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Clotalyst®

Autologous Activation System

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The Clotalyst® Autologous Activation System rapidly produces up to 10 ml of autologous clotting factors from 12 ml of the patient's blood at the point-of-care. When combined with the leukocyte-rich platelet–rich plasma (L-PRP) produced by the GPS III® Platelet Concentration System, the autologous clotting factors from the Clotalyst Autologous Activation System activate platelets and initiate fibrin formation and cross-linking to form a platelet gel in under 15 seconds. When platelet gel is combined with autograft or allograft bone chips, handling is significantly improved.[1]

Simple

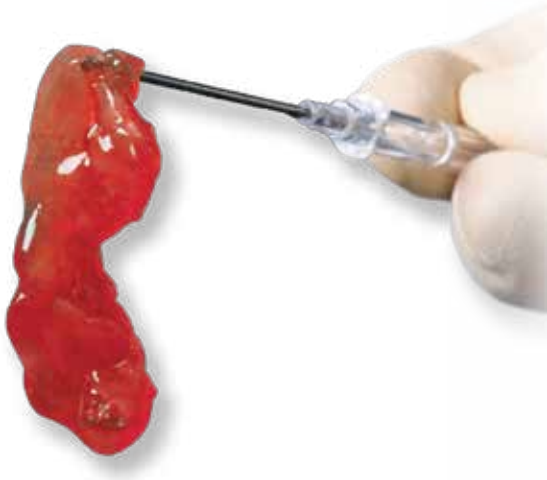
- No heating necessary
- No centrifugation needed
- All components supplied in a single kit

Consistent

- Produces up to 10 ml of activation solution
- Clots platelet-rich plasma in less than 15 seconds
- Clotting factors stable up to 4 hours after preparation[2]

Autologous

- No donor pooled or bovine sources
- May eliminate risk of non-autologous blood borne pathogens
- May eliminate potential non-autologous source related coagulopathies[3]

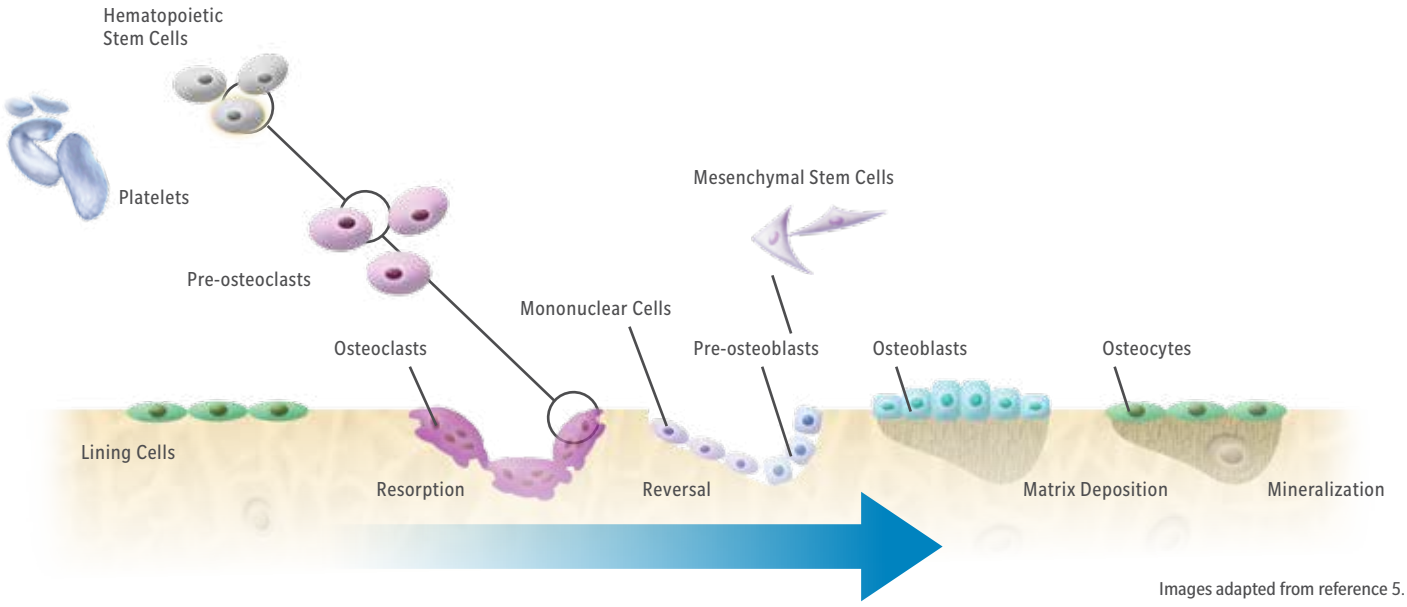


Photos of actual product output following processing instructions.

The Role of Autologous Clotting Factors in Bone Graft Handling

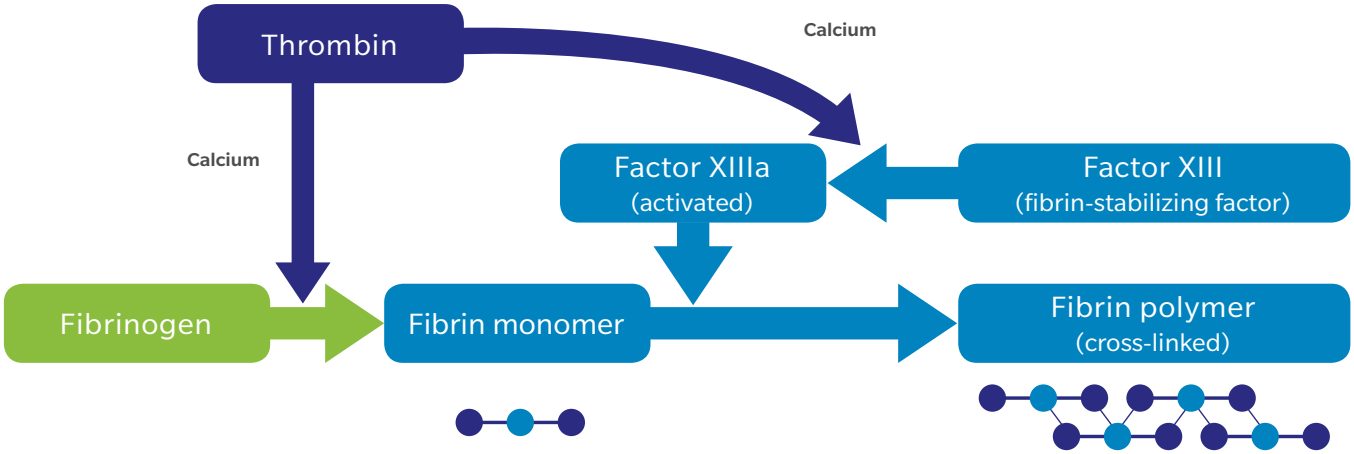
Thrombin binds to receptors on the surface of platelets causing them to release growth factors, coagulation factors, and other platelet activators. Thrombin also causes platelets to aggregate and activate, releasing growth factors such as PDGF, TGF-ß, IGF, EGF and VEGF.[4]

Growth factors and signaling proteins from platelets stimulate the osteoprogenitor cells, as part of the bone remodeling process.[4] Simultaneously, the thrombin begins to cleave fibrinogen to form cross-linked fibrin molecules. This cross-linking forms the structural basis for the platelet gel or clot. Then, the activation of protein Factor XIII begins to stabilize the cross-linking between fibrin molecules.[5]



Images adapted from reference 5.

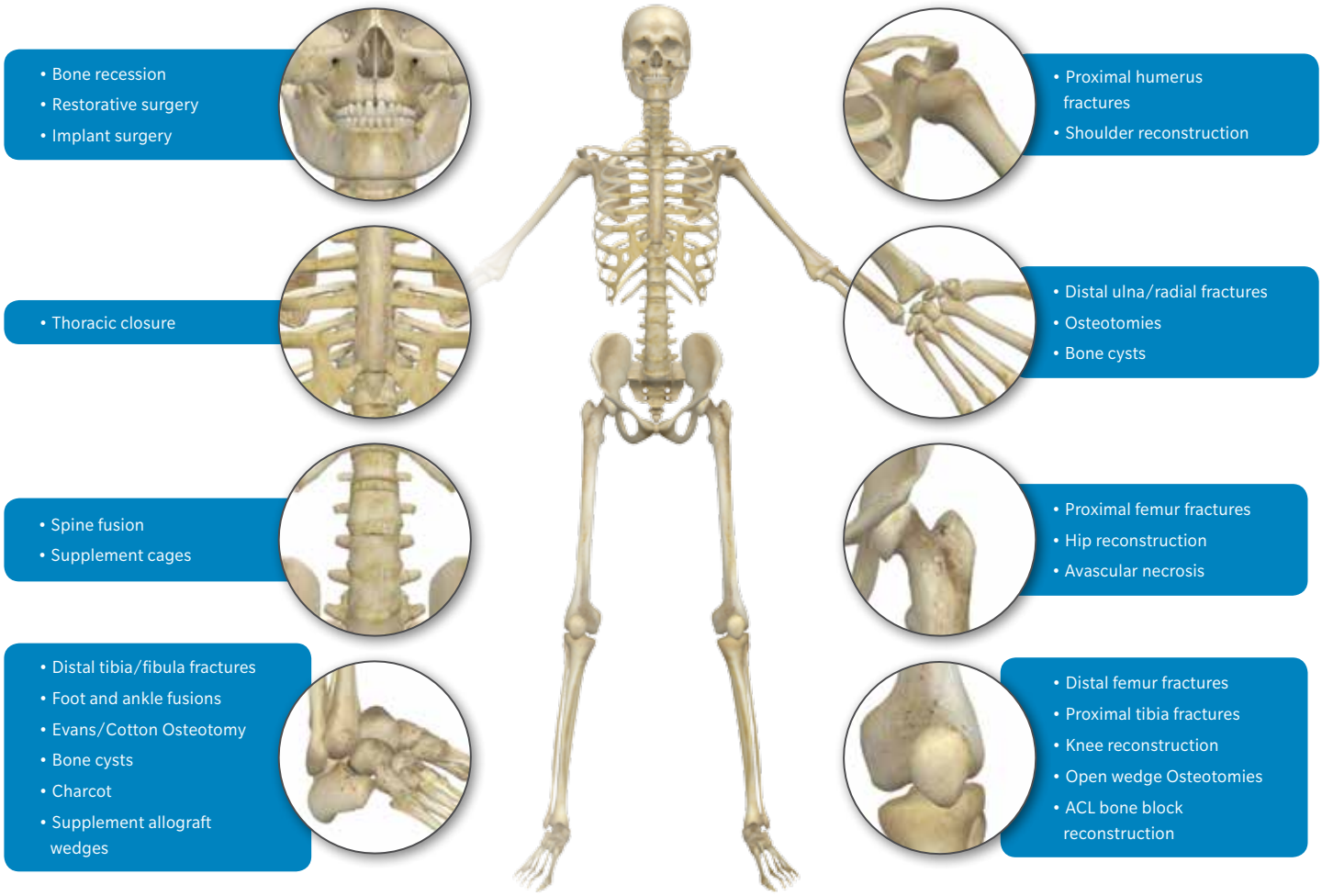
Natural Coagulation Cascade



Images adapted from reference 5.

Examples of Autograft/Allograft Bone Grafting Applications

The output* from the Clotalyst® Autologous Activation System is to be mixed with PRP output from the GPS III® Platelet Concentration System and can be mixed with autograft and/or allograft bone for bone graft handling prior to application to an orthopedic site.



* The safety and effectiveness of the device for bone healing and hemostasis has not been established.

References

1. Bench data on file in Verification and Validation Report OT000134. 2006.
2. Bench data on file in Verification and Validation Report BB000005. 2010.
3. Strieff, M.B., Ness P.M. (2002). Acquired F.V Inhibitors: A Needless Iatrogenic Complication of Bovine Thrombin Exposure. Transfusion, 42(1), 18–26.
4. Han, B., Woodell-May, J., Ponticiello, M., Zhi Yang, Nimni, M. The Effect of Thrombin Activation of Platelet-Rich Plasma on Demineralized Bone Matrix Osteoinductivity.
5. Robbins, Stanley L., Ramzi S. Cotran, and Vinay Kumar. Pathologic Basis Of Disease. 7th ed. Philadelphia: Saunders, 1984.

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