

Patient Implant Card

The current version of the Patient Implant Card is located in the front pocket of every Subject Binder shipped to your site. If you cannot locate, please contact your Site Manager.

1.1 Does every patient need a patient implant card?

 Any patient who receives the CLAAS[®] implant index procedure should receive a patient implant card. For patients who receive the CONTROL procedure, please follow the instructions per the Manufacturer.

2.1 When do I provide the patient with their patient implant card?

The patient implant card should be provided to the subject after the procedure and prior to discharge.

3.1 Do I need to fill out the patient implant card before I give it to the subject?

• Yes. All fields should be completed prior to providing to implant card to the subject. Be sure to clearly note the Lot Number of the implant.

4.1 Who do I ask for more patient implant cards?

 If you need more patient implant cards, your visiting Field Clinical Specialist may have more. Otherwise, please reach out to your Site Manager.

5.1 If the subject was an intent to treat for CLAAS[®] but did not receive an implant, do they still require a Patient Implant Card?

If the patient did not receive an implant, they do not need a patient implant card. •