

Standardization and Behavioral Checklist

Technique/Individual Step	Description	Initiation	Completion
Clinical Assessment-Clinic Visit Research Coordinator (Screened for eligibility)	Obtaining surgical consent and conducting clinical assessment— <u>Baseline Assessment</u> Questionnaire filled out	Not applicable (NA)	NA
Instrument Prep Scrub technicians set up instrument trays prior to surgery or during turn over			
Active Filtration Instrument Prep Step 1	LR solution prep	LR solution warming initiated	LR solution warming completed
Active Filtration Instrument Prep Step 2	Instrument is taken out of the box, seals are broken, and chamber (along with tubing) is set up on the tray Liposuction vacuum is set up at the foot of the operating room (OR) table	Instrument taken out of sealed box by scrub technician If instrument was already removed, start time begins when seal is broken	Setup complete once scrub technician ceases any setup activity related to the grafting process (confirm)
Passive Filtration Instrument Prep	Instrument is taken out of the box, seals are broken, and mesh bag is set up on the tray Tubing is removed from packaging and left on the tray Tubing connected to vacuum port and the drain bag is laid out on the instrument tray	Instrument seal broken	Setup complete once scrub technician ceases any setup activity related to the grafting process (confirm)
Centrifugation	Centrifuge is in the OR with the rest of the surgical kit Syringes with caps (plungers removed) and centrifuge insert are laid out on the instrument tray	Syringes or centrifuge insert laid out on the tray	Set up complete once scrub technician ceases any setup activity related to the grafting process (confirm)

Technique/Individual Step	Description	Initiation	Completion
Patient Enters OR (Overall OR time)	Patient wheeled into OR on stretcher	Patient barcode read or time patient entered the OR is called out	Patient barcode read as patient leaves OR or when patient is wheeled out of OR
Patient/Site Prep (Includes patient prep, anesthetic prep, and site markup)	Patient is positioned on the table by physician assistant (PA) and anesthesiologist Patient is administered anesthetic then cleaned and draped	Anesthetic time called out or anesthesiologist administers medication intravenously	All drapes are placed.
Operative Procedure			
Procedure Time	This includes the entire procedure, graft replacement, and revision in addition to the fat grafting procedure	First incision by surgeon Or introduction of local anesthetic, tumescence, etc	Final suture in place or dressing complete
Fat Grafting Procedure			
Active Filtration System			
Final Instrument Setup	Product prepared for use just before fat grafting commences	Scrub technician connects vacuum port to waste container with accompanying tubing Or Scrub technician brings chamber over to the patient area	Scrub technician connects liposuction tube to patient port
Fat Harvesting Step 1	Infuse patient with tumescence solution	Surgeon inserts infusion needle/ cannula into donor site	Surgeon removes needle / cannula
Fat Harvesting Step 2	Time for tumescence solution to take effect	Removal of needle after infusion of tumescence solution	Insertion of liposuction cannula into patient
Fat Harvesting Step 3	Prep harvest liposuction cannula already attached to vacuum	Surgeon inserts liposuction cannula into patient	Surgeon removes liposuction cannula from the patient

Technique/Individual Step	Description	Initiation	Completion
	Surgeon may perform this action several times; observer will record each time that surgeon inserts liposuction cannula into patient and removes it from the patient		
Fat Processing	<p>Fat collects in processing chamber of the Active Filtration system along with Ringer's lactate (LR) solution</p> <p>This step includes:</p> <ol style="list-style-type: none"> 1. 3 washes 2. turning the lever for 15 seconds <p>Vacuuming out wastage</p>	Scrub technician connects lactated Ringer's solution to chamber	Completion of last vacuuming of wastage after third wash
Fat Delivery/Transfer to Surgeon	<p>Prep fat for delivery to recipient site</p> <p>Can be injected into multiple smaller syringes; observer will record total time</p>	Scrub technician connects 60 cc catheter tip syringe to the processing chamber in order to start fat extraction	Scrub technician injects fat from 60 cc catheter tip syringe to last 10 cc luer lock syringe
Recipient Site Prep (optional)	Preparing site for fat grafting	Surgeon prepares site with injection cannula or large bore IV, breaks scar, etc.	Surgeon completes preparation and initiates grafting
Fat Grafting/Reconstruction	Scrub technician hands syringe to surgeon for fat injection and surgeon contours area as they inject the fat	Surgeon injects fat into recipient site	Surgeon closes up cannula sites
Instrument Breakdown/Disposal	Instrument breakdown consists of disengaging all tubing from chamber and vacuum	Scrub technician disconnects patient port from liposuction cannula	Dispose of tubing and chamber into waste container

Technique/Individual Step	Description	Initiation	Completion
Passive Filtration System			
Final Instrument Setup	Product prepared for use just before fat grafting commences	Scrub technician sets up easel with mesh bag (to be followed by drain bag - placed below the level of the filter bag)	Scrub technician completes connecting vacuum port to the waste container using tubing
Final Instrument Setup (optional task) This will only be done if tubing system is used for infusing LR solution into the bag	LR bag is attached to the mesh bag using a tubing set attached to inlet port on the mesh bag	Scrub technician attaches tubing to LR bag	Attach other end to inlet port on mesh bag
Fat Harvesting Step 1	Infuse patient with tumescence solution	Surgeon inserts infusion needle / cannula into donor site	Surgeon removes needle / cannula from donor site
Fat Harvesting Step 2	Time for tumescence solution to take effect	Removal of needle after infusion of tumescence solution	Insertion of liposuction cannula into patient
Fat Harvesting Step 3	Prep Toomey syringe for harvest; fitted with a liposuction cannula Surgeon may perform this action several times; observer will record each time surgeon inserts liposuction cannula and removes from the patient	Surgeon inserts liposuction cannula into patient to begin harvest	Surgeon removes liposuction cannula from patient when lipoaspirate volume is met
Fat Harvesting Step 4	Transfer of fat to scrub technician for processing	Surgeon hands the Toomey syringe to scrub technician	Scrub technician places syringe in syringe rack or on the instrument tray and places plastic adaptor on the syringe (provided in kit)

Technique/Individual Step	Description	Initiation	Completion
Fat Processing Step 1	Transfer fat to processing bag This may occur several times depending on the number of Toomey syringes used for harvest; observer will record all times that this occurs	Scrub technician attaches syringe (with adaptor) to the mesh bag via the tissue port	Scrub technician completes transfer of all the content from Toomey syringe into the mesh bag
Fat Processing Step 2	Gravity drainage Scrub technician opens vacuum port to allow excess fluid to drain out (2-6 minutes)	Scrub technician opens vacuum port	Scrub technician closes clamp to drain bag or closes vacuum port
Fat Processing Step 3	Fat washing LR solution inserted into bag using syringe This steps includes: 1. 2 wash cycles at minimum 2. 1:1 ratio 3. 15 sec of manual agitation	Aspirate LR or saline into 60 cc syringe to add to the bag for washing	Scrub technician injects solution into bag
Fat Processing Step 3 (optional task) If using a tubing system for RL	Fat wash-LR solution using tubing RL bag is attached to the mesh bag using a tubing set attached to inlet port on the mesh bag	Scrub technician opens the clamp and allows mesh bag to fill with RL	Scrub technician closes clamp and disconnects inlet tubing set
Fat Processing Step 4	Processing (repeated twice) Bag is agitated manually and impurities are forced towards drain port using a scraper Drain port/clamp on the tubing connected to drain bag is	Scrub technician begins agitating bag	(All impurities drained into waste bag) Scrub technician closes clamp to waste container after 2 washes If slider is used, end time is after final use of slider

Technique/Individual Step	Description	Initiation	Completion
	opened to allow the impurities to drain		
Fat Delivery/Transfer to Surgeon Step 1	Prep fat for delivery to recipient site	Scrub technician attaches Toomey syringe with adaptor to patient port to extract last fat aliquot	Scrub technician completes extracting all fat from the bag
Fat Delivery/Transfer to Surgeon Step 2	Fat is transferred into smaller delivery syringes	Scrub technician transfers fat to first 10 cc luer lock syringe from Toomey syringe	Scrub technician transfers fat to last 10 cc luer lock syringe
Recipient Site Prep (optional)	Preparing site for fat grafting	Surgeon prepares site with injection cannula or large bore IV, breaks scar, etc	Surgeon completes preparation and initiates grafting
Fat Grafting/Reconstruction	Surgeon contours area as they inject the fat	Surgeon injects fat into recipient site	Surgeon closes patient with last suture
Instrument Breakdown/Disposal	Instrument breakdown consists of disengaging all tubing from the mesh bag	Disconnect drain port from waste container	Dispose of tubing and bag into waste container
Centrifugation			
Fat Harvesting	Liposuction into syringe Surgeon may perform this action several times; observer will record each time that surgeon inserts liposuction cannula into and removes from the patient	Surgeon inserts cannula into donor site	Surgeon removes cannula for the last time
Fat Processing Step 1	Scrub technician transfers fat into several small syringes for centrifuge, caps are placed on the syringes	Scrub tech organizes / consolidates fat in 10 mL syringes	Scrub tech completes transfer of fat to last syringe and caps all syringes

Technique/Individual Step	Description	Initiation	Completion
Fat Processing Step 2	Centrifuge processing according to Coleman technique	Scrub technician adds first syringe into centrifuge insert	Scrub technician removes last syringe from centrifuge insert
Fat Processing Step 3	Remove impurities from syringes	Scrub technician pours out oil from top of first syringe, adds wick	Scrub technician allows blood to drain out from bottom of last syringe
Fat Transfer/Delivery to Surgeon	Processed fat transferred to delivery syringe	Scrub technician transfers fat into 10 mL delivery syringe	Scrub technician completes fat transfer to last 10 mL delivery syringe
Recipient Site Prep (optional)	Prepare site for fat grafting	Surgeon prepares site with injection cannula or large bore IV, breaks scar, etc	Surgeon completes preparation and initiates grafting
Fat Grafting/Reconstruction	Surgeon contours area as they inject the fat	Surgeon injects fat into recipient site	Surgeon closes patient with last suture
Instrument Breakdown/Disposal	Syringe caps removed and disposed of	Syringe caps removed	Syringes disposed into waste container

STANDARDIZATIONS

Below is a list of standardizations that will be employed in the design and conduct of the study.

Recruitment and eligibility:

- Research coordinator will approach all potential patients at the clinic visit prior to the scheduled surgery to obtain consent

Randomization

- Surgeons will not be made aware of the fat grafting procedure assignment until the day of surgery
- Surgeons will not be able to override the treatment assignment in favor of another
- If treatment assignment is not maintained as stipulated by the randomization scheme it will be considered a protocol deviation

Instrument prep

- *Revolve*
 - Ringers Lactate should be warmed 45 minutes before the procedure
- *Puregraft*
 - Ringers Lactate does not need warming for the Puregraft technique, surgeon discretion

Surgical procedure

- All participating faculty, physician assistants and scrub technicians should have performed at least 5 procedures of each active filtration (Revolve TM), passive filtration (Puregraft TM), and centrifugation
 - Participants will also be trained via in-services conducted by PI prior to study initiation
- All participating surgeons should have performed at least 5 procedures each active filtration (Revolve TM), passive filtration (Puregraft TM), and centrifugation
 - PI will have a discussion with all participating surgeons and a standardized surgical technique will be agreed upon and written up by the PI prior to study initiation
 - For example, tumescence will be performed for all fat graft techniques, minimum of 500 mL, maximum of 1000mL
 - Manufacturer's instructions will be followed for the filtration device systems
 - In the case of the active system, fat processing will be measured when the warmed LR solution is connected to the device
 - Fat will then be washed 3 times as per manufacturer's instructions

- In the case of the passive filtration system, the fat processing will be measured from when harvested fat is injected into the mesh bag as per manufacturer's instructions
 - During fat processing, the mesh bag should be agitated with a hand-massaging action and washed 2 times as per manufacturer's instructions
- Fat will be processed only by the surgeon or scrub technicians, regardless of fat grafting technique, with no involvement of non-study personnel (ie, residents, medical students, etc)

Active Filtration System Data Collection Form

Patient ID	_____
Date	____/____/____
Technique	

Technique/Individual Step	Initiation	Completion
Instrument Setup		
Revolve™ Instrument Prep Step 1 Ringers Lactate solution prep Ringers Lactate solution warming is initiated and then completed	____:____:____ H H m m s s	____:____:____ H H m m s s
Revolve™ Instrument Prep Step 2 Instrument is taken out of the box, seals are broken, and chamber along with tubing is set up on the instrument tray Liposuction vacuum is set up at the foot of the operating room (OR) table	____:____:____ H H m m s s	____:____:____ H H m m s s
Patient OR time (Overall OR time) Patient wheeled into OR on stretcher and leaves after surgical procedure is complete	____:____:____ H H m m s s	____:____:____ H H m m s s
Patient/Site Prep (Includes patient prep, anesthetic prep, and site markup) Patient is positioned on the table by physician assistant (PA) and anesthesiologist. Patient is administered anesthetic, cleaned, and draped	____:____:____ H H m m s s	____:____:____ H H m m s s
Procedure Time This includes the entire procedure, graft replacement,	____:____:____ H H m m s s	____:____:____ H H m m s s

Technique/Individual Step	Initiation	Completion
and revision in addition to the fat grafting procedure		
Final Instrument Setup Product prepared for use just before fat grafting commences	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Harvesting Step 1 Infuse patient with tumescence solution	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Harvesting Step 2 Time for tumescence to take effect	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Harvesting Step 3 Prep harvest liposuction cannula already attached to vacuum Surgeon may perform this action several times. Observer will record each time that surgeon inserts liposuction cannula into patient and removes it from the patient	____:____:____ H H m m s s ____:____:____ H H m m s s ____:____:____ H H m m s	____:____:____ H H m m s s ____:____:____ H H m m s s ____:____:____ H H m m s s
Fat Processing Step 4 Fat collects in processing chamber of the Revolve system along with Ringer's lactate (RL) solution This step includes: <ol style="list-style-type: none"> 3 washes Turning the lever for 15 seconds Vacuuming out wastage	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Delivery/Transfer to Surgeon Prep fat for delivery to recipient site Can be injected into multiple smaller syringes. Observer will record total time	____:____:____ H H m m s s	____:____:____ H H m m s s

Technique/Individual Step	Initiation	Completion
Recipient Site Prep (optional) Preparing site for fat grafting	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Grafting/Reconstruction Surgeon contours the area as they inject the fat	____:____:____ H H m m s s	____:____:____ H H m m s s
Instrument Breakdown/Disposal Instrument breakdown consist of disengaging all tubing from chamber and vacuum	____:____:____ H H m m s s	____:____:____ H H m m s s

Fat	Volume
Harvested	____.____ mL
Grafted	____.____ mL

Staff	Log in time	Log out time
Nurse	____:____:____ H H m m s s	____:____:____ H H m m s s
Scrub technician	____:____:____ H H m m s s	____:____:____ H H m m s s
	____:____:____ H H m m s s	____:____:____ H H m m s s
	____:____:____ H H m m s s	____:____:____ H H m m s s
	____:____:____ H H m m s s	____:____:____ H H m m s s

Passive Filtration System Data Collection Form

Patient ID	_ _ _ _ _
Date	_ _ _ _ / _ _ _ _ / _ _ _ _
Technique	

Technique/Individual Step	Initiation	Completion
Instrument Setup		
Puregraft® Instrument is taken out of the box, seals are broken, and mesh bag along with tubing is set up on the instrument tray Tubing is removed from packaging and left on the instrument tray Tubing connected to vacuum port and the drain bag is laid out on the instrument tray	_ _ _ : _ _ : _ _ H H m m s s	_ _ _ : _ _ : _ _ H H m m s s
Patient OR time (Overall OR time) Patient wheeled into OR on stretcher and leaves after surgical procedure is complete	_ _ _ : _ _ : _ _ H H m m s s	_ _ _ : _ _ : _ _ H H m m s s
Patient/Site Prep (Includes patient prep, anesthetic prep, and site markup) Patient is positioned on the table by physician assistant (PA) and anesthesiologist. Patient is administered anesthetic, cleaned, and draped	_ _ _ : _ _ : _ _ H H m m s s	_ _ _ : _ _ : _ _ H H m m s s
Procedure Time This includes the entire procedure, graft replacement, and revision in addition to the fat grafting procedure	_ _ _ : _ _ : _ _ H H m m s s	_ _ _ : _ _ : _ _ H H m m s s

Technique/Individual Step	Initiation	Completion
Final Instrument Setup Product prepared for use just before fat grafting commences	____:____:____ H H m m s s	____:____:____ H H m m s s
Final Instrument Setup (optional task) This will only be done if tubing system is used for infusing solution into the bag RL bag is attached to the mesh bag using a tubing set attached to inlet port on the mesh bag	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Harvesting Step 1 Infuse patient with tumescence solution	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Harvesting Step 2 Time for tumescence to take effect	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Harvesting Step 3 Prep Toomey syringe for harvest. Fitted with a liposuction cannula. Surgeon may perform this action several times. Observer will record each time surgeon inserts liposuction cannula into patient and removes it from the patient	____:____:____ H H m m s s ____:____:____ H H m m s s ____:____:____ H H m m s	____:____:____ H H m m s s ____:____:____ H H m m s s ____:____:____ H H m m s
Fat Harvesting Step 4 Transfer of fat to scrub technician for processing	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Processing Step 1 Standardization: LR in a bag for connection into mixing bag or use syringe	____:____:____ H H m m s s ____:____:____	____:____:____ H H m m s s ____:____:____

Technique/Individual Step	Initiation	Completion
Transfer fat to processing bag This may occur several times depending on the number of Toomey syringes used for harvest. Observer will record all times that this occurs	H H m m s s ____:____:____ H H m m s	H H m m s s ____:____:____ H H m m s
Fat Processing Step 2 Gravity drainage Scrub technician opens vacuum port to allow excess fluid to drain out (2-6 minutes)	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Processing Step 3 Fat washing-RL solution inserted into bag using syringe This steps includes: <ol style="list-style-type: none"> 1. 2 wash cycles at minimum 2. 1:1 ratio 3. 15 sec of manual agitation 	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Processing Step 3 (optional task) If using a tubing system for RL RL bag is attached to the mesh bag using a tubing set attached to inlet port on the mesh bag	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Processing Step 4 Processing (repeated twice) Bag is agitated manually and impurities are forced towards drain port using a scraper. Drain port/clamp on the tubing connected to drain bag is opened to allow the impurities to drain	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Delivery/Transfer to Surgeon Step 1	____:____:____ H H m m s s	____:____:____ H H m m s s

Technique/Individual Step	Initiation	Completion
Prep fat for delivery to recipient site		
Fat Delivery/Transfer to Surgeon Step 2 Fat is transferred into smaller delivery syringes	____:____:____ H H m m s s	____:____:____ H H m m s s
Recipient Site Prep Preparing site for fat grafting	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Grafting/Reconstruction Surgeon contours the area as they inject the fat	____:____:____ H H m m s s	____:____:____ H H m m s s
Instrument Breakdown/Disposal Instrument breakdown consists of disengaging all tubing from the mesh bag	____:____:____ H H m m s s	____:____:____ H H m m s s

Fat	Volume
Harvested	____.____ mL
Grafted	____.____ mL

Staff	Log in time	Log out time
Nurse	____:____:____ H H m m s s	____:____:____ H H m m s s
Scrub technician	____:____:____ H H m m s s	____:____:____ H H m m s s
	____:____:____ H H m m s s	____:____:____ H H m m s s
	____:____:____ H H m m s s	____:____:____ H H m m s s
	____:____:____ H H m m s s	____:____:____ H H m m s s

Centrifugation System Data Collection Form

Patient ID	_____
Date	__/__/__
Technique	_____

Technique/Individual Step	Initiation	Completion
Instrument Setup		
Centrifuge Centrifuge is in the OR with the rest of the surgical instruments. Syringes with caps (plungers removed) and centrifuge insert are laid out on the instrument tray	____:____:____ H H m m s s	____:____:____ H H m m s s
Patient OR time (Overall OR time) Patient wheeled into OR on bed and transferred to PACU after surgical procedure is complete	____:____:____ H H m m s s	____:____:____ H H m m s s
Patient/Site Prep (Includes patient prep, anesthetic prep, and site markup) Patient is positioned on the table by physician assistant (PA) and anesthesiologist. Patient is administered anesthetic, cleaned, and draped	____:____:____ H H m m s s	____:____:____ H H m m s s
Procedure Time This includes the entire procedure, graft replacement, and revision in addition to the fat grafting procedure	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Harvesting Step 1 Infuse patient with tumescence solution	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Harvesting Step 2	____:____:____	____:____:____

Technique/Individual Step	Initiation	Completion
Time for tumescence to take effect	H H m m s s	H H m m s s
Fat Harvesting Step 3 Liposuction into syringes Surgeon may perform this action several times. Observer will record each time that surgeon inserts liposuction cannula into patient and removes it from the patient	____:____:____ H H m m s s ____:____:____ H H m m s s ____:____:____ H H m m s	____:____:____ H H m m s s ____:____:____ H H m m s s ____:____:____ H H m m s
Fat Processing Step 1 Scrub technician transfers fat into several small syringes for centrifuge, caps are placed on the syringes	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Processing Step 2 Centrifuge- processed according to Coleman technique	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Processing Step 3 Remove impurities from syringes	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Transfer/Delivery to Surgeon Processed fat is now transferred to delivery syringe	____:____:____ H H m m s s	____:____:____ H H m m s s
Recipient Site Prep Preparing site for fat grafting	____:____:____ H H m m s s	____:____:____ H H m m s s
Fat Grafting/Reconstruction Surgeon contours the area as they inject the fat	____:____:____ H H m m s s	____:____:____ H H m m s s
Instrument Breakdown/Disposal Syringes are disposed off, instrument set sent to core	____:____:____ H H m m s s	____:____:____ H H m m s s

Fat		Volume	
Harvested		____.____	mL
Grafted		____.____	mL

Staff	Log in time	Log out time
Nurse	____:____:____ H H m m s s	____:____:____ H H m m s s
Scrub technician	____:____:____ H H m m s s	____:____:____ H H m m s s
	____:____:____ H H m m s s	____:____:____ H H m m s s
	____:____:____ H H m m s s	____:____:____ H H m m s s
	____:____:____ H H m m s s	____:____:____ H H m m s s