 Building 191 Murdoch University South St, Murdoch, WA 6150 Ph: (08) 9360 2888 Fax: (08) 9360 2899 www.orthocell.com.au	Title Tendon Patient Information and Consent		Doc. Type Form
	Doc. No. 51- PM -08	Issue No. 2	Date Effective 04.06.10
	Site Murdoch	Ref SOP 11-PM-07	Review Period 12 months from date effective

Page 2 of this document **MUST BE COMPLETED** and **RETURNED** to **ortho.cell**. Manufacturing cannot commence without completion of this form.

You may keep this page (page 1) for your records and information

PROCEDURE INFORMATION

The **Autologous Tenocyte Implantation**, or **ATI**, product is designed to assist and improve the natural regeneration of your damaged/injured tendon. The process uses your own cells (autologous) to repair tendon injuries such as those caused by tears and degeneration.

Manufacture of the product starts with the biopsy of a small piece of healthy tendon in a procedure under local anaesthetic. This tendon biopsy is then sent to **ortho.cell**'s laboratories where the cells (tenocytes) in the tissue are retrieved. The extracted cells are cultured to increase their numbers before being returned as a high-density cellular suspension. The tendon defect is then treated via insertion of the healthy autologous tenocytes into the site of the injury.

The product is manufactured aseptically in a dedicated manufacturing facility in which **ortho.cell** undertake extensive testing during manufacture and prior to release of the product to ensure quality and safety before it is returned to you.

Post-operatively you will require physiotherapy and some rehabilitation. Please speak to your medical practitioner for a more in-depth review of the procedure, product and recovery process.


There may be risks associated with the biopsy acquisition and implantation process which are similar to those for any minor medical procedure. It is important that you discuss these risks with your medical practitioner prior to consenting to ATI.

MEDICAL ASSESSMENT

Your medical practitioner is responsible for performing an assessment of your suitability for the ATI treatment. This may also assist **ortho.cell** to optimise the manufacture of your implant to help assure the highest level of quality and safety.

As part of the manufacturing process, samples of your blood will be tested for HIV, HTLV, Hepatitis B, Hepatitis C and Syphilis and these results, in combination with your medical assessment, will ultimately determine your suitability for treatment. Your answers and personal information will remain confidential.

The manufacturing process cannot begin until this consent form is received.

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Have you		
1. Ever had a bone-muscular systemic disease (rheumatoid arthritis/disease, systemic lupus erythematosus (SLE) ankylosing spondylosis)? COMMENT:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Ever had a joint sepsis, infections associated with bones / joints? COMMENT:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
In the last 12 months have you		
3. Had any immunisations/vaccinations? COMMENT:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4. Had a blood/body fluid splash to the eyes, mouth, nose or to broken skin? COMMENT:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5. Had a tattoo (including cosmetic tattooing), skin piercing, electrolysis or acupuncture? COMMENT:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6. Had a blood transfusion? COMMENT:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
7. Do you know of anyone in your family who had or has Creutzfeldt-Jacob disease (CJD)? COMMENT:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
8. From 1 January 1980 through to 31 December 1996 inclusive, have you spend (visited or lived) a total time which adds up to 6 months or more in England, Scotland, Wales, Northern Ireland, the Channel Islands or the Isle of Man? COMMENT:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
To the best of your knowledge have you		
9. Ever "used drugs" by injection or been injected, even once, with drugs not prescribed by a doctor or dentist? COMMENT:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
10. Ever had a test which showed you had hepatitis B, hepatitis C, HIV or HTLV? COMMENT:	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Consent and Authority Statements

Patient –

By signing below I agree that

- My medical practitioner has adequately informed me about the **ortho.cell** manufacturing process and the treatment I am about to undertake
- The answers I have given are true and correct to the best of my knowledge

I understand that

- **ortho.cell** intends to use my tissue sample in the manufacture of an autologous tenocyte product (ATI)
- The tissue sample and its derivatives (cells) may be used by **ortho.cell** in association with quality control and quality assurance processes directly associated with the manufacture of this ATI
- Superfluous or rejected tissue or derivatives will be discarded without further notice to me

Patient Name:

Sign:

Date:

Medical Practitioner – I have witnessed the patient sign this document and have undertaken the medical assessment. I deem this patient to be suitable for treatment with ATI.

Medical Practitioner (Witness) Name:

Sign:

Date: