

## PalinGen SportFlow

PalinGen SportFlow introduces a pathway to REGENERATIVE MEDICINE in the office setting utilizing cryopreserved amniotic fluid. PalinGen SportFlow is a human placental derived allograft processed from healthy donors. This human tissue has been tested prior to and after processing to ensure a healthy, clean, safe cryopreserved product. Amniotic fluid is known to contain collagen substrates, growth factors, amino acids, carbohydrates, and cytokines needed for wound healing.

This membrane is rich with the basic components necessary for tissue repair, and provides an antimicrobial environment<sup>1</sup>, anti-inflammatory characteristics,<sup>2</sup> with anti-adhesion and anti-fibrotic properties.<sup>3</sup>

With these capabilities and characteristics this human allograft fluid is useful in a variety of conditions that can be treated in the physician's office, and implanted with a 20-23g needle:

Orthopedic Surgery – For use in synovial injuries, injured chondral surfaces, chronic tendinopathies, tendinosis, and chronic fasciosis.<sup>4-6</sup>

**Pain / Physiatrist** – Chronic pain, trigger points, back pain, treated with facet implants.<sup>7</sup>

**General and Plastic Surgeons** – Reduce post operative scar formation and adhesions. Intrinsically anti-fibrotic, anti-adhesion, easily resorbed in vivo, anti-inflammatory. Reduces risk of post-operative complications. <sup>8,9</sup>

**Burn Specialists** – Excellent topical wound therapy due to its antimicrobial and anti-inflammatory properties. Reduces scarring. Can be applied topically.<sup>10</sup>

Wound Specialists – Excellent intradermal peri-wound therapy, provides a healthy antimicrobial, regenerative wound environment. Balances the wound environment, contributes to the development of angiogenesis.<sup>11</sup>

**Dental Surgery** – Post-procedure implants promote tissue regeneration, potential to resolve gum insufficiency, reduces the time to form bone in the jaw in preparation for implants.<sup>12</sup>

PalinGen SportFlow does not require fetal sacrifice; recovery is performed with maternal consent during live birth



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PalinGen SportFlow is obtained from healthy donors who have volunteered to donate their amniotic fluid after undergoing elective Caesarian delivery. Each donor has submitted their past medical history, social history, and serologies for Medical Director review. The donated tissue is collected aseptically, then tested before processing, then again on the final product. We have developed our procedures based on 21CFR Part 1271 and the American Association of Tissue Banks standards.

As the amnion (innermost layer of the placenta) and amniotic fluid protect the fetus during development, our PalinGen SportFlow provides the same protection to injured or traumatized tissue. We remove the chorion to reduce the risk of graft host reaction, as the chorion has been known to contain maternal antigens. <sup>13</sup> Class II antigen expression is mitigated, immunogenicity is minimized. <sup>14</sup>

PalinGen SportsFlow has been cryopreserved prior to packaging to preserve the quality of the product. The product may be implanted through small-bored needles. Amniotic fluid is immunologically privilege, reducing the risk of inflammatory reactions after local implantation. 15,16

PalinGen SportFlow comes in four different volumes and is packaged for easy use in the office setting. Please see package insert for instructions for use.

0.25ml	PS-010025	PalinGen SportFlow small .25
0.50ml	PS-010050	PalinGen SportFlow medium .5ml
1.0ml	PS-010100	PalinGen SportFlow large 1.0ml
2.0ml	PS-010200	PalinGen SportFlow xlarge 2.0ml

PalinGen SportFlow is regulated by the FDA under 21 CFR Part 1271 and Section 361 of the Public Health Service Act. Stored at -65c to -80c cryopreservation temperatures, shipped in containers that have validated for 48 hours or 72 hours. Donors are prescreened through an intensive and complete medical review and pre-natal evaluation.

- Medical Director does a behavioral risk assessment, reviews the donor medical history, and screens fluids for communicable diseases.
- The amniotic fluid and membrane is recovered aseptically by skilled technicians at medical centers.
- The amniotic fluid and membrane is processed and packaged at an AATB accredited tissue bank.
- All processed tissue is tested extensively per USP quidelines prior to any lot release.

