Medikan Co., Ltd.
Before use, read this manual carefully and use Adivive exactly as instructed in the manual. Please also read and observe all safety information.
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ABOUT THE ADIVIVE™ FAT TRANSFER SYSTEM

Adivive™ is a medical device used for autologous fat removal and transplantation with an exclusive pre-sterilized single-use 50ml Fat Processing Unit (FPU). Adivive™ is an all-in-one closed system for infiltration, aspiration, centrifuging, filtering, harvesting, and transferring of autologous fat tissue within a completely closed-circuit procedure.

⚠️ Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

The Adivive™ System is intended for use in the following surgical specialties when the aspiration of soft tissue is desired:

- Plastic & Reconstructive Surgery
- General Surgery
- Dermatological Surgery
- Obstetrician & Gynecological Surgery
- Aesthetic Surgery

The Adivive™ System is indicated for use when harvesting of highly concentrated pure fatty tissue for aesthetic body and facial contouring is desired. The system is not in any way intended to be used for harvesting stem cells or fat cells or meant to be used for reasons other than collecting whole autologous fat tissue intended for aesthetic contouring.

CHASSIS LABEL

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation. Page 2
**ADIVIVE™ SYSTEM DESCRIPTION AND FIGURES**

Based on the centrifuge unit with a built-in vacuum and suction pump, the Adivive™ System is comprised of:

1. Centrifuge body with control panel
2. Connection tube
3. FPU Control footswitch
4. Other Adivive™-exclusive accessory components, including a single-use 50ml FPU

*Adive™ System Diagram*
In addition to the main centrifuge body, there are a total of 20 single-use or reusable system components. Below is a picture and description for each of those components. Note that cleaning and sterilization instructions for the reusable components are located beginning on page 13 of this manual. Prior to treatment, periodically inspect all reusable parts and replace as necessary by calling Medi-Khan Customer Service.

<table>
<thead>
<tr>
<th>Number</th>
<th>Component Name &amp; Figure</th>
<th>Description of Use</th>
<th>Remarks</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>50ml Fat Processing Unit (FPU)</td>
<td>Single use only. Supplied sterile. Closed circuit FPU for infiltration solution, aspirated fats, filtering, and re-injection of fat tissue. During all procedures, fat tissue stays within the same 50ml FPU. Green FPU Screw Cap for covering the 50ml FPU frontal tip after aspiration and before centrifugation to prevent harvested fat tissue from flowing out. Screw clear Piston Screw into the piston to close or open the flow gate of the piston within the 50ml FPU. Care should be taken to not strip the screw. Screw tight before infiltration, aspiration and re-injection. Unscrew 3-4 full turns before centrifugation and filtering of free oils.</td>
<td>Pre-sterilized, Single-use Disposable</td>
</tr>
<tr>
<td></td>
<td>Component</td>
<td>Description</td>
<td>Reuse Notes</td>
</tr>
<tr>
<td>---</td>
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<td>-------------</td>
</tr>
<tr>
<td>2</td>
<td>FPU Air Hose</td>
<td>Attaches the 50ml FPU to the centrifuge through the FPU Connector 2. Through this FPU Air Hose, vacuum pressure for aspiration and positive pressure for the infiltration and injection are transmitted from the vacuum pump to the patient’s body.</td>
<td>Reusable per instructions on page 13-14 of this manual.</td>
</tr>
<tr>
<td>3</td>
<td>FPU Connector 1</td>
<td>Attaches to the 50ml FPU. Used for manually injecting the harvested fat tissue or removing the impurities from harvested fat tissue after centrifugation.</td>
<td>Reusable per instructions on page 13-14 of this manual.</td>
</tr>
<tr>
<td>4</td>
<td>FPU Connector 2</td>
<td>Attaches the 50ml FPU to the FPU air hose that attaches to the system body for infiltration, aspiration, suction and injecting.</td>
<td>Reusable per instructions on page 13-14 of this manual.</td>
</tr>
<tr>
<td>5</td>
<td>FPU Push Stick</td>
<td>Used in conjunction with the FPU Connector 1 for pushing the weighted mesh piston within the 50ml FPU to remove impurities after centrifugation or to move fat tissue from one 50ml FPU to another.</td>
<td>Reusable per instructions on page 13-14 of this manual.</td>
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</tbody>
</table>

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.  Page 5
<table>
<thead>
<tr>
<th></th>
<th>Component</th>
<th>Description</th>
<th>Reusability</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>FPU Weight Adapter</td>
<td>Used for moving fat tissue from one 50ml FPU to another or for balancing the same weight of fat tissue within two 50ml FPUs.</td>
<td>Reusable per instructions on page 13-14 of this manual.</td>
</tr>
<tr>
<td>7</td>
<td>Luerlock Adapter IV</td>
<td>Connects a physician-preferred cannula to the 50ml FPU</td>
<td>Reusable per instructions on page 13-14 of this manual.</td>
</tr>
<tr>
<td>8</td>
<td>Luerlock Adapter 2</td>
<td>Used for moving the harvested fat tissue from the 50mL FPU containers to 1, 3, 5, 10 or 20 mL syringes.</td>
<td>Reusable per instructions on page 13-14 of this manual.</td>
</tr>
</tbody>
</table>

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.  Page 6
The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.  

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<tbody>
<tr>
<td>9</td>
<td>3 Way Valve</td>
<td>Connects the 50ml FPU to the tumescent fluid and the Tumescent Cannula. Used for transferring the tumescent solution to the body through the cannula.</td>
</tr>
<tr>
<td>10</td>
<td>Suction Cannula Ø4 260mm</td>
<td>4mm diameter x 260mm length</td>
</tr>
<tr>
<td>11</td>
<td>Suction Cannula Ø3 260mm</td>
<td>3mm diameter x 260mm length</td>
</tr>
<tr>
<td>12</td>
<td>Tumescent Needle Ø2.5 260mm</td>
<td>2.5mm diameter x 260mm length</td>
</tr>
<tr>
<td>13</td>
<td>Injection Cannula Ø4 170mm</td>
<td>4mm diameter x 170mm length</td>
</tr>
<tr>
<td>14</td>
<td>Injection Cannula Ø3 170mm</td>
<td>3mm diameter x 170mm length</td>
</tr>
</tbody>
</table>
15. **Power Cable**

   Power cord with built-in ground connection.  
   | Reusable |

16. **Piston Screw Driver**

   Used for screwing or unscrewing the piston flow gate and plastic Piston Screw.  
   | Reusable per instructions on page 13-14 of this manual. |

17. **Tumescent Hose**

   Used for infiltration of tumescent solution to the desired body part(s) through the 3 Way Valve, connected to 50ml FPU and the Tumescent Cannula.  
   | Reusable per instructions on page 13-14 of this manual. |

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.  
Page 8
The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.  

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Details</th>
<th>Reusability</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>Bucket Clip (FPU Rotor Clip)</td>
<td>Four bucket clips used for holding the buckets within the centrifuge body unit during the centrifugation of liposuctioned fat tissue within the 50ml FPUs.</td>
<td>Reusable per instructions on page 13-14 of this manual.</td>
</tr>
<tr>
<td>19</td>
<td>Bucket (FPU Rotor Case)</td>
<td>Four buckets used for containing and holding the 50ml FPUs during the centrifugation of liposuctioned fat tissue.</td>
<td>Reusable per instructions on page 13-14 of this manual.</td>
</tr>
<tr>
<td>20</td>
<td>FPU Control Footswitch</td>
<td>Used for controlling the vacuum pressure and the positive pressure during infiltration, liposuction, and injection of fat tissue.</td>
<td>Reusable</td>
</tr>
</tbody>
</table>

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation. Page 9
ADIVIVE™ SYSTEM SPECIFICATIONS

**Model or Type:** LK-101

**Dimensions:** 445 mm (W) x 540 mm (L) x 350 mm (H)

**Net Weight:** 35 Kg (77 Lbs)

**Growth Weight w/Package:** 52 Kg (115 Lbs)

**Rated Voltage and Frequency:** Single Phase 110V/60 Hz +/- 10%

**Consumption Electricity:** 500 W

**Vacuum Pump:** Piston type, 2 cylinders, 2 heads, dry vacuum pump

**Maximum Vacuum Pressure:** 90 kPa (-680 mmHg), 13.151 PSI, 0.965 Bar

**Maximum Exhaust Flow Rate:** 25 L/min

**Maximum Air Pressure:** 1 kgf/sq. cm

**Motor:** UL standard 1 motor, 1/10 Horsepower

**Vacuum Control Valves:** 5 Solenoid Valves

**CONTROL BOARD DISPLAY**

1. **Digital Vacuum Gauge** – for indicating a pressure when aspirating or supplying a pressure through the FPU Air Hose of the 50ml FPU.
2. **Pressure Operation Lamp** – for indicating the operation when supplying a pressure through the FPU Air Hose.
3. **Vacuum Operation Lamp** – for indicating the operation when aspirating the vacuum through the FPU Air Hose.
4. **FPU Air Hose Connection Port** – connecting port for the FPU Air Hose connection.
5. **RPM/RCF Display** – LED display for input of rotations per minute (RPM) or relative centrifugal force (RCF) values.
6. **Time Display** – display of the input of operation time when centrifuging at RPM or RCF.
7. **Brake** – 3 levels (low, medium, high) of brakes for the protection of each separated layer by RPM or RCF while centrifuging.
8. **Door Opening Display** – LED displaying the open or closed status of the centrifuge door.
9. **Safety Imbalance Display** – LED displaying any imbalance during the centrifugation with automatic deceleration and system stoppage.
10. **Control and Enter Keys**- used to increase or decrease centrifugation times, RPM or RCF values.
11. **Start Button** – used for starting centrifugation
12. **Stop Button** – Used for stopping centrifugation
13. **Program Button** – Used for setting pre-programmed RPM and cycle time values

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.  Page 10
SAFETY INSTRUCTIONS

ELECTRICAL SHOCK SAFETY:
The 50ml FPU and metallic, stainless steel cannulas are connected to the Adivive™ System through the completely insulated Silicone FPU Air Hose in order to prevent electrical shock hazards.

MAINTENANCE INSTRUCTIONS

MALFUNCTION SAFETY:
If the system has a maintenance problem during the procedure, the surgeon can call service repair by calling MD Resource 510-732-9950. However, even if instant maintenance is not available, physicians can easily rely on their own conventional and manual method of liposuction and fat transplantation using normal syringes and cannulas.

WARNINGS
Federal law restricts this device to sale by or on the order of a physician.

The Adivive™ System should be used by physicians who are trained in liposuction and fat transfer techniques.

The Adivive™ System will not, in and of itself, produce significant weight reduction.

The Adivive™ System is recommended for use in autologous fat transplantation.

The Adivive™ System should be used with extreme caution in patients with chronic medical conditions, such as diabetes, heart or lung disease, circulatory diseases, or obesity.

The volume of blood loss and endogenous body fluid may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely fluid replacement is essential for patient safety.

Do not use the Adivive™ System if any type of fluid enters the unit or the overflow warning light on the lower left front panel of the system appears, due to risk of contamination. **Immediately contact MD Resource for Adivive System servicing: 510-732-9950.**

Do not bend, twist, or crimp the air hose line to the 50ml FPU as it may block the air pressure during the infiltration, aspiration, or injection process.

Do not drop the 50ml FPU. If you do drop it, open a new sterile FPU container to continue the procedure.

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.
All reusable components of the Adivive™ System must be cleaned and sterilized according to the instructions in this manual. All single-use disposable components must be replaced before using the system on another patient.

The Adivive™ System is designed to contour the body by removing localized deposits of excess fat through small incisions.

Use of the Adivive™ System is limited to those physicians who, by means of residency training or sanctioned continuing medical education, have demonstrated proficiency in suction lipoplasty.

Results of this procedure will vary depending upon patient age, surgical site, and experience of the surgeon.

Results of this procedure may or may not be permanent.

The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.

The Adivive™ System is designed only to be used in conjunction with the exclusive 50ml FPUs.

When placing the 50ml FPUs containing harvested fat tissue into the centrifuge, make sure the tissue volume in each syringe is the same to keep the weight balanced during the centrifugation process.

During centrifugation, place the 50ml FPUs into the buckets in an even number and symmetrically to maintain balance.

Reusing the single-use 50ml FPUs could result in cross-contamination leading to pyrexia, infection, and spread of disease. In addition, a used FPU may negatively affect the FPU product performance and cause degradation of materials.

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.
CLEANING AND STERILIZATION INSTRUCTIONS FOR ADIVIVE™ REUSABLE COMPONENTS

All reusable Adivive™ components must be properly cleaned and sterilized prior to use. Clean all of the reusable components immediately after treatment. Sterilize via autoclave immediately before use.

The following Adivive™ components are reusable:

1. FPU Air Hose (TP-105)
2. FPU Connector 1 (TP-106)
3. FPU Connector 2 (TP-107)
4. FPU Push Stick (TP-108)
5. FPU Weight Adapter (TP-111)
6. 3 Way Valve (TP-112)
7. Luerlock Adapter (TP-113)
8. Luerlock Adapter IV (TP-119)
9. 4mm Suction Cannula (TP-201)
10. 3mm Suction Cannula (TP-202)
11. 2.5mm Tumescent Injection/Infiltration Cannula (TP-203)
12. 4mm Injection Cannula (TP-204)
13. 3mm Injection Cannula (TP-205)
14. Tumescent Hose (SP-107)
15. Bucket Clip (W-725)
16. Bucket (W-724)
17. Piston Screw Driver (TP-110)

RESUSABLE COMPONENT WARNINGS AND PRECAUTIONS
(See Safety and Precautions sections for additional system warnings and precautions)

⚠️ It is required that all reusable components be cleaned and sterilized prior to treatment to prevent blood and debris from drying on the reusable components and to prevent potential cross contamination.

⚠️ During cleaning of the intricate reusable components it is important to thoroughly scrub and rinse with hot water where potential contamination may occur (e.g., cannula or syringe connectors) to ensure proper cleaning.

⚠️ The 50ML FPUs are designed for single treatment use. Re-use may negatively affect product performance, cause degradation of materials, and compromise sterility, thus causing undue risk to patient.

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation. Page 13
Cleansing Instructions

1. Disassemble Adivive™ System and accessories from the centrifuge unit to access all reusable components required to be sterilized. All of the reusable components must be individually separated (See pages 3-9 of this manual for individual component illustrations).
2. Rinse each reusable component with hot water. Use a stiff bristle brush to thoroughly scrub all crevices and areas to ensure proper removal of all debris.
3. Soak all reusable components in a medical grade enzymatic cleaner. Follow the enzymatic cleaner manufacturer’s guidelines for the correct dilution, temperature, water quality (i.e. pH, hardness), exposure time and rinsing.
4. After soaking, rinse all reusable components with hot water for a minimum of 2 minutes or as specified in the enzymatic cleaner instructions. Thoroughly rinse inside of cannulas and any other reusable components that have hard to access areas with hot water using a 10-60cc syringe.
5. Visually inspect the reusable components to ensure they are free of debris and cleaner.
6. Dry all reusable components using a clean, soft, lint-free cloth or clean compressed air.

Sterilization Instructions

Gravity Setting

1. Sterilize all reusable components immediately prior to use.
2. Place components in autoclavable pouches. Use multiple pouches if necessary.
3. Adjust the autoclave to GRAVITY SETTING. Set the autoclave to 270°F (132°C) for 60 minutes with a 30 minute dry cycle. Remove the reusable components from autoclave and place in sterile field.

Prevac Setting

1. Sterilize all reusable components immediately prior to use.
2. Place components in autoclavable pouches. Use multiple pouches if necessary.
3. Adjust the autoclave to PREVAC SETTING. Set the autoclave to 270°F (132°C) for 6 minutes with a 35 minute dry cycle. Remove the reusable components from autoclave and place in sterile field.

Cleaning of the Centrifuge Rotor and Basin

1. Using a Sani-Cloth® Plus, thoroughly wipe the centrifuge chamber to ensure that it is free of any debris.
2. Using a Sani-Cloth® Plus, thoroughly wipe the centrifuge rotor and crevices where potential contamination could occur.

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation. Page 14
The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.

INSTALLATION AND CONNECTION OF ACCESSORY COMPONENTS

PRIOR TO INSTALLATION

1. Place Adivive™ System on a smooth, horizontal surface prior to use in the operating room to keep the centrifuge balanced.
2. Make sure there is adequate air circulation.
3. Avoid the external environmental factors such as hot weather or humidity, which may cause malfunction or erosion.
4. Install the Adivive™ System in a place with no exposure to erosive gas, which may damage metallic parts.
5. Use singular phase 110V/60Hz

CONNECTING 50 ML FAT PROCESSING UNITS AND ACCESSORIES

All accessory components of this Adivive™ System are designed and manufactured to be used exclusively with the Adivive™ System and 50ml FPU as described in this manual. The Adivive™ System can only perform in its intended use for all-in-one, closed-circuit autologous fat transfer, when its accessory components are assembled in the appropriate manner.

ASSEMBLING THE 50ML FAT PROCESSING UNIT

1. Remove the 50ml FPU, green FPU Screw Cap, and Mesh Piston from the sterile packaging.
2. Insert the Mesh Piston into the 50ml FPU.
3. Using the Piston Screwdriver, screw the clear Piston Screw located inside the Mesh Piston clockwise until tight and secure. When tightening, be careful not to strip the screw as fluid could leak or be drawn into the system and cause contamination.
The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation. Page 16
b. If you are performing infiltration, connect the 3 Way Valve to the distal end of the 50ml FPU first. Once the 3 Way Valve is in place, attach the desired tumescent cannula. Then connect one end of the Tumescent Hose to the 3 Way Valve and the opposite end with the Tumescent Hose spike to the infiltration bag/bottle.

4. Finally, connect the FPU Control Footswitch to the footswitch connection port located on the lower-left back corner of the centrifuge.

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation. Page 17
PREPARING HARVESTED TISSUE FOR CENTRIFUGATION

1. Detach 50ml FPU from FPU Connector 2.

2. Detach cannula from the distal end of the 50ml FPU and screw on the green FPU Screw Cap provided in the sterile packaging with the 50ml FPU. The green FPU Screw Cap must be securely screwed on to prevent fluid leakage and damage to the cap during centrifugation.

3. Once the 50ml FPUs are detached from the Adivive™ System check to make sure the aspirate volumes in each are balanced before proceeding to step 4. To balance the 50ml FPUs, attach FPU Connector 1 and the FPU Push Stick to the proximal end of the 50ml FPU and the FPU Weight Adapter between the two 50ml FPUs you wish to balance. Turn the FPU Push Stick clockwise to transfer the tissue for balance. Make sure the piston is level to the fat prior to spinning and that there are no air gaps.

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation. Page 18
4. Using the Piston Screwdriver, unscrew the Piston Screw located inside the 50ml FPU counterclockwise 3-4 full turns.

5. Carefully place 50ml FPUs into the centrifuge buckets and buckets clips inside the Adivive™ system and check to ensure they are all the way in the buckets prior to centrifugation. Make sure that the 50ml FPUs are placed into the centrifuge buckets symmetrically.

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.
PREPARING CENTRIFUGED TISSUE FOR INJECTION

1. Remove 50ml FPU(s) from the centrifuge bucket(s).
2. Attach FPU Connector 1 and FPU Push Stick to the proximal end of the 50ml FPU to squeeze out impurities after the centrifugation cycle.

3. a. You may also use the FPU Push Stick to manually inject tissue after the centrifugation process.

4. The Luerlock Adapter 2 is used to transfer harvested tissue to a small volume syringe (e.g. 1ml, 3ml, 5ml, or 10ml) for injection into smaller treatment areas. You can also attach a provided Injection cannula to the distal end of the 50ml FPU to perform manual tissue injection for larger areas by turning the Push Stick clockwise.

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation. Page 20
OPERATION OF THE 50 ML FAT PROCESSING UNIT & THE ADIVIVE™ SYSTEM

CONNECTING THE 50 ML FAT PROCESSING UNIT TO THE ADIVIVE™ SYSTEM FOR OPERATION:
After completing the Installation and Connection of Accessory Components, you can now connect the 50ml FPU to the Adivive™ system for use.

1. First, connect one end of the FPU Air Hose to the Air Hose Connection Port on the front control panel of the Adivive™ system and the other end of the FPU Air Hose to the FPU Connector 2.
2. Next, connect the 50ml FPU to FPU Connector 2, turn 90⁰ and lock into place.
3. Finally, insert the female end of a required Adivive™ cannula into the 50ml FPU and screw clockwise to tighten.

STARTING OPERATION OF THE ADIVIVE™ SYSTEM:
1. Switch on the Adivive™ System using the ON/OFF switch on the front control panel.
2. Connect the 50ml FPU, FPU Air Hose, FPU Connector 2, and the Adivive™ required cannula to the system per the above instructions.
3. Connect the electrical wire cord of the FPU Control Foot Switch to the connection port on the lower back of the centrifuge.
4. Accordingly, use the FPU Control Foot Switch to control the suction and pressure of the Adivive™ System with the Low Pressure, High Pressure, or Vacuum Foot Pedals to infiltrate, harvest/aspirate, or inject fat tissue.

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation. Page 21
THE COMPONENTS & THE USE OF THE VACUUM

THE COMPONENTS FOR VACUUM:
The vacuum of the Adivive™ System consists of one built-in vacuum pump, 5 built-in solenoid control valves, one built-in air-filter, one vacuum gauge, one LED lamp, one FPU Air Hose, one FPU Connector 2, and the 50ml FPU.

CONNECTING THE TUBING:
1. The Silicone FPU Air-hose (15 mm diameter) connects from the centrifuge to the 50ml FPU through the FPU Connector 2.
2. The 50ml FPU is used as your suction handle as well as a collection container of aspirated fat tissue. So, the Adivive™ System does not need to have a separate suction handle.
3. The raw material of the FPU Air Hose is made from Silicone, Dow Corning Pharma-80 tubing in compliance with international standards.
4. The FPU Air Hose tubing is also test-certified chemically and mechanically at tensile strength of over 27 kgf/sq.mm and at 10% of elongation ratio so as to withstand the enough negative vacuum pressure.

THE USE OF THE VACUUM:
1. The vacuum is used for drawing the tumescent solution into the 50ml FPU before infiltrating the solution into the desired patient areas and also for the harvesting/liposuction portion of the procedure following infiltration.
2. While drawing up the infiltration solution into the 50ml FPU using the vacuum and infiltrating the tumescent solution into the patient’s treatment area by air pressure, the 3 Way Valve is connected between the tip of the 50ml FPU and the Adivive™ infiltration cannula. The Tumescent Hose is attached to the one protruding branch of the 3 Way Valve so that the Tumescent Hose can be connected to the poly vinyl bag containing the prepared tumescent solution.
3. By pressing the Vacuum Pedal on the FPU Control Foot Switch, the vacuum draws up the tumescent solution into the 50ml FPU. Then, by pressing the Low or High Pressure Pedals, the tumescent solution is injected into the patient’s treatment area from where you harvest/liposuction.
4. For the harvesting/liposuction portion of the procedure, remove the 3 Way Valve and replace the tumescent cannula with the suction cannula which is directly connected to the distal end of the 50ml FPU. Then, by pressing the Vacuum Pedal, the fat tissue and infiltration solution are harvested into the 50 ml FPU.

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation. Page 22
TESTING THE VACUUM & PRESSURE PRIOR TO INFILTRATION AND HARVESTING/LIPOSUCTION:

1. First check to make sure each connection point is secure when starting operation of the Adivive™ System.

2. After each connection is secure, test the operation by pressing the Vacuum Pedal and the Pressure Pedals to ensure the vacuum and pressure are functioning properly. While pressing the vacuum pedal, the weighted-mesh piston within the 50ml FPU should move upward toward the FPU Connector and FPU Air Hose. By pressing the High or Low Pressure Pedal, the weighted-mesh piston should move the opposite way downward toward the tip of the 50ml FPU where the cannula is connected.

3. If the weighted-mesh piston does not move well, use the Piston Screw Driver to be sure the Piston Screw and Silicone O-Ring in the weighted-mesh piston are tight and secure.

CHECKING THE MAXIMUM VACUUM PRESSURE:

1. First, connect the air hose Connector to the vacuum port of the Adivive™ system through the FPU Air Hose.

2. Then block the air-holes at distal end of cannula with hand and press the Vacuum pedal by foot.

3. Check the maximal vacuum pressure at the Digital Vacuum Gauge on the front panel of the system. The vacuum pressure must be over 630 mmHg (84 Kpa).
HELPFUL HINTS AND MAJOR OPERATIONAL STAGES

1. **CONNECTING ADIVIVE™ CANNULAS TO THE 50 ML FAT PROCESSING UNIT:**
   Do not tighten the Adive™ cannulas into the 50 ml FPU too tightly. The metallic head of the cannula can damage the plastic tip of the 50ml FPU if over-tightened.

   ![Image of cannulas being connected to FPU](image1)

2. **TIGHTENING THE PISTON SCREW & SILICONE O RING INTO THE FPU BEFORE USE:**
   Do not forget to tighten the Piston Screw with Silicone O Ring before harvesting or injection. Do not over tighten to avoid damage to the Piston Screw and Silicone O Ring.

   ![Image of piston screw and O ring being tightened into FPU](image2)

3. **CONNECTING THE FPU AIR HOSE TO THE CONNECTION PORT ON THE ADIVIVE™ SYSTEM:**
   As shown in the below figures, there are dented indication marks in each connection point of both the FPU Air Hose and the connection port on the centrifuge. While detaching the FPU Air Hose from the connection port, slightly pull up on the connecting body of the FPU Air Hose.

   ![Image of FPU air hose being connected to centrifuge](image3)

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.  Page 24
HELPFUL HINTS AND MAJOR OPERATIONAL STAGES, CONTINUED

4. **CONNECTING THE 50ML FAT PROCESSING UNIT, 3 WAY VALVE, & CANNULA FOR INFILTRATION:**
   Connect the 50ml FPU, the 3 Way Valve, the Tumescent Hose, and the Adivive™ cannula as in the figures below. Place the infiltration solution bag lower than the 50ml FPU so that the solution does not spill out from the cannula while not infiltrating.

5. **BALANCING THE 50ML FAT PROCESSING UNITS BEFORE CENTRIFUGATION:**
   After harvesting/suctioning the fat tissue, you will need to apply equal volumes (+/- 5ml) of fat aspirates in each 50ml FPU. Verify that the piston is flush or level to the fat prior to spinning and that there are no air gaps. Place the 50ml FPUs in the centrifuge in even numbers (2 or 4 per cycle). Do not spin 1 or 3 50ml FPUs in a given cycle.

6. **CAPPING AND SLIGHTLY UNSCREWING THE 50ML FAT PROCESSING UNIT BEFORE CENTRIFUGATION:**
   Screw and firmly hand-tighten the green FPU Screw Cap onto the 50ml FPU after collecting the fat aspirates and prior to centrifugation. Do not forget to unscrew the Piston Screw and Silicone O Ring 3-4 full turns counterclockwise before centrifugation so that the free oils can flow out from within the 50ml FPU through the piston flow gate during the centrifugation cycle.

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation. Page 25
HELPFUL HINTS AND MAJOR OPERATIONAL STAGES, CONTINUED

7. PRECAUTIONS BEFORE CENTRIFUGATION:
   a. Make sure that the 50ml FPUs are correctly and symmetrically placed into the sterile centrifuge Buckets and Bucket Clips.
   b. After placing the 50ml FPUs into the Buckets, slightly press and cross-check the correct placement of the 50ml FPUs using a sterile hand.

8. CHECK WHETHER THE 50ML FAT PROCESSING UNIT AND PISTON FUNCTIONS NORMALLY:
   After connecting the 50ml FPU to the Adivive™ System, press the vacuum pedal to make sure the piston within the 50ml FPU moves backward towards the FPU Air Hose connection. Also press the low and high pressure pedals to make sure the piston moves forward toward the cannula connection point of the 50ml FPU. If the piston does not move, the connections are not secure. Re-check all connections.

9. REDUCE POSSIBLE TISSUE DAMAGE AT VACUUM OR FPU AIR HOSE CONNECTIONS:
   a. Ensure all connections are secure and piston functions normally. If connections are not secure, the piston will not move and tissue and/or infiltration fluid may travel back through the FPU Air Hose and into the centrifuge and become contaminated. If this occurs, please call MD Resource 510-732-9950 for Customer Service repairs.
   b. The vacuum or the Air Pressure works when pressing the FPU Control Footswitch. By taking your foot off of the pedal, the vacuum or the air-pressure function stops working automatically.
   c. In a case where the vacuum regulator/vacuum switch does not work, the physician should stop using the Adivive™ System and resort to backup harvesting methods. Please contact MD Resource 510-732-9950 if this issue should occur.
   d. Unlike high suction devices, the Adivive™ System employs a low pressure/suction vacuum to reduce mechanical damage to harvested tissue.

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HOW TO SET UP RPM, RCF, & CENTRIFUGE CYCLE TIMES

Display Board of Centrifuge

RPM OR RCF SET UP:
1. Press either the RPM or RCF key first
2. Using the Up or Down arrow keys to set up the desired RPM/RCF value (for example, 3,000 RPM)
3. Press the Enter key to set value

CYCLE TIME SET UP:
1. Press the T Key
2. Using the Up or Down arrow keys to set up the desired centrifuging time (for example, 05 minutes)
3. Press the Enter key to set value

ADDITIONAL INFORMATION:
After setting up the required RPM/RCF/Time, by pressing the Start key, the centrifuge will begin working (for example, if you set up the system for 3,000 RPM for 5 min and press Start, the centrifuge begins spinning for the cycle).
1. After pre-set cycle time ends, the centrifugation begins to slow down and stop. The time and RPM/RCF values will automatically go back to the initial input values.
2. If you need to stop the centrifuge at any point during the cycle, simply press the Stop key and it will begin to slow down and stop.
3. The range of available RPM for the centrifuge is 800 (minimum) – 5,000 (maximum). This centrifuge is not set up to spin at lower than 800 RPM, in order to enhance the control capabilities and performance of the motor.
4. This centrifuge unit can automatically calculate RPM to RCF or RCF to RPM values using the controls on the display board*.

*RCF (relative centrifugal force) is related to the rotating radius and the rotating speed

$$RCF \ (xg) = 11.18 \times r \times (RPM/1,000)^2$$

The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.  Page 27
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<table>
<thead>
<tr>
<th>Troubleshooting and LED Display</th>
</tr>
</thead>
<tbody>
<tr>
<td>Displays brake stages at L, M, or H with LED light. Press Brake key. This function allows you to interrupt a centrifuge cycle if an emergency occurs.</td>
</tr>
<tr>
<td>The Imbalance Display shows when a certain degree of imbalance occurs in the rotor of the centrifuge. When an imbalance gets too severe, the Imbalance LED light comes on with a warning sound. At this time, the centrifuge will automatically stop using a preset deceleration time.</td>
</tr>
<tr>
<td>When the centrifuge door is closed the LED is off and when the door is open, the Door LED is on. While the door is open the centrifuge will not work. If the door opens during the centrifugation cycle, the electrical supply automatically stops. Do not open the door during the centrifugation cycle. The door handle is located on the right side of the centrifuge. Turn clockwise to open the door. To close the door, simply press the door down until you hear a click, which indicates that it is closed.</td>
</tr>
</tbody>
</table>
### Troubleshooting and LED Display, Continued

<table>
<thead>
<tr>
<th>Issue</th>
<th>Check These First</th>
<th>Next Steps</th>
</tr>
</thead>
</table>
| When the system doesn’t work                                        | 1. Check to make sure the power cords to the system and the foot switch are connected correctly.  
2. Check the fuse status in the fuse case inside the centrifuge.                                                                                     | If the problem continues, call for maintenance.                                                 |
| Unusual loud noise or serious trembling of the system               | 1. Check to make sure the system is placed on a stable flat surface.  
2. Check the balance of the centrifuge rotor.  
3. Check whether the volumes of the contents in the 50ml FPs are the same.  
4. Check to make sure the 50ml FPs are placed symmetrically within the centrifuge.              | If the problem continues, call for maintenance.                                                 |
| When the suction is not coming through the 50ml FPU                 | 1. Check to make sure the connections of the 50ml FPU to the connector and the air hose to the system are secured.  
2. Make sure there are no twists or blocks in the FPU Air Hose.  
3. Check for any blocking or clogging within the cannula. Long periods of suction time can clog the cannula with fibrotic fat tissue. | If the problem continues, call for maintenance.                                                 |
| When the piston within the 50ml FPU doesn’t move back and forth at all or functions poorly | 1. The 50ml FPU is single-use only. Do not use the 50ml FPU or piston plunger more than once.                                                                                                                   | If the problem continues after replacing the 50ml FPs with a new one, call for maintenance.     |

**Contact MD Resource for troubleshooting help, maintenance or supplies:** 510-732-9950
WARRANTY & DISCLAIMERS

WARRANTY PERIOD:
1. Centrifuge Unit: 1 year
2. Reusable Components: 1 year
3. 50ml FPU: Single-use only. No warranty.

DISCLAIMERS
For the following, no complimentary replacement is available even within the warranty period:

1. Trouble from erosion on the machine or components with careless management.
2. Trouble from intentional or mistaken input of different materials into the system.
3. Trouble from careless handling and management by users.
4. Trouble from users’ wrong repairing or maintenance.
5. Trouble from users’ own break-down of the system.
6. Trouble from careless drop or impact on the system.
7. Trouble from other mistakes by users.
8. Trouble from natural casualties, disasters, or any other cause beyond our control.

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The centrifuged, harvested fat is only to be used for reimplantation without any additional manipulation.