# PATHOGEN INACTIVATED PLASMA

## USE IN CANADA

The Canadian Agency for Drugs and Technologies in Health (CADTH) published the following recommendation in May 2011.

SDP may be considered as an alternative to standard plasma for certain patients who require a high volume of transfusions annually because they have:

- TTP (both congenital and acquired forms); or,
- HUS with associated factor H deficiency; or,
- clotting factor deficiencies for which specific licensed concentrates may not be readily available (e.g., factor V, factor XI, factor XIII),

and who:

- have experienced an allergic reaction to frozen plasma; or
- have a pre-existing lung disorder; or
- need frozen plasma, but a blood group–compatible product is not available in a timely manner.

SDP has been available in Canada since 2012.

## USE WORLDWIDE

Pathogen inactivated plasma has been used for many years. Some countries such as the UK, Finland and Ireland have completely switched to using SDP. At the present time, SDP plasma is used routinely in Germany, Israel, Norway, France, Switzerland and Portugal. Some of these countries have used SDP since 2002[6].

In January 2013, the US FDA approved a SDP product to treat patients with congenital or acquired TTP[6]. According to Karen Midthun M.D., director of the FDA's Center for Biologics Evaluation and Research, "this product provides a reduced risk of certain viral transmissions."[7]

**ASK YOUR PHYSICIAN IF PATHOGEN INACTIVATED PLASMA MAY BE APPROPRIATE FOR YOU.**

## PATIENT PERSPECTIVE

I was diagnosed with TTP in 2007. While hospitalized, I experienced daily reactions during my plasma exchange treatments, one of which was severe. I will never forget the anxiety and fear I experienced every day. I was well aware that I needed this life-saving treatment, but at the same time I was fearful of having a severe reaction.

It is important to me to spread the word about developments that might improve TTP treatment. If we can further minimize the risk of infection and allergic reactions associated with plasma exchange therapy, it will help make everyone's battle with TTP that much easier.

Answering TTP Foundation is passionate about a unified voice of action to ensure that patients have access to the best treatment, education and support programs. With increased research and awareness, we will get closer to finding a cure for TTP.

Every person touched by TTP provides the community with further insight into this complex and rare disorder. How can you become involved?

1. Register with the community
2. Fundraise for TTP research
3. Volunteer your time
4. Share your experience
5. Participate in support groups

Visit www.AnsweringTTP.org for more information.

Sincerely,
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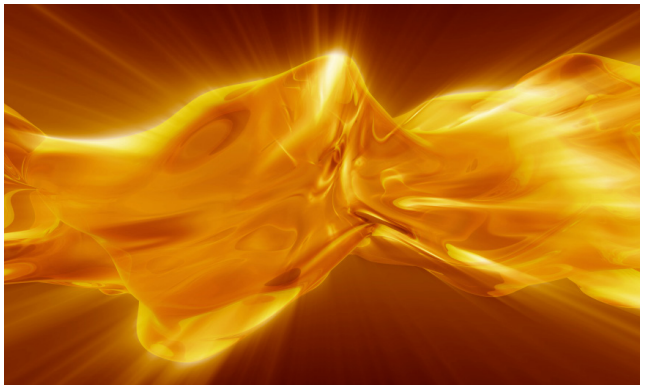
Answering T.T.P.
Thrombotic Thrombocytopenic Purpura Foundation

# Solvent Detergent Plasma (SDP)



## Information about Solvent Detergent Plasma (SDP)

& other pathogen inactivation technologies for the use in the treatment of TTP (Thrombotic Thrombocytopenic Purpura).

Additional information available at
**www.AnsweringTTP.org**

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## WHAT IS PLASMA?

Blood has 4 main components: red blood cells, white blood cells, platelets and plasma. Plasma is the liquid portion of the blood and makes up 55% of our total blood volume[1].

## WHAT IS PLASMA EXCHANGE?

Plasma exchange (also known as plasmapheresis) is a procedure in which a patient's plasma is removed and replaced with donor plasma. Plasma exchange is a first-line treatment for TTP. Compared to other conditions that require plasma, TTP patients need an extraordinary amount of plasma. The average TTP patient has received plasma from about 360 blood donors[2]. Due to the large volume used, TTP patients are at greater risk of infection and side effects associated with the use of plasma. Moreover, since TTP patients are exposed to a large number of plasma donors, they would benefit from any additional measure of plasma safety.

## WHAT IS PATHOGEN INACTIVATED PLASMA?

Historically, products called Fresh Frozen Plasma (FFP) or Cryosupernatant (CSP) have been used as the "replacement products" in plasma exchange. In recent years, new technologies have been introduced that aim to:

1. Further reduce the risk of pathogen transmission (i.e., prevent viruses and bacteria from being passed on to patients receiving plasma exchange); and
2. Reduce the side effects to the blood recipient.

These new technologies result in "pathogen inactivated" plasma products: solvent-detergent plasma (SDP), methylene blue (MB), amotosalen and riboflavin. The use of these products varies around the world. We will focus on how SDP helps to improve the safety for TTP patients.

## 1. SDP REDUCES PATHOGEN TRANSMISSION

The preparation of any blood product is subject to rigorous safety measures, including improved donor selection criteria and screening tests of increasing sensitivity. These methods have reduced the risks of transfusion-transmitted infections, but they still exist and hold increased significance in situations utilizing high volumes e.g. the treatment of TTP with plasma exchange.

SDP is specially treated to inactivate viruses such as HIV, hepatitis B and hepatitis C. Moreover, SDP may protect against emerging pathogens (causes of infection that we don't yet know about).

## REACTIONS ASSOCIATED WITH REPLACEMENT PLASMA

Tell your doctor if you experience any of the following reactions:

- ITCHING
- RASH OR HIVES
- FEVER
- CHILLS OR SHIVERS
- DIZZINESS OR LIGHT-HEADEDNESS
- NAUSEA, VOMITING OR DIARRHEA
- TINGLING
- SWELLING
- CONFUSION
- ANY DIFFICULTY BREATHING

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SDP is considered the current gold standard for viral safety as it successfully inactivates lipid-enveloped viruses such as HIV, HBV and HCV[3]. Moreover, SDP is manufactured by pooling donor plasma together to help neutralize viral particles to further increase safety.

## 2. SDP REDUCES SIDE EFFECTS

According to the 2013 Answering TTP Community survey, 89% of patients experienced side effects during plasma exchange with FFP or CSP. These allergic reactions can range from mild (e.g. muscle spasms, tingling sensation) to severe (e.g. breathing difficulties, anaphylaxis) as a result of this daily, life-saving treatment.

The SDP manufacturing process removes cells, including cell debris, and neutralizes allergens to minimize the risk of allergic reactions. Allergic reactions are reduced up to 60% compared to CSP and 84% compared to FFP with the use of certain SDP products[3].

## SDP EFFICACY TO TREAT TTP

The overall efficacy of SDP product is thought to be comparable with FFP[5].


Sources:
1. http://www.redcrossblood.org/learn-about-blood/blood-components
2. 2013 Answering TTP Community Survey, www.AnsweringTTP.org.
3. Scully M, Longair I, Flynn M, Berryman J, Machin SJ.. Cryosupernatant and solvent detergent fresh-frozen plasma (Octaplas) usage at a single centre in acute Thrombotic Thrombocytopenic Purpura.
4. Vox Sang 2007;93(2):152-158. Albert Farrugia; Guide for the Assessment of Clotting Factor Concentrates, World Federation of Hemophilia, 2003.
5. Optimal Therapy Recommendation for the Use of Solvent/Detergent-Treated Human Plasma [Pilot Project]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2011.
6. Allain JP. 10 years of pathogen reduction/inactivation (PR/PI) Transfus Today 2009; No 6:pg. 5.
7. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm336009.htm