrow aspirate is harvested and used to produce stem cell concentrate.



The surgeon will make a small incision and prepare the cartilage defect. The stem cell concentrate is applied to a pad.



The pad containing the stem cells is placed into the cartilage defect and secured using a fibrin glue.



THE OPTIMAL BIOLOGICAL ENVIRONMENT

Autologous (Def): Cells or tissues obtained from the same individual

The principle of Syngenit™ Surgical is to create an optimal environment for your own cells to differentiate into new articular cartilage. This is done by concentrating undifferentiated stem cells, using some of your bone marrow. These cells are applied to a pad and retained with a fibrin glue. The objective is to enable these undifferentiated bone marrow cells to become cartilage cells and repair your defect.

COMMON QUESTIONS

BEFORE SURGERY

WHAT SHOULD I DO (or not do) THE DAY BEFORE?

At your last clinic appointment you will have received instructions on what to do

WHAT SHOULD I DO (or not do) ON THE DAY?

It is important not to eat or drink beyond the deadline advised by the clinician

THE SURGERY

HOW LONG WILL THE OPERATION TAKE?

Typically the surgery lasts 60 - 90 minutes

WILL I BE GIVEN AN ANAESTHETIC?

You will be given a general anaesthetic and a nerve block to help with pain management

WILL THIS BE PERFORMED ARTHROSCOPICALLY?

The surgeon will make a small incision to treat the cartilage lesion

AFTER SURGERY

HOW LONG WILL I BE REQUIRED TO STAY IN HOSPITAL?

You are likely to have an overnight stay. In some cases you may be discharged on the same day

HOW MUCH PAIN WILL I BE IN AFTER SURGERY?

You are likely to experience some pain/discomfort which will usually be well controlled with pain killers

BACK TO AN ACTIVE LIFE

HOW LONG WILL MY PHYSIOTHERAPY LAST FOR?

You will be encouraged to follow the knee rehabilitation programme, this can typically be 3-6 months.

CAN I GET BACK TO ACTIVE SPORT / TASKS OR WILL I HAVE LIMITATIONS?

Your physiotherapist will work with you to get you back to an active life as soon as possible



DISCLAIMER

This document is for general information purposes and does not constitute an incentive or directive to receive or undertake the surgical techniques described herein. Patients should discuss their clinical needs with appropriate healthcare professional(s) and make an informed decision as to the most appropriate treatment for them. The authors of this document accept no responsibility or liabilities for the decisions made by the patient. Any patient considering their clinical options hereby understands and accepts this statement.

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