

PureGraft® 250 System

INSTRUCTIONS FOR USE EN IN THE UNITED STATES AND CANADA PureGraft® 250 System	INSTRUCTIONS FOR USE ALL COUNTRIES EXCEPT UNITED STATES AND CANADA PureGraft® 250 System
DESCRIPTION The PureGraft® 250 System is a sterile, single use, closed system intended for the preparation and delivery of autologous fat grafts back to the same patient for cosmetic and reconstructive surgery applications. The PureGraft 250 System is composed of the following components: • Puregraft 250 Bag • Puregraft 250 Drain Bag • Combined Adapter	EN: INSTRUCTIONS FOR USE This product is certified as a medical device in the European Union under the Medical Device Directive 93/42/EEC by SGS CE1639, exclusively for the indications of autologous fat transfer. Other non-medical uses such as aesthetic body contouring ascribed to this device are not within the scope of CE certification, and users should be aware product performance and/or safety has not been evaluated by SGS for these purposes.
For optimal performance, the PureGraft 250 System should be used in conjunction with the Puregraft Instrument Set. This set is composed of the following reusable, autoclavable components: • Puregraft Easel • Puregraft Slider	DESCRIPTION The Puregraft® 250 System is a sterile, single use, closed system intended for the preparation and delivery of autologous fat grafts back to the same patient for plastic and reconstructive surgery applications. The Puregraft 250 System is composed of the following components: • Puregraft 250 Bag • Puregraft 250 Drain Bag • Combined Adapter

The Puregraft Easel was designed as a stand to hold the Puregraft 250 Bag for optimal fluid flow and the Puregraft Slider facilitates the movement of excess fluids away from the tissue and into the Puregraft 250 Drain Bag while guiding the tissue towards the port labeled "Tissue" for graft extraction. For storage, sterilization, and proper instructions for usage of these products, see the separate Instructions. For Use included in the product packaging of the Puregraft Instrument Set.

INDICATIONS FOR USE

The Puregraft 250 System is indicated for use in the harvesting, filtering and transferring of autologous fat tissue for reinjecting back into the same patient for aesthetic body contouring.

CONTRAINDICATIONS

The following are contraindications for use of the Puregraft 250 System:

- Intraosseous applications.

STERILITY

- The Puregraft 250 System is sterilized with gamma irradiation

STORAGE AND HANDLING

- Use only if sterilization indicator is red.

WARNINGS

- Single Use Only – Do Not Re-use.
- For Autologous Use Only
- The harvested fat is only to be used for reimplantation without any additional manipulations. Any manipulations beyond those outlined in the Instructions For Use are not recommended.
- Do not attempt to use the Puregraft 250 System during the same procedure. Re-use may compromise the sterility and adversely affect performance of the system.
- This device will not, in and of itself, produce significant weight reduction.
- This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes, heart or lung diseases, circulatory diseases, or obesity.
- The volume of blood loss and endogenous body fluid may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely fluid replacement is essential for patient safety.
- Do not overfill the Puregraft 250 Bag with more than 400 mL of total volume of tissue and/or washing solution.

PRECAUTIONS

- Inspect the Puregraft 250 System packaging for signs of damage prior to using.
- The Puregraft 250 System is for single use only and must be used immediately after removal from the sterile packaging.
- Discard the entire Puregraft 250 System if the packaging is damaged, opened or the sterilization indicator is invalid.
- Aseptic techniques must be used to minimize the possibility of contamination of the Puregraft 250 System.
- Treat all blood and fluids using Universal Precautions (Blood-borne Pathogen Precautions).
- This device is designed to contour the body by removing localized deposits of excess fat through small incisions.
- Use of this device is limited to those physicians who, by means of residency training or sanctioned continuing medical education, have demonstrated proficiency in suction lipoplasty.
- Results of this procedure will vary depending upon patient age, surgical skills, and experience of the surgeon
- Results of this procedure may or may not be permanent.
- The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.
- The Puregraft 250 System is recommended to be used in combination with a Toomey style syringe and the supplied Combined Adapter for tissue transfer into and out of the system.
- The Puregraft 250 System is intended to receive adipose tissue harvested with a 3mm diameter Mercedes-Tip Cannula.
- Overinflating or overfilling of the Puregraft 250 Bag may result in a biohazard to the operating staff and/or device malfunction

OPERATING INSTRUCTIONS

PREPARATIONS:

1. Place sterile Puregraft Easel and Slider in an upright operating position.
2. Open Puregraft pouches containing the Puregraft 250 System, and hang the Puregraft 250 Bag on the Easel. Place the Puregraft 250 Drain Bag well below the level of the Puregraft 250 Bag, and ensure that the pinch clamp is positioned near the Puregraft 250 Bag and in the open position.
3. Note: Lactated Ringer's can be added to the port labeled "Inlet" by using the optional Inlet Tubing Set contained in the Puregraft 250 System, or directly into the port labeled "Inlet" using a Luer Lock syringe. Lactated Ringer's can also be added via port labeled "Tissue" using a Combined Adapter and Toomey style syringe. If using the Inlet Tubing Set, connect the male Luer end to the port labeled "Inlet" on the Puregraft 250 Bag, and hand off the tubing so that the Lactated Ringer's bag can be spiked. Close the pinch clamp to prevent Lactated Ringer's from entering the Puregraft 250 Bag at this time. If using a syringe, pour Lactated Ringer's into a sterile bowl on the sterile field.

TISSUE COLLECTION AND ADDITION:

4. Aseptically collect adipose tissue into a Toomey style syringe and attach a Combined Adapter to each filled syringe.
5. Note: If alternate means of adipose tissue harvest are used, tissue should be aseptically transferred to the Puregraft 250 Bag using Toomey syringes or other tubing and connectors.
6. Attach the tissue-filled syringe to the Puregraft 250 Bag by placing the male portion of the Combined Adapter into the port labeled "Tissue" and pushing the syringe plunger to inject the syringe contents into the bag. Note: Minor fluid seepage can occur during introduction and removal of tissue through the port labeled "Tissue".
7. Injecting 30-50% more tissue than the total desired graft volume, for a total excess fluid is draining into the Puregraft 250 Drain Bag.

TISSUE VOLUME (mL)	WASH VOLUME (mL)
50	50
100	100
150	150
200	150
250	150

8. Agitate the tissue-filled Puregraft 250 Bag manually for approximately 15 seconds ensuring that all corners of the bag are accessed.
9. Open pinch clamp on Puregraft 250 Drain Bag and allow fluid to drain from the Puregraft 250 Bag into the Puregraft 250 Drain Bag for approximately 3 minutes, then close pinch clamp.
10. Repeat Steps 7 & 8 to repeat tissue wash, and open pinch clamp on Puregraft 250 Drain Bag to drain excess rinse fluid for 1-5 minutes depending on preferred graft hydration level.
11. Use Puregraft Slider to guide tissue towards port labeled "Tissue". Close the pinch clamp to the Puregraft 250 Drain Bag.

GRAFT REMOVAL:

12. Aseptically attach a Combined Adapter to an empty sterile Toomey syringe.
13. Attach the sterile syringe to the Puregraft 250 Bag by placing the male portion of the Combined Adapter into the port labeled "Tissue".
14. Remove tissue from the Puregraft 250 Bag by slowly pulling the syringe plunger until syringe is filled. Use the Puregraft Slider as needed to extract the maximum amount of tissue from the Puregraft 250 Bag.
15. Once tissue is removed from the bag, properly dispose of all disposable components using Universal Precautions For Blood-borne Pathogens.

TISSUE VOLUME (mL)	WASH VOLUME (mL)
50	50
100	100
150	150
200	150
250	150

TISSUE VOLUME (mL)	WASH VOLUME (mL)
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100	100
150	150
200	150
250	150

8. Agitate the tissue-filled Puregraft 250 Bag manually for approximately 15 seconds ensuring that all corners of the bag are accessed.
9. Open pinch clamp on Puregraft 250 Drain Bag and allow fluid to drain from the Puregraft 250 Bag into the Puregraft 250 Drain Bag for approximately 3 minutes, then close pinch clamp.
10. Repeat Steps 7 & 8 to repeat tissue wash, and open pinch clamp on Puregraft 250 Drain Bag to drain excess rinse fluid for 1-5 minutes depending on preferred graft hydration level.
11. Use Puregraft Slider to guide tissue towards port labeled "Tissue". Close the pinch clamp to the Puregraft 250 Drain Bag.

TISSUE VOLUME (mL)	WASH VOLUME (mL)
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150	150
200	150
250	150

8. Agitate the tissue-filled Puregraft 250 Bag manually for approximately 15 seconds ensuring that all corners of the bag are accessed.
9. Open pinch clamp on Puregraft 250 Drain Bag and allow fluid to drain from the Puregraft 250 Bag into the Puregraft 250 Drain Bag for approximately 3 minutes, then close pinch clamp.
10. Repeat Steps 7 & 8 to repeat tissue wash, and open pinch clamp on Puregraft 250 Drain Bag to drain excess rinse fluid for 1-5 minutes depending on preferred graft hydration level.
11. Use Puregraft Slider to guide tissue towards port labeled "Tissue". Close the pinch clamp to the Puregraft 250 Drain Bag.

TISSUE VOLUME (mL)	WASH VOLUME (mL)
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TISSUE VOLUME (mL)	WASH VOLUME (mL)
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100	100
150	150
200	150
250	150

8. Agitate the tissue-filled Puregraft 250 Bag manually for approximately 15 seconds ensuring that all corners of the bag are accessed.
9. Open pinch clamp on Puregraft 250 Drain Bag and allow fluid to drain from the Puregraft 250 Bag into the Puregraft 250 Drain Bag for approximately 3 minutes, then close pinch clamp.
10. Repeat Steps 7 & 8 to repeat tissue wash, and open pinch clamp on Puregraft 250 Drain Bag to drain excess rinse fluid for 1-5 minutes depending on preferred graft hydration level.
11. Use Puregraft Slider to guide tissue towards port labeled "Tissue". Close the pinch clamp to the Puregraft 250 Drain Bag.

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14. Remove tissue from the Puregraft 250 Bag by slowly pulling the syringe plunger until syringe is filled. Use the Puregraft Slider as needed to extract the maximum amount of tissue from the Puregraft 250 Bag.
15. Once tissue is removed from the bag, properly dispose of all disposable components using Universal Precautions For Blood-borne Pathogens.

European Reporting Requirements: Any serious incident that has occurred in relation to the device should be reported to Bimini Health Tech and the competent authority of the Member State in which the you, as the user and/or patient, are established.

FR: MODE D'EMPLOI

Ce produit est certifié en tant que dispositif médical dans l'Union européenne en vertu de la directive sur les dispositifs médicaux 93/42/EEC par SGS CE1639, exclusivement pour les indications de transfert de graisse autologue. Les autres utilisations non médicales, telles que les contours esthétiques du corps attribués à cet appareil ne sont pas couvertes par la certification CE et les utilisateurs doivent savoir que la performance et / ou la sécurité du produit n'a pas été évaluée par SGS à ces fins.

DESCRIPTION

Le système Puregraft® 250 est stérile, à usage unique, à circuit fermé, destiné à la préparation et à la réimplantation de greffes de tissu adipeux autologue au/à la même patient(e) pour des applications de chirurgie plastique et reconstructive. Le système Puregraft 250 est constitué des composants suivants :

- Poche Puregraft 250
- Poche de drainage Puregraft 250
- Adaptateur Combiné

Pour une performance optimale, le système Puregraft 250 doit être utilisé avec l'ensemble d'instruments Puregraft. Cet ensemble comprend les composants réutilisables, autoclavables suivants:

- Chevalet Puregraft
- Glissière Puregraft

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CONTRAINDICATIONS

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STERILITY

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STORAGE AND HANDLING

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WARNINGS

- Single Use Only – Do Not Re-use.
- For Autologous Use Only
- The harvested fat is only to be used for reimplantation without any additional manipulations. Any manipulations beyond those outlined in the Instructions For Use are not recommended.
- Do not attempt to use the Puregraft 250 System during the same procedure. Re-use may compromise the sterility and adversely affect performance of the system.
- This device will not, in and of itself, produce significant weight reduction.
- This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes, heart or lung diseases, circulatory diseases, or obesity.
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PRECAUTIONS

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- The Puregraft 250 System is intended to receive adipose tissue harvested with a 3mm diameter Mercedes-Tip Cannula.
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OPERATING INSTRUCTIONS

PREPARATIONS:

1. Place sterile Puregraft Easel and Slider in an upright operating position.
2. Open Puregraft pouches containing the Puregraft 250 System, and hang the Puregraft 250 Bag on the Easel. Place the Puregraft 250 Drain Bag well below the level of the Puregraft 250 Bag, and ensure that the pinch clamp is positioned near the Puregraft 250 Bag and in the open position.
3. Note: Lactated Ringer's can be added to the port labeled "Inlet" by using the optional Inlet Tubing Set contained in the Puregraft 250 System, or directly into the port labeled "Inlet" using a Luer Lock syringe. Lactated Ringer's can also be added via port labeled "Tissue" using a Combined Adapter and Toomey style syringe. If using the Inlet Tubing Set, connect the male Luer end to the port labeled "Inlet" on the Puregraft 250 Bag, and hand off the tubing so that the Lactated Ringer's bag can be spiked. Close the pinch clamp to prevent Lactated Ringer's from entering the Puregraft 250 Bag at this time. If using a syringe, pour Lactated Ringer's into a sterile bowl on the sterile field.

TISSUE COLLECTION AND ADDITION:

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7. Injecting 30-50% more tissue than the total desired graft volume, for a total volume between 50-250mL of tissue into the Puregraft 250 Bag by repeating step 5 above. Ensure excess fluid is draining into the Puregraft 250 Drain Bag.

TISSUE VOLUME (mL)	WASH VOLUME (mL)
50	50
100	100
150	150
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250	150

8. Agitate the tissue-filled Puregraft 250 Bag manually for approximately 15 seconds ensuring that all corners of the bag are accessed.
9. Open pinch clamp on Puregraft 250 Drain Bag and allow fluid to drain from the Puregraft 250 Bag into the Puregraft 250 Drain Bag for approximately 3 minutes, then close pinch clamp.
10. Repeat Steps 7 & 8 to repeat tissue wash, and open pinch clamp on Puregraft 250 Drain Bag to drain excess rinse fluid for 1-5 minutes depending on preferred graft hydration level.
11. Use Puregraft Slider to guide tissue towards port labeled "Tissue". Close the pinch clamp to the Puregraft 250 Drain Bag.

GRAFT REMOVAL:

12. Aseptically attach a Combined Adapter to an empty sterile Toomey syringe.
13. Attach the sterile syringe to the Puregraft 250 Bag by placing the male portion of the Combined Adapter into the port labeled "Tissue".
14. Remove tissue from the Puregraft 250 Bag by slowly pulling the syringe plunger until syringe is filled. Use the Puregraft Slider as needed to extract the maximum amount of tissue from the Puregraft 250 Bag.
15. Once tissue is removed from the bag, properly dispose of all disposable components using Universal Precautions For Blood-borne Pathogens.

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GRAFT REMOVAL:

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15. Once tissue is removed from the bag, properly dispose of all disposable components using Universal Precautions For Blood-borne Pathogens.

European Reporting Requirements: Any serious incident that has occurred in relation to the device should be reported to Bimini Health Tech and the competent authority of the Member State in which the you, as the user and/or patient, are established.

(Tissu), en vue de l'extraction de la greffe. Pour les instructions de stockage, de stérilisation et d'utilisation correcte de ces produits, veuillez consulter les Instructions d'utilisation séparées, incluses dans l'emballage du produit de l'ensemble d'instruments Puregraft.

CONSIGNES D'UTILISATION

L'utilisation du système Puregraft 250 est indiquée pour le prélèvement, le filtrage et le transfert de tissu adipeux autologue (ATF ou Autologous Fat Tissue), en vue d'une réinjection au/à la même patient(e), dans le cadre des procédures de transfert de tissu adipeux autologue (ATF).

CONTRE-INDICATIONS

Les contre-indications relatives à l'utilisation du système Puregraft 250 sont les suivantes:

- Applications intraosseuses.

STÉRILITÉ

- Le système Puregraft 250 est stérilisé par irradiation aux rayons gamma.

STOCKAGE ET MANIPULATION

- Utiliser uniquement si l'indicateur de stérilisation est rouge.

AVERTISSEMENTS

- À usage unique – Ne réutiliser pas ce système.
- Exclusivement réservé pour usage autologue.
- Le chirurgien doit être familiar avec le fonctionnement du système Puregraft 250 et avec la procédure chirurgicale, avant de procéder à l'intervention.
- Ne tentez pas de réutiliser le système Puregraft 250 au cours de la même procédure. Une réutilisation peut compromettre la stérilité, et peut avoir un effet dévalorable sur la performance du système.
- La réutilisation d'un dispositif à usage unique présente des risques significatifs pour le fonctionnement correct du dispositif, dû à l'absence d'instructions d'utilisation du fabricant (IFU ou Instructions For Use).
- La réutilisation et/ou le nettoyage d'un dispositif à usage unique peut avoir des conséquences nocives pour le patient(e), dû à la possibilité de réactions chimiques inconnues au dispositif et/ou de l'exposition du/ de la patient(e) à des agents de nettoyage résiduels.
- La réutilisation d'un dispositif à usage unique pose des risques graves pour le/la patient(e), y compris une perte de la stérilité, pouvant causer une infection.
- La réutilisation d'un dispositif à usage unique pose des risques graves pour le/la patient(e), y compris la transmission de maladies infectieuses d'un patient(e) à l'autre.
- Outre les risques de transmission de maladies infectieuses, la réutilisation des dispositifs à usage unique entraîne des risques graves, pour le/la patient(e), y compris la défaillance mécanique immédiate et/ou prématurée du dispositif, dû à une dégradation matérielle, qui peut mener à une réduction ou détérioration de la performance du produit allant jusqu'à une défaillance catastrophique du dispositif.
- La re-stérilisation de ce dispositif peut résulter en un endommagement important du dispositif ou en la perte de l'intégrité du dispositif.
- Il ne faut pas suremplier la poche Puregraft 250 avec plus de 400mL du volume total de tissu et/ou de solution de lavage.
- Arrêtez immédiatement l'introduction de tout liquide ou tissu dans la poche Puregraft 250, si le matériau de la poche commence à se déformer, car ceci peut entraîner la perte d'intégrité de la poche et la création d'un biohazard pour le personnel exécutant l'intervention.

STORAGE AND HANDLING

- Use only if sterilization indicator is red.

WARNINGS

- Single Use Only – Do Not Re-use.
- For Autologous Use Only
- The surgeon should be familiar with the operation of the Puregraft 250 System and the surgical procedure prior to performing the surgery.
- Do not attempt to re-use the Puregraft 250 System during the same procedure. Re-use may compromise the sterility and adversely affect performance of the system.
- Re-use of a single-use device presents significant risks to the proper operation of the device due to absence of the manufacturer's instructions for Use (IFU).
- Re-use and/or cleaning of a single-use device may result in harm to the patient due to unknown chemical interactions with the device and/or exposure of residual cleaning agents to the patient.
- Re-use of a single-use device poses serious risks for the patient to include loss of sterility which could lead to infection.
- Re-use of a single-use device poses serious risks for the patient to include the transmission of infectious disease from one patient to another.
- In addition to infectious diseases transmission risks, the re-use of a single-use device poses serious risks for the patient to include immediate and/or premature mechanical failure of the device due to material degradation which could lead to reduced or impaired performance of the product up to and including catastrophic failure of the device.
- Re-sterilization of this device may result in significant damage or loss of integrity to the device.
- Do not overfill the Puregraft 250 Bag with more than 400mL of total volume of tissue and/or washing solution.
- Immediately stop the introduction of any fluid or tissue into the Puregraft 250 Bag if the material of the bag begins to deform leading to loss of integrity of the bag and the creation of a biohazard to the operating staff.

PRECAUTIONS

- Inspect the packaging of the Puregraft 250 System before use. Do not use if the sterilization indicator is red.
- The Puregraft 250 System is for single use only and must be used immediately after removal from the sterile packaging.
- Discard the entire Puregraft 250 System if the packaging is damaged, opened or the sterilization indicator is invalid.
- Aseptic techniques must be used to minimize the possibility of contamination of the Puregraft 250 System.
- Treat all blood and fluids using Universal Precautions (Blood-borne Pathogen Precautions).
- This device is designed to contour the body by removing localized deposits of excess fat through small incisions.
- Use of this device is limited to those physicians who, by means of residency training or sanctioned continuing medical education, have demonstrated proficiency in suction lipoplasty.
- Results of this procedure will vary depending upon patient age, surgical skills, and experience of the surgeon
- Results of this procedure may or may not be permanent.
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- The Puregraft 250 System is recommended to be used in combination with a Toomey style syringe and the supplied Combined Adapter for tissue transfer into and out of the system.
- The Puregraft 250 System is intended to receive adipose tissue harvested with a 3mm diameter Mercedes-Tip Cannula.
- Overinflating or overfilling of the Puregraft 250 Bag may result in a biohazard to the operating staff and/or device malfunction

OPERATING INSTRUCTIONS

1. Place the cheville et la glissière stériles Puregraft dans une position de fonctionnement redressée.
2. Ouvrez les emballages extérieurs Puregraft contenant le système Puregraft 250, puis accrochez la poche Puregraft 250 sur le chevalet. Placez la poche de drainage Puregraft 250 bien au-dessous du niveau de la poche Puregraft 250, et assurez que la pince est positionnée près de la poche Puregraft 250 et qu'elle est dans la position ouverte.
3. Note: On peut ajouter de la solution lactée de Ringer à l'orifice étiqueté "Inlet" (Admission) en utilisant le jeu de tubulures d'admission optionnel, ou bien directement dans l'orifice étiqueté "Inlet" (Admission) en utilisant une seringue Luer Lock. On peut également ajouter de la solution lactée de Ringer par le bas de l'orifice étiqueté "Tissue" (Tissue), en utilisant un Adaptateur Combiné et une seringue de type Toomey. Si vous utilisez le jeu de tubulures d'admission, connectez l'extrémité Luer mâle à l'orifice étiqueté "Inlet" (Admission) sur la poche Puregraft 250, puis déposez la tubulure sur la solution lactée de Ringer et laissez la seringue se remplir. Fermez la pince pour empêcher que la solution lactée de Ringer ne puisse pénétrer dans la poche Puregraft 250 à ce moment-là. Si vous utilisez une seringue, versez la solution lactée de Ringer dans un récipient stérile dans le champ stérile.

4. Collectez aseptiquement le tissu adipeux dans une seringue de type de Toomey et connectez un Adaptateur Combiné à chaque seringue remplie.
5. Note: Si des moyens différents de prélèvement de tissu adipeux sont utilisés, le tissu doit être transféré aseptiquement dans la poche Puregraft 250 en utilisant des seringues de Toomey ou autres tubulures et connecteurs.
6. Fournir la seringue remplie de tissu à la poche Puregraft 250, en plaçant la partie mâle de l'Adaptateur Combiné dans l'orifice étiqueté "Tissue" (Tissue), puis poussez sur le piston de la seringue pour vider le contenu de la seringue dans la poche.
7. Note: Un épanchement mineur de liquide peut se produire durant l'introduction et le retrait du tissu à travers l'orifice étiqueté "Tissue" (Tissue).
8. Introduisez 30-50% de tissu dans la poche, par rapport au volume de greffe total souhaité, pour obtenir un volume total entre 50-250 mL de tissu adipeux dans la poche Puregraft 250, en répétant l'étape 5 ci-dessus.
9. Agitez le tissu rempli Puregraft 250 Bag manuellement pendant environ 15 secondes, afin d'assurer que tous les coins de la poche sont atteints.
10. Répétez les étapes 7 et 8 à répétition le lavage de tissu, puis ouvrez la pince sur la poche de drainage Puregraft 250 pour évacuer l'excès de liquide de rinçage pendant 1-5 minutes, selon le taux d'hydratation de greffe préféré.
11. Utilisez la glissière Puregraft pour guider le tissu vers l'orifice étiqueté "Tissue" (Tissue). Fermez la pince sur la poche de drainage Puregraft 250.

sprit. Gelact eerde Ringer-oplossing kan ook via de met "Tissue" gelabelde opening worden toegevoegd met een Gecombineerde Adapter en een Toomey-type spuit. Verder bij gebruik van de inlaatslangenset de materialen Luer-aansluiting met de met "Inlet" gelabelde opening van de Puregraft 250-zak en gaaf de slang af zodat de gelacteerde Ringer-oplossing kan worden aangesloten. Sluit de knijpklem om te voorkomen dat er gelacteerde Ringer-oplossing op dat moment in de Puregraft 250-zak terechtkomt. Giet bij gebruik van een spuit gelacteerde Ringer-oplossing in een steriele schaal op het steriele veld.

VERZAMELEN EN TOEGEVOEGEN WEEFSEL:

- Verzamel weefsel aseptisch in een Toomey-type spuit en plaats een Gecombineerde Adapter op elke gevulde spuit.
- NB: Als er een alternatieve methode voor weefselextractie wordt gebruikt, dient het weefsel aseptisch met Toomey-spuiten of andere slangen en verbindingen naar de Puregraft 250-zak te worden overgebracht.
- Plaats de met weefsel gevulde spuit in de Puregraft 250-zak door de mannelijke kant van de Gecombineerde Adapter in de in de "Tissue" gelabelde opening uit te steken en druk de zuiger van de spuit in om de inhoud in de zak te laten lopen.
- NB: Er kan tijdens het inbrengen en verwijderen van weefsel via de met "Tissue" gelabelde opening een beetje vocht weglopen.
- Voeg 30-50% meer weefsel aan de Puregraft 850-zak toe dan het totaal gewenste transplantaatvolume voor een totaal weefselvolume van 50-250 ml door bovenstaande stap 5 te herhalen.

WASSEN EN VERWERKEN TRANSPLAANT:

- Sluit de knijpklem op de Puregraft 250-afvalzak. Open bij gebruik van de inlaatslangenset de knijpklem van de zak met gelacteerde Ringer-oplossing. Zuig bij gebruik van de spuitmethode gelacteerde Ringer-oplossing uit de steriele schaal in de spuit en steek deze in de met "Inlet" gelabelde opening van de Puregraft 250-zak. Zie onderstaande tabel voor het aanbevelen tot te voegen volume gelact. eerde Ringer-oplossing.

WEEFSELVOLUME (ml)	REINIGINGSVOLUME (ml)
50	50
100	100
150	150
200	150
250	150

- Draai de met weefsel gevulde Puregraft 250-zak met de hand ongeveer 15 seconden lang om zodat alle hoeken van de zak gemengd worden.
- Open de knijpklem op de Puregraft 250-afvalzak en laat de vloeistof ongeveer 3 minuten lang van de Puregraft 250-zak naar de Puregraft 250-afvalzak lopen, sluit dan de knijpklem.
- Herhaal stap 7 en 8 om de weefselreiniging te herhalen, open dan de knijpklem van de Puregraft 250-afvalzak 1-5 minuten om de overvloedige reinigingsvloeistof te laten weglopen, afhankelijk van de gewenste hoeveelheid van het transplantaat.
- Gebruik de Puregraft-schul om het weefsel naar de met "Tissue" gelabelde opening te duwen. Sluit de knijpklem op de Puregraft 250-afvalzak.

VERVUUDEREN TRANSPLAANT:

- Plaats een Gecombineerde Adapter aseptisch op een lege steriele Toomey-spuit.
- Plaats de steriele spuit in de Puregraft 250-zak door de mannelijke kant van de Gecombineerde Adapter in de met "Tissue" gelabelde opening te steken.
- Verwijder weefsel uit de Puregraft 250-zak door langzaam aan de zuiger te trekken totdat de spuit vol zit. Gebruik waar nodig de Puregraft-schul om de maximale hoeveelheid weefsel uit de Puregraft 250-zak te halen.
- Gooi zodra het weefsel uit de zak is verwijderd alle wegwerponderdelen correct weg volgens universele voorzorgsmaatregelen voor ziektekiemen in bloed.

Europees rapportagevereisten: Elk ernstig incident dat zich heeft voorgedaan met betrekking tot het hulpmiddel, moet worden gemeld aan Bimini Health Tech en de bevoegde autoriteit van de lidstaat waarin u, als gebruiker en/of patiënt, bent gevestigd.

PT: Instruções de utilização

Este produto está certificado pela SGS CE1639 como um dispositivo médico na União Europeia sob a Diretiva 93/42/EEC relativa aos Dispositivos Médicos, exclusivamente para as indicações de transferência de gordura autóloga. Outras utilizações não médicas atribuídas a este dispositivo, como o contorno corporal estético, não estão abrangidas pela certificação CE e os utilizadores devem estar cientes de que o desempenho e/ou a segurança do produto não foram avaliados pela SGS para essas finalidades.

DESCRIPÇÃO

O sistema Puregraft® 250 é um sistema fechado estéril, de utilização única, destinado à preparação e administração de enxertos de gordura autólogos novamente no mesmo paciente, para aplicações de cirurgia plástica e reconstrutiva. O sistema Puregraft 250 é composto pelos seguintes componentes:

- Saco Puregraft 250
- Saco de drenagem Puregraft 250
- Adaptador combinado

Para um desempenho ideal, o sistema Puregraft 250 deve ser utilizado em conjunto com o conjunto de instrumentos Puregraft. Este conjunto é composto pelos seguintes componentes reutilizáveis e autoclaváveis:

- Suporte Puregraft
- Sistema desliante Puregraft

O suporte Puregraft foi concebido como um apoio para sustentar o saco Puregraft 250 de forma a obter um fluxo de fluido ideal e o sistema desliante Puregraft facilita o movimento do excesso de fluidos para o rótulo "Tissue" e para o saco de drenagem Puregraft 250, enquanto que o tecido em direção à porta com o rótulo "Tissue" (tecido) para a extração do enxerto. Para obter as instruções de armazenamento, esterilização e as instruções adequadas para a utilização destes produtos, consulte as instruções de utilização específicas incluídas na embalagem do conjunto de instrumentos Puregraft.

INDICAÇÕES DE UTILIZAÇÃO

O sistema Puregraft 250 é indicado para ser utilizado na coleta, filtragem e transferência de tecido adiposo autólogo para rejeição no mesmo paciente, para procedimentos de transferência de gordura autóloga (AFT).

CONTRAINDICAÇÕES

- As seguintes são contraindicações para a utilização do sistema Puregraft 250:
- Aplicações intravenosas.

ESTERILIDADE

O sistema Puregraft 250 é esterilizado com irradiação gama.

ARMAZENAMENTO E MANUSEAMENTO

Utilize somente se o indicador de esterilização estiver vermelho.

ADVERTÊNCIAS

- Apenas para utilização única - Não reutilizar.
- Apenas para utilização autóloga.
- O cirurgião deve estar familiarizado com o funcionamento do sistema Puregraft 250 e o procedimento cirúrgico antes de realizar a cirurgia.
- Não tente reutilizar o sistema Puregraft 250 durante o mesmo procedimento. A reutilização pode comprometer a esterilidade e afetar negativamente o desempenho do sistema.
- A reutilização de um dispositivo de utilização única apresenta riscos significativos para o bom funcionamento do dispositivo devido à ausência das instruções de utilização (IFU) do fabricante
- A reutilização e/ou limpeza de um dispositivo de utilização única pode provocar ferimentos no paciente devido a interações químicas desconhecidas com o dispositivo e/ou a exposição do paciente a agentes de limpeza residuais.
- A reutilização de um dispositivo de utilização única constitui sérios riscos para o paciente, incluindo a perda de esterilidade que pode resultar em infecção.
- A reutilização de um dispositivo de utilização única constitui sérios riscos para o paciente, incluindo a transmissão de doenças infecciosas de um paciente para outro.
- Além dos riscos de transmissão de doenças infecciosas, a reutilização de um dispositivo de utilização única constitui sérios riscos para o paciente, incluindo falha mecânica imediata e/ou prematura do dispositivo devido à degradação do material, que pode levar à redução ou comprometimento do desempenho do produto até e incluindo a falha catastrófica do dispositivo.
- A reesterilização deste dispositivo pode resultar em danos significativos ou perda de integridade do dispositivo.
- Não encha demasiado o saco Puregraft 250 com mais de 400 ml do volume total de tecido e/ou solução de lavagem.
- Interrompa imediatamente a introdução de qualquer fluido ou tecido no saco Puregraft 250 se o material do saco começar a deformarse, provocando a perda de integridade do saco e a criação de um risco biológico para a equipa cirúrgica.

PRECAUÇÕES

- Inspeccione a embalagem do sistema Puregraft 250 quanto a sinais de danos antes da utilização.
- O sistema Puregraft 250 é para utilização única e deve ser utilizado imediatamente após ser removido da embalagem estéril.
- Elimine a totalidade do sistema Puregraft 250 caso a embalagem esteja danificada, aberta ou se o indicador de esterilização estiver inválido.
- Devem utilizar-se técnicas asepticas para minimizar a possibilidade de contaminação do sistema Puregraft 250.
- Utilize as Universal Precautions [precauções universais] (bio-hoene Pathogen Precautions [precauções de agentes patogénicos transmitidos pelo sangue]) para lidar com todo o sangue e fluidos.
- Insulfar ou encher excessivamente o saco Puregraft 250 pode resultar em risco biológico para a equipa cirúrgica e/ou mau funcionamento do dispositivo.
- Recomendase que o sistema Puregraft 250 seja utilizado em conjunto com uma seringa estilo Toomey e com o adaptador combinado fornecido para transferir o tecido para dentro e para fora do sistema.
- O sistema Puregraft 250 destina-se a receber tecido adiposo recolhido com uma cânula com ponta Mercedes de 3 mm de diâmetro.

PREPARAÇÃO:

- Coloque o suporte Puregraft e o sistema desliante estéreis numa posição de funcionamento vertical.
- Abra as bolsas Tyvek que contêm o sistema Puregraft 250 e pendure o saco Puregraft 250 no suporte. Coloque o saco de drenagem Puregraft 250 bem abaixo do nível do saco Puregraft 250 e certifique-se de que o grampo de aperto está posicionado perto do saco Puregraft 250 e na posição aberta.
- Nota: Pode adicionar lactato de Ringer à porta com o rótulo "Inlet" (entrada) utilizando um conjunto de tubos de entrada opcional ou diretamente na porta com o rótulo "Inlet" (entrada) utilizando uma seringa Luer Lock. Também é possível adicionar lactato de Ringer através da porta com o rótulo "Tissue" (tecido) utilizando um adaptador combinado e uma seringa do estilo Toomey. Se estiver a utilizar o conjunto de tubos de entrada, ligue a extremidade Luer macho à porta com o rótulo "Inlet" (entrada) no saco Puregraft 250 e entregue a tubagem para que o saco do lactato de Ringer possa ser perfurado. Feche o grampo de aperto para evitar que o lactato de Ringer entre no saco Puregraft 250 neste momento. Se estiver a utilizar uma seringa, verifique o lactato de Ringer numa tampa estéril no campo estéril.

COLHEITA E ADIÇÃO DE TECIDO:

- Recolha o tecido adiposo asepticamente para uma seringa do estilo Toomey e ligue um adaptador combinado a cada seringa cheia.
- Nota: Se forem utilizados meios alternativos de colheita de tecido adiposo, o tecido deve ser transferido asepticamente para o saco Puregraft 250 utilizando seringas Toomey ou outros tubos e conectores.
- Ligue a seringa cheia com tecido ao saco Puregraft 250 colocando a parte macho do adaptador combinado na porta com o rótulo "Tissue" (tecido) e empurrando o êmbolo da seringa para esvaziar o conteúdo da seringa no saco.
- Nota: Pode ocorrer uma pequena infiltração de fluido durante a introdução e a remoção de tecido através da porta com o rótulo "Tissue" (tecido).
- Introduza 30-50% de tecido adicional relativamente ao volume total de enxerto desejado, para um volume total entre 50-250 ml de tecido no saco Puregraft 250, repetindo o passo 5 acima. Certifique-se de que o excesso de fluido seja drenado para o saco de drenagem Puregraft 250.

LAVAGEM E PROCESSAMENTO DO ENXERTO:

- Feche o grampo de aperto no saco de drenagem Puregraft 250. Caso utilize o conjunto de tubos de entrada, abra o grampo de aperto no saco de lactato de Ringer. Caso utilize o método da seringa, puxe o lactato de Ringer da tampa estéril para a seringa e ligue a porta com o rótulo "Inlet" (entrada) do saco Puregraft 250. Consulte a tabela abaixo para obter o volume de lactato de Ringer que se recomenda que seja adicionado.

VOLUME DE TECIDO (ml)	VOLUME DE LAVAGEM (ml)
50	50
100	100
150	150
200	150
250	150

- Agite manualmente o saco Puregraft 250 cheio com tecido por aproximadamente 15 segundos para garantir que todos os cantos do saco sejam acedidos.
- Abra o grampo de aperto no saco de drenagem Puregraft 250 e deixe o fluido drenar do saco Puregraft 250 para o saco de drenagem Puregraft 250 durante aproximadamente 3 minutos e, a seguir, feche o grampo de aperto.
- Repita as etapas 7 e 8 para repetir a lavagem do tecido e abra o grampo de aperto no saco de drenagem Puregraft 250 para drenar o excesso de fluido de enaguamento por 1-5 minutos, dependendo do nível de hidratação desejado para o enxerto.
- Utilize o sistema desliante Puregraft para guiar o tecido em direção à porta com o rótulo "Tissue" (tecido) e feche o grampo de aperto do saco de drenagem Puregraft 250.

REMOÇÃO DO ENXERTO:

- Ligue de forma aseptica um adaptador combinado a uma seringa Toomey estéril vazia
- Ligue a seringa estéril ao saco Puregraft 250, colocando a parte macho do adaptador combinado na porta com o rótulo "Tissue" (tecido).
- Remova o tecido do saco Puregraft 250 pundo lentamente o êmbolo da seringa até que a seringa esteja cheia. Use o sistema desliante Puregraft conforme necessário para extrair a quantidade máxima de tecido do saco Puregraft 250.
- Assim que o tecido tenha sido removido do saco, elimine adequadamente todos os componentes descartáveis utilizando as precauções universais para os agentes patogénicos transmitidos pelo sangue.

REQUISITOS EUROPEUS DE RELATÓRIO: Qualquer incidente grave que tenha ocorrido relacionado ao dispositivo deve ser relatado à Bimini Health Tech e à autoridade competente do Estado Membro no qual se encontre o utilizador e/ou paciente.

JP: 使用説明書

本製品は、SGS CE1639による医療機器指令93/42/EECに基づき、自己移植移転の適応に限定した医療機器として欧州連合において認証されています。美容目的の体型矯正など本機器のその他の非医学的な使用はCE認証の適用範囲外となるため、ユーザは、こうした使用を目的とした製品の性能および/または安全性がSGSによって評価されていないことを念頭に置きようとしてください。

概要
Puregraft®250システムは滅菌、単回使用、閉鎖系システムで美容および再建外科利用における脂肪組織自家移植時に用いられる脂肪組織を準備することを意図したデバイスです。Puregraft®250システムは以下の構成部品から成っています。

- Puregraft 250 Bag
- Puregraft 250 Drain Bag
- Combined Adapter

オプションとして、Puregraft®250システムはPuregraft Instrument Setと一緒に使用することができます。このセットは以下のオートクレープ滅菌による再使用構成部品から成っています。

- Puregraft Easel
- Puregraft Slider

Puregraft EaselはPuregraft 250 Bagを立てて保持するよう設計されており、液体追加が容易になっています。また、Puregraft Sliderは、Tissueポートへグラフトを寄せ、余分な液体をPuregraft 250 Drain Bagへ排液することができます。保管、滅菌および適切な機器の使用はPuregraft Instrument Setに同梱されている別のIFUをご覧ください。

適応

Puregraft®250システムは自家脂肪移植時の脂肪組織の採取、ろ過および移動に用いることを意図しています。

禁忌

- 以下はPuregraft®250システムの禁忌です。
- 血管内投与

滅菌

- Puregraft®250システムはガンマ線で滅菌されています。

保管及び取扱

- 滅菌インジケータが赤の場合のみ使用してください。

警告

- 単回使用、再使用禁止。
- 自家移植専用
- 術者等は使用前に、Puregraft®250システムの操作及び外科的手技に熟習しておくこと。
- Puregraft®250システムは同一手技内であっても再使用しないこと。再使用は無菌性及びシステムパフォーマンスに悪念が生じます。
- 使用説明書からの逸脱、すなわち、単回使用品の再使用は、機器の適正使用に対して重大なリスクがあります。
 - 再使用又は単回使用品を洗浄しての再使用は、洗浄剤の残留やそれによる未知の化学的相互作用に起因して患者に対して有害な結果となる可能性があります。
 - 単回使用品の再使用は、感染症を引き起こす無菌性の喪失によって患者にとって深刻なリスクが発生します。
 - 単回使用品の再使用は、他の患者の感染症の伝播によって患者にとって深刻なリスクが発生します。
 - 感染症の伝播リスクに加えて、単回使用品の再使用は、機能の低下又は損傷、致命的な機能不全を含む機器の変化によって即時及び又は早期に機器の機械的な不具合が発生し患者にとって深刻なリスクが発生します。
 - 機器の再滅菌は機器に対して重大な損傷や完全性の喪失をもたらす恐れがあります。
 - Puregraft 250 Bagへ排液する組織及び廃液の総量は400mlを超えないこと。
 - バッグの安全性が失われた場合、操作者に感染症のリスクが生じた場合は直ちにPuregraft 250 Bagへの排液を止めること。

事前注意

- 使用前にPuregraft 250システムの包装に損傷がないか確認してください。
- Puregraft 250システムは単回使用品であり、滅菌包装から取り出したら直ちに使用するようになっています。
- 包装に損傷がある、開封されている、滅菌インジケータが無効の場合はPuregraft 250システムすべてを破棄してください。
 - Puregraft 250システムのコンタミネーションを最小化するために無菌操作を行ってください。
 - すべての血液や液体は普遍的予防策(血液媒介病原体に関する注意事項)に基づき取り扱ってください。
 - Puregraft 250バッグを過剰に膨張させたり充満し過ぎたりすると、オースタッフへの生物学的災害や機器の誤動作が発生する恐れがあります。
 - Puregraft 250システムはシステム外に組織を移動する場合、Toomeyスタイルシリンジ及びCombined Adapterを用いることが推奨されています。
 - Puregraft 250システムは3mm径のMercedesチップカニューラを用いて脂肪組織が採取されることを意図しています。

操作方法

- 準備:**
- 無菌のPuregraft イーゼル / スライダー (Puregraft Easel and Slider) を直立した操作位置に設置してください。
 - Puregraft 250システムはTissueポートを開け、Puregraft 250 BagをPuregraft Easelに付ける。Puregraft 250 Drain BagをPuregraft 250 Bagより低い位置に置く。そして、pinch clampがPuregraft 250 Bag近傍で、閉状態になっていることを確認する。
 - 注意: Lactated Ringer'sはInletと書かれたポートに同梱されているInlet Tubing Set (optional) を用いて接続するか、Luer Lock syringeを用いて直接導入することができます。また、Lactated Ringer'sはTissueと書かれたポートにCombined Adapter 及び Toomeyスタイルシリンジを用いても導入することができます。Inlet Tubing Setを用いる場合は、Puregraft 250 BagのInletポートのオスルー・コネクターに接続し、続いてLactated Ringers Bagにスライクします。この時点でPinch clampを閉じておき、Puregraft 250 BagにLactated Ringer'sがすべて流れてしまわないようにします。シリンジを用いる場合は、Lactated Ringer'sを滅菌されたボウルに注いでおきます。

組織採取と導入

- 無菌的に脂肪組織をToomeyスタイルシリンジに採取し、それぞれのシリンジにCombined Adapterを取り付けおきます

注意:もし他の脂肪組織採取方法の場合は、無菌的に脂肪組織をToomeyスタイルシリンジ又は他のチューブやコネクタ等を用いてPuregraft 250 Bagに導入してください。Puregraft 250 Bagへ脂肪組織を採取したシリンジを接続し(TissueポートへCombined Adapterのオスコネクタ部を接続する)、シリンジが空になるまでプランジャーを押してPuregraft 250 Bagに脂肪組織を導入する。注意:Tissueポートへの導入時にわずかに漏れが見られる場合があります。

- 上記の手順を繰り返すことにより、必要な移植組織の総量よりも30〜50%多めの量、すなわち組織総量50〜250mlを、Puregraft 250バッグ (Puregraft 250

Bag) に注入します。グラフト洗浄と処理

Puregraft 250 Drain BagのPinch clamp閉じる。Inlet Tubing Setを使用しの場合は、Lactated Ringer'sのPinch clampを開ける。シリンジ法の場合は、滅菌されたボウルからLactated Ringer'sをシリンジで取り取ってからPuregraft 250 BagのInletポートに接続する。推奨されるLactated Ringer's量は以下の表を参照のこと。

脂肪組織体積 (ml)	洗浄液体体積 (ml)
50	50
100	100
150	150
200	150
250	150

- Puregraft 250 Bagを手で約15時間、4回まで全体がいきわたるようやさしく反転させます。
- Puregraft 250 Drain BagのPinch clampを開け、約3分間、Puregraft 250 BagからPuregraft 250 Drain Bagへ排液し、pinch clampを閉じる。
- 手順7及び8を繰り返して組織を洗浄し、Puregraft 250 Drain BagのPinch clampを開けて希望水和レベルまで余分な廃液を1〜5分間排液する。
- Puregraft Sliderを用いてTissueポートへ組織を掻き寄せる。Puregraft 250 Drain BagのPinch clampを閉じる。
- グラフトの取り出し
- 無菌的に空のToomeyスタイルシリンジにCombined Adapterを取り付ける。
- Puregraft 250 BagのTissueポートに空のシリンジのCombined Adapterのオスコネクタ部を接続する。
- 4分くらいシリンジのプランジャーをシリンジがいっぱいになるまで引いてPuregraft 250 Bagから脂肪組織を取り出す。必要に応じてPuregraft Sliderを用いてPuregraft 250 Bagに残った脂肪組織を掻き寄せる。
- いったんPuregraft 250 Bagから組織を取り出したら、それらは普遍的予防策(血液媒介病原体に関する注意事項)に基づき取り扱ってください。

TR: KULLANMA TALİMATI

Bu ürün, yalnızca otolog yağ alıktarını endikasyonları için SGS CE1639 tarafından Tibbi Cihaz Direktifi 93/42/EEC kapsamında Avrupa Birliği'nde tıbbi cihaz olarak onaylanmıştır. Bu cihaz atfedilen estetik viçut şekillenimle ilgili diğer tıbbi olmayan uygulamalar CE sertifikası kapsamında değildir ve kullanıcılar, ürün performansını veya güvenliğini bu amaçlar için SGS tarafından değerlendirilmediğini bilmelidir.

TANIM

Puregraft® 250 Sistemi, plastik ve rekonstrüktif cerrahi uygulamaları için otolog yağ greftlerinin hazırlanması ve aynı hastaya geri verilmesine yönelik steril, tek kullanımlık, kapalı bir sistemdir. Puregraft 250 Sistemi aşağıdaki bileşenlerden oluşur:

- Puregraft 250 Torba
- Puregraft 250 Drenaj Torbası
- Kombine Adaptör

Optimum performans için Puregraft 250 Sistemi, Puregraft Alet Seti ile birlikte kullanılmalıdır. Bu set, aşağıdaki yeniden kullanılabılır otoklavlanabilir bileşenlerden oluşur:

- Puregraft Sepha
- Puregraft Sürgü

Puregraft Sepha, optimum sıvı akışı için Puregraft 250 Torbasını tutacak bir stand olarak tasarlanmıştır ve Puregraft Sürgü, greft ekstraksiyonu için dokuyu "Tissue" etiketli porta doğru yönlendiren fazla sıvının dokudan uzakla ve Puregraft 250 Drenaj Torbasına hareketini kolaylaştır. Bu ürünlerin saklanması, sterilizasyonu ve uygun kullanımlarını Talimatı için Puregraft Alet Setinin ürün ambalajında bulunan aynı Kullanma Talimatına bakın.

KULLANIM ENDİKASYONLARI

Puregraft 250 Sistemi, Otolog Yağ Alıktarını (AFT) prosedürleri için aynı hastaya yeniden enjekte edilmek üzere otolog yağ dokusunun toplanması, filtrelenmesi ve aktarılmasında kullanılması endeklerir.

KONTRENDİKASYONLAR

Aşağıdakiler, Puregraft 250 Sisteminin kullanımı için kontrendikasyonlardır:

- Intravenöz uygulamalar.

STERİLİTE

- Puregraft 250 Sistemi gama radyasyonu ile sterilize edilmektedir.

SAKILAMA VE MUAMELE

- Yalnızca sterilizasyon göstergesi kırmızıya kullanan.

UYARILAR

- Yalnızca Tek Kullanımlık – Yeniden Kullanımayn.
- Yalnızca Otolog Kullanımı İçindir.
- Cerrah, ameliyatı gerçekleştirmeden önce Puregraft 250 Sisteminin çalışmasına ve cerrahi prosedüre ağına olmalıdır.
- Aynı prosedür sırasında Puregraft 250 Sisteminin yeniden kullanılamay denemeyin. Yeniden kullanımı, steriliteyi tehlikeye atabilir ve sistemin performansını olumsuz etkileyebilir.
- Tek kullanımlık bir cihazın yeniden kullanılması, üreticinin Kullanma Talimatının (FU) bulunmaması nedeniyle cihazın uygun çalışmasına önemli riskler getirir.
- Tek kullanımlık bir cihazın yeniden kullanılması veya temizlenmesi, cihazla bililmeyen kimyasal etkileşimler ve/veya hastanın aktif temizlik maddelerine maruz kalması nedeniyle hastaya zarar verebilir.
- Tek kullanımlık bir cihazın yeniden kullanılması hasta için enfeksiyosuz yol açabilecek sterilite kaybı dahil olmak üzere ciddi riskler oluşturur.
- Tek kullanımlık bir cihazın yeniden kullanılması buluşa hastalığın bir hastadan diğerine bulaşmasn dahil olmak üzere hasta için ciddi riskler oluşturur.
- Bulaşıcı hastalık bulaşma risklerinin aynı sıra tek kullanımlık cihazların yeniden kullanılması, cihazın aynı arızasına kadar ve dahil olmak üzere ürünün performansını düşmesine veya bozulmasına yol açabilecek malzeme bozulması nedeniyle cihazın aynı ve/veya erken mekanik arızasını içeren ciddi riskler oluşturur.
- Bu cihazın yeniden sterilize edilmesi, cihazda önemli hasara veya bütünlüklü kaybına neden olabilir.
- Puregraft 250 Torbasını 400 ml'den fazla toplam dokü hacmi ve/veya yıkama solüsyonu ile ağırlı doldurmayın.
- Torbanın malzemesi deformale olmasa bulaşarak torbanın bütünlüğünün kaybolmasına ve cerrahi personel için büyükölçek tehlike oluşmasına neden olurrsa, Puregraft 250 Torbasına herhangi bir sıvı veya dokü girirgin derhal durdurun.

ÖNLEMLER

- Kullanılmadan önce Puregraft 250 Sistemi ambalajın hasar belirtiltleri açısından inceleyin.
- Puregraft 250 Sistemi yalnızca tek kullanımlıktır ve steril ambalajından çıkıldıktan hemen sonra kullanılmıdır.
- Ambalaj hasarlıysa, alçışmsa veya sterilizasyon göstergesi geçirerse Puregraft 250 Sisteminin tamamını atın.
- Puregraft 250 Sisteminin kontaminasyonu olasılığın en aza indirmek için aseptik teknikler kullanılmıdır.
- Kan ve sıvıların tamamına Evrensel Önlemler (Kanla Bulaşan Patojen Önlemleri) kullanılarak muamele edilm.
- Puregraft 250 Torbasının aynı işlemiye veya aynı doldurulması, çalışan personel için büyükölçek tehlikeye ve/veya cihaz arızasına neden olabilir.
- Puregraft 250 Sisteminin, sistemin için ve dışına dokü aktarımı için Toomey tarzı bir sırınga ve verilen Kombine Adaptör ile birlikte kullanılması önerilir.
- Puregraft 250 Sistemi, 3 mm çaplı bir Mercedes-Uçlu Kanül ile toplanan adipöz dokusunu almak için tasarlanmıştır.

ÇAĞIRTILMA TALİMATI

HAZIRLIK:

- Steril Puregraft Sepha ve Sürgüyü dış çalışma konumuna getirin.
- Puregraft 250 Sisteminin içeren Tyvek poşetlerini açın ve Puregraft 250 Torbasını Sephanın üzerine asın.
- Puregraft 250 Drenaj Torbasını Puregraft 250 Torba servisinin oldukça altına yerleştirgin ve sıkıştırma işlemi için Puregraft 250 Torbasına oldukça yakın ve sıkı konumda olduğundan emin olun.
- Not: Laktatlı Ringer, isteğe bağlı Giriş Tüpü Seti kullanılarak "Inlet" etiketli porta veya bir Luer Kilitli sırınga kullanılarak doğrudan "Inlet" etiketli porta eklenilebilir. Laktatlı Ringer, Kombine Adaptör ve Toomey tarzı sırınga kullanılarak "Tissue" etiketli portı yoluyla da eklenilebilir. Giriş Tüpü Setini kullanıyorsanız, erkek Luer ucunu Puregraft 250 Torbası üzerindeki "Inlet" etiketli porta bağlayın ve Laktatlı Ringer torbasının çivilenbilmesi için tüpü okun. Bu sırada Puregraft 250 Torbasına Laktatlı Ringerin girmesini önlemek için sıkıştırma klempini kapatın. Sırınga kullanıyorsanız, Laktatlı Ringeri steril alanda steril bir kaseye dökün.
- DOKU TOPLAMAMA VE EKİLEME
- Adipöz dokuyu aseptik olarak Toomey tarzı bir sırıngayla toplayın ve doldurulmuş her sırıngaya bir Kombine Adaptör takın.

Not: Alternatif adipöz dokü alma yöntemleri kullanılıyorsa, Toomey sırıngaları veya diğer boru ve konektörler kullanılarak dokü aseptik olarak Puregraft 250 Torbasına aktarılmalıdır.

5. Dokü dokulu sırıngayla Puregraft 250 Torbasına, Kombine Adaptörün erkek kısmını "Tissue" etiketli porta yerleştirterek ve sırınga içeriğini torbaya bopatmak için sırınga pistonunu iterek takın.

Not: "Tissue" etiketli porttan dokunun yerleştirilmesi ve çıkılması sırasında küçük sıvı sızmızı meydana gelebilir.

6. Yukarıdaki 5. adım tekrarlanarak Puregraft 250 Torbasına toplam 50-250 ml dokü hacmi için istenen toplam greft hacminden %30-50 daha fazla dokü koyun. Fazla sıvının Puregraft 250 Drenaj Torbasına akışından emin olun.

GREFT YIKAMA VE İŞLEMİ:

- Puregraft 250 Drenaj Torbasındaki sıkıştırma klempini kapatın. Giriş Tüpü Setini kullanıyorsanız, Laktatlı Ringerin 250 Drenaj Torbasına hareketini kolaylaştır. Bu ürünlerin saklanması, sterilizasyonu ve uygun kullanımlarını Talimatı için Puregraft Alet Setinin ürün ambalajında bulunan aynı Kullanma Talimatına bakın.

DOKU HACMI (ml)	YIKAMA HACMI (ml)
50	50
100	100
150	150
200	150
250	150

- Doku ile dolu olan Puregraft 250 Torbası, torbanın tüm köşelerine erişildiğinden emin olarak yaklaşık 15 saniye boyunca elle çalkalayın.
- Puregraft 250 Drenaj Torbasındaki sıkıştırma klempini açın ve yaklaşık 3 dakika boyunca sıvının Puregraft 250 Torbasından Puregraft 250 Drenaj Torbasına aktarılmasını izin vein, ardından sıkıştırma klempini kapatın.
- Doku yıkamaı tekrarlamaak için Adım 7'e 8'i tekrarlayın ve tercih edilen greft hidrasyon seviyesine bağlı olarak fazla durulama sıvısını 1-5 dakika boyunca aktarmk için Puregraft 250 Drenaj Torbasını üzerindeki sıkıştırma klempini açın.
- Dokuyu "Tissue" etiketli porta yönlendirmek için