



EMA/369770/2014 Rev.2

Update of 7 October 2019:

The marketing authorisation for MACI expired on 1 July 2018 following the decision of the marketing authorisation holder, Vericel Denmark ApS, not to pursue the renewal of the marketing authorisation.

3 July 2014

**MACI (matrix applied characterised autologous cultured chondrocytes)
implant**

Indication	MACI is used to repair cartilage defects of the bones of the knee joint.
Reason for shortage	Following a company takeover the approved European manufacturing site for MACI will close and MACI will therefore become unavailable in the EU unless a new manufacturing site is approved and manufacture resumes.
Member States affected	United Kingdom, Denmark and Greece.
Information to healthcare professionals	<ul style="list-style-type: none">• MACI will become unavailable in the EU once the European manufacturing site has closed.• The company will therefore no longer accept orders for biopsy kits for treatment with the MACI implant. Surgeons should treat any new patients with a suitable alternative.• Patients whose biopsy kits have already been sent to the company should be able to complete treatment with MACI. Surgeons should notify the company by 12 July 2014 of any patients who wish to complete treatment.• To ensure that treatment can be completed, implantation with MACI should occur before 22 August 2014.• In case surgery cannot be scheduled before 22 August 2014, the patient's biopsy will be preserved at an appropriate facility and the company will investigate the feasibility of manufacturing MACI at an alternative manufacturing site to allow implantation at a later date.

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MACI (matrix applied characterised autologous cultured chondrocytes) implant

	<ul style="list-style-type: none">• Those patients who do not wish to be treated with MACI will have their stored biopsies destroyed.• Surgeons and hospitals will receive a letter from the marketing authorisation holder.• Additional advice may be available from the national competent authority.
Information to patients	<ul style="list-style-type: none">• MACI will become unavailable in the EU once the European manufacturing site has closed.• If you are currently awaiting implantation with MACI, you should speak to your surgeon so that he can make arrangements for you to complete your treatment with MACI.• If you are a new patient requiring a repair of cartilage defects, your doctor will treat you with a suitable alternative.• Additional advice may be available from the national competent authority.

Medicine no longer authorised