



Frequently Asked Questions

Q. What is GRAFT?

A. GRAFT (General Registry of Autologous Fat Transfer) is a central, web accessible database in which board certified plastic surgeons can contribute fat grafting cases performed to any area of the body. You can find a lot of helpful information regarding GRAFT on The PSF website at: <u>thepsf.org/GRAFT</u>

Q. Is GRAFT mandatory for ASPS membership renewal?

A. All ASPS members are required to complete the "Attestation Questions" for GRAFT at the time of membership renewal, but participation in the GRAFT Registry is not a requirement for ASPS members at this time. The attestation questions that members are required to answer are listed below:

1. I have performed autologous fat grafting procedures over the past year: Yes/No (If Yes)

2. I have submitted my fat grafting cases to The PSF GRAFT Registry: Yes/ No

Q. How do I access GRAFT?

 A. The website to sign-up for GRAFT for the first time is: <u>https://psrn.plasticsurgery.org/Signup/Login.aspx</u>
Once you have registered, the website you will use for data entry for GRAFT is: <u>https://psrn.plasticsurgery.org/Dashboard/login.aspx</u>

Q. What do I need to register for GRAFT?

A. You will only need to enter your ASPS Member ID and your Last Name to login into the sign-up portal for GRAFT. You will provide your practice information sign a Business Associate and a master registry participation agreement. Please refer to the PSRN sign up portal step by step guide for a quick overview of how to register. Once this step is completed, you will be emailed a username and password to login to the PSRN dashboard for GRAFT data entry.

Q. What do I need to login to GRAFT?

A. After you complete your registration at the PSRN sign-up portal, you will be emailed a username and password reset link to login to the GRAFT Dashboard for data entry.

Q. I'm a resident. Can I enter cases into GRAFT?

A. No, only board certified plastic surgeons, practicing within the US are eligible to participate in GRAFT. GRAFT is now open for participation for ASPS members in Brazil and Canada.

Q. I'm an International ASPS member. Can I enter cases into GRAFT?

A. GRAFT is now open to ASPS members outside the US in Brazil and Canada. Discussions are ongoing on making the GRAFT Registry available to International members in other countries. We will let you know if/when GRAFT is available in other countries.

Q. Why do we need the GRAFT Registry?

A. Data from GRAFT will be used for providing insight into the safety of fat grafting procedures and to establish best practice guidelines that will have a broad impact on the plastic surgery community. There has been an increase in regulatory activity related to fat grafting and regenerative medicine, the ASPS and PSF want to be sure that we have plastic surgery information to help inform future regulatory decisions.

Q. Do I have to enter every fat grafting procedure that I perform?

A. Yes—all fat grafting procedures will be captured, regardless of the area of the body.

Q. What kind of information will be collected in the GRAFT Registry?

A. The GRAFT Registry will capture technique and complications information on fat grafting procedures.

Q. How much data do I have to enter?

A. When you first enter a case, no more than 10 questions will be asked. At follow-up, there will be less than 5 questions to answer. Our aim is to make this as streamlined as possible by identifying key questions that will be helpful in tracking/understanding the evolution of fat grafting procedures.

Q. How do I enter data into GRAFT?

A. Each member (or member's designee) will directly enter data into GRAFT through the data entry portal. You will **not** be required to download any software to your computer to begin data entry. In the near future, we will be rolling out technology that would allow data to be directly extracted from EHRs or other practice management type of applications.

A GRAFT App is also available to registered users **within the US** for data entry using their smart phone or iPad. The links to download this App are available the GRAFT data entry dashboard and on The PSF website. GRAFT App is not available to members outside of US.

Q. Is GRAFT collecting data on pediatric cases?

A. Yes. All fat grafting procedures performed to any area of the body, for reconstructive or aesthetic surgery, are eligible for submission into GRAFT, regardless of age. Since the goal of GRAFT is to collect all fat grafting procedures, there is no restriction on age of patients included in the Registry. In the long term, any data collected on patients under 18 years of age will help establish the outcomes and safety of fat grafting in pediatric patients. No patient identifiable information will be submitted to the GRAFT Registry, to protect the privacy of subjects and maintain confidentiality.

Q. What are the follow-up time-points?

A. There is one short term time point (less than 3 months) and one long-term follow-up time point (more than 3 months). We are asking that data be entered at the time the patient returns to your clinic for follow-up. We are not asking for patients to return to clinic outside of standard of care.

Q. Do I have to enter a follow-up form every time a patient returns to clinic? For example, if a patient had fat grafting for initial rhinoplasty procedure, do I have to enter every rhinoplasty related follow-up visit?

A. No, only the follow-up visits related to fat grafting procedure need to be entered into GRAFT.

We recommend recording at least one short term time point (less than 3 months) and one long-term follow-up time point (more than 3 months) if there are no complications. If patient returns to clinic more often, with any complications related to fat grafting, then additional visits should be recorded.

Q. If a patient returns to clinic for a second fat transfer, will this be added as a follow-up visit or do I create a new baseline?

A. To enter a second fat transfer for the same patient, you will have to create a new baseline form.

Q. What are you going to do with the data?

A. The main purpose is for quality improvement/healthcare operations so members will be able to log and track their individual cases for benchmarking purposes. From an aggregate perspective, ASPS/PSF will be able to collect and assess overall procedure use, practice patterns, complications/safety, etc. Aggregate results will be shared with the membership in frequent reports through society publications, presentations and when enough cases are collected through peer reviewed journals. This data will be helpful in ongoing conversations with FDA and others as regulatory questions are raised.

Q. Will it cost me money to participate?

A. There is no fee to participate in the GRAFT Registry. The case submission is free of charge. If your site requires an IRB review, you will be responsible for this expense.

Q. Will I have access to data that I contribute?

A. You will have access to data entered by your site at all times. In addition, you will be able to retrieve benchmark reports and track your practice patterns based on data entered from your site.

Q. What will I get if I participate?

A. You will not be compensated for your participation in the GRAFT Registry. You will be able to retrieve benchmark reports and track your practice patterns based on data entered from your site. You will be able to benchmark your practice data against the aggregate data collected in GRAFT. The data you contribute will provide insight into safety of fat grafting procedures and also help address any concerns raised by FDA or other agencies that may regulate fat grafting.