NeoGraft®

NeoGraft 2.0®

User Manual

Document part number: MED011XN101-C0, September 2021

NeoGraft 2.0® User Manual

Document part number: MED011XN101-C0

September 2021

NeoGraft®

Chapter 1
About this Manual

Chapter Contents:

1.1. Use of the Manual

Warning

- Use of controls or adjustments, or performance of procedures other than those specified herein, may be hazardous and are not authorized by the manufacturer.
- Personnel operating or maintaining the system are required to read this manual and to become thoroughly familiar with all its safety requirements and operating procedures before attempting to use or operate the system.
- This User Manual is an integral part of the medical device and should be retained throughout the life cycle of the device. Documentation may be discarded once the device is upgraded or replaced and as long as there were no incidents regarding the safety and effectiveness of the device.
- It is unsafe to start using the device before reading and understanding the entire User Manual.
- The user should make sure that he/she has qualifications and training in the proper use of the device, and is familiar with the indications, contra-indications and operating procedures recommended in this User Manual.

Please read the entire User Manual before trying to operate the device.

This manual has been prepared to aid medical and technical personnel to understand and operate the system. Do not operate the system before reading this manual and gaining a clear understanding of system operation. If any part of this manual is not clear, contact your Venus Concept representative for clarification.

This manual should always accompany the system, and all personnel operating the system must know its location.

The operating instructions of your device are provided electronically and not on paper. Nevertheless, it is possible to obtain a printed copy upon request, by telephone or by mail, from your Venus Concept representative.

If you decide to loan or sell the equipment, its documentation must be provided with the medical device.

1.2. Scope of the Manual

This User Manual includes:

- **Chapter 1: About this Manual**

  Provides information on the use and scope of the manual, document conventions, and a list of the used symbols.

- **Chapter 2: Safety and Regulatory Information**

  Provides general safety and regulatory information on the system, its intended use, possible hazards, and compliance with international standards, and shows the system's identification label.

- **Chapter 3: Installation**

  Provides information regarding the system installation, and its electrical and environmental requirements, equipment list, electrical connection and installation of handpieces and other system parts and accessories.

- **Chapter 4: System Description**

  Describes the system's main components and their descriptions.

- **Chapter 5: Operating Instructions**

  Provides detailed instructions on how to operate the system and describes its main interfaces.

- **Chapter 6: Advanced Features and Settings**

  Provides detailed information on the Properties screen and its features.

- **Chapter 7: Care and Maintenance**

  Provides information on general user care and maintenance, including cleaning instructions.

- **Chapter 8: Troubleshooting**

  Provides solutions to some problems that may arise while operating the system.

- **Chapter 9: Specifications**

  Provides a detailed list of the system's technical information and specifications.

- **Appendix A: Clinical Guide**

  Provides a clinical guide and detailed information on how to use the device to perform the hair transplantation.

- **Appendix B: Manufacturer Warranty**

  Provides the manufacturer warranty information.

1.3. Document Conventions

The following messages in this manual prompt the reader to pay special attention to specific points:

Warning

Warnings indicate precautions and instructions which, if not followed, may result in injury.

Caution

Cautions indicate instructions, that if not followed may result in damage to the equipment or to the quality of treatment.

Note

Notes provide information to aid in obtaining optimum equipment performance or procedure results.

1.4. Symbols

Table 1-1 describes the symbols that are used in this manual or on the product.

Table 1-1. Glossary of Symbols Used in this Manual or on the Product

Symbol	Description
	Waste of Electrical and Electronic Equipment (WEEE) Marking
	Type B equipment
	Manufacturer (accompanied by the name and address of the manufacturer)
	Date of manufacture
	Country of manufacture
	Consult Instruction for Use.
	Temperature limits
	Mobile device weight

Table 1-1. Glossary of Symbols Used in this Manual or on the Product

	Keep dry.
	Do not use if the packaging was damaged or opened.
	Device reference
	Device serial number
	Device batch number
	Expiration date
	Do not re-use, single use, use only once
	Sterilized with ethylene oxide
	Sterilized by radiation
	Indication that the device has not been sterilized
	The device can be machine washed

Table 1-1. Glossary of Symbols Used in this Manual or on the Product

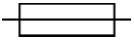
	Indication that the device should be steam-sterilized at 134°C or 135°C in a pre-vacuum air removal autoclave
	Protective earth
	Fuse
	Alternating current
	Do not tilt: risk of tipping
	Non-ionizing electromagnetic radiation
O/I	Switch Off/On
CE 0459	"Conformité Européene" Symbol (CE Marking)
	Warning: A Warning alerts the user to the possibility of serious injury, death, or serious adverse reactions associated with the use or misuse of the system.

Table 1-1. Glossary of Symbols Used in this Manual or on the Product

	Caution: A Caution alerts the user to the possibility of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or damage to the equipment.

NeoGraft®

Chapter 2

Safety and Regulatory Information

Chapter Contents:

2.1. Introduction

> ***Warning***
>
> Read this chapter carefully to be familiar with all of safety requirements and procedures prior to operating the system.

The system is designed for a safe and reliable treatment when used in accordance with proper operating and maintenance procedures as outlined in this manual. Only qualified personnel, trained by an authorized trainer, can use the system and perform the treatments. The operator and all other personnel operating or maintaining the system should be familiar with all of the safety information provided in this manual.

The primary objective should always be in maximizing the safety of both the patient and the treatment operator.

You should carefully read the User Manual instructions before installing or using the system to become familiar with all safety requirements and operating procedures, and thereby prevent accidents, injury and reduce the risk of damaging the machine.

The NeoGraft 2.0® system is designed for professional use only. The manufacturer cannot be held responsible for damage or injury caused by improper use or for uses other than those for which this machine is intended.

2.2. Intended Use

The NeoGraft 2.0® is a surgical instrument, composed of motors and accessories, and is indicated for use during surgical procedures for cutting soft tissues.

The NeoGraft 2.0® is intended for suction-assisted follicular extraction and re-implantation of autografts.

2.3. Training and Guidance

The user must receive proper clinical and technical training from the distributor or its authorized dealer before operating the device.

This device is intended particularly for high-level health care professionals, e.g. plastic surgeons, dermatologists and cosmetic doctors. Nonetheless, in certain countries, some hair transplant operations can be performed by assistants or by trained nurses.

Venus Concept disclaims any responsibility for any problem resulting from using a different protocol than the one outlined in this User Manual.

In case of any doubt or questions on hair transplant by F.U.E. (Follicular Unit Extraction), contact your authorized distributor.

2.4. Manufacturer's Liability

The manufacturer cannot accept liability in the following conditions:

- Failure to comply with the of the manufacturer's recommendations (including the electrical and environmental requirements) when installing the system
- Any service or repair performed by unauthorized persons
- The use of an electrical installation not in accordance with regulations
- Use of accessories, consumables or spare parts other than those supplied by Venus Concept or its official distributor
- Non-compliance with the instructions in this User Manual

> ***Note***
>
> The manufacturer reserves the right to change the device and/or documentation without notice.

2.5. Safety Information

Warning

- Personnel operating or maintaining the system are required to read this manual and to become thoroughly familiar with all its safety requirements and operating procedures before attempting to use or operate the system.
- The system should be protected against unauthorized use.
- High voltage is present inside the system. Do not attempt to open its casing.
- Always be aware of the possible dangers of using the system and take proper precautions as described in this manual.
- The system must be serviced by Venus Concept and/or its official distributor authorized service personnel only.

- All operators must be familiar with the system controls and know how to shut down the system in case of a problem.
- Do not touch the inner parts of the system. The system services and repairs must be performed by qualified personnel only. Failure to do so will void all service agreements.
- Disconnect the system from the mains power supply before servicing (pull out the plug from the electricity socket).
- Do not use the system unless all enclosure panels are properly in place.
- Do not tamper with the controls or attempt to open up the system.
- Do not abuse, sit or lean on the system.

- A patient history should be completed prior to treatment to ensure that no complications could arise. It is important to verify that the patient does not fall under the exclusion criteria.
- The product should not be in contact with other equipment.
- For patients with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemakers may occur, or the pacemaker may be damaged. In case of doubt, approved qualification advice should be obtained.
- The patient should be fully informed of the treatment protocol and the expected results, and should sign the informed consent form prior to beginning of the treatments.
- Grafts donor and receiver site belongs to the SAME patient.
- Only authorized persons are allowed to stand near the system during the treatment.
- Stop the treatment in case of unexpected changes in the patient's condition.
- Do not drop the handpieces. If a handpiece is dropped, turn off the system immediately. Do not use a broken handpiece and call the local service representative.
- There are no user-serviceable parts inside the system. ONLY VENUS CONCEPT PERSONNEL MAY SERVICE THE SYSTEM, ESPECIALLY INSIDE ITS CABINET.

2.5.1. Environmental Conditions

- Do not use or store the device in a wet environment (humidity of between 30% and 60%).
- Respect storage temperature between -10°C (14°F) and 50°C (122°F)
- Do not use the device in an electrical or electro-magnetic radiation environment that does not comply with the applicable regulations and standards.
- Do not overload an electrical outlet.
- The power cable must be plugged into an appropriate outlet that is properly installed and grounded in accordance with local codes and ordinances.
- Ensure that the device cords do not interfere with the movement of the system or persons.
- When the device is not in use, or in case of emergency, unplug the power cable from the mains outlet.
- Operating altitude should be lower than 2000 meters.
- Do not place the device near a radiator or other heat sources.
- Do not place the device against the wall, cabinets or other furniture.
- Place the device on a level and horizontal floor.

2.5.2. Device and its Accessories

- Stop using the device if a system malfunction or operating problem occurs.
- Always use the system's wheel brakes to stop it from moving and/or falling.
- When moving the device, make sure to disconnect its power cable and footswitches.
- Do not block or place any object within 4 cm of the system's ventilation openings.
- The extracting, the implanting and the incision handpieces are of B type. During the surgery, the user should not be in contact with any other electrical devices.

2.5.3. Maintenance

- Make sure that the person in charge of the maintenance has the necessary skills to conduct servicing of the device and strictly follows the procedures described in this manual.
- No maintenance procedures, other than those specified in this manual, are permitted.
- Lifetime of the device is five years, with maintenance every two years.

2.5.4. Hygiene and Safety Conditions

Any person who cleans/sterilizes the equipment must wear the appropriate personal protective equipment (PPE) (e.g. gowns, gloves and facial protection) during the cleaning/sterilization process.

Critical or semi-critical equipment, labeled as "single use" or "disposable", must not be reused.

The cleaning/sterilization procedure described in this manual must be accessible and incorporated into the site-specific procedures.

It is recommended for any orientation process for new staff to include a checklist of the key steps in cleaning/sterilization procedure, as described in this manual.

The equipment is to be stored in clean areas that are protected from contamination, vermin, and excessive handling. The equipment must never be stored beneath a sink, in the soiled equipment cleaning area or adjacent to the area where treatment procedures are performed.

All equipment must be inspected for damage and cleanliness. Remove any damaged (rusted, cracked, pitted) equipment from service. Devices that are soiled must not be used until they are properly cleaned.

Instruments must be disassembled for sterilization according to the instructions in this manual.

The water used for the cleaning process must be colorless, clean and without sediment.

Temperature of the cleaning area must be between +15°C and +25°C.

2.6. Electrical and Mechanical Safety

- Keep all covers and panels of the system closed. Removing the covers creates a safety hazard.
- Perform maintenance procedures only when the system is shut down and disconnected from the mains power.
- Move the system slowly and carefully. The system is heavy and may cause injury if proper care is not taken when moving it.
- The system is grounded through the grounding conductor in the power cable. This protective grounding is essential for safe operation.

2.7. Fire Safety

Warning

There is risk of fire if the system is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment. Some materials, e.g. darkly colored clothing or cotton wool, when saturated with oxygen, may be ignited by the high temperatures produced in normal use of the equipment.

- Do not use the system in the presence of explosive or flammable materials.
- If germicide wipes are used for cleaning and disinfecting the system, it must be allowed to fully dry before the system can be used again.

2.8. Disposal and Recycling

Any disposal and recycling should be in accordance with the current landfill legislation and standards for disposal and recycling of electrical medical device in your country [refer to European Directive 2012/19/EU: Waste Electrical and Electronic Equipment (WEEE)].

Venus Concept or its authorized distributor can undertake this task. However, the transportation cost and other possible expenses should be covered by the user.

2.9. System Label

Figure 2-1 shows the system identification label that is affixed on the system console.

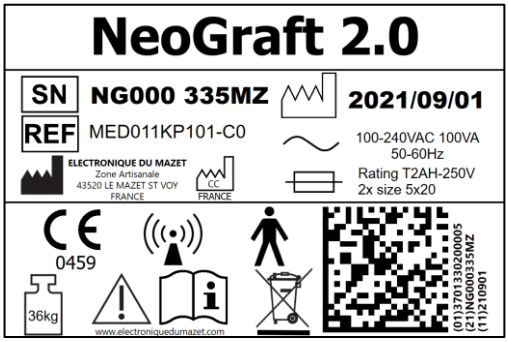


Figure 2-1. System Identification Label

Note

Any labels shown in this User Manual are provided for presentation purposes only and are subject to change without prior notice.

2.10. Contact Information

All inquiries: Venus Concept USA Inc.

1880 N Commerce Pkwy, Ste 2
Weston, FL 33326, USA

Tel: 1-888-907-0115
Fax: 1-855-907-0115

Email: info@venusconcept.com

Manufacturer: Electronique Du Mazet

ZA Route de Tence

43520 Le Mazet Saint Voy – France

Chapter 3
Installation

Chapter Contents:

3.1. General

The system must be installed only by a qualified Venus Concept and/or its official distributor technician.

3.2. Electrical Requirements

The system should be connected to a mains power supply with the following output:

- Single phase
- 100-240 VAC
- 50-60 Hz
- 100 VA

As long as the electrical outlet meets the above requirements, the system automatically adjusts itself to the local mains voltage.

> ***Warning***
>
> - For continued protection against fire, only fuses that are indicated on the system label can be installed in the system.
> - Only use a compatible power cord which is approved for the local mains electricity.

3.3. Environmental Requirements

- Corrosive materials can damage the electronic parts. Ensure that the environment is free from corrosive material.
- Metallic dust can damage the electrical equipment. Ensure that the environment is free from metallic dust.
- For optimal operation, the system should be placed in a room with an ambient temperature of 15º-25ºC (59º-77ºF) and a relative humidity of 30%-60%.
- Store the device in a dry and clean room.
- Do not store the system in outdoor conditions.
- Clearly define your storage areas, including quarantine areas for nonconforming medical devices.
- Items with "Keep away from light" label (especially sterile products) should be kept in light proof containers.
- Store the products on elevated shelves to avoid dust, dirt and contamination.
- Pest control procedure should be established.

3.3.1. Sterile Products

Products that are dispatched in a sterile state should generally be stored, handled and transported in a manner that protects their packaging from exposure to moisture, direct sunlight and damage to ensure they remain sterile.

Sterile products should be considered unsterile if their packaging loses its integrity. Their batch number and expiration date should be recorded. Incorporate a system to ensure that the medical device inventory is properly rotated (i.e. either "first in first out" or "expiration date" driven) and that any device exceeding its expiry date, or shelf life, is quarantined.

3.4. Receiving the Shipment

The system is packed in a wooden box and protected with polystyrene foams (on top and on bottom). The wooden box is fumigated and is in compliance with the NIMP15 standard. A truck with tailgate is required for its transportation.

The weight of the packaged device is 88 kg. The size of the wooden box is 73 × 76 × 138 cm (L × W × H). The weight of the unpacked device is 36 kg.

Upon receiving the shipment, make sure that the box is in good condition and is placed with its imprinted arrows facing up, as shown in Figure 3-1.

Figure 3-1. Shipping Box with its Arrows Facing Up

> ***Warning***
>
> Device should be handled by authorized movers.
>
> Beware of the risk of tipping if the system is subjected to horizontal forces equal to 25% of its weight.

3.5. Unpacking the System

To unpack the system:

1. From the front cover of the wooden box, remove its connecting screws. It is recommended to use a power screwdriver for this purpose.
2. Open the front cover, as shown in Figure 3-2.

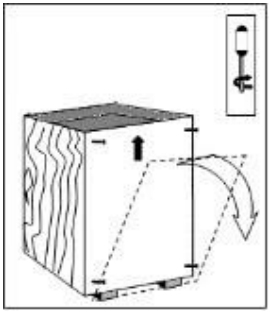


Figure 3-2. Opening the Front Cover of the Shipping Box

3. Remove the cardboard which is placed vertically next to the device, as shown in Figure 3-3.

Figure 3-3. Removing the Protective Cardboard

4. Remove all accessories and documents from the box.
5. Remove the protective foams from the system.
6. Release the system's wheel locks.
7. Carefully lift and remove the system from the box and place it on the floor.

3.6. Equipment List

The system is supplied with a packing list, indicating all items and accessories that are included in the shipping box.

Upon unpacking the system, verify that you have received all items that are on the packing list.

The system includes the following main items:

- System console
- Articulated arm
- Handpiece tray
- Handpiece holders
- Cup holder
- Cup
- Extraction handpiece
- Incision handpiece
- Implantation handpiece
- Waste jar
- Footswitches
- Power cable
- User Manual

3.7. Installing the Articulated Arm

Figure 3-4 shows the articulated arm, which should be installed on the system.

Figure 3-4. Articulated Arm

To install the articulated arm:

1. Position the articulated arm over its pivot on the system console, as shown in Figure 3-5.

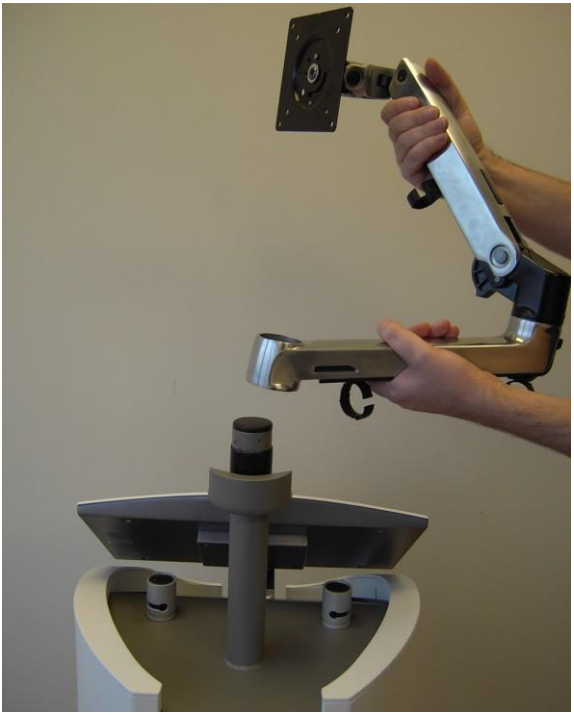


Figure 3-5. Positioning the Articulated Arm on the System

2. Insert the articulated arm's base onto its pivot, as shown in Figure 3-6.

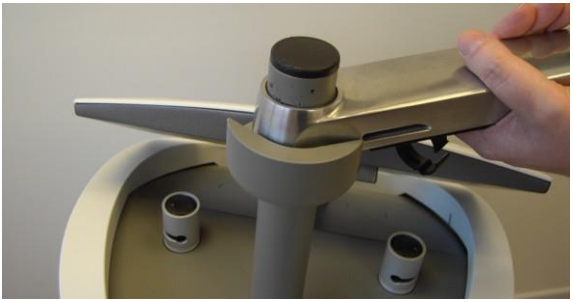


Figure 3-6. Inserting the Articulated arm onto its Pivot

3. Verify that the articulated arm is properly installed, as shown in Figure 3-7.

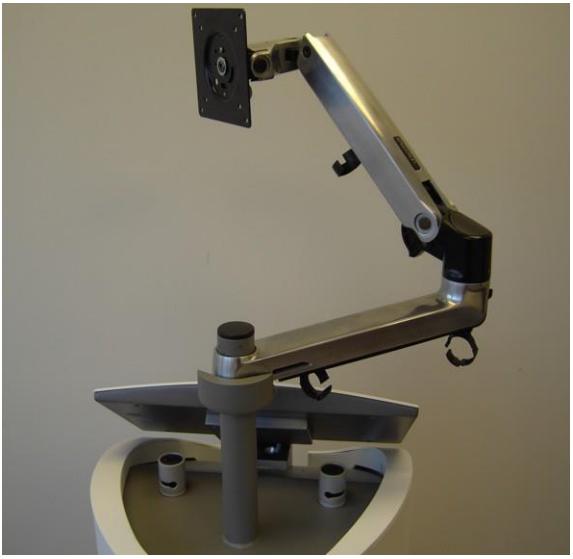


Figure 3-7. Articulated Arm Installed

3.8. Installing the Handpiece Tray

Figure 3-8 shows the handpiece tray, which should be installed on the articulated arm.

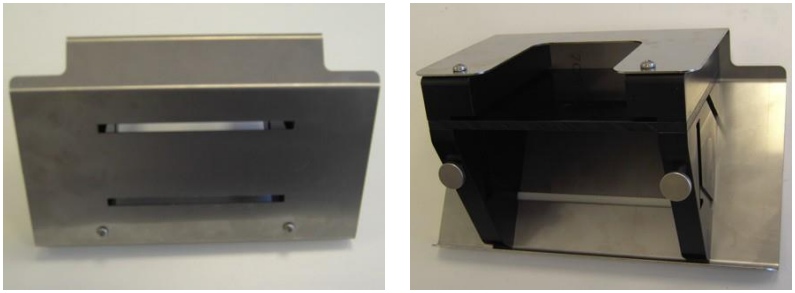


Figure 3-8. Handpiece Tray

To install the handpiece tray

1. Align the handpiece tray with its base on the articulated arm, as shown in Figure 3-9.

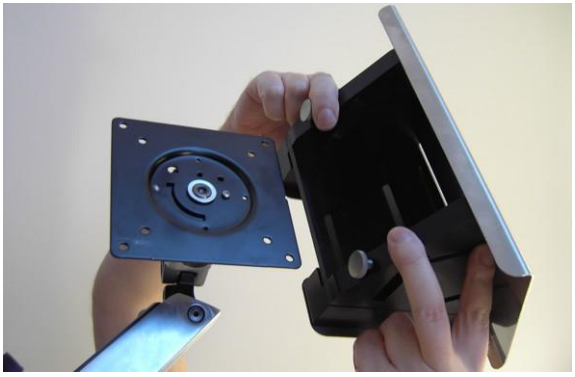


Figure 3-9. Aligning the Handpiece tray with its Base on the Articulated Arm

2. Insert the handpiece tray onto its base, and push it all the way, as shown in Figure 3-9.

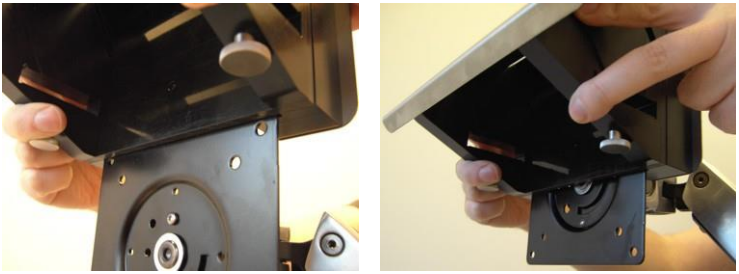


Figure 3-10. Inserting the Handpiece Tray onto its Base

3. Verify that the handpiece tray is mounted properly on its base on the articulated arm, as shown in Figure 3-11.

Figure 3-11. Handpiece Tray Mounted on its Base

4. From the bottom of the handpiece tray, tighten its thumb screw, as shown in Figure 3-12.

Figure 3-12. Tightening the Handpiece Tray's Thumb Screw

5. Verify that the handpiece tray is properly installed on the articulated arm, as shown in Figure 3-13.

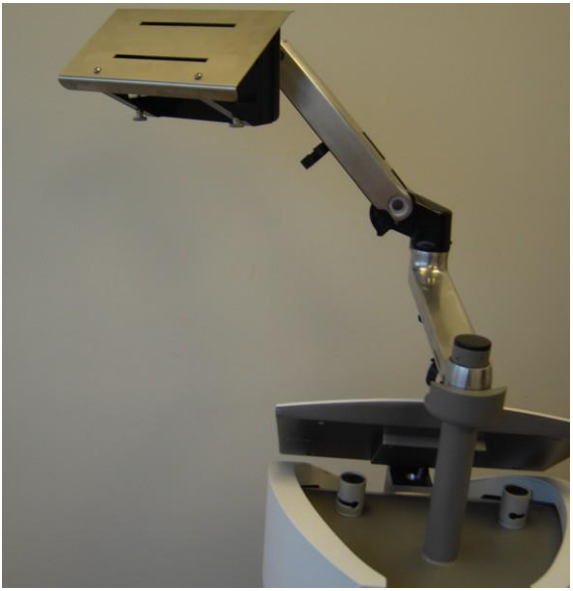


Figure 3-13. Handpiece Tray Installed

3.9. Installing the Handpiece Holders

To install the handpiece holders:

1. Insert the lower handpiece holder into the lower slot on the hanpiece tray, as shown in Figure 3-14.

Figure 3-14. Inserting the Lower Handpiece Holder

2. Push the handpiece holder in, as shown in Figure 3-15.

Figure 3-15. Pushing the Lower Handpiece Holder in

3. Insert the upper handpiece holder into the upper slot on the hanpiece tray, as shown in Figure 3-16.

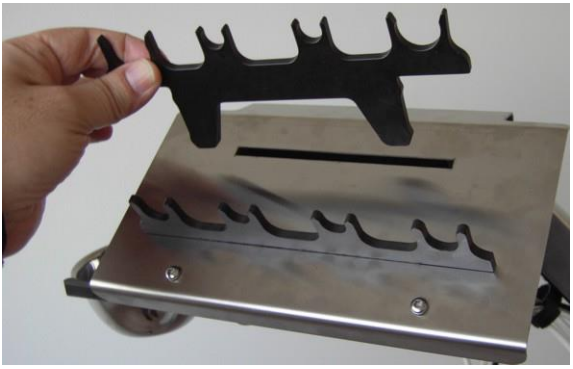


Figure 3-16. Inserting the Upper Handpiece Holder

4. Push the handpiece holder in, as shown in Figure 3-17.

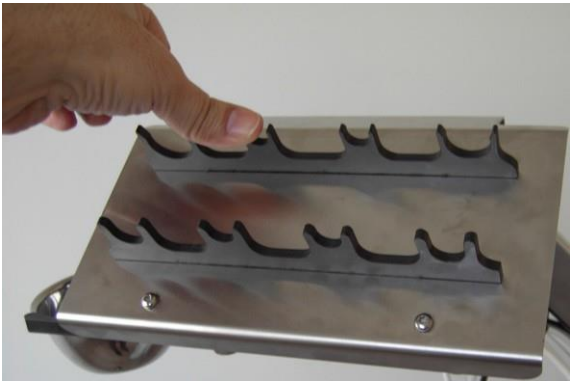


Figure 3-17. Pushing the Upper Handpiece Holder in

To remove a handpiece holder:

- Pull the handpiece holder out the handpiece tray.

3.10. Installing the Cup Holder

Note

The cup holder can be installed on the left or right side of the handpiece tray, as desired. For the purpose of illustration, the figures in this guide show the installation of the cup holder on the left side.

To install the cup holder:

1. From the bottom of the handpiece tray, release (but do not remove) the cup holder's thumb screw, as shown in Figure 3-18.

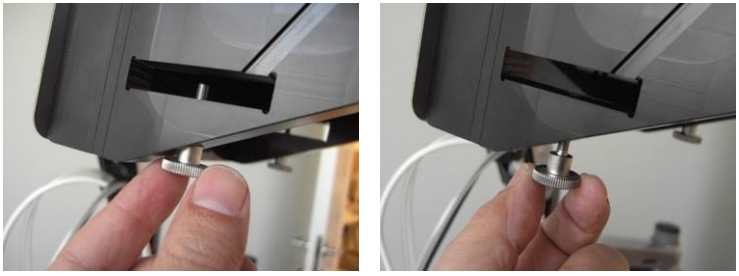


Figure 3-18. Releasing the Cup Holder's Thumb Screw

2. Insert and push in the cup holder into its slot on the handpiece holder, as shown in Figure 3-19.

Figure 3-19. Inserting the Cup Holder into its Slot

3. Tighten the handpiece holder's thumb screw, as shown in Figure 3-20.

Figure 3-20. Tightening the Cup Holder's Thumb Screw

To remove the cup holder:

1. From the bottom of the handpiece tray, release (but do not remove) the cup holder's thumb screw, as shown in Figure 3-18.
2. Pull the cup holder out of the handpiece tray.

3.11. Installing the Cup

To install the cup:

1. Insert and push in the cup into the cup holder, as shown in Figure 3-21.

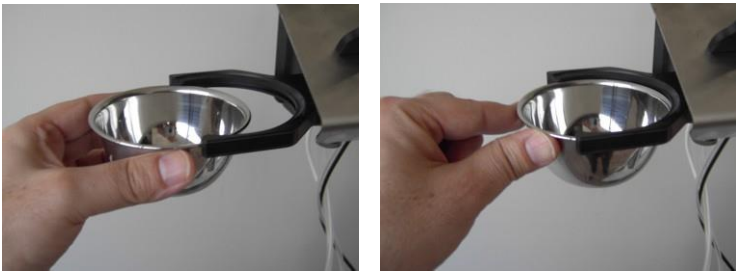


Figure 3-21. Inserting the Cup into the Cup Holder

2. Verify that the cup sits firmly on the cup holder, as shown in Figure 3-22.

Figure 3-22. Cup Installed

To remove the cup:

- Pull the cup out of the cup holder.

3.12. Installing the Footswitches

3.12.1. Connecting the Left Footswitch

To connect the left footswitch:

1. Place the footswitch on the floor, next to the system's left side, as shown in Figure 3-23.

Figure 3-23. Left Footswitch Placed on the System's Left Side

2. Align the pins of the footswitch's cable connector with the corresponding holes of the footswitch receptacle on the system's rear side, as shown in Figure 3-24.

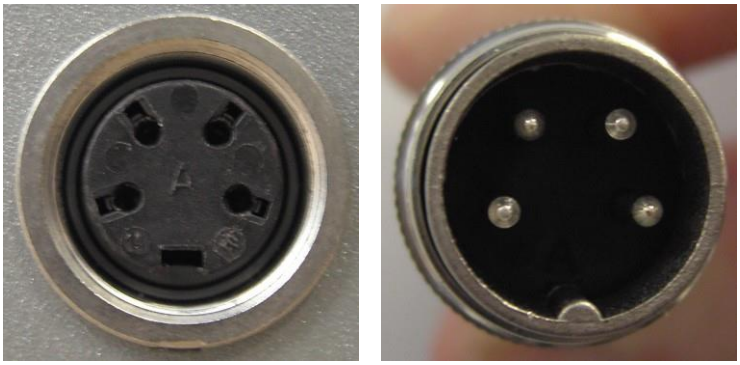


Figure 3-24. Aligning the Pins of the Footswitch's Connector with its Receptacle's Corresponding Holes

3. Connect the footswitch connector to its receptacle, by inserting the connector and screwing it in, as shown in Figure 3-25.

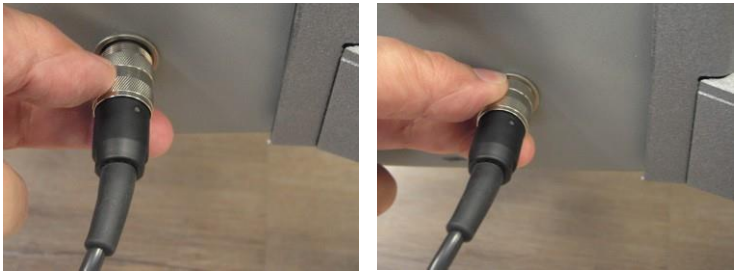


Figure 3-25. Connecting the Left Footswitch's Cable to its Connector on the System's Rear Side

Note

The left Footswitch must be connected to the footswitch connection receptacle that is located on the right side of the system's rear side, as shown in Figure 3-26.

4. Verify that the footswitch is properly connected to the system, as shown in Figure 3-26.

Figure 3-26. Left Footswitch's Cable Connected

To remove the footswitch:

- Disconnect the footswitch cable from its connector on the system's rear side.

3.12.2. Connecting the Right Footswitch

To connect the right footswitch:

1. Place the footswitch on the floor, next to the system's right side, as shown in Figure 3-27.

Figure 3-27. Right Footswitch Placed on the System's Right Side

2. Align the pins of the footswitch's cable connector with the corresponding holes of the footswitch receptacle on the system's rear side, as shown in Figure 3-28.

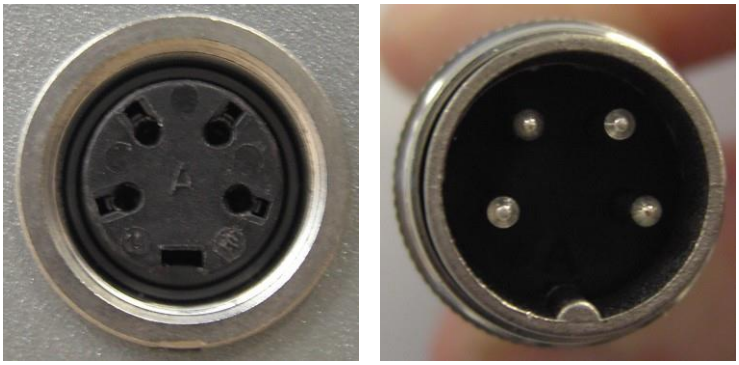


Figure 3-28. Aligning the Pins of the Footswitch's Connector with its Receptacle's Corresponding Holes

3. Connect the footswitch connector to its receptacle, by inserting the connector and screwing it in, as shown in Figure 3-29.

Figure 3-29. Connecting the Right Footswitch's Cable to its Connector on the System's Rear Side

Note

The right Footswitch must be connected to the footswitch connection receptacle that is located on the left side of the system's rear side, as shown in Figure 3-30.

4. Verify that the footswitch is properly connected to the system, as shown in Figure 3-30.

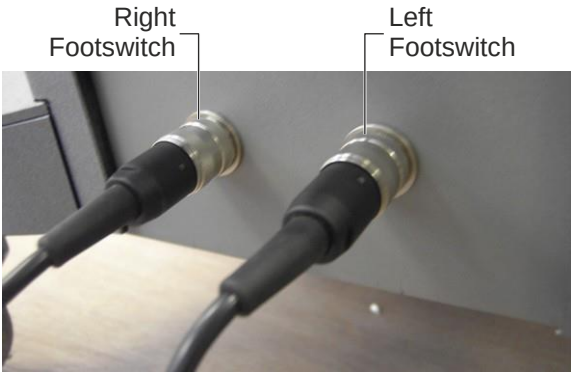


Figure 3-30. Right and left Footswitch Cables Connected

To remove the footswitch:

- Disconnect the footswitch cable from its connector on the system's rear side.

3.13. Installing the Waste Jar

To install the waste jar:

1. Mount the rubber gasket on the jar's black stopper, as shown in Figure 3-31.

Figure 3-31. Installing the Rubber Gasket on the Stopper

2. Verify that the gasket is properly mounted on the stopper, as shown in Figure 3-32.

Figure 3-32. Rubber Gasket Installed on the Stopper

3. Insert the stopper into the neck of the jar, as shown in Figure 3-33.

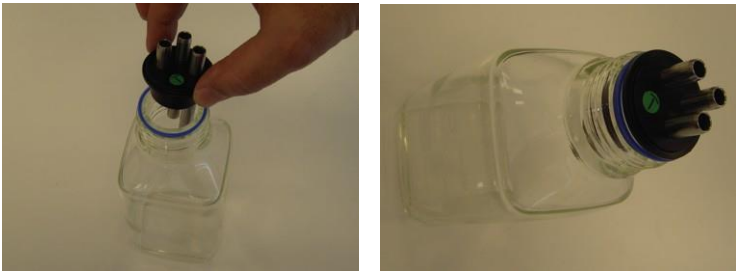


Figure 3-33. Inserting the Stopper into the Jar's Neck

4. Close and tighten the jar's lid, as shown in Figure 3-34.

Figure 3-34. Closing the Jar's Lid

5. Verify that the jar is properly assembled and the lid is tightly closed, as shown in Figure 3-35.

Figure 3-35. Waste Jar Assembled

6. Place the jar in its housing on the system's front side, as shown in Figure 3-36.

Figure 3-36. Waste Jar Placed in its Housing on the System

To dismantle the waste jar:

1. Remove the waste jar from the system.
2. Unscrew and remove the jar's lid.
3. Remove the black stopper from the jar.
4. Remove the rubber gasket from the black stopper.

> ***Warning***
>
> Contents of the waste jar must be discarded as biohazard waste.

3.14. Installing the Filter

To install the filter:

1. Remove the filter's caps, as shown in Figure 3-37.

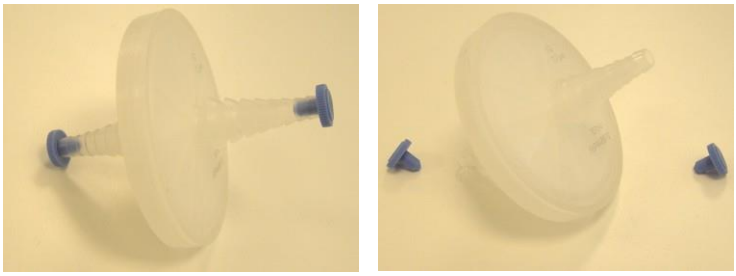


Figure 3-37. Removing the Filter's Caps

2. Connect the longer piece of the vacuum tube to its quick connector fitting, as shown in Figure 3-38.

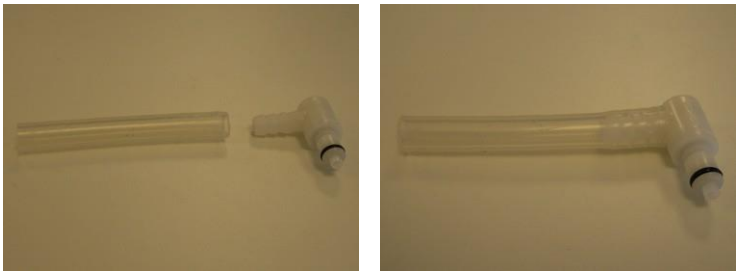


Figure 3-38. Connecting the Long Vacuum Tube to its Quick Connector Fitting

3. Connect the other end of the vacuum tube to the filter's **Inlet** port, as shown in Figure 3-39.

Figure 3-39. Connecting the Long Tube and Fitting to the Filter's Inlet Port

4. Connect the shorter piece of the vacuum tube to the filter's **Outlet** port, as shown in Figure 3-40.

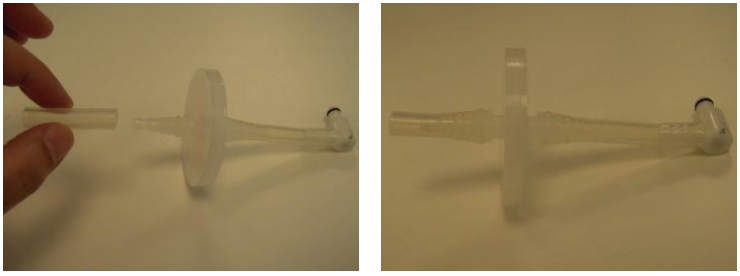


Figure 3-40. Connecting the Short Vacuum Tube to the Filter's Outlet port

5. Connect the quick connector of the filter assembly to vacuum port on the system's front side, as shown in Figure 3-41.

Figure 3-41. Connecting the Filter Assembly to the System's Vacuum Connector

6. Connect the other end of the filter assembly to the shorter pipe of the waste jar's stopper, as shown in Figure 3-42 and Figure 3-43.

Figure 3-42. Connecting the Vacuum Tube to the Waste Jar

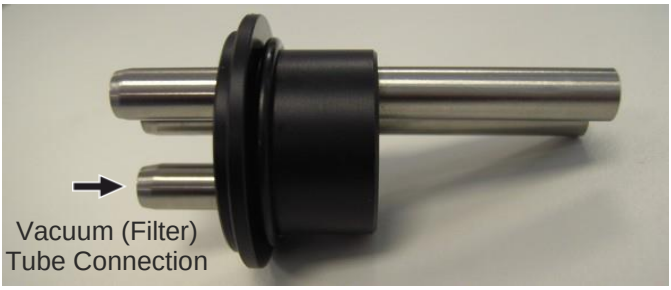


Figure 3-43. Vacuum (Filter) Tube to be Connected to the Stopper's Shorter Pipe

7. Verify that the filter is properly installed, as shown in Figure 3-44.

Figure 3-44. Filter Assembly Installed

To remove the filter:

1. Verify that the system is turned off or placed in the Standby state.
2. Disconnect the two tubes from the filter.
3. Remove and discard the filter.

3.15. Installing the Extraction Handpiece

Warning

The single-use punches are supplied non-sterile and must be properly sterilized, as described in Chapter 7, before the treatment.

Each punch must be discarded in a hazardous sharps disposal container after use.

Note

Make sure that all handpiece components are properly cleaned and sterilized, as described in Chapter 7, before installing/using them.

Note

The single-use tubing is supplied sterile. After each treatment, the tubing must be discarded as hazardous medical waste.

To install the extraction handpiece:

1. Align the red mark of the Extraction Handpiece Cable Connector with the red mark of the corresponding receptacle on the system's rear side, as shown in Figure 3-45.

Figure 3-45. Aligning the Red mark of the Handpiece Cable Connector with the Red Mark on the Receptacle

2. Push the connector into the receptacle, as shown in Figure 3-46.

Figure 3-46. Connecting the Handpiece Cable Connector

3. Verify that the connector is pushed all the way into the receptacle, as shown in Figure 3-47.

Figure 3-47. Handpiece Cable Connected

4. Align the pins of the handpiece motor connector with the corresponding holes of the handpiece cable connector, as shown in Figure 3-48.

Figure 3-48. Aligning the Connectors of the Handpiece Cable amd the Handpiece Motor

5. Connect the handpiece motor to the handpiece cable connector, by pushing the motor into the connector, as shown in Figure 3-49.

Figure 3-49. Pushing the Handpiece Motor into the Handpiece Cable Connector

6. Connect the handpiece's contra-angle head to the motor, by pushing the head onto the motor, as shown in Figure 3-50.

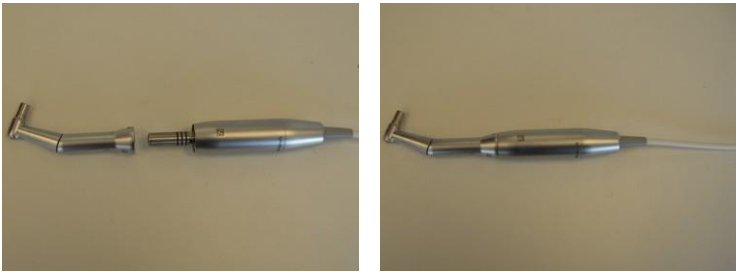


Figure 3-50. Pushing the Contra-Angle Head onto the Motor

7. Align the handpiece punch with the hole on the contra-angle head, as shown in Figure 3-51.

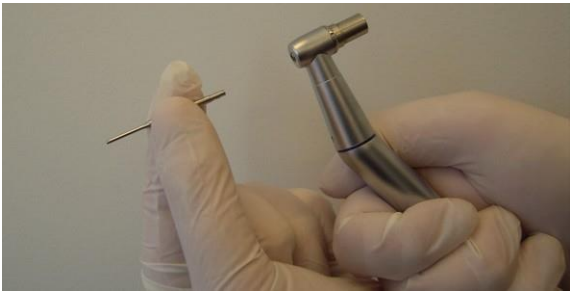


Figure 3-51. Aligning the Punch with the Handpiece Tip Hole

8. Connect the punch to the handpiece, by pushing the punch into the handpiece while pushing the contra-angle head's button, as shown in Figure 3-52.

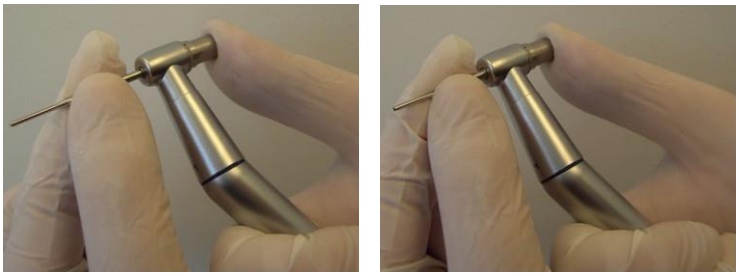


Figure 3-52. Pushing the Punch into the Handpiece while Pushing the Contra-Angle Head's Button

9. Verify that the punch clicks in and sits firmly within the contra-angle head, as shown in Figure 3-53.

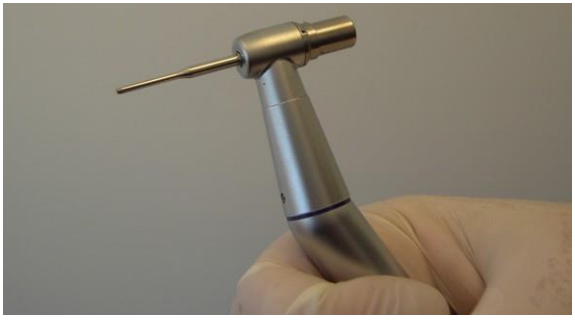


Figure 3-53. Punch Installed

10. Assemble the graft collector, as shown in Figure 3-54.

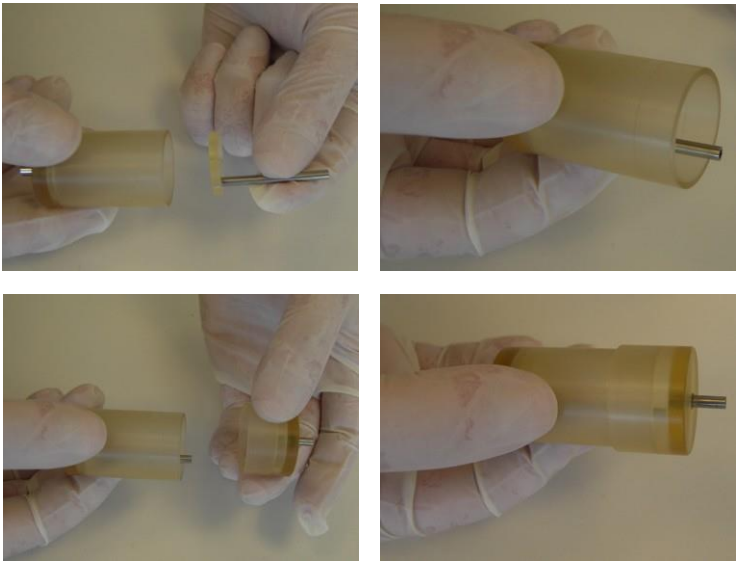


Figure 3-54. Assembling the Graft Collector

11. Attach the clamp to the handpiece, as shown in Figure 3-55.

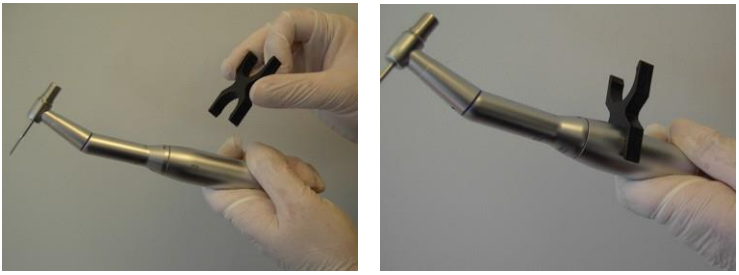


Figure 3-55. Attaching the Clamp to the Handpiece

12. Attach the graft collector to the clamp (on the handpiece), with its Graft Side Facing the Handpiece Head, as shown in Figure 3-56.

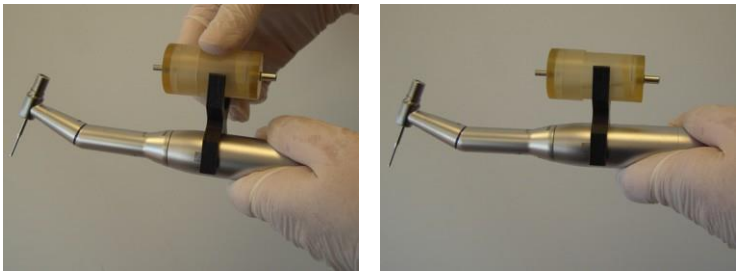


Figure 3-56. Attaching the Graft Collector to the Handpiece Clamp

13. Connect the Sterile graft tube to the graft collector's Graft side, as shown in Figure 3-57.

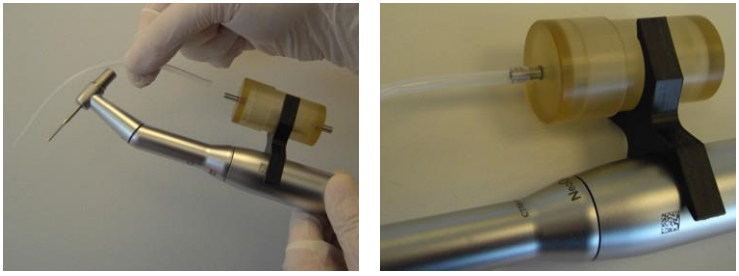


Figure 3-57. Connecting the Graft Tube to the Graft Collector's Graft Side

14. Connect the other end of the graft tube to the hole on the contra-angle head's button, as shown in Figure 3-58.

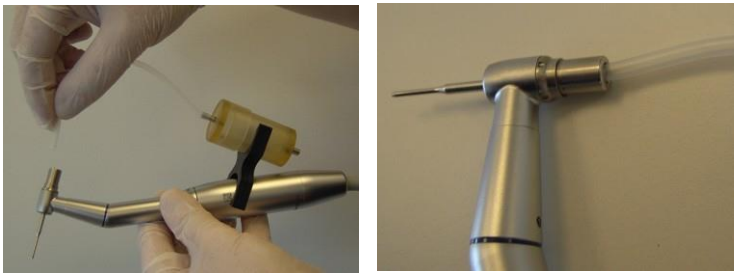


Figure 3-58. Connecting the Graft Tube to the Handpiece

15. Connect the Sterile extraction tube to the graft collector's Suction side, as shown in Figure 3-59.

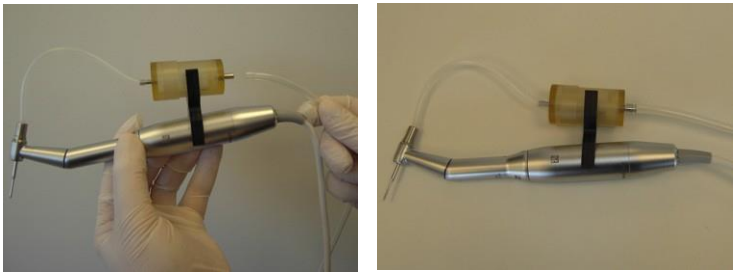


Figure 3-59. Connecting the Extraction Tube to the Graft Collector's Suction Side

16. Place the extraction handpiece on the handpiece holder, as shown in Figure 3-60.

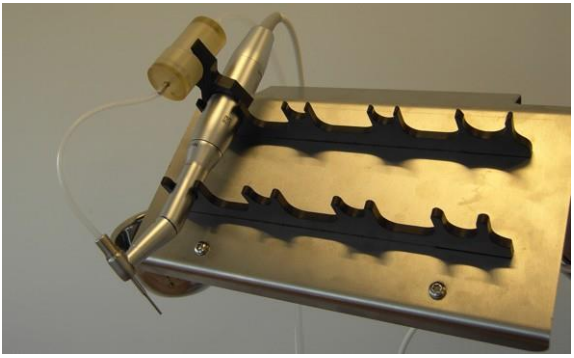


Figure 3-60. Placing the Extraction Handpiece on the Handpiece Holder

17. Connect the extraction tube to the jar, as shown in Figure 3-61.

Figure 3-61. Connecting the Extraction Tube to the Jar

18. If the other inlet pipe of the jar is not to be used, cover it with a silicon cap, as shown in Figure 3-62.

Figure 3-62. Silicon Cap Connected to the Waste Jar's Unused Inlet Pipe

> ***Caution***
>
> In order to avoid leakage, always make sure that all inlet pipes of the waste jar are properly covered/blocked.

19. Position the extraction tube's thick inset next to the system's left electrovalve, as shown in Figure 3-63.

Figure 3-63. Positioning the Extraction Tube's Thick Inset Next to the Left Electrovalve

20. Push (and hold) the electrovalve while inserting the extraction tube's thick inset inti the electrovalve's slot, as shown in Figure 3-64.

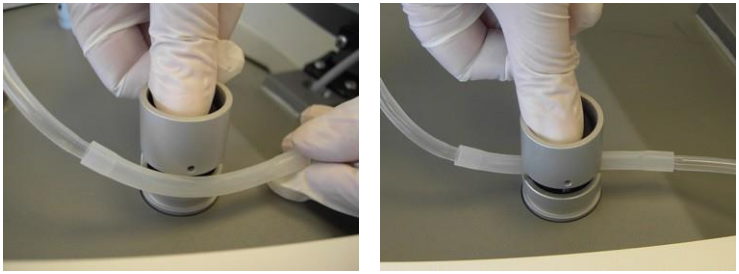


Figure 3-64. Inserting the Extraction Tube's Thick Inset into the Left Electrovalve's Slot

21. Release the electrovalve and verify that the tube is properly inserted into its slot, as shown in Figure 3-65.

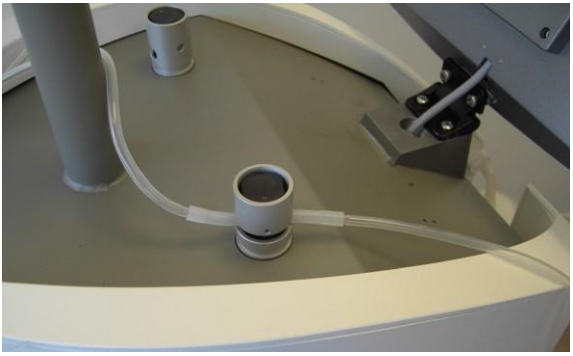


Figure 3-65. Extraction Tube Inserted into the Left Electrovalve

22. Insert the handpiece's cable and tubing into the cable/tube holders on the articulated arm, as shown in Figure 3-66.

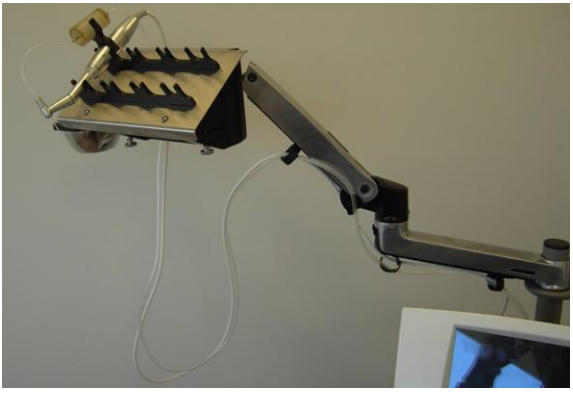


Figure 3-66. Extraction Handpiece Cable and Tubing Inserted into the Articulated Arm's Cable/Tube Holders

23. Fasten (but do not tighten) the cable/tube holders to secure the cable and tubing (loosely) within them.

Note

For proper system operation, each of the air outlets on the system's rear side must be covered, either by a properly-installed implantation handpiece tubing, or a Luer lock air cap, as shown in Figure 3-85 and Figure 3-86.

To remove the extraction handpiece:

1. Disconnect the graft collector from the handpiece clamp.
2. Remove any grafts from the graft collector.
3. Dismantle the graft collector.
4. Remove the handpiece cable and tubing from the cable/tube holders on the articulated arm.
5. Remove the extraction tube from the electrovalve by pushing the electrovalve and pulling the tube out of its slot.
6. Disconnect the tubes from the handpiece and from the system.
7. Discard the used tubing as hazardous medical waste.
8. Disconnect the clamp from the handpiece.
9. Remove the punch by pushing the button on the contra-angle handpiece head.
10. Discard the punch in a hazardous sharps disposal container.
11. Pull and disconnect the contra-angle head from the handpiece motor.
12. Pull and disconnect the motor from the handpiece cable.
13. Disconnect the handpiece cable from its connector on the system's rear side.
14. Clean and sterilize the handpiece components, as described in Chapter 7.

3.16. Installing the Incision Handpiece

Warning

The single-use incision blades are supplied sterile.

Each blade must be discarded in a hazardous sharps disposal container after use.

Note

Make sure that all handpiece components are properly cleaned and sterilized, as described in Chapter 7, before installing/using them.

Caution

Do not sterilize the cable of the incision handpiece.

To install the incision handpiece:

1. Connect the cable connector of the incision handpiece to its receptacle on the system's rear side, while aligning the white mark of the cable connector with the white mark of the receptacle, as shown in Figure 3-67.

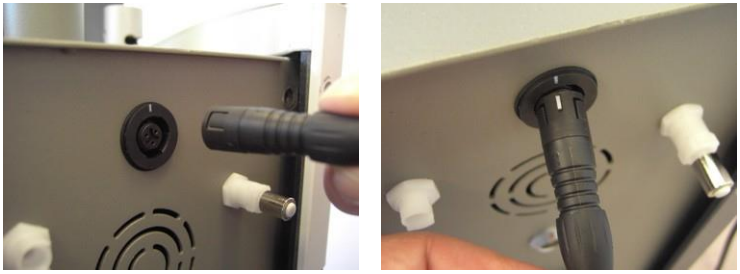


Figure 3-67. Connecting the Incision Handpiece to the System While Aligning the White mark of the Handpiece Cable Connector with the White Mark on the Receptacle

2. Push the connector well into the receptacle and verify that it is connected properly, as shown in Figure 3-68.

Figure 3-68. Handpiece Cable Connected

3. Insert the base of the incision blade into the blade holder's slot, as shown in Figure 3-69.

Figure 3-69. Inserting the Incision Blade into the Blade Holder's Slot

4. Carefully push the blade well into the blade holder, as shown in Figure 3-70.

Figure 3-70. Incision Blade Inserted into the Blade Holder

5. Insert the blade holder into the handpiece base, as shown in Figure 3-71.

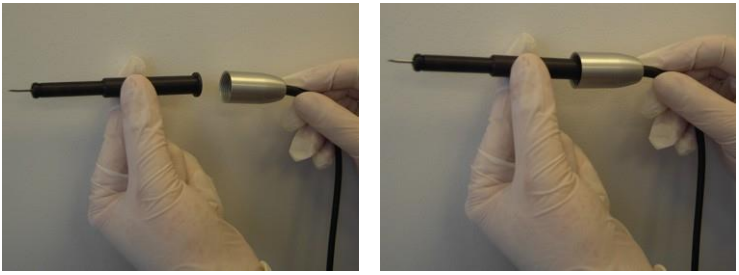


Figure 3-71. Inserting the Blade Holder into the Handpiece Base

6. Insert the handpiece body onto the blade holder, as shown in Figure 3-72.

Figure 3-72. Inserting the Handpiece Body onto the Blade Holder

7. Screw the handpiece body to the handpiece base, as shown in Figure 3-73.

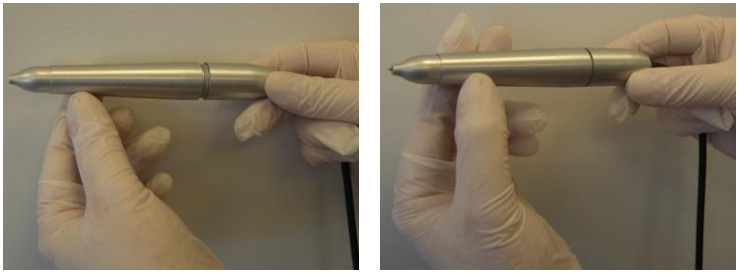


Figure 3-73. Screwing the Handpiece Body to the Handpiece Base

8. Verify that the handpiece is properly assembled, as shown in Figure 3-74.

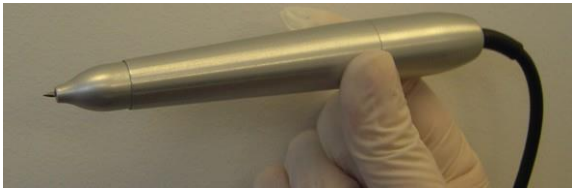


Figure 3-74. Incision Handpiece Assembled

9. Use the adjuster at the head of the handpiece to adjust the length of the incision blade, as shown in Figure 3-75.

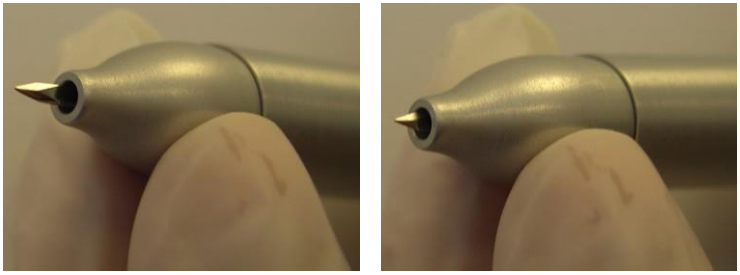


Figure 3-75. Adjusting the Length of the Incision Blade

10. Place the incision handpiece on the handpiece holder, as shown in Figure 3-76.

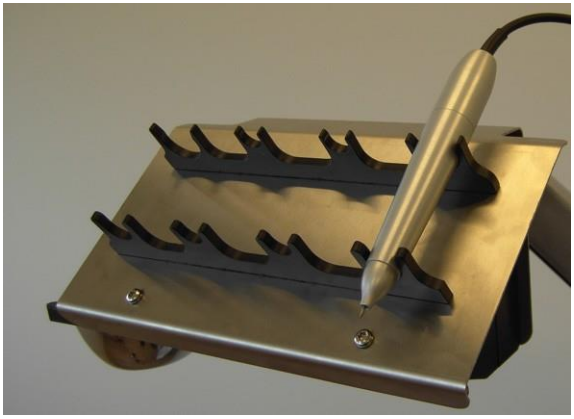


Figure 3-76. Placing the Incision Handpiece on the Handpiece Holder

11. Insert the handpiece's cable into the cable/tube holders on the articulated arm, as shown in Figure 3-77.

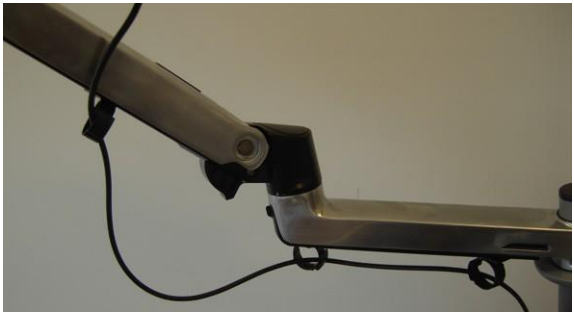


Figure 3-77. Incision Handpiece Cable Inserted into the Articulated Arm's Cable/Tube Holders

12. Fasten (but do not tighten) the cable/tube holders to secure the cable (loosely) within them.

To remove the incision handpiece:

1. Unscrew the handpiece body from the handpiece base.
2. Remove the blade holder from the handpiece base.
3. Carefully remove the blade from the blade holder.
4. Discard the blade in a hazardous sharps disposal container.
5. Remove the handpiece cable from the cable/tube holders on the articulated arm.
6. Disconnect the handpiece cable from its connector on the system's rear side.
7. Clean and sterilize the handpiece components, as described in Chapter 7.

> ***Caution***
>
> Do not sterilize the cable of the incision handpiece.

3.17. Installing the Implantation Handpiece

Note

Make sure that all handpiece components are properly cleaned and sterilized, as described in Chapter 7, before installing/using them.

Note

The single-use tubing is supplied sterile. After each treatment, the tubing must be discarded as hazardous medical waste.

To install the implantation handpiece:

1. Insert the Piston into the implanter head, as shown in Figure 3-78.

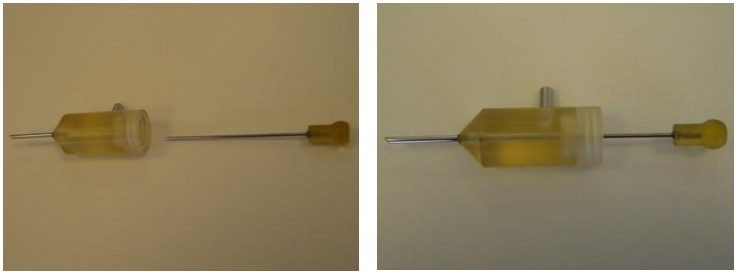


Figure 3-78. Inserting the Handpiece Piston into the Implanter Head

2. Verify that the tip of the piston is aligned with the implanter head's suction port, as shown in Figure 3-81.
3. Connect the implanter head to the handpiece body, by inserting the base of the piston into the handpiece, as shown in Figure 3-79.

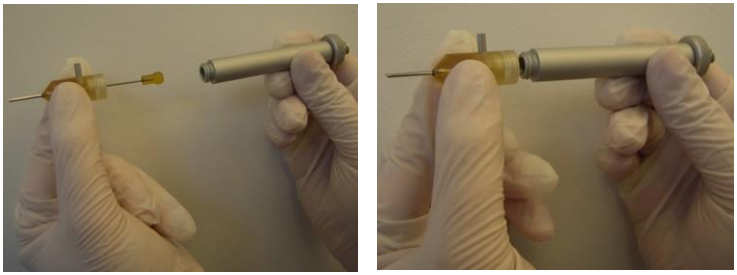


Figure 3-79. Connecting the Head to the Handpiece Body

4. Screw the head to the handpiece, as shown in Figure 3-80.

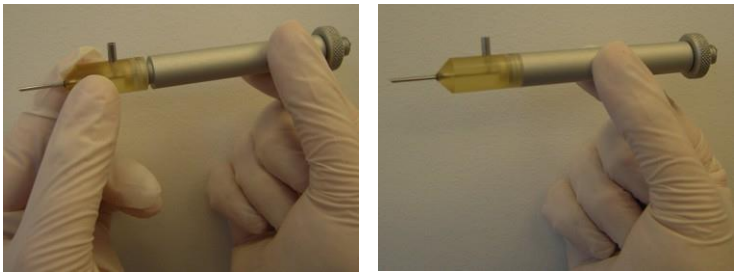


Figure 3-80. Screwing the Head to the Handpiece Body

5. Use the adjusting screw of the handpiece to set the implanter head's piston tip at the correct position, as shown in Figure 3-81.

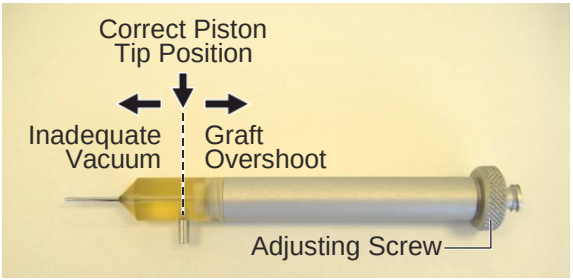


Figure 3-81. Correct Positioning of the Piston within the Implanter Head

> ***Caution***
>
> During the implantation procedure, the previously-extracted grafts are sucked into the implanter head, to be inserted in the recipient site.
>
> During this stage, it is important to have the implanter head's piston tip at the correct position, i.e. aligned with the implanter head's suction port, as shown in Figure 3-81. At this position, the graft can be sucked up and then pushed towards the recipient site.
>
> - If the piston tip is shifted outwards, there will not be enough vacuum to suck the graft into the handpiece.
> - If piston tip is shifted inwards, the graft may be sucked too strongly, causing it to overshoot towards the waste jar.

6. Connect the screw end of the sterile implantation tube to the handpiece, by screwing the tube's connector to the handpiece base, as shown in Figure 3-82.

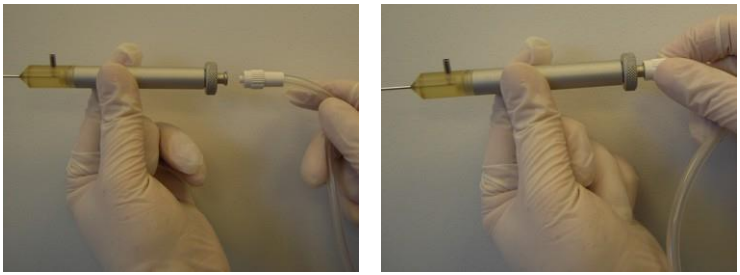


Figure 3-82. Connecting the Screw End of the Implantation Tubing to the Handpiece Base

7. Connect the distal end of the implantation tube to the suction port of the implanter head, as shown in Figure 3-83.

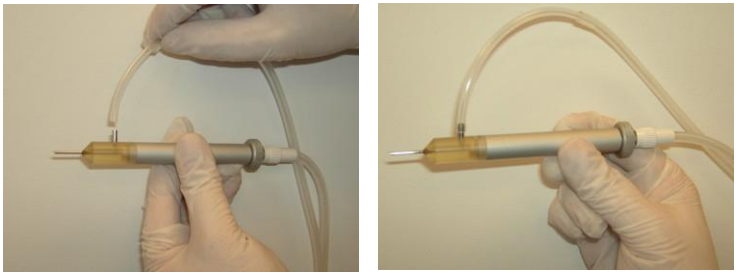


Figure 3-83. Connecting the Distal End of the Implantation Tubing to the Implanter Head

8. Place the implantation handpiece on the handpiece holder, as shown in Figure 3-84.

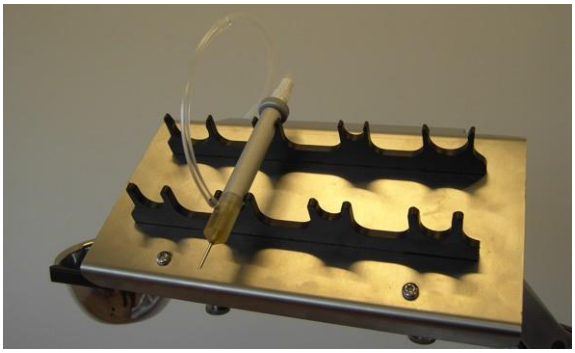


Figure 3-84. Placing the Implantation Handpiece on the Handpiece Holder

9. Connect the Luer lock end of the implantation tube to the system's air outlet port #1, on the left side of the system's rear side, as shown in Figure 3-85.

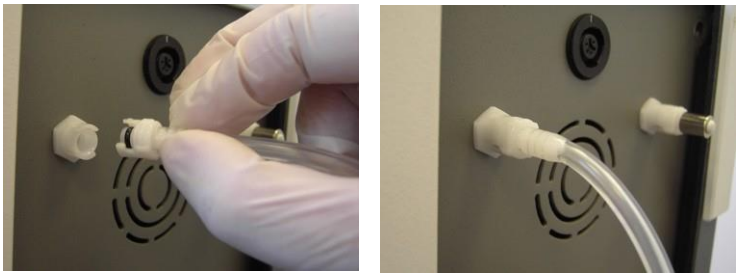


Figure 3-85. Connecting the Luer Lock of the Implantation Tubing to the System's Left Air Outlet Port

10. Proceed as follows:

- If two implantation handpieces are to be used simultaneously, connect the Luer lock end of the implantation tube of the second handpiece to the system's air outlet port #2, on the right side of the system's rear side.
- If only one implantation handpieces is to be used, attach a Luer lock air cap to the system's air outlet port #2, on the right side of the system's rear side, as shown in Figure 3-86.

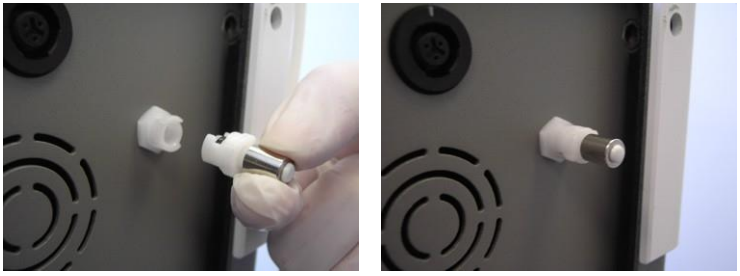


Figure 3-86. Connecting the Luer Lock Air Cap to the System's Air Outlet Port #2

11. Connect the Proximal end of the implantation tube to the waste jar, as shown in Figure 3-87.

Figure 3-87. Connecting the Proximal End of the Implantation Tubing to the Jar

12. Proceed as follows:

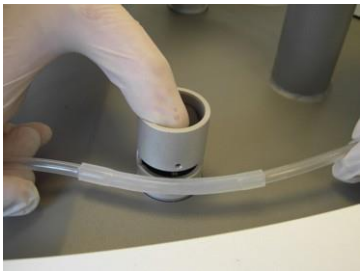
- If two implantation handpieces are to be used simultaneously, connect the proximal end of the implantation tube of the second handpiece to the other inlet pipe of the waste jar.
- If only one implantation handpieces is to be used, cover the waste jar's unused inlet pipe with a silicon cap.

> ***Caution***
>
> In order to avoid leakage, always make sure that all inlet pipes of the waste jar are properly covered/blocked.

13. Position the implantation tube's thick inset next to the system's right electrovalve, as shown in Figure 3-88.

Figure 3-88. Positioning the Implantation Tube's Thick Inset Next to the Right Electrovalve

14. Push (and hold) the electrovalve while inserting the implantation tube's thick inset inti the electrovalve's slot, as shown in Figure 3-89.



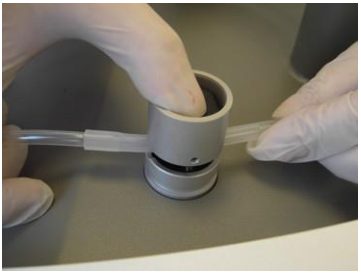


Figure 3-89. Inserting the Implantation Tube's Thick Inset into the Right Electrovalve's Slot

15. Release the electrovalve and verify that the tube is properly inserted into its slot, as shown in Figure 3-90.

Figure 3-90. Implantation Tube Inserted into the Right Electrovalve

16. If two implantation handpieces are to be used simultaneously, repeat the above steps to insert the implantation tube of the second handpiece into the system's left electrovalve

17. Insert the handpiece's tubing into the cable/tube holders on the articulated arm, as shown in Figure 3-91.

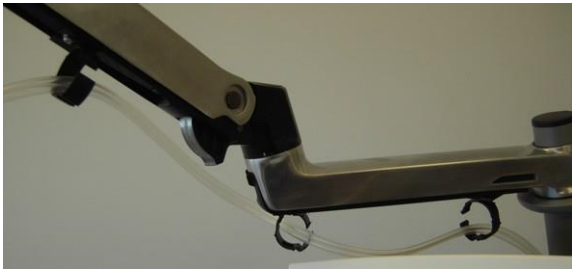


Figure 3-91. Implantation Handpiece Tubing Inserted into the Articulated Arm's Cable/Tube Holders

18. Fasten (but do not tighten) the cable/tube holders to secure the tubing (loosely) within them.

To disconnect the implantation handpiece:

1. Remove the handpiece tubing from the cable/tube holders on the articulated arm.
2. Remove the implantation tube from the electrovalve by pushing the electrovalve and pulling the tube out of its slot.
3. Disconnect the tubes from the handpiece, waste jar and the system.
4. Discard the used tubing as hazardous medical waste.
5. Unscrew and remove the implanter head from the handpiece body.
6. Remove the piston from the implanter head.
7. Clean and sterilize the handpiece components, as described in Chapter 7.

3.18. Connecting the System to the Mains Power

> ***Caution***
>
> Before connecting the system to the power outlet, make sure that the mains electricity is in compliance with the system's electrical requirements, as described in section 3.2.
>
> In case of doubt, contact your Venus Concept representative.

To connect the system to electricity:

1. Connect the power cable to the power connection port, as shown in Figure 3-92.

Figure 3-92. Power Connection Port on the System's Rear Side

2. Plug the other end of the power cable to the mains power supply.

Chapter 4
System Description

Chapter Contents:

4.1. General Description

The NeoGraft 2.0® system is a minimally-invasive hair transplantation device, using three separate handpieces for extracting the grafts, performing the recipient site incisions and implanting the grafts.

4.2. System Components

The following figures show the main components of the NeoGraft 2.0® system:

- Figure 4-1. System Components (Front)
- Figure 4-2. System Components (Waste Jar)
- Figure 4-3. System Components (Upper Rear)
- Figure 4-4. System Components (Lower Rear)

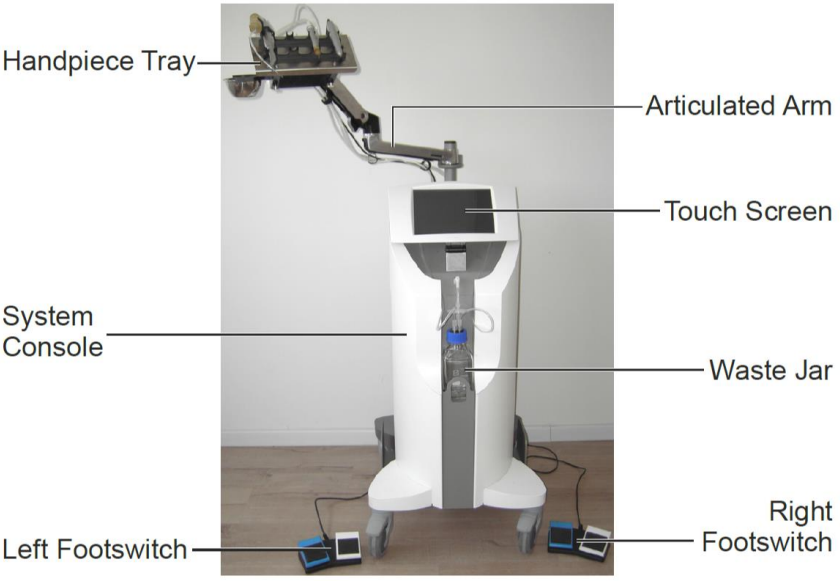


Figure 4-1. System Components (Front)

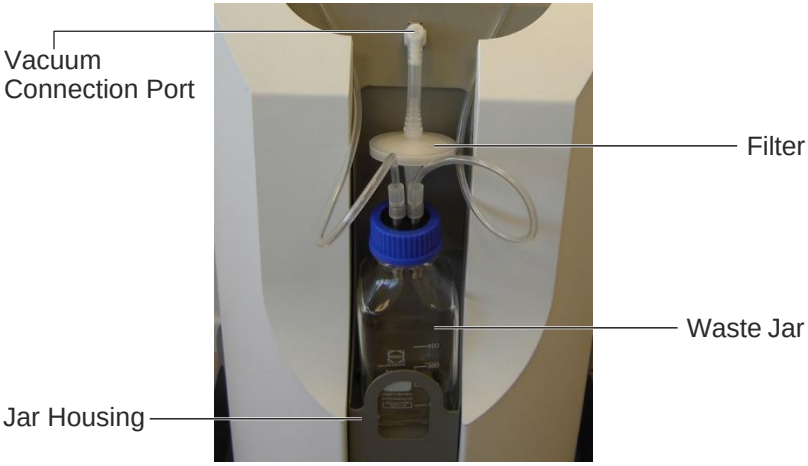


Figure 4-2. System Components (Waste Jar)

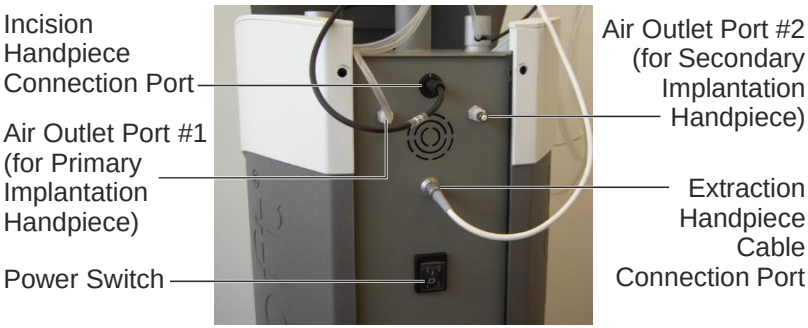


Figure 4-3. System Components (Upper Rear)

Figure 4-4. System Components (Lower Rear)

4.3. System Console

The system console, as shown in Figure 4-1, is the main enclosure that holds and contains all external and internal system components.

4.4. Touch Screen

The touch screen, as shown in Figure 4-1, is the primary means of communication between the user and the system.

The on-screen graphical user interface keeps the user informed of the system status and operating parameters at all times.

Via the touch screen, the user controls and monitors the system operation, using the touch-sensitive buttons and indicators.

4.5. Waste Jar

> ***Warning***
>
> Contents of the waste jar must be discarded as biohazard waste.

Waste jar, as shown in Figure 4-2, is the glass container that collects the particles and fluids that are sucked through the handpieces.

> ***Caution***
>
> - Be careful not to overfill the waste jar.
> - Contents of the waste jar must not exceed ¾ of its volume.
> - Always make sure that the system is turned off or in Standby state before disconnecting the waste jar's vacuum connections.

4.6. Filter

The filter, as shown in Figure 4-2, prevents the penetration of any waste particles or fluids from the waste jar into the system.

4.7. Handpiece Tray

The handpiece tray is installed on the articulated arm, as shown in Figure 4-5, enabling the user to position it conveniently during the treatment.

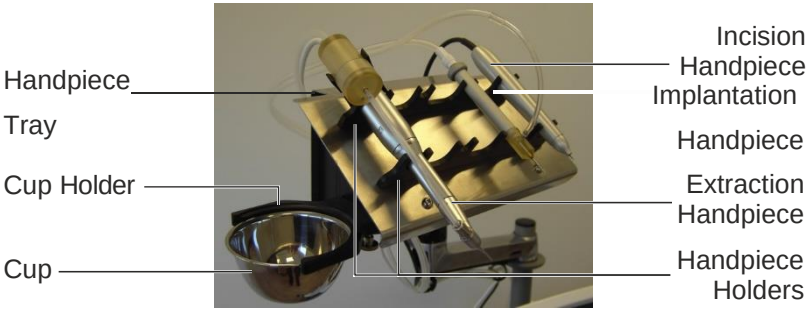


Figure 4-5. Handpiece Tray Components

The handpiece holders, mounted on the handpiece tray, hold the handpieces securely on the tray when they are not in use.

The cup holder (which can be installed on the left or right side of the handpiece tray, as per the user preference) holds the cup on the side of the tray.

4.8. Footswitches

The system is equipped with two footswitches (left and right), as shown in Figure 4-6.

Figure 4-6. Left and Right Footswitches

Each footswitch has two pedals (blue and white), as shown in Figure 4-6.

- On the left footswitch:
  - The blue pedal activates the extraction handpiece (vacuum and motor) when the **Extract** mode is **On**.
  - The white pedal is not in use and pressing it has no effect.
- On the right footswitch:
  - The blue pedal activates the vacuum on the implantation handpiece when the **Implant** mode is **On**.
  - The white pedal activates the graft ejection on the implantation handpiece when the **Implant** mode is **On**.
- On the left footswitch when using two implantation handpieces:
  - The blue pedal activates the vacuum on the implantation handpiece when the **Implant** mode is **On**.
  - The white pedal activates the graft ejection on the implantation handpiece when the **Implant** mode is **On**.

4.9. Electrovalves

Figure 4-7 shows the system's two (left and right) electrovalves, which are mounted on the top of the system console.

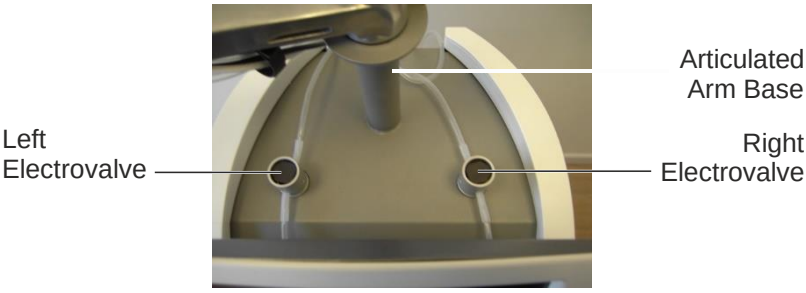


Figure 4-7. Electrovalves

Electrovalves are footswitch-operated valves that cut/release the air flow through the tubes that are inserted through them.

4.10. Power Switch

Figure 4-8 shows the power switch, which is located on the system's rear side, as shown in Figure 4-3.

Figure 4-8. Power Switch

The power switch turns the system on/off.

4.11. Extraction Handpiece

Figure 4-9 shows the extraction handpiece.

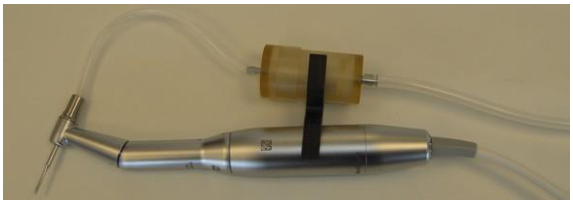


Figure 4-9. Extraction Handpiece

The extraction handpiece is comprised of a cable (connected to the system), a motor and a hollow shafted contra angle head into which a punch is inserted.

Graft extraction is carried out by the rotating punch. The punch penetrates the tissue, until the arrector muscle. The vacuum sucks the graft into the graft collector that is attached to the handpiece.

In order to guide the penetration of the punch according to depth bulb, a polyethylene tube can be cut to appropriate length and inserted into the punch (tube supplied by Venus Concept).

The graft collector is emptied when 50 to 100 grafts are collected.

All grafts are then controlled and aligned on a tray soaked with saline solution.

0.8 mm, 0.9 mm and 1.0 mm punches are supplied with the device.

4.12. Incision Handpiece

Figure 4-10 shows the incision handpiece.

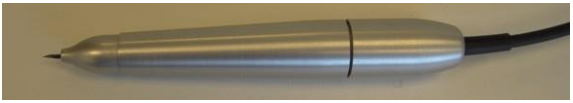


Figure 4-10. Incision Handpiece

The incision handpiece is used during the incision phase of the treatment and enables the user to control the depth of the incision, which is carried out with a blade or a needle.

The handpiece is connected to the system via its cable, and using its sensor counts the number of incisions, which is displayed on the screen.

Different kinds of blades or needles can be used to create the incisions (slits – small incisions made to receive the follicular units in the recipient site).

The length of the blade or needle can be adjusted, depending on the length of the follicular unit, by turning the handpiece head.

4.13. Implantation Handpiece

Figure 4-11 shows the implantation handpiece.

Figure 4-11. Implantation Handpiece

The implantation handpiece uses a pneumatic system to control the movement of the piston that is placed inside the head of the implanter and screwed to the handpiece.

During the implantation phase, the previously-extracted grafts can be placed on a sterile glove or gauze pad, as shown in Figure 4-12.

Figure 4-12. Grafts on a Sterile Glove (Left) and on a Gauze Pad (Right)

Each graft is sucked into the needle of the implanter and then pushed by the piston into the previously-made small incisions (slits) to be re-implanted.

Two implantation handpieces are supplied with the system, enabling two operators to perform the implantation at the same time.

0.8 mm, 0.9mm and 1.0 mm implanters are supplied with the system.

NeoGraft®

Chapter 5

Operating Instructions

Chapter Contents:

5.1. Turning the System On/Off

To turn on the system:

1. Verify that all desired handpieces and accessories are properly installed on the system, as described in Chapter 3.
2. Verify that the power cable is connected to the power connection port on the rear side of the system console and is plugged into the mains power supply.
3. From the rear side of the system console, turn on the power switch, as shown in Figure 5-1.

Figure 5-1. Turning on the Power Switch

4. Wait for system to complete the start process and display the Login Account Selection screen, as shown in Figure 5-2.

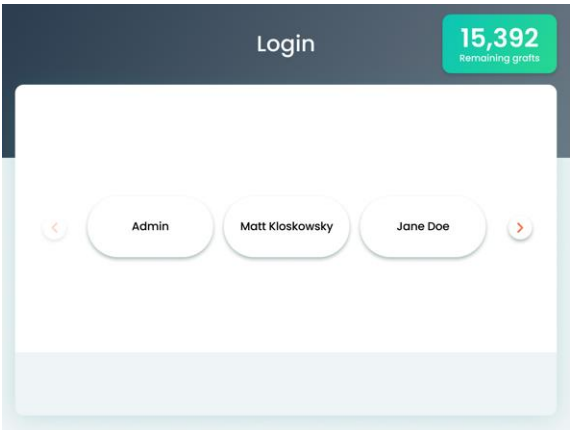


Figure 5-2. Login Account Selection Screen

Note

The **Remaining Grafts** indicator appears only in systems with the Graft Purchasing configuration.

To turn off the system:

1. From the rear side of the system console, turn off the power switch.

2. Verify that the screen is turned off and the system is shut down.

5.2. Selecting the User Account

To select the user account:

1. Verify that the system is turned on and the Account Selection screen appears, as shown in Figure 5-2.
2. From the Login Account Selection screen, press the desired user account; the Login Password screen appears, as shown in Figure 5-3.

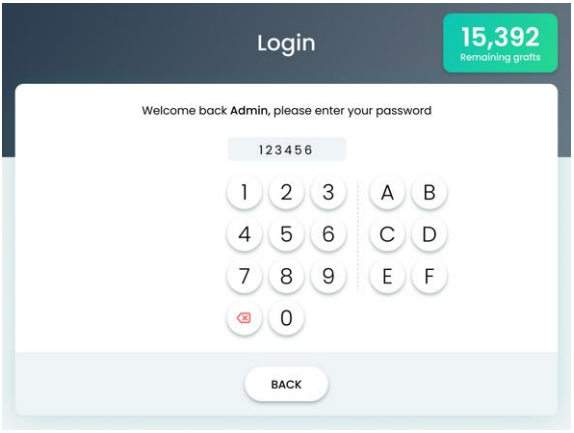


Figure 5-3. Login Password Screen

5.3. Logging In/Out

> ***Warning***
>
> Do not disclose your password to unauthorized users. Providing the password to unauthorized users may result in patient injury.

To log in:

1. Verify that the Login screen appears, as shown in Figure 5-3.

> ***Note***
>
> To return to the Account Selection screen (without entering the password), press the **Back** button.

2. Enter your user account's password; the system logs you into your user account and the Patient Profile screen appears, as shown in Figure 5-4.

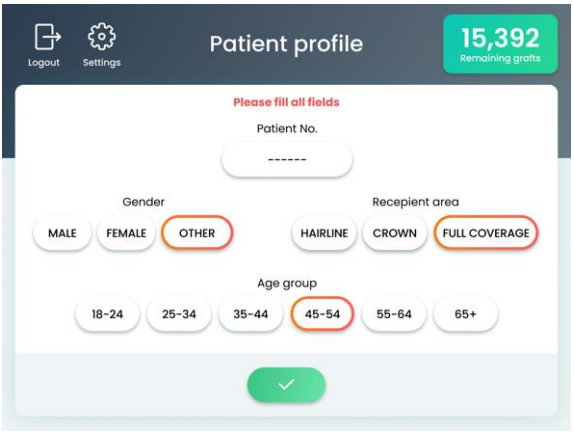


Figure 5-4. Patient Profile Screen

Note

When logging in, if you enter an incorrect password, the following message appears:
Invalid password. Please try again

If you enter the incorrect password five times, the system disables your user account and displays the following message:
Account disabled. Please contact admin

For information on Enabling/Disabling a User, refer to Chapter 6.

To log out:

1. Verify that the Patient Profile screen appears, as shown in Figure 5-4.
2. Press the **Logout** button; the Log Out screen appears, as shown in Figure 5-5.

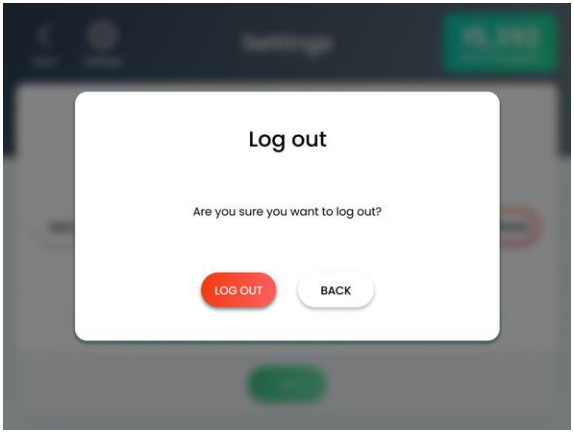


Figure 5-5. Log Out Screen

3. Press the **Log Out** button;
   - The system logs out of the user account.
   - The Login Account Selection screen appears, as shown in Figure 5-2.

5.4. Setting the Patient Profile

Note

It is mandatory to fill all fields in the Patient Profile screens. The Confirm button (enabling to proceed to the Treatment screen) remains disabled until all entries are entered/selected.

To set the patient profile:

1. Verify that the Patient Profile screen appears, as shown in Figure 5-4.
2. In the Patient Profile screen, enter the patient number as follows:
   - **i.** Tap inside the **Patient No.** field box; a numeric keyboard appears.
   - **ii.** Using the numeric keyboard, type a unique 6-digit number.
   - **iii.** Press the **Confirm** button to enter the number and close the numeric keyboard.
3. In the Patient Profile screen, select the relevant entry to set the following information for the current patient:
   - **Gender**
   - **Recipient Area**
   - **Age Group**

3. Press the **Confirm** button; the Donor Site Treatment screen appears, as shown in Figure 5-6.

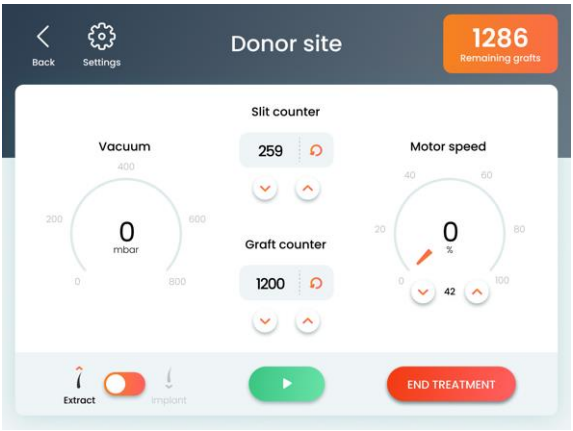


Figure 5-6. Donor Site Treatment Screen

5.5. Treatment Screens

5.5.1. Donor Site

Figure 5-7 shows the Donor Site treatment screen.

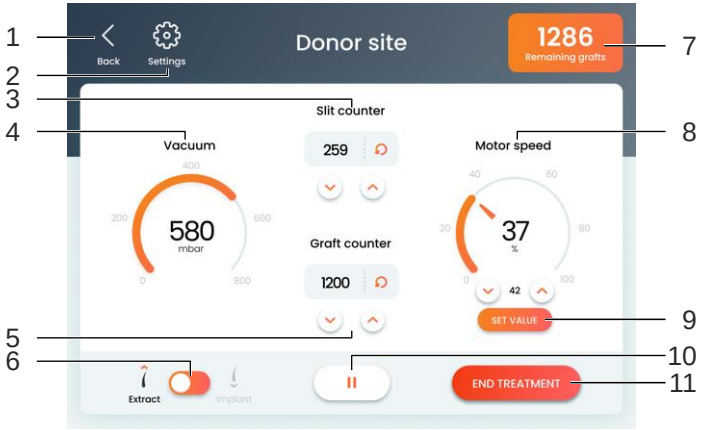


Figure 5-7. Donor Site Treatment Screen Elements

Elements of the Donor Site treatment screen, as indicated by numbers in Figure 5-7, are described below.

1. **Back button** – Allows you to return to the previous (Patient Profile) screen.

   Upon pressing the **Back** button, a dialog box with the following message appears:
   Going back will reset the patient profile. Are you sure?

2. **Settings button** – Displays the Settings screen.

   For detailed description of the Settings screen, refer to Chapter 6.

3. **Slit Counter** –
   - Indicates the number of slits that the incision handpiece has performed during the current treatment.
   - Enables you to adjust the counter by pressing the **Up**/**Down** buttons.
   - Enables you to reset the counter by pressing the **Reset Counter** button.
4. **Vacuum indicator** – Indicates the current vacuum level.
5. **Graft Counter** –
   - Indicates the number of grafts that the Extraction handpiece has extracted during the current treatment.
   - Enables you to adjust the counter by pressing the **Up**/**Down** buttons
   - Enables you to reset the counter by pressing the **Reset Counter** button.
6. **Extract/Implant Selector** – Toggles between the Donor Site and Recipient Site treatment screens (Extract and Implant modes, respectively).
7. **Remaining Grafts indicator** – Appears only in systems with the Graft Purchasing configuration and indicates the remaining number of purchased Grafts on the system.
8. **Motor Speed controller** – Indicates the current motor speed level and enables you to adjust the motor speed (in %), by swiping the wheel or pressing the **Up**/**Down** buttons.
9. **Set Value button** – Appears upon changing the Motor Speed value and pressing it saves and applies the new value.
10. **Start/Pause button** – Toggles the treatment state between Start and Pause.
11. **End Treatment button** – Ends the current treatment session.

5.5.2. Recipient Site

Figure 5-8 shows the Recipient Site treatment screen.

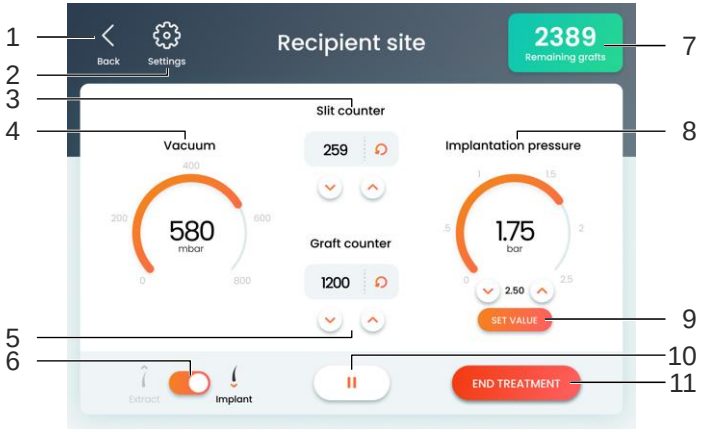


Figure 5-8. Recipient Site Treatment Screen Elements

Elements of the Recipient Site treatment screen, as indicated by numbers in Figure 5-8, are described below.

1. **Back button** – Allows you to return to the previous (Patient Profile) screen.

   Upon pressing the **Back** button, a dialog box with the following message appears:
   Going back will reset the patient profile. Are you sure?

2. **Settings button** – Displays the Settings screen.

   For detailed description of the Settings screen, refer to Chapter 6.

3. **Slit Counter** –
   - Indicates the number of slits that the incision handpiece has performed during the current treatment.
   - Enables you to adjust the counter by pressing the **Up**/**Down** buttons.
   - Enables you to reset the counter by pressing the **Reset Counter** button.
4. **Vacuum indicator** – Indicates the current vacuum level.
5. **Graft Counter** –
   - Indicates the number of grafts that the Extraction handpiece has extracted during the current treatment.
   - Enables you to adjust the counter by pressing the **Up**/**Down** buttons
   - Enables you to reset the counter by pressing the **Reset Counter** button.
6. **Extract/Implant Selector** – Toggles between the Donor Site and Recipient Site treatment screens (Extract and Implant modes, respectively).
7. **Remaining Grafts indicator** – Appears only in systems with the Graft Purchasing configuration and indicates the remaining number of purchased Grafts on the system.
8. **Implantation Pressure controller** – Indicates the current pressure level and enables you to set the desired pressure (in Bar), by swiping the wheel or pressing the **Up**/**Down** buttons.
9. **Set Value button** – Appears upon changing the Implantation Pressure value and pressing it saves and applies the new value.
10. **Start/Pause button** – Toggles the treatment state between Start and Pause.
11. **End Treatment button** – Ends the current treatment session.

5.6. Operating in the Extraction Phase

To operate in the Extraction phase (refer to section 5.5.1):

1. Verify that the Donor Site Treatment screen appears, as shown in Figure 5-9.

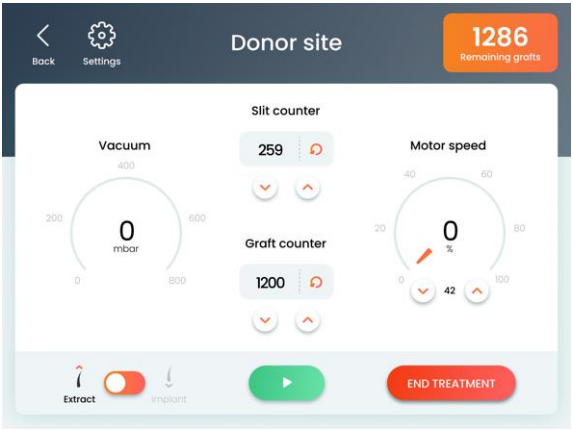


Figure 5-9. Donor Site Treatment Screen (in Pause State)

2. Press the **Start** button;
   - The vacuum pump starts operating.
   - The vacuum indicator displays the vacuum level, as shown in Figure 5-10.

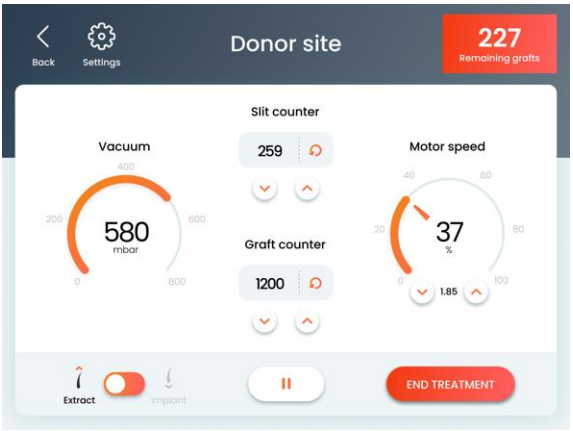


Figure 5-10. Donor Site Treatment Screen (in Start State)

3. Adjust the motor speed as follows:
   - **i.** In the **Motor Speed** controller, swipe the wheel or Press the **Up**/**Down** arrow buttons to set the desired motor speed value; the **Set Value** button appears.
   - **ii.** Press the **Set Value** button to save and apply the setting.
4. Position the extraction handpiece at the treatment site.

5. On the left footswitch, press the blue pedal;
   - The handpiece motor starts operating (to extract the graft).
   - The vacuum sucks the extracted graft into the handpiece's graft collector.
   - The **Graft Counter** increments the indicated number by one.
6. Release the footswitch pedal; the handpiece motor stops operating.
7. Repeat the above steps to extract additional grafts, as desired.

5.7. Operating in the Incision Phase

To operate in the incision phase:

1. Using the incision handpiece, make a slit in the recipient site; The **Slit Counter** increments the indicated number by one.
2. Repeat the above step to make additional slits, as desired.

5.8. Operating in the Implantation Phase

5.8.1. Calibrating Implanter Head

Upon the initial installation of the implanter head in the implantation handpiece, the implanter's piston remains in the forward position and cannot be moved by turning the handpiece's adjusting screw. Calibrating the implanter head places the implanter head's piston tip at the correct position, as shown in Figure 5-11.

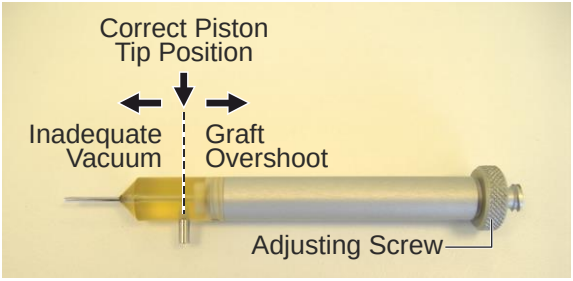


Figure 5-11. Correct Positioning of the Piston within the Implanter Head

In order to ensure proper loading of grafts into the handpiece, it is important to calibrate the implanter head before performing the procedure.

Caution

During the implantation procedure, the previously-extracted grafts are sucked into the implanter head, to be inserted in the recipient site.

During this stage, it is important to have the implanter head's piston tip at the correct position, i.e. aligned with the implanter head's suction port, as shown in Figure 5-11. At this position, the graft can be sucked up and then pushed towards the recipient site.

- If the piston tip is shifted outwards, there will not be enough vacuum to suck the graft into the handpiece.
- If piston tip is shifted inwards, the graft may be sucked too strongly, causing it to overshoot towards the waste jar.

To calibrate the implanter head:

1. From the Treatment screen, toggle the **Extract/Implant Selector** to **Implant** (to display the Recipient Site Treatment screen) and press the **Start** button, as described in section 5.8.2 on page 5-19.
2. Unscrew the adjusting screw by 3-4 full turns (from the Zero position).
3. Press the blue pedal of the footswitch that operates the implantation handpiece to pull the piston to the back position.
4. Disconnect the distal end of the implantation tube from the suction port of the implanter head.
5. Hold the handpiece against light to see through the semi-transparent implanter head.

6. While looking through the implanter head, turn the adjusting screw of the handpiece to move the implanter head's piston tip to the correct position, as shown in Figure 5-11.
7. Connect the distal end of the implantation tube to the suction port of the implanter head.

5.8.2. Performing the Implantation

To perform the implantation (refer to section 5.5.2):

1. Verify that the Recipient Site Treatment screen appears. If not, from the treatment screen, toggle the **Extract/Implant Selector** to **Implant**; the Recipient Site Treatment screen appears, as shown in Figure 5-12.

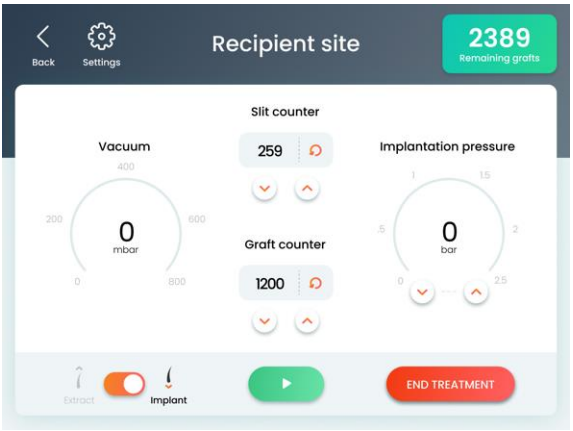


Figure 5-12. Recipient Site Treatment Screen (in Pause State)

3. Press the **Start** button;
   - The vacuum pump starts operating.
   - The vacuum indicator displays the vacuum level, as shown in Figure 5-13.

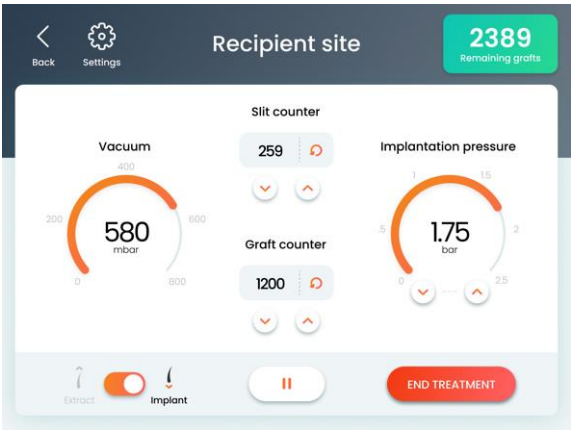


Figure 5-13. Recipient Site Treatment Screen (in Start State)

4. Adjust the implantation pressure as follows:
   - **i.** In the **Implantation Pressure** controller, swipe the wheel or Press the **Up**/**Down** arrow buttons to set the desired implantation pressure value; the **Set Value** button appears.
   - **ii.** Press the **Set Value** button to save and apply the setting.
5. Point the implantation handpiece at the previously-extracted graft.
6. On the right footswitch, press the blue pedal; the vacuum sucks the graft into the handpiece's implanter head.

Note

If you are using two implantation handpieces, you can use the left footswitch for operating the left handpiece and the right footswitch for the right handpiece (in the Implantation mode).

7. Release the footswitch pedal.

8. Position the implantation handpiece on the previously-made slit at the treatment site.

9. On the right footswitch, press the white pedal to eject the graft into the slit.

Note

If you are using two implantation handpieces, you can use the left footswitch for operating the left handpiece and the right footswitch for the right handpiece (in the Implantation mode).

10. Release the footswitch pedal.

11. Repeat the above steps to implant additional grafts, as desired.

5.9. Returning to the Patient Profile Screen

> ⚠ ***Caution***
>
> Returning from the Treatment screen to the Patient Profile screen resets the currently-set patient profile.

To return from the Treatment screen to the Patient Profile screen:

1. From the Treatment screen, press the **Back** button; the Patient Profile Reset Attention screen appears, as shown in Figure 5-14.

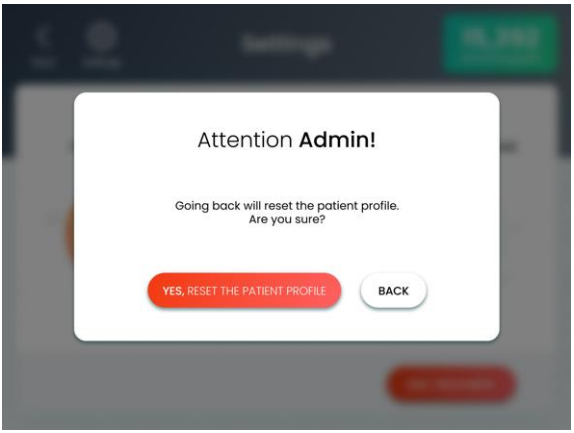


Figure 5-14. Patient Profile Reset Attention Screen

2. Press the **Yes, Reset the Patient Profile** button;
   - The system resets the currently-set patient profile.
   - The Patient Profile screen appears, as shown in Figure 5-15.

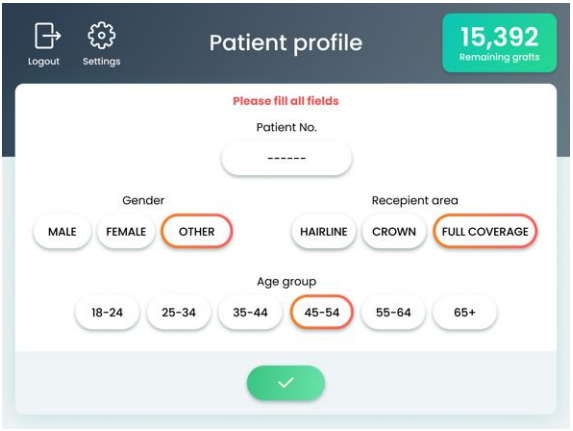


Figure 5-15. Patient Profile Screen

5.10. Ending the Treatment

To end the treatment:

1. From the Treatment screen, press the **End Treatment** button; the Finalizing Treatment Attention screen appears, as shown in Figure 5-16.

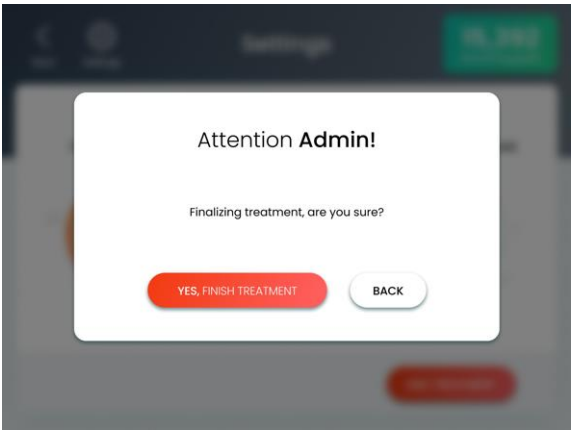


Figure 5-16. Finalizing Treatment Attention Screen

2. Press the **Yes, Finish Treatment** button;
   - The system Ends the current treatment session.
   - The Patient Profile screen appears, as shown in Figure 5-15.

NeoGraft®

Chapter 6

Advanced Features and Settings

Chapter Contents:

6.1. Settings screen

Features in the Settings screen, as described in Table 6-1, enable the user to personalize the system, and allow the qualified Venus Concept technicians to update the system software and control various settings.

Table 6-1. Settings Screen Features

Icon	Description	See Section
	**Accounts** – Allows the system administrator to add/remove users, enable/disable users, and edit user names and passwords.	6.2
	**Activate** – Enables you to extend the use of a restricted device and activate the purchased grafts.	6.3 6.4
	**Language** – Enables you to select the interface language.	6.5

Table 6-1. Settings Screen Features (cont.)

Icon	Description	See Section
	**Technician Mode** – Allows qualified Venus Concept technicians to access the Technician mode.	6.6
	**Information** – Displays information regarding the system software and hardware.	6.7
	**Back** – Closes the Settings screen and returns to the previous screen.	–

To access the Settings screen:

- From the Patient Profile or Treatment screen, press the **Settings**  button; the Settings screen appears.

6.2. Managing User Accounts

Note

The **Accounts** feature is available only in the Administrator mode.

This feature enables the system administrator to perform the following procedures:

- Adding a User *(see section 6.2.2 on page 6-7)*
- Renaming a User *(see section 6.2.3 on page 6-11)*
- Changing a User Password *(see section 6.2.5 on page 6-15)*
- Enabling/Disabling a User *(see section 6.2.4 on page 6-13)*
- Removing a User *(see section 6.2.6 on page 6-18)*

6.2.1. Accessing the Accounts Screen

To access the Accounts screen:

1. Log in to the system as the Administrator (with the Administrator login code which is provided with the installation documents).
2. Access the Settings screen, as described in section 6.1.

3. From the Settings screen, press the **Accounts** icon, as shown in Table 6-1; the Accounts screen appears, as shown in Figure 6-1.

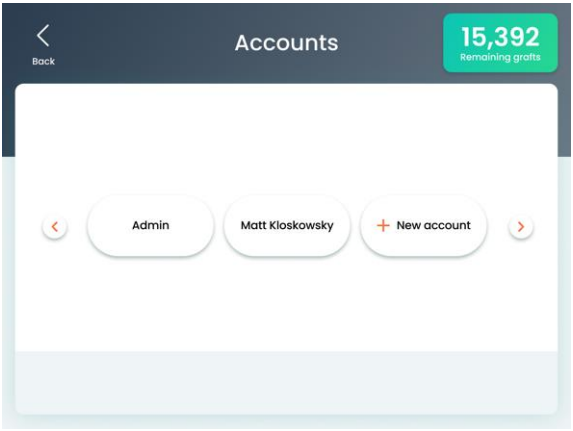


Figure 6-1. Accounts Screen

The Accounts screen displays all system users.

6.2.2. Adding a User

To add a user:

1. Access the Accounts screen, as described in section 6.2.1.
2. In the Accounts screen, tap the **+ New Account** button; the New Account (Step 1 of 3) screen appears, as shown in Figure 6-2.

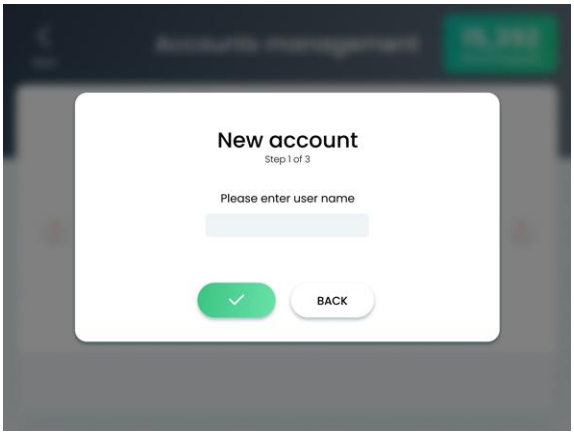


Figure 6-2. New Account (Step 1 of 3) Screen

3. Tap inside the **Name** box; the virtual keyboard appears, as shown in Figure 6-3.

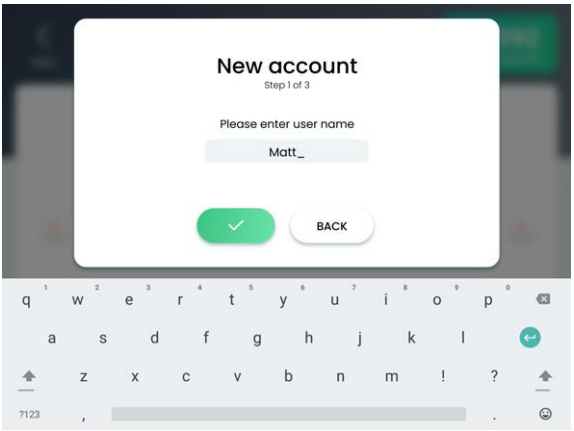


Figure 6-3. Virtual Keyboard in New Account (Step 1 of 3) Screen

4. Type the desired name for the new user account.

Note

The user name must be unique. There cannot be two users with the same name.

5. Press the **Confirm** button; the New Account (Step 2 of 3) screen appears, as shown in Figure 6-4.

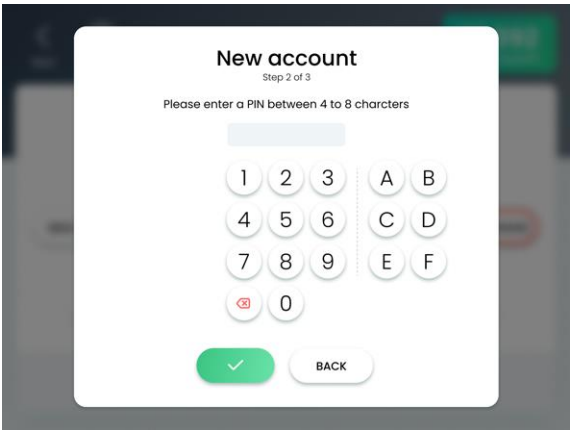


Figure 6-4. New Account (Step 2 of 3) Screen

6. Type the desired password (login PIN code).

> ***Note***
>
> The password must have 4 to 8 characters and be unique. There cannot be two users with the same password.

7. Press the **Confirm** button; the New Account (Step 2 of 3) screen appears, as shown in Figure 6-5.

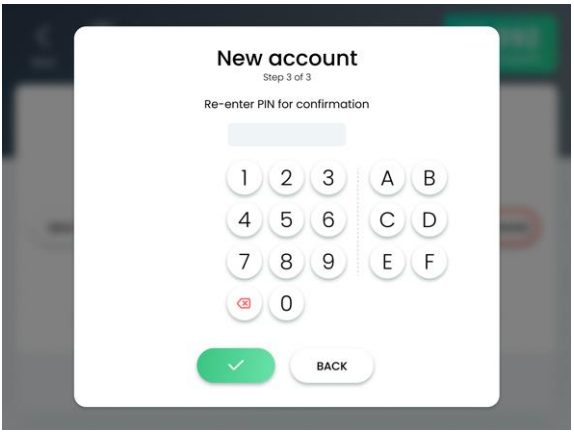


Figure 6-5. New Account (Step 3 of 3) Screen

8. Re-enter the password (login PIN code).
9. Press the **Confirm** button to close the Enter New PIN screen and return to the Accounts screen.
10. Verify that the newly-added user appears in the Accounts screen, as shown Figure 6-1.
11. Press the **Back** button to close the Accounts screen and return to the Settings screen.

6.2.3. Renaming a User

To rename a user:

1. Access the Accounts screen, as described in section 6.2.1.
2. In the Accounts screen, tap the User entry that is to be renamed; the selected user's Account screen appears, as shown in Figure 6-6.

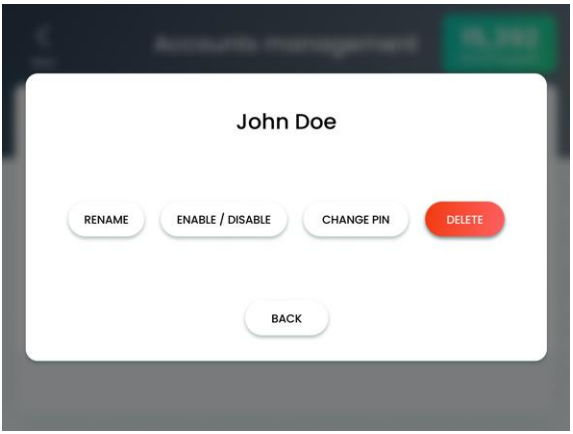


Figure 6-6. Selected User's Account Screen

3. Press the **Rename** button; the Rename screen appears, as shown in Figure 6-7.

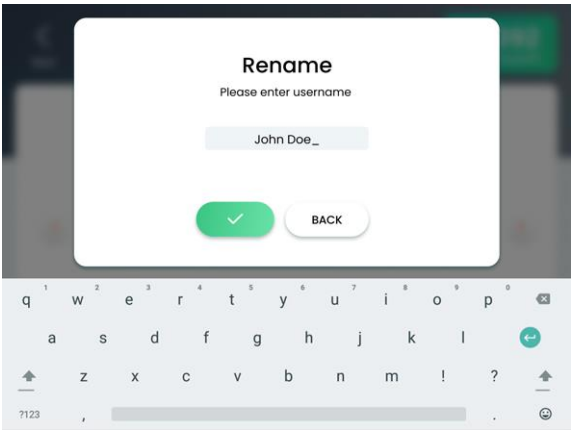


Figure 6-7. Rename Screen

4. Type the desired user name, using the virtual keyboard, as shown in Figure 6-7.

> ***Note***
>
> The user name must be unique. There cannot be two users with the same name.

5. Press the **Confirm** button to close the Rename screen and return to the Accounts screen.
6. Verify that the renamed user appears properly in the Accounts screen, as shown in Figure 6-1.
7. Press the **Back** button to close the Accounts screen and return to the Settings screen.

6.2.4. Enabling/Disabling a User

To enable/disable a user:

1. Access the Accounts screen, as described in section 6.2.1.
2. In the Accounts screen, tap the User entry that is to be enabled/disabled; the selected user's Account screen appears, as shown in Figure 6-8.

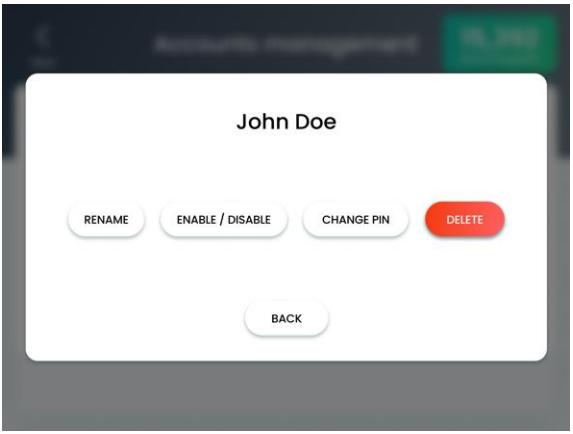


Figure 6-8. Selected User's Account Screen

3. Press the **Enable/Disable** button; the following message appears:
   Are you sure you want to enable/disable <selected user's> account?

   Note

   The **Enable/Disable** button toggles the selected user's status to Enabled and Disabled.

4. Press the **Confirm** button to apply and return to the Accounts screen.
5. Press the **Back** button to close the Accounts screen and return to the Settings screen.

6.2.5. Changing a User Password

To change a user password:

1. Access the Accounts screen, as described in section 6.2.1.
2. In the Accounts screen, tap the User entry whose password is to be changed; the selected user's Account screen appears, as shown in Figure 6-9.

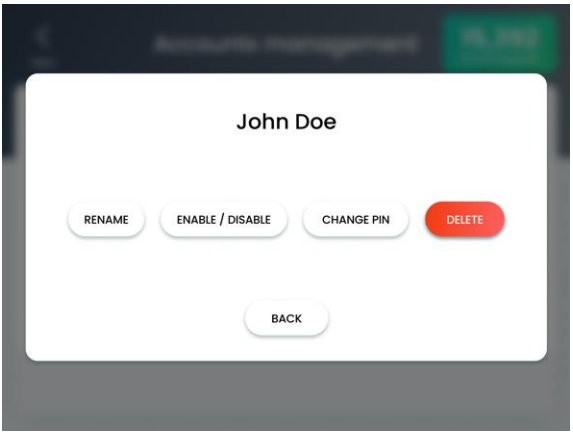


Figure 6-9. Selected User's Account Screen

3. Press the **Change PIN** button; the Change PIN (Step 1 of 2) screen appears, as shown in Figure 6-10.

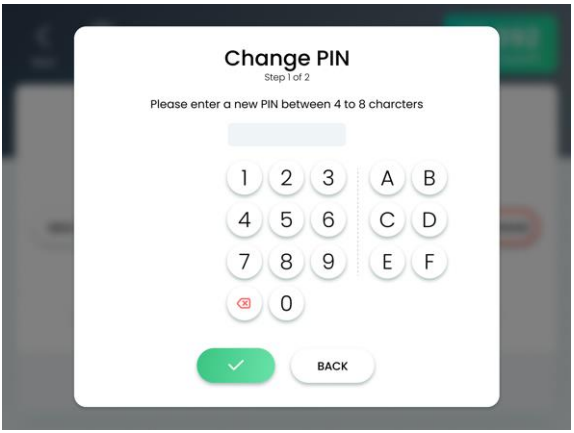


Figure 6-10. Change PIN (Step 1 of 2) Screen

4. Type the desired password (login PIN code).

> ***Note***
>
> The password must have 4 to 8 characters and be unique. There cannot be two users with the same password.

5. Press the **Confirm** button; the **Change PIN** button; the Change PIN (Step 2 of 2) screen appears, as shown in Figure 6-11.

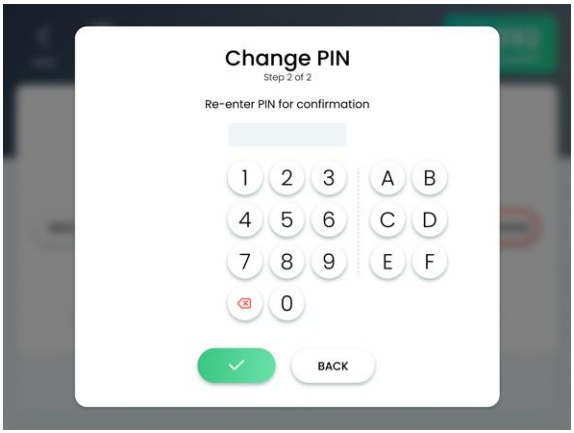


Figure 6-11. Change PIN (Step 2 of 2) Screen

6. Press the **Confirm** button to apply the change and return to the Accounts screen.
7. Press the **Back** button to close the Accounts screen and return to the Settings screen.

6.2.6. Removing a User

The system allows the Administrator to remove Users.

> ***Note***
>
> The Administrator itself cannot be removed.

To remove a user:

1. Access the Accounts screen, as described in section 6.2.1.
2. In the Accounts screen, tap the User entry that is to be removed; the selected user's Account screen appears, as shown in Figure 6-12.

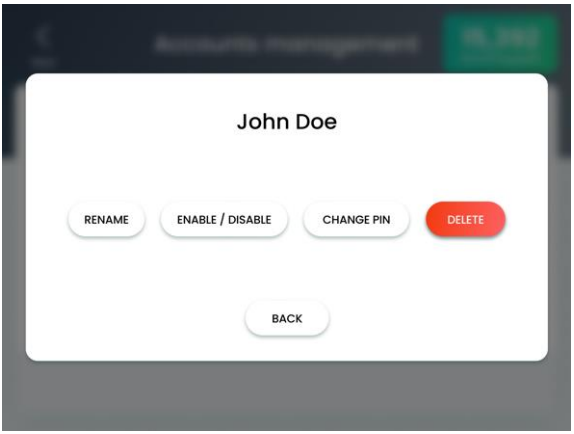


Figure 6-12. Selected User's Account Screen

3. Press the **Delete** button; the Delete User screen appears, as shown in Figure 6-13.

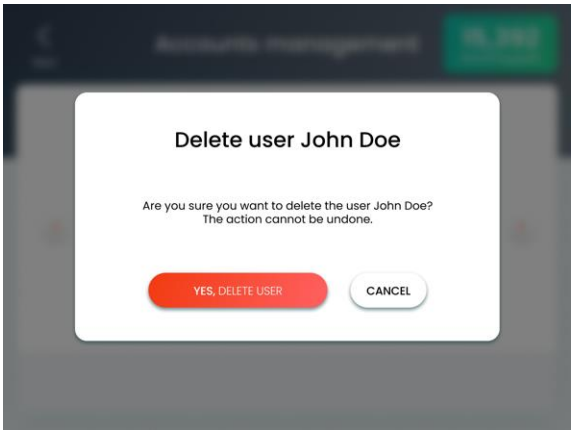


Figure 6-13. Delete User Screen

4. Press the **Yes, Delete User** button to apply the deletion and return to the Accounts screen.
5. Verify that the deleted user does not appear in the Accounts screen, as shown in Figure 6-1.
6. Press the **Back** button to close the Accounts screen and return to the Settings screen.

6.3. Extending the Activation Period

Use of the system may be restricted to either a specific date (Expiration Date) or a limited time of operation (Operation Time).

- If the system use is restricted to a specific date, the effective Expiration Date is displayed. One week before the Expiration Date, the following message appears:

  Your activation period is about to expire. Please contact your area CSA to receive your new activation code (Expiration Date: MMM-DD-YYYY).

- If the Expiration Date has passed without extending it, the following message appears:

  Activation period has expired. Expiration Date: MMM-DD-YYYY. Please enter new Activation Code.

- If the system use is restricted to a limited Operation Time, the remaining Operation Time (in hours) appears. If the remaining Operation Time is less than 10 hours, the following message appears:

  Remaining Operation Time: XX:YY hours

  If the remaining Operation Time is less than one hour, the color of the message text becomes red. If no Operation Time has remained, the following message appears:

  Your activation period has expired. Please enter new activation code.

- If the system use is restricted to both a specific date and a limited Operation Time, both the effective Expiration Date and the remaining Operation Time appear with the above messages.

To extend the activation period of a restricted system:

1. Access the Settings screen, as described in section 6.1.
2. From the Settings screen, press the **Activate** icon, as shown in Table 6-1; the Customer Portal screen appears, as shown in Figure 6-14.

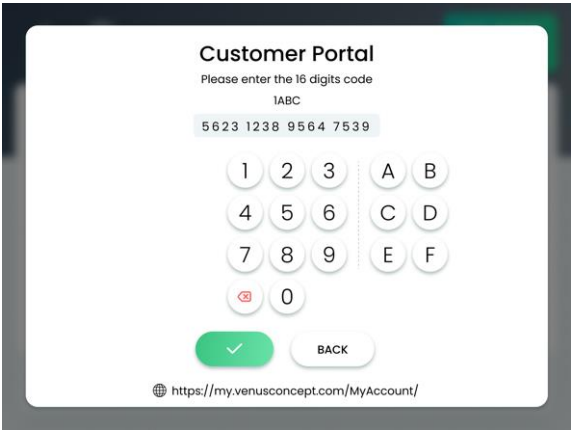


Figure 6-14. Customer Portal Screen

3. Contact your local Venus Concept representative and indicate the **Key Number** that is displayed on top the screen. The representative will provide a new 16-character Activation Code.
4. Enter the new Activation Code in the screen.
5. Press the **Confirm** button to close the Activation screen and return to the Settings screen.

> ***Note***
>
> To abort the Activation screen and return to the Settings screen, press the **Back** button.

6.4. Activating the Purchased Grafts

The system can be used in the following configurations:

- Unlimited Grafts – In this configuration, the use of system is not restricted to the number of purchased grafts.
- Graft Purchasing – In this configuration, the use of system is restricted to the number of purchased grafts.

This section describes how to activate the purchased grafts in the Graft Purchasing configuration.

> ***Note***
>
> These instructions are not relevant with the Unlimited Grafts configuration.

To add purchased grafts to the system:

1. Contact your Venus Concept representative to purchase the desired number of grafts and receive the 16-digit code for activating the purchased grafts.
2. Access the Settings screen, as described in section 6.1.
3. From the Settings screen, press the **Activate** icon, as shown in Table 6-1; the Customer Portal screen appears, as shown in Figure 6-15.

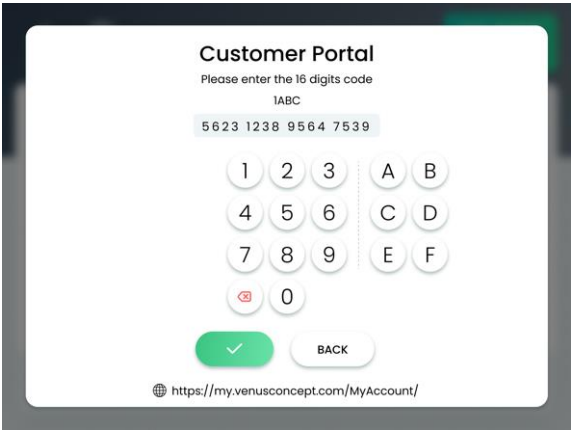


Figure 6-15. Customer Portal Screen

4. Enter the 16-digit graft Activation Code in the screen.
5. Press the **Confirm** button to close the Activation screen and return to the Settings screen.

> ***Note***
>
> To abort the Activation screen and return to the Settings screen, press the **Back** button.

6.5. Setting the Interface Language

To set the interface language:

1. Access the Settings screen, as described in section 6.1.
2. From the Settings screen, press the **Language** icon, as shown in Table 6-1; the Language screen appears, as shown in Figure 6-16.

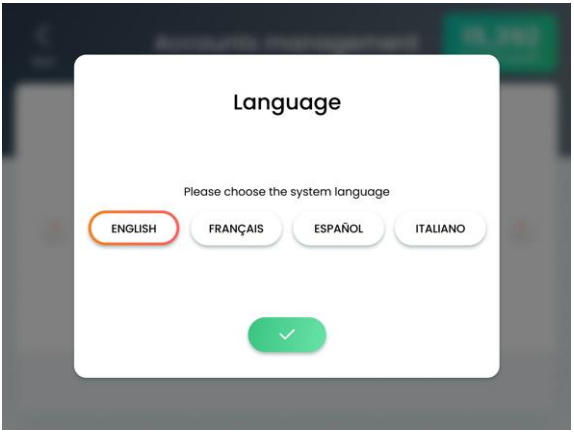


Figure 6-16. Language Screen

3. Tap the desired language to select it.
4. Press the **Confirm** button to close the Language screen and return to the Settings screen.

6.6. Technician Mode

This feature is password protected and is to be used only by qualified Venus Concept technicians.

> ***Warning***
>
> Attempting to bypass the password protection and to access the Technician mode may result in patient injury and/or system damage/malfunction.

6.7. Displaying the System Information

To display the system information:

1. Access the Settings screen, as described in section 6.1.
2. From the Settings screen, press the **Information** icon, as shown in Table 6-1; the Information screen appears.
3. Press the **Confirm** button to close the Information screen and return to the Settings screen.

Chapter 7

Care and Maintenance

Chapter Contents:

7.1. Cleaning the System

Use the following guidelines to clean the system:

- Clean/Wipe the system's external parts at least once a week.
- To ensure safety, turn off the system before wiping any of the surfaces.
- Avoid using detergents such as ammonia, acetone, hydrochloric acid, chlorine bleach, and other fluids that can damage or destroy plastic or metal components.

7.2. Cleaning the Waste Jar Components

To clean the waste jar and its components:

1. Remove the waste jar from the system.
2. Open and remove the jar's lid.
3. Remove the black stopper from the jar.
4. Remove the rubber gasket from the stopper.
5. Empty the jar's contents.

> ***Warning***
>
> Contents of the waste jar must be discarded as biohazard waste.

6. Soak the waste jar and all of its components in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for 5 lit of water) at room temperature
(15C - 25°C) for a minimum of 10 minutes.
7. Remove the components from the ultrasonic bath and clean each component with an appropriate brush for a minimum of 20 seconds:
    - Use a bottle brush to brush inside the glass jar.
    - Use an interdental brush to brush inside the cylindrical parts of the black stopper.
    - Use a toothbrush to brush inside and outside of all of the other parts.
8. Rinse each part with lukewarm running tap water WFI (Water for injection) for a minimum of 10 seconds.
9. Dry each part, using a disposable wipe.
10. Visually inspect the parts and make sure that they are clean, intact and in good condition.
    - Any soiled part must be re-cleaned.
    - Any damaged (e.g. broken, twisted, rusty) part should be discarded.

7.3. Cleaning the Extraction Handpiece

7.3.1. Disconnecting the Extraction Handpiece Components

To disconnect the extraction handpiece components:

1. Remove the handpiece from the system.
2. Disconnect all tubes from the handpiece and discard them.

> ***Warning***
>
> Used tubes must be discarded as biohazard waste.

3. Disconnect the graft collector from the handpiece clamp.
4. Disconnect the clamp from the handpiece.
5. Disconnect the punch from the handpiece.
6. Disconnect the contra-angle head from the handpiece.
7. Disconnect the motor from the cable connector.

7.3.2. Cleaning the Graft Collector and the Handpiece Clamp

To clean the graft collector and the handpiece clamp:

1. Dismantle the **graft collector** and remove its components.
2. Soak all components of **the graft collector and the handpiece clamp** in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for 5 lit of water) at room temperature (15°C - 25°C) for a minimum of 10 minutes.
3. Remove the components from the ultrasonic bath and clean each component with an appropriate brush (e.g. toothbrush or interdental brush) for a minimum of 20 seconds. Make sure to brush inside and outside the container, its lid, both sides of the filter and the stainless steel rod screw hole.
4. **Graft collector only:** Using a syringe, filled with 3 ml of ANIOS CLEAN EXCEL D detergent solution at room temperature (15°C - 25°C), flush the inside of the stainless steel rod, joins on the lid and inside the container and the stainless steel rod screw hole. Flush each part with 3 ml of the solution.
5. Rinse each part with Water WFI (Water For Injection) for a minimum of 10 seconds.
6. **Graft collector only:** Once again, soak all components of the graft collector in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for 5 lit of water) at room temperature (15°C - 25°C) for a minimum of one minute.

7. **Graft collector only:** Remove the components from the ultrasonic bath and clean each component with an appropriate brush (e.g. toothbrush or interdental brush) for a minimum of 20 seconds. Make sure to brush inside and outside the container, its lid, both sides of the filter and the stainless steel rod screw hole.
8. **Graft collector only:** Using a syringe, filled with 3 ml of ANIOS CLEAN EXCEL D detergent solution at room temperature (15°C - 25°C), flush the inside of the stainless steel rod, joins on the lid and inside the container and the stainless steel rod screw hole. Flush each part with 3 ml of the solution.
9. **Graft collector only:** Rinse each part with Water WFI (Water For Injection) for a minimum of 10 seconds.
11. Dry each part, using a disposable wipe.
12. Visually inspect the parts and make sure that they are clean, intact and in good condition.
    - Any soiled part must be re-cleaned.
    - Any damaged (e.g. broken, twisted, rusty) part should be discarded.

7.3.3. Cleaning and Lubricating the Contra-Angle Handpiece Head

To clean the handpiece contra-angle head:

1. Spray inside of the contra-angle head with AquaCare to remove physiological serum and impurities before cleaning/disinfection.
2. Soak the component in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for 5 lit of water) at room temperature (15°C - 25°C) for a minimum of 10 minutes.
3. Remove the component from the ultrasonic bath and clean its inside and outside with an appropriate brush (e.g. toothbrush or interdental brush) for a minimum of 20 seconds.
4. Using a syringe, filled with 3 ml of ANIOS CLEAN EXCEL D detergent solution at room temperature (15°C - 25°C).Flush each part with 3 ml of the solution.
5. Rinse each part with Water WFI (Water For Injection) for a minimum of 10 seconds.
6. Once again, soak all components in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for 5 lit of water) at room temperature (15°C - 25°C) for a minimum of one minute.
7. Remove the component from the ultrasonic bath and clean its inside and outside with an appropriate brush (e.g. toothbrush or interdental brush) for a minimum of 20 seconds.
8. Using a syringe, filled with 3 ml of ANIOS CLEAN EXCEL D detergent solution at room temperature (15°C - 25°C).Flush each part with 3 ml of the solution.
9. **Graft collector only:** Rinse each part with Water WFI (Water For Injection) for a minimum of 10 seconds.

10. Dry the external parts, using a disposable wipe.

11. Dry the internal parts, using Spraynet.

12. Visually inspect the parts and make sure that they are clean, intact and in good condition.

- Any soiled part must be re-cleaned.
- Any damaged (e.g. broken, twisted, rusty) part should be discarded.

13. Lubricate the contra-angle head with the Lubrifluid.

> ***Caution***
>
> In order to avoid corrosion, it is essential to perform proper lubrication of the component.

14. Place the contra-angle head vertically on a gauze pad, to absorb the excess oil, for about 2 minutes.

7.3.4. Cleaning the Handpiece Motor

> ***Caution***
>
> The handpiece motor is maintenance free. Do not spray any lubricant or cleaning solution into the motor.

To clean the handpiece motor:

1. Using a soft bristle brush, clean the external surface of the handpiece motor under running water (< 38ºC).
2. Rinse the exterior and interior of the motor with running water (< 38ºC) for 10 seconds.
3. Disinfect the external surface of the motor, using a soft bristle brush, soaked with a suitable detergent or disinfectant solution. The suitable solutions include:
   - Detergent or detergent-disinfectant (pH 6- 9.5), recommended for cleaning/disinfection of dental or surgical instruments
   - Quaternary ammonium- and/or enzyme-based surfactants

> ***Caution***
>
> - Do not use solutions that are corrosive or contain chlorine, acetone aldehydes or bleaches.
> - Do not soak in physiological liquid (NaCl).

To perform automatic cleaning/disinfection of the handpiece motor:

Use the following guidelines:

- Verify that the machine washable symbol  is engraved on the instrument.
- Use a validated cleaner-disinfectant with the adequate detergent.
- Select the specified washing cycle for the instrument, which should be compatible with the detergent manufacturer's instructions.
- Use the following recommended temperatures:
  - Pre-wash – Water: cold to maximum 35°C (95°F) – Duration 2 min.
    Wash – Water: 50°C to 65°C (122°F to 149°F – Duration 5 min.
  - Rinsing:
    Water: cold to maximum 35°C (95°F) – Duration 2min.
  - Thermal disinfection:
    Water: 80°C to 97°C (176°F to 206.6°F) – Duration 5 min.
    Drying:
    Air: 65°C to 75°C (149°F to 167°F) – Duration 25 min.

7.3.5. Cleaning the Handpiece Cable

To clean the handpiece cable:

1. Verify that the handpiece motor is disconnected from the handpiece cable, and the handpiece cable is disconnected from the system.
2. Clean and disinfect the external surface of the motor, using a wipe, soaked with a suitable detergent or disinfectant solution. The suitable solutions include:
   - Detergent or detergent-disinfectant (pH 6- 9.5), recommended for cleaning/disinfection of dental or surgical instruments
   - Quaternary ammonium- and/or enzyme-based surfactants

> ***Caution***
>
> - Do not use solutions that are corrosive or contain chlorine, acetone aldehydes or bleaches.
> - Do not use any product containing silicone.
> - Do not soak in physiological liquid (NaCl).

3. Rinse the cable with cold running water (< 35°C [< 95°F]).
4. Spray the cable with Spraynet to remove the rinsing water immediately. If required, wipe with a sterile non-woven wipe.
5. Visually check the cable for cleanliness. If required, re-clean with a soft brush.
6. Roll up the cable (with a minimum crown radius of 50mm) and stow immediately in approved packaging for steam sterilization.

7.3.6. Cleaning the Punch

> ***Caution***
>
> - Each punch must be **perfectly clean before** performing the sterilization.
> - Used punch must be discarded as biohazard waste.

To clean the punch:

1. Soak the punch in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for 5 lit of water) at room temperature (15°C - 25°C) (59°F-77°F) for a minimum of 10 minutes.
2. Remove the punch from the ultrasonic bath.
3. Using a syringe, filled with 3 ml of ANIOS CLEAN EXCEL D detergent solution, flush inside the punch.
4. Rinse the punch with lukewarm (25°C - 35°C) (77°F-95°F) Water WFI (Water For Injection) for a minimum of 10 seconds.
5. Once again, soak the punch in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for 5 lit of water) at room temperature (15°C - 25°C) (59°F-77°F) for a minimum of one minute.
6. Remove the punch from the ultrasonic bath and clean it with an appropriate brush (e.g. a toothbrush or interdental brush) for a minimum of 20 seconds.
7. Rinse the punch with lukewarm (25°C - 35°C) (77°F-95°F) Water WFI (Water For Injection) for a minimum of 10 seconds.
8. Dry the punch, using a disposable wipe.

7.4. Cleaning the Incision Handpiece

7.4.1. Disconnecting the Incision Handpiece Components

To disconnect the incision handpiece components:

1. Remove the handpiece from the system.
2. Unscrew the handpiece body from the handpiece base.
3. Remove the blade holder from the handpiece base.
4. Carefully remove the blade from the blade holder.
5. Discard the blade in a hazardous sharps disposal container.

7.4.2. Cleaning the Incision Handpiece Body and Blade Holder

To clean the incision handpiece body and blade holder:

1. Soak the components of in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for
   5 lit of water) at room temperature (15°C - 25°C) for a minimum of 10 minutes.
2. Remove the components from the ultrasonic bath and clean each component with an appropriate brush (e.g. toothbrush or interdental brush) for a minimum of 20 seconds. Make sure to brush inside and outside of the components.
3. Use an interdental brush (Ø 8-7 mm) to clean the internal parts of the handpiece body for a minimum of 20 seconds.

4. Rinse each part with Water WFI (Water For Injection) for a minimum of 10 seconds.
5. Once again, soak the components in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for 5 lit of water) at room temperature (15°C - 25°C) for a minimum of one minute.
6. Remove the components from the ultrasonic bath and clean each component with an appropriate brush (e.g. toothbrush or interdental brush) for a minimum of 20 seconds. Make sure to brush inside and outside of the components.
7. Rinse each part with Water WFI (Water For Injection) for a minimum of 10 seconds.
8. Dry each part, using a disposable wipe.
9. Visually inspect the parts and make sure that they are clean, intact and in good condition.
    - Any soiled part must be re-cleaned.
    - Any damaged (e.g. broken, twisted, rusty) part should be discarded.

7.4.3. Cleaning the Handpiece Cable

To clean the handpiece cable:

1. Verify that the handpiece body and blade holder are disconnected from the handpiece cable, and the handpiece cable is disconnected from the system.
2. Clean and disinfect the external surface of the handpiece cable and its connectors, using a wipe, soaked with a suitable detergent or disinfectant solution. The suitable solutions include:
   - Detergent or detergent-disinfectant (pH 6- 9.5), recommended for cleaning/disinfection of dental or surgical instruments
   - Quaternary ammonium- and/or enzyme-based surfactants

   Caution
   - Do not use solutions that are corrosive or contain chlorine, acetone aldehydes or bleaches.
   - Do not use any product containing silicone.
   - Do not soak in physiological liquid (NaCl).
3. Rinse the cable with cold running water (< 35°C [< 95°F]).
4. Spray the cable with Spraynet to remove the rinsing water immediately. If required, wipe with a sterile non-woven wipe.
5. Visually check the cable for cleanliness. If required, re-clean with a soft brush.

7.5. Cleaning the Implantation Handpiece Components

7.5.1. Disconnecting the Implantation Handpiece Components

To disconnect the implantation handpiece components:

1. Remove the handpiece from the system.
2. Disconnect the tubes from the handpiece and discard them.

> ***Warning***
>
> Used tubes must be discarded as biohazard waste.

3. Unscrew and disconnect the handpiece head from the handpiece body.
4. Unscrew and disconnect the handpiece base from the handpiece body.
5. Remove the piston from the handpiece head.
6. Unscrew and disconnect the stainless steel tube connector from the handpiece head.

7.5.2. Cleaning the Implantation Handpiece Components

To clean the implantation handpiece components:

1. Dismantle the handpiece and remove its components.
2. Soak all components of the implanter head in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for 5 lit of water) at room temperature
(15°C - 25°C) for a minimum of 10 minutes.
3. Remove the components from the ultrasonic bath and clean each component with an appropriate brush (e.g. toothbrush or interdental brush) for a minimum of 20 seconds. Make sure to brush inside and outside of the components.
4. Slide the piston inside the head, and perform 3 back and forth movements, to remove residues from the lumen.
5. Using a syringe, filled with 3 ml of ANIOS CLEAN EXCEL D detergent solution, flush the inside of the head, the needle, and the lumen of adjustment screw. Flush each part with 3 ml of the solution.
6. Use an interdental brush (Ø 8-7 mm) to clean the internal parts of the handpiece body for a minimum of 20 seconds.
7. Rinse each part with Water WFI (Water For Injection) for a minimum of 10 seconds.
8. Once again, soak all components of the implanter head in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for 5 lit of water) at room temperature (15°C - 25°C) for a minimum of one minute.

9. Remove the components from the ultrasonic bath and clean each component with an appropriate brush (e.g. toothbrush or interdental brush) for a minimum of 20 seconds. Make sure to brush inside and outside of the components.

10. Slide the piston inside the head, and perform 3 back and forth movements, to remove residues from the lumen.

11. Using a syringe, filled with 3 ml of ANIOS CLEAN EXCEL D detergent solution at room temperature (15°C - 25°C), flush the inside of the stainless steel rod, joins on the lid and inside the container and the stainless steel rod screw hole. Flush each part with
3 ml of the solution.

12. Rinse each part with Water WFI (Water For Injection) for a minimum of 10 seconds.

10. Dry each part, using a disposable wipe.

11. Visually inspect the parts and make sure that they are clean, intact and in good condition.

- Any soiled part must be re-cleaned.
- Any damaged (e.g. broken, twisted, rusty) part should be discarded.

7.6. Cleaning the Cup

To clean the cup:

1. Remove the cup from the system.
2. Soak the cup in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for 5 lit of water) at room temperature (15°C - 25°C) for a minimum of 10 minutes.
3. Remove the cup from the ultrasonic bath and clean it with an appropriate brush (e.g. a toothbrush) for a minimum of 20 seconds.
4. Rinse the cup with Water WFI (Water For Injection) for a minimum of 10 seconds.
5. Once again, soak the cup in an ultrasonic bath, filled with ANIOS CLEAN EXCEL D 0.5% enzymatic detergent solution (25 ml for 5 lit of water) at room temperature (15°C - 25°C) for a minimum of one minute.
6. Remove the cup from the ultrasonic bath and clean itwith an appropriate brush (e.g. a toothbrush) for a minimum of 20 seconds.
7. Rinse the cup with Water WFI (Water For Injection) for a minimum of 10 seconds.
8. Dry the cup, using a disposable wipe.

7.7. Sterilizing the System Components

The following components can be sterilized as described in this section:

- Cup
- Cup holder
- Handpiece holders
- All components of the waste jar
- All components of the extraction handpiece
- All components of the implantation handpiece
- All components of the incision handpiece, except for the handpiece cable

> ***Caution***
>
> Do not sterilize the cable of the incision handpiece.

Note

The single-use extraction handpiece punches are not pre-sterilized. Each punch must be sterilized before use, and discarded in a hazardous sharps disposal container after use.

Note

Quality of sterilization is dependent on the cleanliness of the components. Make sure to perfectly clean each item befor performing the sterilization.

To sterilize each component:

1. Pack each item in a pouch suitable for steam sterilization.
2. Perform autoclave sterilization, using the following settings:
   - Temperature: 135°C (273.2°F)
   - Duration: 3 minutes
   - Dry time: 20 minutes

7.8. Replacing the Filter

The hydrophobic filter must be replaced it becomes wet and its color changes to gray.

To replace the filter:

1. Turn off the system or place it in the Standby state.
2. Disconnect the filter's vacuum tube from the system.
3. Disconnect the two tubes from the filter.
4. Remove and discard the filter.
5. Install the new filter, as described in Chapter 3.

7.9. Replacing the Extraction Handpiece Contra-Angle Head Nozzle

The nozzle is located on the tip of the contra-angle head, as shown in Figure 7-1. The nozzle should be replaced if a vacuum leak is detected from the contra-angle head.

Figure 7-1. Contra-Angle Head Nozzle

> ***Caution***
>
> The screwdriver, provided for performing the nozzle replacement, is not sterile and cannot be sterilized.
>
> Make sure to clean, lubricate, and sterilize the contra-angle head after replacing the nozzle.

To replace the nozzle of the extraction handpiece contra-angle head:

1. Verify that the contra-angle head is disconnected and removed from the handpiece body.
2. Insert the screwdriver into the two slots of the contra-angle head nozzle.

3. Hold the vacuum part (at the tip of the contra-angle head) with your fingers, to stop it from turning, while unscrewing the nozzle.
4. Remove and dispose of the defective nozzle in an appropriate container used for soiled objects.
5. Insert the new nozzle into the hole at the tip of the contra-angle head.
6. Hold the vacuum part (at the tip of the contra-angle head) with your fingers, to stop it from turning, while screwing the nozzle into the head.
7. Clean the screwdriver with a disinfectant wipe and dry it with a clean, dry cloth.
8. Clean and lubricate the contra-angle head, as described in section 7.3.3 on page 7-7.
9. Sterilize the contra-angle head, as described in section 7.7 on page 7-20.

7.10. Replacing the Implantation Handpiece Head Yellow-Ring/Seal

The repeated movement of the piston can tear/damage or wear out the seal by enlarging the seal's internal diameter, hindering the piston's free movement.

To prevent any infiltration of the liquid inside the tubing connected to the compressor, always make sure that the seal is in good condition.

The implantation handpiece head replacement kit includes:

- 0.8 mm seals (×3)
- 1.0 mm seals (×6)
- 1.25 mm seals (×3)
- Yellow ring
- Screwdriver

To replace the yellow ring and/or seal:

1. Verify that the implanter head is disconnected and removed from the handpiece body.
2. If replacing the seal, select the appropriate seal for the head and piston (e.g. for a 0.8 mm head and piston, use the 0.8 mm seal).
3. Using the yellow screwdriver, unscrew and remove the yellow ring from the handpiece head.
4. Proceed as follows:
   - If replacing the seal:
     - **i.** Remove the old seal.
     - **ii.** Insert the new seal into its groove in the handpiece head.
   - If replacing the yellow ring, discard the old ring and use the new one.
5. Insert the yellow ring into the head.
6. Using the yellow screwdriver, gently screw (but do not over-tighten) the yellow ring to the handpiece head.
7. Align the holes of the seal and the yellow ring by inserting the piston into the hole and moving it back and forth in a twisting motion.
8. Make sure that the piston is sliding properly and that the holes are aligned and centered within their groove.
9. Using the yellow screwdriver, gently tighten the yellow ring to the handpiece head.

Chapter 8
Troubleshooting

Chapter Contents:

8.1. General

This Chapter provides solutions to some problems that may arise while operating the system.

- Section 8.2 (Table 8-1) provides solutions to various system problems.

If you are not able to solve the problem using the provided solutions, contact your local Venus Concept service representative.

8.2. System Problems

Table 8-1. Troubleshooting Problems

Problem	Possible Causes	Solution
Display screen is off.	• Electricity Supply problem • Blown fuses • Software problem	• Check the mains power. • Check the fuses on the back of the unit.
• Low or no vacuum • Displayed Vacuum is OK, but there is no vacuum in handpiece	• Air leakage • Water infiltrated the hydrophobic filter • Handpiece not working properly	• Check all tubing and handpiece connections. • Replace the filter. • Replace the handpiece.
Low or no pressure	• Air leakage • Clogged tubes • Footswitch not connected properly	• Check handpiece connections • Change the tubing. • Check the footswitch connection.

Table 8-1. Troubleshooting Problems

Problem	Possible Causes	Solution
Implantation handpiece does not suck the grafts	• Vacuum problem • Bad tubing connection • Improper implantation handpiece head piston position • Incorrect implanter size	• Check all connections. • Adjust the piston position by turning the handpiece's adjusting screw. • Adjust the Implantation Pressure. • Change the tubing. • Use a syringe to unblock the handpiece by flushing saline solution into it. • Replace the implanter with one with the correct diameter.

Table 8-1. Troubleshooting Problems

Problem	Possible Causes	Solution
Grafts are not sucked into the extracting handpiece and/or do not go into the graft collector.	• Vacuum problem • Clogged punch or contra-angle head	• Check handpiece connection. • Replace the punch. • Clean or replace the contra-Angle head. • Replace contra-angle head nozzle.
No or low contra-Angle motor rotation	• Improper handpiece connection • Low motor speed setting • Clogged or damaged contra-angle head • Motor malfunction	• Verify proper handpiece connection. • Adjust the Motor Speed setting. • Clean or replace the contra-Angle head. • Replace the motor.

NeoGraft®

Chapter 9

Specifications

Chapter Contents:

9.1. System Specifications

Dimensions:	W × D × H (not packed): 45 × 40 × 100 cm (17.7 × 15.8 × 39.4inch)
Weight:	36 kg (79.4 lbs)
Color:	White and gray
Electrical requirements:	100 - 240 VAC, 50 - 60 Hz
Main fuses:	2 × 5 × 20 T2AH – 250 VAC (qty = 2)
Operating temperature:	+15°C to +25°C (+59°F to +77°F)
Humidity conditions:	Max. 60%

Maximum internal pressure:	2.5 bars
Implantation handpiece pressure:	0 to 2.5 bars
Contra-angle head rotation speed:	0 to 3000 rpm
Maximum vacuum:	-800 mbars
Device Classification:	I in U.S.A II in Canada IIa in europe
Applied parts:	B type

9.2. List of approved accessories

The following table list the different accessories with their own EC mark which can be supplied / used with the Neograft 2.0®.

These accessories have been selected and tested during the conception process of the Neograft 2.0®. The use of an unapproved accessory is the responsibility of the user.

Designation	Reference	Manufacturer	CE Mark
Sterile blade	SP90	Swann Morton	CE0086
Sterile blade	SP91	Swann Morton	CE0086
Extractor cleaning spray	AquaCare	Bien air	CE
Extractor cleaning spray	Spraynet	Bien air	CE
Extractor Lubricating spray	Lubrifluid	Bien air	CE
Stainless steel cup	308SSB	Agencinox	CE
Extraction tubing	PH-96-3560 PH-96-3555	SUMI	CE 1011
Tubing implantation	PH-96-2555	SUMI	CE 1011
Punch 0.8	1302240	Electronique du Mazet	CE0459
Punch 0.9	1304353	Electronique du Mazet	CE0459
Punch 1.0	1302241	Electronique du Mazet	CE0459
Punch 1.25	1302242	Electronique du Mazet	CE0459

NeoGraft®

Appendix A

Clinical Guide

Chapter Contents:

A.1. Introduction

NeoGraft 2.0® is a minimally-invasive hair transplantation system.

The system uses three separate handpieces, for extracting the grafts, making incisions at the recipient site, and implanting the grafts.

Figure A-1 shows the three handpieces that are used with the system.

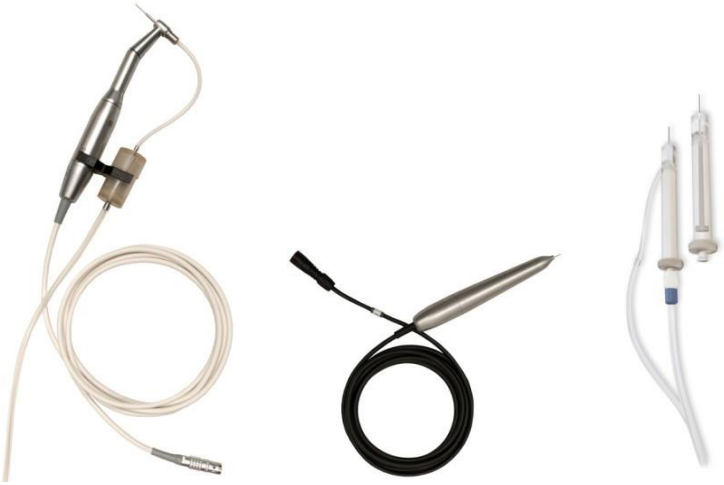


Figure A-1. Extraction (Left), Incision (Middle) and Implantation (Right) Handpieces

A.2. Indications

The NeoGraft 2.0® is a surgical instrument, composed of motors and accessories, and is indicated for use during surgical procedures for cutting soft tissues.

The NeoGraft 2.0® is intended for suction-assisted follicular extraction and re-implantation of autografts.

The NeoGraft 2.0® is used for permanent hair transplantation for all skin types, all hair densities, and any type of baldness pattern deemed treatable by the physician.

A medical physician should determine the patient eligibility for a hair transplantation procedure. Device can be used on both male and female patients.

A.3. Contraindications

- Any Active condition in the surgical area, such as infections, psoriasis, eczema, and rash
- Any form of skin cancer in or nearby the treated area
- History of keloid scarring or abnormal wound healing
- Hemophilia or other blood clotting conditions
- Over the counter medications with anticoagulative properties
- Use of certain drugs, such as beta blockers or antidepressants, that may cause telogen effluvium, a type of hair loss which can affect the entire scalp
- Hormonal replacement therapy or thyroid issues (active thyroid disease)
- Uncontrolled hypertension

A.4. Warnings

- The physician should perform a hair transplantation procedure only after receiving adequate training and familiarity with hair transplantation safety and with the device.
- The physician should perform a hair transplantation procedure only after a thorough review and confirmation of any medications/drugs the patient may be taking.
- Observe all safety precautions, as described in this Clinical Guide and elsewhere in this User Manual.
- If hair loss stems from genetic factors, such sensitivity to DHT or male-pattern baldness, hair loss may continue and adversely affect the results.

A.5. Precautions

Caution is advised in treating patients with any systematic disorder/change, including:

- History of bleeding coagulopathies or use of anticoagulants, with the exception of preventive low dose aspirin medication
- Pacemaker, internal defibrillator, or any active implant in the body
- Severe concurrent conditions, such as cardiac disorders
- Pregnancy and nursing

A.6. Complications and Side Effects

The most common side effects are minor pain and edema (redness and swelling) which generally occurs immediately after surgery and typically resolves within 48 - 96 hours. Post-operative itching in the recipient area is also a common side effect after a hair transplant. This effect typically subsides when the crusting on the scalp flakes off, typically within two weeks.

Other minor side effects may include:

- Donor alopecia
- Follicular cysts
- Post-operative bleeding
- Shock loss
- Visible scarring
- Infection

A.7. Patient Consultation

The physician should conduct a patient consultation prior to surgery and provide detailed information on the nature of their problem, the surgical options, risks, benefits, complications, and anticipated outcome prior to surgery. The patient consultation should also include a medical history and examination with particular attention paid to contraindications and any drugs which may be in the patient's system at the time of the surgery.

A.8. Treatment Procedure

Prior to extraction, the donor site should be prepped by shaving down the area, ear to ear, with a zero-guard trimmer. The area should then be properly cleaned and disinfected per common practice.

A.8.1. Treatment Parameter Settings

There are only two adjustable treatment parameters on the NeoGraft 2.0® system, which are Motor Speed and Implantation Pressure:

- The extraction handpiece, utilizing the system's vacuum (which is not adjustable), cores and extracts the graft after 3-5 rotations of the punch. A starting Motor Speed of 15% has been found to work with most hair densities. The Motor Speed can be set to higher or lower from this starting point.
- The implantation handpiece inserts the graft into the recipient site. A starting Implantation Pressure of 1.0 bar has been found to work with most hair densities. The Implantation Pressure can be set to higher or lower from this starting point, based on the patient's tissue density.

A.8.2. General Principles

The NeoGraft 2.0® system is designed to enable the most minimally invasive hair transplantation possible.

Prior to the start of the procedure, the Physician should examine the hair density and the donor quality, and determine the appropriate punch size to use.

Figure A-2 shows the graft extraction process.

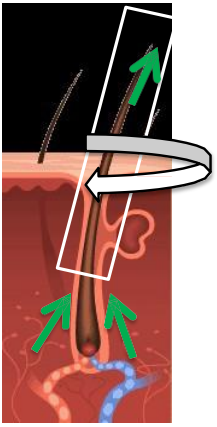


Figure A-2. Graft Extraction

The extraction handpiece punctures the tissue, and as the punch rotates it scores the depth of tissue. The punch is limited in depth due to a depth limiter (which is set at the start of the procedure). The punch penetration is limited to just above the bulb of the graft. As the punch is removed, the system's mild suction extracts the graft through the handpiece, within which it flows (less than 4 inches) into the graft collection canister.

The recipient sites are created, using the incision handpiece, prior to implanting the grafts.

During the implantation phase, the implantation handpiece injects each graft into the recipient site without manipulating the bulb of the graft.

Treatment with the NeoGraft 2.0 system, with the two traits described above (with zero bulb interaction), allows the least amount of trauma to the bulb of the graft.

A.9. Handpiece Placement and Technique

A.9.1. Extraction Handpiece

Use the extraction handpiece as follows:

1. Center the punch over the follicular unit and pierce the skin at the same angle as the hair.
2. Once the punch has reached the depth limiter, perform an extract and drag technique, in which the graft is removed at an angle adjacent to the scalp.
3. Once grafts are harvested, they rest in the graft collection canister until they are ready to be sorted by the provider. The sorting, counting and trimming of the grafts are carried out manually.

A.9.2. Incision Handpiece

Use the incision handpiece as follows:

1. Load the incision handpiece with a blade or a surgical needle to make the recipient slits.
2. Make slits in the direction of the existing or the desired hair line.

> ***Note***
>
> It is the user's responsibility to determine the density of the recipient site incision, based on each individual patient's hair type and density.

A.9.3. Implantation Handpiece

Use the implantation handpiece as follows:

1. Load the grafts, one at a time, from the sterile field into the implantation handpiece.
2. Eject the graft into the slit (one graft per slit) in the direction of the existing hairs.

After placement of grafts, during the healing process, the recipient sites will close on their own.

A.10. Cleaning and Sterilization

Clean and sterilize the handpieces and other relevant system components, as described in Chapter 7.

A.11. Post-Treatment Procedure

As with most medical procedures, physicians may differ with after-care. Below are a few recommendations which have been deemed as best practices for post-op hair transplants:

- Immediately after the treatment a bandage with antibiotic ointment should be applied to the donor site and remain there for 48 hours post-op. The bandage should then be removed and redressed at 24-hour intervals.
- The recipient sites and newly-implanted grafts can be gently sprayed with saline solution to keep the area moist and to decrease any dryness and itching.
- Patients should not use a hat or any type of hair covering which may dislodge the implanted grafts for two weeks post-op.
- To minimize hyperpigmentation, patients should be asked to avoid excessive sun exposure for two weeks post-op.
- Patients should refrain from any aggressive hair washing and shower spray, and from directly contacting the implanted grafts, until they have been secured in the scalp, typically after two weeks. Patients may massage the donor site, but are not to touch the recipient area with their fingers for 7 days post op, as this may cause the grafts to dislodge. After 7 days they may begin to wash their hair normally.
- Patients should wait for one month post-op before resuming Rogaine 5% foam.
- Patients must wait 6-8 weeks before they can dye their hair. It is recommended to use semi-permanent dye so as not to damage their grafts.
- Follow-up examinations should be performed as prescribe by the physician.

Appendix B
Manufacturer Warranty

Chapter Contents:

B.1. Manufacturer Warranty

Your authorized distributor warranties your device against all defects, provided that:

- Any and all repairs, modifications and expansion of the unit and adjustments of the NeoGraft 2.0® are made solely by Venus Concept or its authorized distributor.
- Conditions and facilities in the operating room meet all relevant legal requirements.
- NeoGraft 2.0® is used only by qualified and trained personnel in accordance with the instructions in this User Manual.
- The machine is used solely for the intended use for which it was designed.
- NeoGraft 2.0® is regularly maintained according to the instructions of the manufacturer. All legal requirements concerning the use of the device are respected.

Warranty conditions:

- Inappropriate use of the NeoGraft 2.0® and/or failure to maintain it properly relieves Venus Concept and its authorized distributors and representatives from any responsibility whatsoever in case of damages, injuries, defects, malfunctions, etc.
- The authorized distributor provides warranty and after-sales service. The warranty covers parts and labor. All other services are determined on the basis of the conditions set by the distributor.
- The guarantee is void in case of failure to comply strictly with the instructions for use of the NeoGraft 2.0® in this User Manual.
- NeoGraft 2.0® has one year's warranty.
- Transportation cost and packaging are not included in the warranty.

B.2. Warranty Certificate

This form must be returned to Venus Concept or its authorized distributor upon delivery of your device.

I, Mr., Ms., Doctor _____

Acknowledge receipt of NeoGraft 2.0® Serial No. _____ in working order and all accessories that match the packing list.

I acknowledge having received all necessary instructions for proper use, maintenance, cleaning, sterilization, etc. of the device.

I bind to use only consumables and accessories supplied by Venus Concept and its authorized distributor.

I acknowledge having read the User Manual thoroughly and having well noted the conditions of the warranty and after-sale service.

If Venus Concept or its distributor does not receive this form duly completed, no more than one month after delivery, Venus Concept will be absolved from any responsibility regarding guarantee and after-sale service or any consequence due to a device fault.

Date _____

Venus Concept or its Authorized Distributor	Customer