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Revision B
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nSTRIDE® APS Kit

ATTENTION ADMINISTERING PERSONNEL

CAUTION - INVESTIGATIONAL DEVICE. Limited by Federal (or United States) law to investigational use.

DESCRIPTION

The nSTRIDE APS Kit consists of an nSTRIDE Cell Separator, an nSTRIDE Concentrator, ACD-A (Anticoagulant Citrate Dextrose Solution, Solution A, USP) for blood processing, and blood draw accessories.

The nSTRIDE APS Kit permits autologous protein solution (APS) to be prepared at the point-of-care from a small volume of the patient's blood. The nSTRIDE APS Kit aids separation and concentration of the patient's own blood components by density through the use of a Biomet Biologics centrifuge.

MATERIALS

Blood-draw components, when supplied in this kit, are packaged, labeled and sterilized as indicated by the manufacturer's labeling. Components in this kit are not made with natural rubber latex. The materials used for needles, syringes, tubing, connectors, nSTRIDE Cell Separator, and nSTRIDE Concentrator may consist of polymers and elastomers suitable for use in medical devices.

ACD-A (Anticoagulant Citrate Dextrose Solution, Solution A, USP) is manufactured and supplied by Citra Labs LLC, Braintree, MA. For further information regarding ACD-A, please consult the ACD-A IFU included with this kit or contact the supplier at 1-800-299-3411.

The ACD-A included in this system is only for use with nSTRIDE APS Kit. NOT FOR DIRECT INTRAVENOUS INFUSION.

INDICATIONS FOR USE

The nSTRIDE APS Kit is designed to be used for the safe and rapid preparation of autologous protein solution (APS) from a small sample of blood at the patient's point of care. The APS is to be injected intra-articularly for the treatment of knee osteoarthritis and associated symptoms.

CONTRAINDICATIONS

- nSTRIDE APS Kit is not for use in patients with systemic inflammatory conditions.
- Do not inject APS in the knees of patients having knee joint infections or skin diseases or infections in the area of the injection site.
- nSTRIDE APS is not intended for use in patients with leukemia, metastatic malignant cells, or who are receiving chemotherapeutic treatment.

WARNINGS

- FOR AUTOLOGOUS USE ONLY. APS should only be injected into the patient from whom the APS was derived. Process only one patient's blood per disposable.
- Only use prepared APS intra-articularly, as directed. NOT FOR DIRECT INTRAVENOUS INFUSION.
- STERILE CONTENTS. Single use device. Do not reuse. Use contents of nSTRIDE APS Kit immediately after its packaging is opened.
- Do not use sterile components in nSTRIDE APS Kit if package is opened or damaged.
- Use proper safety precautions to guard against needlestick injury. Discard used needles in "sharps" containers.
- The administering personnel are to be thoroughly familiar with the equipment and the procedure prior to using this device. Strict aseptic administration technique must be followed.

POSSIBLE ADVERSE EFFECTS FROM BLOOD DRAW AND INTRA-ARTICULAR INJECTION

1. Damage to blood vessels, hematoma and/or infection.
2. Temporary or permanent nerve damage that may result in pain or numbness.
3. Transient pain, swelling, burning and/or effusion of the injected joint may occur after intra-articular injection of APS.
4. Early or late post-injection infection.

STERILITY

nSTRIDE APS Kit device system is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. ACD-A is sterilized by the supplier using steam sterilization. Do not re-sterilize. Do not use any component from an opened or damaged package or after expiration date. Single Use Only.

INSTRUCTIONS FOR USE

Store in original packaging. The contents of the kit must be used immediately after they have been removed from the packaging. The nSTRIDE APS Kit is intended for single use. Discard the entire disposable kit after one use, using acceptable disposal methods for products potentially contaminated with blood.

Inject the full amount of APS into one knee only. If treatment is bilateral, a separate nSTRIDE APS Kit must be used for each knee. Discard any unused APS. Use strict aseptic technique throughout the following procedures:

PROCEDURE ONE: Use the nSTRIDE Cell Separator to collect the cells.

1. **DRAW:** Draw **5ml** of anticoagulant into 60 ml syringe, attach to 18-gauge apheresis needle and prime it with anticoagulant. Slowly draw 55 ml of blood into the 60 ml syringe. Gently, but thoroughly mix the whole blood and anticoagulant upon collection to prevent coagulation. This results in 60 ml of anticoagulated blood in the syringe.
2. **LOAD: Ensure that the cell separator remains upright.** Unscrew clear cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load the anticoagulated blood from the 60 ml syringe into center blood port #1. Unscrew and discard protective inner piece from cap tethered to port #1. Fasten cap onto port #1. Place nSTRIDE Cell Separator filled with anticoagulated blood in centrifuge.
3. **BALANCE:** Fill counterbalance tube with 60 ml of sterile saline/water (equal to volume of blood in nSTRIDE Cell Separator). Place filled counterbalance directly opposite from the blood-filled nSTRIDE Cell Separator in the centrifuge.
4. **PROCESS:** Close centrifuge lid. Set centrifuge to process at 3200 RPM for 15 minutes. Press the start button. Once the cycle is complete, open centrifuge and remove nSTRIDE Cell Separator.
5. **EXTRACT PPP:** Unscrew yellow cap on port #2, and save yellow cap. Connect 30 ml syringe to port #2. Slowly tilt the nSTRIDE Cell Separator while withdrawing all of the platelet poor plasma (PPP). Remove 30 ml syringe from port #2, cap with a sterile syringe cap, and discard. Replace yellow cap on port #2.
6. **RESUSPEND CELLS:** Holding nSTRIDE Cell Separator in the upright position, unscrew red cap on port #3. Attach a 10 ml syringe to port #3. Extract 2 ml of cell solution into the 10 ml syringe. Leave the 10 ml syringe attached to port #3. Shake nSTRIDE Cell Separator vigorously for 30 seconds.
7. **EXTRACT CELLS:** Immediately after suspending the cells, extract remaining cell solution into the attached 10 ml syringe, approximately 6ml total. Remove 10 ml syringe from port #3.

PROCEDURE TWO: Use the nSTRIDE Concentrator to prepare the APS.

1. **LOAD:** Ensure white beads in nSTRIDE Concentrator are evenly distributed prior to loading. Unscrew cap on port #1. Slowly load the contents of the 10ml syringe (prepared in Step 7 above) into port #1. Unscrew and discard the protective inner piece from the cap tethered to port #1. Remove the syringe and fasten the tethered cap onto port #1.
2. **MIX:** Twist and piston the mixing paddle for 30 seconds. Be sure to push and twist the paddle to the floor of nSTRIDE Concentrator's upper chamber to saturate the beads. There should be no white beads visible. Place into centrifuge.
3. **BALANCE:** Place the counterbalance directly opposite from the nSTRIDE Concentrator in the centrifuge.
4. **PROCESS:** Close centrifuge lid. Set centrifuge to process at 2000 RPM for 2 minutes. Press the start button. Once the cycle is complete, open centrifuge and remove nSTRIDE Concentrator. Gently swirl nSTRIDE Concentrator to resuspend APS.
5. **EXTRACT APS**: Unscrew red cap on port #2 and extract APS using a sterile 10 ml syringe, approximately 2-3ml total. Remove 10 ml syringe from port #2, and cap the syringe with a sterile syringe cap.

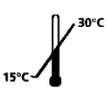
INJECTION PROCEDURE RECOMMENDATIONS:

- Use prepared APS within 4 hours after drawing blood from patient. The safety and effectiveness of frozen stored APS has not been established.
- Remove synovial fluid or effusion before injecting APS. Do not use the same syringe for removing synovial fluid and for injecting APS, but the same needle should be used. Take particular care to remove the tip cap of the syringe and needle aseptically.
- Inject APS into the knee joint through an 18 to 22 gauge needle. To ensure a tight seal and prevent leakage during administration, secure the needle tightly while firmly holding the luer hub.
- Inject APS at a single anatomical location. Do not partition APS into multiple injections or inject at multiple locations.
- Injection of additional fluids into the knee in conjunction with APS may dilute APS and affect its safety and effectiveness.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA. FAX: 574-372-3968.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

Symbol Legend
 Manufacturer
 Date of manufacture
 Do not reuse
 Caution, see instructions for use
 Sterilized using irradiation
 Sterile
 Temperature Limitations
 Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
 Use by date
 Catalogue number
 Batch code