

# Patient Educational Leaflet

## SpheChon 10-70 spheroids/cm<sup>2</sup> implantation suspension spheroids of human autologous matrix-associated chondrocytes

**Read all of this leaflet carefully before you are administered this cell therapy because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor or physiotherapist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What SpheChon is and what it is used for
2. What you need to know before you are administered SpheChon
3. How SpheChon is administered to you
4. Possible side effects
5. Contents of the pack and other information

#### 1. What SpheChon is and what it is used for

SpheChon is a cell therapy used to **repair damage to the cartilage of the knee** in adults and in adolescents whose bones in the joint have finished growing. Cartilage is a hard smooth layer inside your joints, on the ends of the bones. It protects the bones and allows joints to work smoothly. SpheChon is used in adults, or adolescents whose bones have finished growing, when the cartilage in the knee joint is damaged, for example by acute injury, such as a fall or long-term wear due to incorrect weight bearing on the joint. SpheChon is used to treat defect sizes from 1 cm<sup>2</sup> to 10 cm<sup>2</sup>.

SpheChon consists of spheroids made of cartilage cells and cartilage material derived from your own body. To make the spheroids, a small cartilage sample is taken from one of your joints during a minor operation, and then grown in the laboratory to make the cell therapy. The spheroids are implanted by surgery to the damaged cartilage area and stick to the damaged part. They are then expected to repair the damage with healthy and functional cartilage over time.

#### 2. What you need to know before you are administered SpheChon

##### Do not use SpheChon if

- the bones in the knee joint have not finished growing
- you have advanced joint and bone inflammation with damage in the affected joint (osteoarthritis)
- you are infected with human immunodeficiency virus (HIV; the virus that causes acquired immunodeficiency syndrome [AIDS]), hepatitis B virus or hepatitis C virus

##### Warnings and precautions

Talk to your doctor before you are administered SpheChon, if you have any other joint problems or excess weight, as this may reduce the success of the procedure.

SpheChon should preferably be implanted into an otherwise healthy joint. Other joint problems should be corrected before or at the time of SpheChon implantation.

You may experience bleeding into the knee joint and possibly into the surrounding area after treatment, especially if you have an increased tendency of bleeding or if bleeding during the treatment

could not be fully stopped. You may also have an increased tendency to form blood clots in your veins. Your doctor will check in advance your risk of bleeding as well as your risk of blood clots formation due to the treatment. In these cases, you will get medications to decrease the risk of bleeding, or medications to prevent blood clot formation after the treatment.

### Rehabilitation program

Follow the rehabilitation program strictly after implantation. **Only** resume **physical activity when instructed** by your doctor. Resuming vigorous activity too soon may reduce the benefit and durability of SpheChon.

### Other cases in which SpheChon cannot be supplied

Even if the cartilage sample has already been taken, it is still possible that you cannot be treated with SpheChon. This can occur because the sample taken is not of sufficient quality to manufacture the product. Your doctor might have to select an alternative treatment for you.

### **Children and adolescents**

SpheChon **shall not be used** in children or adolescents whose bones in the knee joint have not finished growing.

### **Other medicines and SpheChon**

Tell your doctor if you are using, have recently used or might use any other medicines.

### **Pregnancy and breast-feeding**

SpheChon is **not recommended** for pregnant or breast-feeding women, as it is administered during surgery. Ask your doctor for advice if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

### **Driving and using machines**

The surgical procedures to remove a sample of your cartilage and to implant this cell therapy will have a major influence on your ability to drive and use machines. Driving cars and using machines may be limited during the rehabilitation period. Strictly follow the advice of your doctor or physiotherapist.

## **3. How SpheChon is administered to you**

SpheChon will be carefully stored by medical staff in the hospital and can only be implanted by a specialist doctor in a medical facility. The product must only be used in the patient for whom it has been prepared.

***Treatment with SpheChon is a two-step procedure:***

### **Visit 1:**

#### **Evaluation of the damage to the cartilage, sample and blood taking**

On the first visit, the doctor will examine the damage to your knee cartilage during an exploratory operation. This is usually done as keyhole surgery through very small incisions (cuts), using a special instrument to look inside the knee (arthroscopy).

If SpheChon is appropriate for you, the doctor will take a small **cartilage sample from your joint**. Most likely this will be from the same knee joint that has to be treated. Your cartilage cells are extracted from this sample in a laboratory and are then grown to make the spheroids that constitute SpheChon. The process takes about 6 to 8 weeks.

### **Visit 2:**

#### **SpheChon implantation**

SpheChon is implanted into the damaged area of cartilage in the knee during a second operation. This may also be carried out by keyhole surgery.

#### **Rehabilitation**

In order to allow your knee joint to recover well, you will have to follow an individual rehabilitation program. This may take up to one year. Your doctor or physiotherapist will advise you.

**Very important:** Carefully follow the recommendations of your doctor and physiotherapist. The risk of treatment failure may increase if you do not **follow your rehabilitation schedule**.

Be very careful when bending and putting weight on your treated joint. During the rehabilitation period, the amount of weight you can put on the joint will increase gradually. How quickly this occurs depends on factors such as your body weight and the extent of the damage to the cartilage. Depending on the condition of the treated knee joint, you may have to wear a brace.

Ask your doctor or physiotherapist if you have any further questions about treatment with SpheChon.

#### **4. Possible side effects**

Like all medicines, this cell therapy can cause side effects, although not everybody gets them. Side effects appearing after the implantation of SpheChon are mostly related to the surgery. The recorded side effects, either caused by the cell therapy or the surgery, were in most cases not serious.

**If you get any of the following serious side effects, you should immediately contact a doctor:**

- hypersensitivity (allergy) (one or more of the following symptoms may occur: skin redness, swelling in the treated area, low blood pressure, difficulties to breathe, swollen tongue or throat, weak and rapid pulse, sickness, vomiting, diarrhoea, dizziness, fainting, fever)
- blood clot in a vein (one or more of the following symptoms may occur: swelling in the leg, pain, increased warmth in the leg)

#### **Other side effects**

Side effects can occur with the following frequencies:

**Common:** may affect up to 1 in 10 people

- accumulation of fluid in the knee
- pain in the knee
- swelling in the knee
- accumulation of excess fluid in the bone marrow
- pain

**Uncommon:** may affect up to 1 in 100 people

- increase in size of the cartilage cells, softening of cartilage. *You may notice symptoms such as swelling or pain of the tissues around the knee.*
- cracking sounds in the knee
- joint lock in the knee
- impairment of walking
- tissue lump that may occur in the knee, fragment of cartilage or bone that freely floats in the knee joint space. *You may notice symptoms such as painless heavy swelling of the treated knee, sudden pain or problems to move the treated knee.*
- cartilage cells in SpheChon do not survive and grow
- any damage of knee cartilage
- ligament disorder
- tendon inflammation
- muscle weakness
- pain in the front of the knee or kneecap
- swelling of the treated leg due to obstructed flow of tissue fluid via the lymph vessels
- scar tissue pain
- blockage of a blood vessel in the lung
- inflammation of the inner layer of the joint capsule

**Rare:** may affect up to 1 in 1000 people

- disorder of bone formation, death of bone tissue, bone formation outside the skeleton. *You may notice symptoms such as swelling or pain of the tissues around the knee.*
- infection at the site of implantation
- inflammation of the knee joint caused by bacteria or fungi
- partial or complete detachment of the tissue beneath the bone and surrounding cartilage
- inflammation of the bone marrow caused by bacteria or fungi
- inflammation of the skin and/or the soft tissue caused by bacteria or fungi
- pain below the kneecap due to inflammation of the soft tissue
- inflammation of veins combined with the formation of a blood clot located near the surface of the skin (symptoms: e.g. redness and/or warmth of the skin along the vein, tenderness, pain)
- healing complication in the area of treatment
- reopening of a closed wound
- bruising

**Very rare:** may affect up to 1 in 10,000 people

- discomfort

**Not known:** frequency cannot be determined

- excessive scar tissue formation within the knee joint and/or surrounding of soft tissues
- infection of the lungs

## **Reporting side effects**

If you get any side effects, talk to your doctor or physiotherapist. This includes any possible side effects not listed in this leaflet.

## **5. Contents of the pack and other information**

### **What SpheChon contains**

- The active substance of SpheChon are spheroids that consist of cartilage cells and cartilage material derived from your own body.  
SpheChon contains 10-70 spheroids per cm<sup>2</sup> of the cartilage defect.
- The other ingredient is sodium chloride used as transport solution.

### **What SpheChon looks like and contents of the pack**

Implantation suspension.

SpheChon contains spheroids that consist of living cartilage cells for the repair of cartilage defects. The spheroids look like small white to yellowish pearls. They are transported in a clear colourless solution. SpheChon is delivered to the doctor in a container ready for application. The container may be a syringe or a special application system called co.fix that is a catheter (narrow tube) with a stem length of 150 mm.

The applicator co.fix 150 is packed in a sterile tube and additionally surrounded by an extra bag. The pre-filled syringe is packed in a sterile tube and additionally surrounded by an extra bag.

### **Manufacturer**

CO.DON GmbH  
Warthestraße 21  
14513 Teltow, Germany

**This leaflet was last revised in December 2023**

This document has been approved by HSA as of 15- DEC-2023