

SELPHYL SAFETY

There is virtually no risk of allergic reaction. The Selphyl® System is used to rapidly collect and isolate a patient's own PRP for injection and contains no animal or synthetic products.

There have been no known side effects associated with Selphyl® reported to date. As with any injectable procedure, some patients may experience some mild and temporary irritation, swelling, bruising, itching, discoloration or tenderness at the injection site.

The Selphyl® System was cleared for marketing under premarket notification (510(k)) submission numbers BK120009 and BK120008. Factor Medical, LLC in conjunction with Cascade Medical Enterprises, LLC markets the FIBRINET® Autologous Fibrin & Platelet System in the U.S. under the trade name Selphyl® PRFM. The CE mark certification has been granted in Europe.