DESCRIPTION: StablePlate RX™ is a lyophilized derivative of canine platelets developed for the treatment of acute uncontrolled hemorrhage in bleeding patients secondary to thrombocytopenia. This product is supplied in a vial as a sterile, non-pyrogenic white to off-white cake that, when reconstituted with 8 milliliters of sterile water for injection (WFI) becomes a white suspension. StablePlate RX™ has a final particulate concentration of 1.5 x 10^9 particles per milliliter. The biological source materials are: in-date, leukoreduced canine platelets collected by apheresis or whole blood donation. The rehydrated material contains: HEPES, NaCl, KCl, NaHCO3, dextrose, trehalose, ethanol, and polysucrose in addition to canine platelets.

INDICATION: An intravenous administration developed for the treatment of acute uncontrolled hemorrhage in bleeding patients secondary to thrombocytopenia.

DOSAGE AND ADMINISTRATION: StablePlate RX™ is for intravenous administration. A dose of 3.0 x 10^9 particles per kilogram is recommended. The product is administered by a single intravenous bolus infusion. One vial treats a 5 kilogram patient.

Rehydration instructions:

Draw 8 milliliters of sterile water for injection (WFI) into a sterile syringe and needle.
Slowly add the WFI into the vial allowing the cake to become immersed in the WFI.
DO NOT USE HYPERTONIC SOLUTIONS for rehydration.
Gently mix the WFI by swirling the vial to rehydrate the cake. Do not SHAKE or FOAM.
Allow the rehydrated solution to sit for 3-5 minutes before use.
Draw into a syringe using a needle greater than or equal to 20 gauge.

Dosing instructions:

Administer through a catheter system greater than or equal to 22 gauge.
Give as a slow intravenous bolus.
Do not mix with other products or solutions.
Flush catheter with appropriate amount of saline after administration.

CONTRAINDICATIONS: Do not administer through filter systems. Do not administer with other fluids.

WARNINGS: Not for use in Humans. Keep out of reach of children.

PRECAUTIONS: The safe use of StablePlate RX™ has not been evaluated for use in animals under 9 months of age or during pregnancy.

ADVERSE REACTIONS: In GLP preclinical trials, both multiple dosing schedules and high dosing amounts were evaluated without evidence of adverse event. For technical assistance or to report suspected adverse reactions to StablePlate RX™, contact BodeVet, Inc. at 240-408-8060 or email Dr. Anne Hale at ahale@bodevet.com. For additional information about adverse drug experience reporting animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/AnimalVeterinary/SafetyHealth

SAFETY AND EFFECTIVENESS SUMMARY: A GLP acute toxicity study in canines (Study ID 1) found no definitive product related toxicities following infusion of greater than 49 times the dose of StablePlate RX™ in beagles. Noteworthy are the lack of macroscopic and microscopic findings (histopathological) in regards to micro-emboli or thrombosis related (organ ischemic) lesions in either species. Detailed hematological and hemostatic data taken acutely and sub-acutely after exposures did not reveal evidence of increased fibrinolytic and coagulation activities. No adverse events due to product administration were seen at any dosing level in Study ID 2. Study ID 3 evaluated the effectiveness of StablePlate RX™ by measuring its effect on bleeding. The lowest levels demonstrating effectiveness based on particle concentration were determined. Table 1 defines safety and effectiveness in canines.

Table 1. Preclinical Safety and Effectiveness Studies

Pathological Condition (N)	Study Description	Study ID	Test Article	Mean Particles Infused per Kg
Normal (12)	Single Dose Acute Toxicity in canine IV Infusion	1	StablePlate RX™	1.0 X 10^{10}
Coronary Artery Surgery (8)	Single acute dose Coronary Artery Bypass Graft Surgery (CABG) study in canine, **highest** of three doses infused	2	StablePlate RX™	5.11 X 10^9
Coronary Artery Surgery (8)	Single acute dose Coronary Artery Bypass Graft Surgery (CABG) study in canine, three dose levels	3	StablePlate RX™	1.57 X 10^9 (MED)†

*Per µL Blood Volume

†A minimum effective dose (MED) was defined in study ID 3.

STORAGE CONDITIONS: Unopened vials should be stored at room temperature (18 to 30 °C). This product should be utilized immediately after rehydration. The rehydrated product is not considered active after 1 hour post-rehydration. DO NOT REFRIGERATE OR FREEZE.

HOW SUPPLIED: 1.5 x 10^{10} particles per vial in a 50 milliliter vial, in a single carton.

U.S. Patent No. 8,486,617 U.S. Patent No. 7,811,558