

QUESTIONS & ANSWERS

Considering Amniotic Biologic Grafts?

For many surgeons, the question is no longer whether amniotic biologic grafts have a role in surgery, but how and when to incorporate them effectively. With growing clinical experience supporting their use in tissue healing and adhesion management, amniotic allografts are becoming an important consideration in pelvic surgery. This guide provides straightforward answers to common questions regarding their clinical applications, safety profile, handling characteristics, and practical use in everyday surgical practice.

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Understanding Surgical Biologics

This guide answers the questions surgeons most frequently ask about biologic allografts in OB-GYN surgery, organized into four key topics.

Q1 What are surgical biologics?

Surgical biologics are naturally derived tissue products used to support the body's healing response following surgery. In pelvic procedures, amniotic allografts are commonly utilized as a biologic barrier and healing scaffold to help support tissue repair while minimizing excessive inflammation, fibrosis, and adhesion formation. These products are derived from donated placental tissue and are processed according to strict tissue banking standards before being used in surgery.

Q2 What is an amniotic allograft?

An amniotic allograft is a biologic tissue graft derived from the amniotic membrane of donated placental tissue. The amniotic membrane contains naturally occurring extracellular matrix proteins, growth factors, cytokines, and structural components that support normal tissue healing. The graft is placed directly over surgical sites where tissue has been dissected, cauterized, or manipulated.

Q3 How is an amniotic allograft different from a synthetic adhesion barrier (Seprafilm, etc.)?

Synthetic barriers are designed primarily to create physical separation between tissues during healing. Amniotic allografts provide both a physical barrier and a biologic scaffold containing naturally occurring extracellular matrix components that support the body's healing process. Many surgeons view amniotic allografts as a next-generation approach that combines barrier protection with biologic support.

Understanding Surgical Biologics

Q4 Why are more surgeons incorporating biologics into surgery?

As surgical techniques continue to evolve, many surgeons are increasingly focused on optimizing healing, reducing fibrosis, minimizing adhesion formation, and improving tissue quality after surgery. Biologic grafts offer a simple way to support these objectives without significantly altering surgical workflow.

Q5 How do biologic grafts support healing?

Amniotic allografts provide a protective biologic covering over surgically traumatized tissue. The graft serves as both a physical barrier and biologic scaffold, helping support organized tissue healing while reducing tissue-on-tissue contact during the critical healing period.

Q6 What are adhesions and why are they important?

Adhesions are bands of scar tissue that can form between tissues and organs following surgery. Pelvic adhesions may contribute to chronic pelvic pain, infertility, bowel complications, difficult reoperations, and increased surgical complexity during future procedures.

Why OB-GYN Surgeons Use Them

Q1 Why would I consider using a biologic graft?

Every surgical procedure initiates a healing response. Whenever tissue is cut, cauterized, dissected, or manipulated, inflammation occurs. While healing is necessary, excessive inflammation can contribute to fibrosis, scarring, and adhesion formation. Many surgeons utilize biologic grafts to support optimal healing while helping reduce factors that contribute to problematic scar tissue formation.

Q2 Which OB-GYN procedures commonly utilize biologic grafts?

Biologic grafts are commonly utilized in procedures involving significant tissue dissection or where adhesion formation is a concern, including hysterectomy, myomectomy, endometriosis excision, ovarian surgery, pelvic reconstructive surgery, robotic gynecologic procedures, laparoscopic gynecologic procedures, and other pelvic surgeries.

Q3 Are biologic grafts procedure-specific?

No. Most surgeons evaluate biologic graft use based on tissue trauma and healing considerations rather than the name of the procedure. If tissue is being cut, dissected, cauterized, or manipulated, biologic support may be beneficial.

Q4 Can biologic grafts be used in robotic surgery?

Yes. Amniotic allografts are commonly used in robotic-assisted procedures and can typically be delivered through standard minimally invasive surgical approaches.

Why OB-GYN Surgeons Use Them

Q5 Can biologic grafts be used in laparoscopic procedures?

Yes. Amniotic allografts are frequently utilized in laparoscopic surgery and can be easily incorporated into minimally invasive workflows.

Q6 How do surgeons decide when to use a biologic graft?

Many surgeons evaluate whether a procedure involves significant tissue dissection, cauterization, inflammation, or areas where adhesion formation may become problematic. The decision is often based on healing goals rather than the specific procedure being performed.

Q7 What are the potential benefits surgeons hope to achieve?

Surgeons commonly utilize biologic grafts with the goal of supporting healthy tissue healing, minimizing fibrosis, reducing adhesion formation, and optimizing tissue quality following surgery.

Safety & Clinical Evidence

Q1 Are amniotic allografts safe?

Yes. Amniotic allografts have been utilized extensively throughout the United States across multiple surgical specialties and have demonstrated an excellent safety profile.

Q2 How many surgical applications have utilized amniotic allografts?

Amniotic allografts have been used in more than 500,000 surgical applications, providing extensive real-world clinical experience.

Q3 Is there a risk of disease transmission?

The risk is extremely low. Donors undergo comprehensive medical and social screening, and all donated tissue is subjected to extensive infectious disease testing and processing before being released for clinical use.

Q4 Is there a risk of rejection?

Amniotic tissue is considered immune-privileged and has been widely utilized because of its low immunogenicity. Unlike transplanted organs, these grafts do not require tissue matching or immunosuppressive medications.

Safety & Clinical Evidence

Q5 Are these products FDA regulated?

Yes. Human tissue allografts are regulated by the FDA under Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) regulations and are processed in accordance with applicable FDA requirements.

Q6 Are there published studies supporting amniotic allografts?

Yes. Numerous published studies across multiple surgical specialties have evaluated the use of amniotic tissue for supporting healing, reducing inflammation, minimizing fibrosis, and reducing adhesion formation.

Q7 Are there studies specific to OB-GYN surgery?

Yes. Clinical literature exists evaluating amniotic tissue in gynecologic and pelvic surgical applications, particularly regarding adhesion reduction and tissue healing. Your 6Sixty Biologics representative can provide published literature upon request.

Q8 Why haven't I heard more about biologics in pelvic surgery?

Historically, much of the commercial focus for biologics has been in wound care, orthopedics, and spine surgery. As awareness grows regarding the importance of pelvic healing and adhesion prevention, biologic utilization in OB-GYN continues to expand.

Facility Approval & Getting Started

Q1 Is my hospital already approved to use these products?

In most cases, yes. Our biologic grafts are currently approved within more than 85% of hospital systems throughout the United States. There is a strong likelihood your facility has already completed the approval process and has access to these products.

Q2 How do I know if my facility has approved the graft?

Simply contact your 6Sixty Biologics representative. They can quickly verify facility approval status, inventory availability, and any facility-specific requirements prior to scheduling a case.

Q3 What if my facility has not approved the product?

Our team can work with surgeons and hospital administration to support the facility review process and provide the necessary clinical and product information.

Q4 Does the graft cost my patient anything?

No. The graft is typically billed through the facility as part of the overall surgical procedure and does not result in a separate bill to the patient. In many cases the graft receives additional reimbursement above the standard procedure reimbursement.

Facility Approval & Getting Started

Q5 How do I request a biologic graft for an upcoming procedure?

Simply notify your 6Sixty Biologics representative. They can recommend an appropriate graft size and ensure product availability for your scheduled procedure.

Q6 How do I determine which graft size to use?

Your representative can provide recommendations based on the procedure, anatomy involved, and surgeon preference.

Q7 Will using a biologic graft change my surgical workflow?

Typically very little. Most surgeons find biologic grafts easy to incorporate into existing procedures with minimal additional operative time.

Q8 Can someone provide training or case support?

Yes. 6Sixty Biologics representatives are available to provide product education, procedural support, and assistance with implementation when needed.

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Have More Questions?

To find out more about 6Sixty Biologics products, or to discuss biologic allografts for an upcoming procedure, contact your 6Sixty Biologics representative.

6sixty.com

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