

PureGraft® 850 System

<p>INSTRUCTIONS FOR USE IN THE UNITED STATES AND CANADA PureGraft® 850 System</p>	<p>INSTRUCTIONS FOR USE ALL COUNTRIES EXCEPT UNITED STATES AND CANADA PureGraft® 850 System</p>
<p>DESCRIPTION</p> <p>The Puregraft® 850 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 850 System is composed of the following components:</p> <ul style="list-style-type: none">Puregraft 850 Bag Puregraft 850 Drain Bag Combined Adapter Puregraft Slider	<p>EN: INSTRUCTIONS FOR USE</p> <p>This product is certified as a medical device in the European Union under the Medical Device Directive 93/42/EEC by SGS CE139, exclusively for applications 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 that product performance and/or safety has not been evaluated by SGS for these purposes.</p>
<p>For optimal performance, the Puregraft 850 System should be used in conjunction with the Puregraft Instrument Set. This set is composed of the following reusable, autoclavable components:</p> <ul style="list-style-type: none">Puregraft Easel Puregraft Slider	<p>FR: INSTRUCTIONS POUR L'USAGE</p> <p>Ce produit est certifié en tant que dispositif médical en l'Union européenne en vertu de la directive sur les dispositifs médicaux 93/42/CE par SGS CE139, exclusivement pour les indications de transfert de tissu adipeux 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.</p>

The Puregraft 850 System was designed as a stand to hold the Puregraft 850 Bag for optimal fluid flow and the Puregraft Slider facilitates the movement of excess fluids away from the tissue and into the Puregraft 850 Drain Bag while guiding the tissue towards the port labeled "Tissue" for graft extraction. For storage, sterilization, and proper instructions for use of these products, see the separate Instructions for Use included in the product packaging of the Puregraft 850/TS instrument Set.

INDICATIONS FOR USE

The Puregraft 850 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 850 System: Intravenous applications.

STERILITY

- The Puregraft 850 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 manipulation. Any manipulations beyond those outlined in this Instruction For Use are not recommended.
- Do not attempt to re-use the Puregraft 850 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 disorders, 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 overflow the Puregraft 850 Bag with more than 1275 mL of total volume of tissue and/or washing solution.

PRECAUTIONS

- Inspect the Puregraft 850 system package for signs of damage prior to use.
- The Puregraft 850 System is for single use only and must be used immediately after removal from the sterile packaging.
- Discard the entire Puregraft 850 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 850 System.
- Treat all blood and fluids using Universal Precautions (Blood-borne Pathogen Precautions).
- This device is designed to contact 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 lipoaspiration.
- Results of this procedure will vary depending upon patient age, surgical sites, 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 850 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.
- There is currently no use/function for the port labeled "AIR/XY". Do not use this port for tissue or fluid addition/ removal.
- The Puregraft 850 System is intended to receive adipose tissue harvested with a 3mm diameter Mercedes-Tip Cannula.
- Overstuffing or overfilling of the Puregraft 850 Bag may result in a biohazard to the operating staff and/or device malfunction.

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- Discard the entire Puregraft 850 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 850 System.
- Treat all blood and fluids using Universal Precautions (Blood-borne Pathogen Precautions).
- Over inflating or over filling of the Puregraft 850 Bag may result in a biohazard to the operating staff and/or device malfunction.
- The Puregraft 850 System is recommended to be used in combination with a Toomey syringe and the supplied Combined Adapter for tissue transfer into and out of the system.
- The Puregraft 850 System is intended to receive tissue harvested with a 3mm diameter Mercedes-Tip Cannula.

OPERATING INSTRUCTIONS

- Place sterile Puregraft Easel and Slider in an upright operating position.
- Open Tyvek pouches containing the Puregraft 850 System, and hang the Puregraft 850 Bag on the Easel. Place the Puregraft 850 Drain Bag well below the level of the Puregraft 850 Bag, and ensure that the pinch clamp is positioned near the Puregraft 850 Bag and in the open position.
- Note: Lactated Ringer's can be added to the port labeled "Inlet" by using an optional Inlet Tubing Set 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 850 Bag, and hand off the tubing so that the Lactated Ringers bag can be spiked. Close the pinch clamp to prevent Lactated Ringer's from entering the Puregraft 850 Bag at this time. If using a syringe, pour Lactated Ringer's into a sterile bowl on the sterile field.

TISSUE COLLECTION AND ADDITION:

- Aseptically collect adipose tissue into a Toomey style syringe and attach a Combined Adapter to each filled syringe.

Note: If alternate means of adipose tissue harvest are used, tissue should be aseptically transferred to the Puregraft 850 Bag using Toomey syringes and the port labeled "Tissue".

- Attach the tissue-filled syringe to the Puregraft 850 Bag by placing the male portion of the Combined Adapter into the port labeled "Tissue" and pushing the syringe plunger to empty the syringe contents into the bag.

- Minor fluid seepage can occur during introduction and removal of tissue through the port labeled "Tissue".
- Introduce 30-50% more tissue than the total desired graft volume, for a total volume between 200-850mL of tissue into the Puregraft 850 Bag by repeating step 5 above. Ensure excess fluid is draining into the Puregraft 850 Drain Bag.

GRAFT WASHING AND PROCESSING:

- Close the pinch clamp on the Puregraft 850 Drain Bag. If using the Inlet Tubing Set, open the pinch clamp to the bag of lactated Ringer's and add approximately 100 to 425 mL to the Puregraft 850 Bag at a 2:1 ratio of graft tissue: Lactated Ringer's according to the table below:

INPUT TISSUE VOLUME (mL)	WASH VOLUME (mL)	DRAIN TIME (MIN)
200	100	2
400	200	3
600	300	4
850	425	6

- Detach the Puregraft 850 Bag from the Easel. Gently invert the tissue-filled Puregraft 850 Bag manually for approximately 30 seconds to ensure that all corners of the bag are accessed.
- Open pinch clamp on Puregraft 850 Drain Bag and allow fluid to drain from the Puregraft 850 Bag into the Puregraft 850 Drain Bag for approximately 2-6 minutes (see Table 1 for detailed drain time information), then close pinch clamp.

- Repeat Steps 7 & 8 to repeat tissue wash, and open pinch clamp on Puregraft 850 Drain Bag to drain excess rinse fluid for 3-6 minutes depending on preferred graft hydration level.

- Use Puregraft Slider to guide tissue towards port labeled "Tissue". Close the pinch clamp to the Puregraft 850 Drain Bag.

- Repeat Steps 7 & 8 to repeat tissue wash, and open pinch clamp on Puregraft 850 Drain Bag to drain excess rinse fluid for 2-6 minutes depending on preferred graft hydration level.
- Use Puregraft Slider to guide tissue towards port labeled "Tissue". Close the pinch clamp to the Puregraft 850 Drain Bag.

- Repeat Steps 7 & 8 to repeat tissue wash, and open pinch clamp on Puregraft 850 Drain Bag to drain excess rinse fluid for 2-6 minutes depending on preferred graft hydration level.

- Attach the sterile syringe to the Puregraft 850 Bag by placing the male portion of the Combined Adapter into the port labeled "Tissue".
- Remove tissue from the Puregraft 850 Bag by slowly pulling the syringe plunger until syringe is filled. Use the Puregraft Slider as needed to extract the remaining tissue from the Puregraft 850 Bag.

Note: Significant fluid and liquid content may be present in the last 10-20 mL of remaining tissue Discard the final 20 mL of tissue output.

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

Le cheval Puregraft® a été conçu pour servir de support à la poche Puregraft 850 afin d'obtenir un écoulement optimal des fluides et liquides ; la glissière Puregraft facilite l'écoulement de l'excédent de liquide, l'éloignement du tissu à l'amont à la poche de drainage Puregraft 850, tout en guidant le tissu vers l'orifice étiqueté "Tissue" (Tissu), en vue de l'extraction de la greffe. Pour les instructions de stockage, de stérilisation et d'emballage correcte de ces produits, veuillez consulter les instructions d'utilisation séparées, inclues dans l'emballage du produit de l'ensemble d'instruments Puregraft .

CONSIGNES D'UTILISATION

L'utilisation du système Puregraft 850 est indiquée pour le prélèvement, le filtrage et le transfert de tissu adipeux autologue (ATU 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 850 sont les suivantes :

- Applications intraveineuses.

STERILITE

- Le système Puregraft 850 est stérilisé par irradiation aux rayons gamma.

STOCKAGE ET MANIPULATION

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

AVERTISSEMENTS

- À usage unique – Ne réutilisez pas ce système.
- Exclusivement réservé pour usage autologue.
- Ne tentez pas de modifier le produit sans autorisation de l'ingénieur ou du fabricant.
- Ne tentez pas de réutiliser le système Puregraft 850 au cours de la même procédure. Une réutilisation peut compromettre la stérilité et peut avoir un effet défavorable 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/la patient(e), dû à la possibilité de réactions chimiques inconnues au dispositif et/ou de l'exposition du/du patient(e) à des agents pathogènes.
- 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'une patient(e) à une 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 en on la perte d'intégrité du dispositif.
- Il ne faut pas sur-remplir la poche Puregraft 850 plus de 1275mL du volume total de tissu et/ou de solution de lavage.
- Arrêtez immédiatement l'introduction de tout liquide ou tissu dans la poche Puregraft 850, si le matériel de la poche com mence à se déformer, car ceci peut entraîner la perte d'intégrité de la poche et la création d'un biorisque pour le personnel exécutant l'intervention.

INDICATIONS FOR USE

The Puregraft 850 System is indicated for use in the harvesting, filtering and transferring of autologous fat tissue for reinjecting back into the same patient for Autologous Fat Transfer (ATF) procedures.

CONTRAINDICATIONS

The following are contraindications for use of the Puregraft 850 System:

- Intravenous applications.

STERILITY

- The Puregraft 850 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 surgeon should be familiar with the operation of the Puregraft 850 System and the surgical procedure prior to performing the surgery.
- Do not attempt to re-use the Puregraft 850 System during the same procedure. Re-use may compromise the sterility and adversely affect performance of the system.
- The 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 clearing 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 850 Bag with more than 1275mL of total volume of tissue and/or washing solution.
- Immediately stop the introduction of any fluid or tissue into the Puregraft 850 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 Puregraft 850 System package for signs of damage prior to use.
- Puregraft 850 System is for single use only and must be used immediately after removal from the sterile packaging.
- Discard the entire Puregraft 850 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 850 System.
- Treat all blood and fluids using Universal Precautions (Blood-borne Pathogen Precautions).
- Over inflating or over filling of the Puregraft 850 Bag may result in a biohazard to the operating staff and/or device malfunction.
- The Puregraft 850 System is recommended to be used in combination with a Toomey syringe and the supplied Combined Adapter for tissue transfer into and out of the system.
- The Puregraft 850 System is intended to receive tissue harvested with a 3mm diameter Mercedes-Tip Cannula.

OPERATING INSTRUCTIONS

PREPARATIONS:

- Place sterile Puregraft Easel and Slider in an upright operating position.
- Open Tyvek pouches containing the Puregraft 850 System, and hang the Puregraft 850 Bag on the Easel. Place the Puregraft 850 Drain Bag well below the level of the Puregraft 850 Bag, and ensure that the pinch clamp is positioned near the Puregraft 850 Bag and in the open position.
- Note: Lactated Ringer's can be added to the port labeled "Wash" by using an optional Inlet Tubing Set or directly into the port labeled "Wash" 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 "Wash" on the Puregraft 850 Bag, and hand off the tubing so that the Lactated Ringers bag can be spiked. Close the pinch clamp to prevent Lactated Ringer's from entering the Puregraft 850 Bag at this time. If using a syringe, pour Lactated Ringer's into a sterile bowl on the sterile field.

TISSUE COLLECTION AND ADDITION:

- Aseptically collect adipose tissue into a Toomey style syringe and attach a Combined Adapter to each filled syringe.

Note: If alternate means of adipose tissue harvest are used, tissue should be aseptically transferred to the Puregraft 850 Bag using Toomey syringes and the port labeled "Tissue".

- Attach the tissue-filled syringe to the Puregraft 850 Bag by placing the male portion of the Combined Adapter into the port labeled "Tissue" and pushing the syringe plunger to empty the syringe contents into the bag.
- Minor fluid seepage can occur during introduction and removal of tissue through the port labeled "Tissue".
- Introduce 30-50% more tissue than the total desired graft volume, for a total volume between 200-850mL of tissue into the Puregraft 850 Bag by repeating steps 5 above. Ensure excess fluid is draining into the Puregraft 850 Drain Bag.

GRAFT WASHING AND PROCESSING:

- Close the pinch clamp on the Puregraft 850 Drain Bag. If using the Inlet Tubing Set, open the pinch clamp to the bag of lactated Ringer's and add approximately 100 to 425 mL to the Puregraft 850 Bag at a 2:1 ratio of graft tissue: Lactated Ringer's according to Table 1 below:

INPUT TISSUE VOLUME (mL)	WASH VOLUME (mL)	DRAIN TIME (MIN)
200	100	2
400	200	3
600	300	4
850	425	6

- Detach the Puregraft 850 Bag from the Easel. Gently invert the tissue-filled Puregraft 850 Bag manually for approximately 30 seconds to ensure that all corners of the bag are accessed.

- Open pinch clamp on Puregraft 850 Drain Bag and allow fluid to drain from the Puregraft 850 Bag into the Puregraft 850 Drain Bag for approximately 2-6 minutes (see Table 1 for detailed drain time information), then close pinch clamp.

Note: Significant fluid and liquid content may be present in the last 10-20 mL of remaining tissue Discard the final 20 mL of tissue output.

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

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/CE par SGS CE139, exclusivement pour les indications de transfert de tissu adipeux 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.

- Placez l'épave stérile Puregraft Easel et Slider dans une position opérationnelle verticale.
- Ouvrez les emballages étanches Tyvek contenant le système Puregraft 850, puis accrochez la poche Puregraft 850 dans le chéneau. Placez la poche de drainage Puregraft 850 bien en dessous du niveau de la poche Puregraft 850, et assurez que la pince est positionnée près de la poche Puregraft 850 et/ou elle est en position ouverte.
- Remarque : Le sérum lactaté de Ringer peut être ajouté à l'orifice étiqueté "Wash" (Admission) en utilisant le jeu de tubulures d'admission optionnel, ou bien directement dans l'orifice étiqueté "Admission" en utilisant une seringue Luer Lock. On peut également ajouter de la solution lactacée de Ringer par le biais de l'orifice étiqueté "Tissue" (Tissu), en utilisant un Adaptateur Combiné et une seringue de type de Toomey. Si vous utilisez le jeu de tubulures d'admission, connectez l'extrémité Luer mâle à l'orifice étiqueté "Wash" (Admission) sur la poche Puregraft 850, puis déposez la solution lactacée de Ringer sur la poche Puregraft 850. Si vous utilisez une seringue, versez la solution lactacée de Ringer dans un récipient stérile dans le champ stérile.

COLLECTE ET AJOUT DE TISSU:

- Collectez aseptiquement le tissu adipeux dans une seringue de type de Toomey et connectez un Adaptateur Combiné à chaque seringue remplie.

Note: Si des moyens différents de prélèvement de tissu adipeux sont utilisés, le tissu doit être transféré aseptiquement dans la poche Puregraft 850 en utilisant des seringues de Toomey ou autres tubulures et connecteurs.

- Fixez la seringue remplie de tissu sur la poche Puregraft 850, en plaçant la partie mâle de l'Adaptateur Combiné à l'orifice étiqueté "Tissue" (Tissu), puis appuyez sur le piston de la seringue pour vider le contenu de la seringue dans la poche Puregraft 850 (Tissu), puis ouvrez le piston de la seringue pour vider le contenu de la seringue au même endroit.
- Note: Un épanchement mineur de liquide peut se produire durant l'introduction et le retrait du tissu à travers l'orifice étiqueté "Tissue" (Tissu).
- Introduisez 30-50% de plus de tissu adipeux dans la poche de greffe totale souhaitée, pour obtenir un volume total entre 200-850 mL de tissu adipeux dans la poche Puregraft 850, en repétant l'étape 5 ci-dessus.

LAGAGE ET TRAITEMENT DES GREFFES:

- Fermez la pince sur la poche de drainage Puregraft 850. Si vous utilisez le jeu de tubulures d'admission, ouvrez la pince vers la poche de solution lactacée de Ringer et ajoutez environ 100 à 425 mL à la poche Puregraft 850, selon un rapport de 2:1 de tissu de greffe: solution lactacée de Ringer, conformément au Tableau 1 ci-dessous:

Volume de greffe (mL)	Volume de Tissu (mL)	Temps de lavage (MIN)
200	100	2
400	200	3
600	300	4
850	425	6

- Retirez la pince sur la poche de drainage Puregraft 850.

RETRAIT DE GREFFE:

- Fixez aseptiquement un Adaptateur Combiné à une seringue de Toomey stérile vide.
- Fixez la seringue stérile sur la poche Puregraft 850 en plaçant la partie mâle de l'Adaptateur Combiné dans l'orifice étiqueté "Tissue" (Tissu).

- Retirez le tissu de la poche Puregraft 850 en tirant lentement sur le piston de la seringue, jusqu'à ce que la seringue soit pleine. Utilisez la glissière Puregraft 850 pour la nécessité pour extraire le tissu restant de la poche Puregraft 850.

- Répétez les étapes 7 & 8 à fin de répéter le lavage de tissu, puis ouvrez la pince sur la poche de drainage Puregraft 850 pour évacuer l'excès de liquide de ringer pendant 2-6 minutes, selon le taux d'hydratation de greffe préféré.

- Après avoir terminé Puregraft pour guider le tiss vers l'orifice étiqueté "Tissue" (Tissu), fermez la pince sur la poche de drainage Puregraft 850.

RETRAIT DE GREFFE:

- Fixez aseptiquement un Adaptateur Combiné à une seringue de Toomey stérile vide.
- Fixez la seringue stérile sur la poche Puregraft 850 en plaçant la partie mâle de l'Adaptateur Combiné dans l'orifice étiqueté "Tissue" (Tissu).

- Retirez le tissu de la poche Puregraft 850 en tirant lentement sur le piston de la seringue, jusqu'à ce que la seringue soit pleine. Utilisez la glissière Puregraft 850 pour la nécessité pour extraire le tissu restant de la poche Puregraft 850.

- Répétez les étapes 7 & 8 à fin de répéter le lavage de tissu, puis ouvrez la pince sur la poche de drainage Puregraft 850 pour évacuer l'excès de liquide de ringer pendant 2-6 minutes, selon le taux d'hydratation de greffe préféré.

- Après avoir terminé Puregraft pour guider le tissu vers l'orifice étiqueté "Tissue" (Tissu), fermez la pince sur la poche de drainage Puregraft 850.

Exigences européennes en matière de signalement : Tout incident grave survenant en rapport avec le dispositif doit être signalé à Biimi Health Tech et à l'autorité compétente de l'Etat membre dans lequel l'utilisateur et/ou le patient sont admis.

DE: GEBRAUCHSANLEITUNG

Dieses Produkt ist von der SGS CE1639 in der Europäischen Gemeinschaft gemäß der Medizinprodukte-Richtlinie 93/42/EEG als Medizinprodukt ausschließlich für die Indikationen der autologen Fettübertragung zertifiziert. Andere nichtmedizinische Anwendungen, wie ästhetische Körperformung, die diesen Produkt auch zugeschrieben werden, fallen nicht in den Anwendungsbereich dieser CE-Zertifizierung, und der Anwender sollte sich im Klaren sein, dass diese Produktkategorien und/oder deren Sicherheit für diese Zwecke von SGS nicht evaluiert wurden.

BESCHREIBUNG

Das Puregraft® 850 System ist ein steriles, geschlossenes Einwegsystem für den plastischen und rekonstruktiven Chirurgiemarkt. Es dient der Präparation und Bereitstellung autologer Fetttransplantate, die denselben Patienten wieder verabreicht werden. Das Puregraft 850 System umfasst folgende Komponenten:

- Puregraft 850 Beutel
- Puregraft 850 Drainagebeutel
- Kombinierter Adapter

Für optimale Leistung sollte das Puregraft 850 System in Verbindung mit dem Puregraft Instrument Set verwendet werden. Dieses Set umfasst folgende wiederverwendbare, autoklavierbare Komponenten:

- Puregraft Easel
- Puregraft Schieber

Der Puregraft Ständer wurde als Gestell konstruiert, an dem der Puregraft 850 Beutel für optimalen Flüssigkeitsfluss aufgehängt wird. Mit dem Puregraft Schieber kann überschüssige Flüssigkeit vom Gewebe weg und in den Puregraft 850 Drainagebeutel geleitet und das Gewebe zu der mit „Tissue“ (Tissu) gekennzeichneten Öffnung abgewegt werden. Für Lagerung, Sterilisation und Anweisungen zur Verwendung dieser Produkte siehe separate Gebrauchsanleitungen, die der Puregraft 850 System Instrument Set beiliegen.

INDIKATION
Das Puregraft 850 System ist zur Entnahme, zum Filtern und zur Übertragung von autologem Fettgewebe zur Reinjektion in denselben Patienten zwecks Eigenfett-Transplantation indiziert.

KONTRAINDIKATION

Nachfolgend sind die Kontraindikationen für die Verwendung des Puregraft 850 Systems aufgeführt:

- Intravenöse Anwendungen

STERILITÄT

- Das Puregraft 850 System wird mit Gammabestrahlung sterilisiert.

LAGERUNG UND HANDBAHUNG

- Goi de gehele Puregraft 850 weg als de verpakking beschadigd is, geopend is of als de sterilisatie-indicator ongediagd is.
- Er dienen aseptische technieken te worden gebruikt om de kans op besmetting van de Puregraft 850 te minimaliseren.
- Behandel alle bloed en vloeistoffen met universele voorzorgsmaatregelen [voorzorgsmaatregelen voor ziektekiemen in bloed].
- Als de Puregraft 850 teveel wordt opgeblazen of gevuld, kan dit een biogevaar voor het bediende personeel en/of een storing opleveren.
- Het wordt aanbevolen om de Puregraft 850 te gebruiken samen met een Toomey-type spuit en de meegeleverde Gecombineerde Adapter om het weefsel in het systeem te brengen en eruit te halen.
- De Puregraft 850 is bedoeld voor vetweefsel dat wordt weggenomen met een canule van 3 mm diameter met een Mercedes-punt.

BEIDINGSINSTRUCTIES: VOORBEREIDING:

- Plaats steriele Puregraft-ezel en -schulf in een rechtstaande werkpositie.
- Open de Tiyek-zakjes waarin de Puregraft 850 zit en hang de Puregraft 850-zak aan de ezel. Plaats de Puregraft 850-afval zak ver genoeg beneden de Puregraft 850-zak en zorg dat de knijpklem zich nabij de Puregraft 850-zak en in de open stand bevindt.
- NB: Er kan gelacteerde Ringer-oplossing toegevoegd aan de met "Wash" gelabelde opening door de inlaatansluiting openzetten te gebruiken, of niet te gebruiken met "Wash" gelabelde opening met een Luer-Lock-spuut. Gelacteerde Ringer-oplossing kan ook via de met "Tissue" gelabelde opening worden toegevoegd met een Gecombineerde Adapter en een Toomey-type spuit. Verbind bij gebruik van de inlaatansluiting de mannelijke Luer-aansluiting met de met "Wash" gelabelde opening van de Puregraft 850-zak en geef de slang af zodat de gelacteerde Ringer-oplossing kan worden aangesloten. Sluit de knijpklem om te voorkomen dat er lacteërde Ringer-oplossing op dat moment in de Puregraft 850-zak terechtkomt. Giet bij gebruik van een spuit gelacteerde Ringer-oplossing in een steriele schaal op het steriele veld.

VERZAMELEN EN TOEVOEGEN WEEFSEL:

- Verzamel vetweefsel aseptisch in een Toomey-type spuit en plaats een Gecombineerde Adapter op elke gevulde spuit.
- NB: Als er een alternatieve methode voor vetweefselextractie wordt gebruikt, dient het weefsel aseptisch met een naald en een verdelingsnaald in de verdelingsnaald te worden overgebracht.
- Plaats de met weefsel gevulde spuit in de Puregraft 850-zak door de mannelijke kant van de Gecombineerde Adapter in de met "Tissue" gelabelde opening 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 vloeistof weglopen.
- Voeg 30-50% meer weefsel aan de Puregraft 850-zak toe dan het totaal gemiddelde transplantaatvolume voor een totaal weefselvul- ume van 200-850 ml door bovenstaande stap 5 te herhalen.

WASSEN EN VERWERKEN TRANSPLANTAAT:

- Sluit de knijpklem op de Puregraft 850-afvalzak. Open bij gebruik van de inlaatansluiting de knijpklem van de zak met gelacteerde Ringer-oplossing en voeg ongeveer 100 tot 425 ml toe aan de Puregraft 850-zak van de verhouding 2:1 voor transplantaatweefsel - gelacteerde Ringer-oplossing volgende onderstaande tabel 1:

Weefselvolume (ml)	Reinigingsvolume (ml)	Uitlooptijd (MIN)
200	100	2
400	200	3
600	300	4
850	425	6

Tabel 1.

NB: Zorg bij gebruik van de spuitmethode gelacteerde Ringer-oplossing uit de steriele schaal in de spuit en steek deze in de met "Wash" gelabelde opening van de Puregraft 850-zak. Blijf gelacteerde Ringer-oplossing toevoegen totdat het juiste volume is bereikt.

- Verwijder de Puregraft 850-zak uit de ezel. Draai de met weefsel gevulde Puregraft 850-zak voorzichtig met de hand ongeveer 30 seconden lang zodat alle hoeken van de zak gemengd worden.
- Open de knijpklem op de Puregraft 850-afvalzak en laat de vloeistof ongeveer 2-6 minuten lang van de Puregraft 850-zak naar de Puregraft 850-afvalzak vloeien (zie tabel 1 voor gedetailleerde uitooploeiende), sluit dan de knijpklem.
- Herhaal stap 7 en 8 om de weefselhoeveel te herhalen, open dan de knijpklem van de Puregraft 850-afvalzak 2-6 minuten om de overvloedige reinigingsvloeistof te laten weglopen, afhankelijk van de gewenste natheid van het transplantaat.
- Gebruik de Puregraft-schulf om het weefsel naar de met "Tissue" gelabelde opening te duwen. Sluit de knijpklem op de Puregraft 850-afvalzak.
- VERHUIDEREN TRANSPLAANT:
- Plaats een Gecombineerde Adapter aseptisch op een lege steriele Toomey-spuut.
- Plaats de steriele spuit in de Puregraft 850-zak door de mannelijke kant van de Gecombineerde Adapter in de met "Tissue" gelabelde opening te steken.
- Verwijder weefsel uit de Puregraft 850-zak door langzaam aan de zuiger te trekken totdat de spuit vol zit. Gebruik waar nodig de Puregraft-schulf om het resterende weefsel uit de Puregraft 850-zak te halen.
- NB: Er kan een aanzienlijke hoeveelheid vloeistof in de laatste 10-20 ml resterend weefsel zitten. Gooi de laatste 20 ml weefselextract weg.
- Goi zodra het weefsel uit de zak is verwijderd alle wegverpoderdelen correct weg volgens universele voorzorgsmaatregelen voor ziektekiemen in bloed.

Europese rapportageveristen: 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 patient, 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. Outros utilizadores e/ou médicos autorizados 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.

DESCRIÇÃO

O sistema Puregraft® 850 é um sistema fechado estéril, de utilização única, destinado à preparação e administração de enxertos de gordura dura autólogo para uso no mesmo paciente, para aplicações de cirurgia plástica e reconstructiva. O sistema Puregraft 850 é composto pelos seguintes componentes:

- Saco Puregraft 850
- Saco de drenagem Puregraft 850
- Adaptador combinado
- Para um desempenho ideal, o sistema Puregraft 850 deve ser utilizado em conjunto com o conjunto de instrumentos Puregraft. Este conjunto é composto pelos seguintes componentes reutilizáveis e autoclaváveis:

- Supporte Puregraft
- Sistema deslizante Puregraft

O suporte Puregraft foi concebido como um apoio para sustentar o saco Puregraft 850 de forma a obter um fluxo de fluido ideal e o sistema deslizante Puregraft facilita o movimento do excesso de fluidos para longe do tecido e para o saco de drenagem Puregraft 850, enquanto ajuda o tecido em direção à porta com o rótulo "Tissue" (tecido) para a extração do enxerto. Para obter as instruções de montagem, 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 850 é indicado para ser utilizado na colheita, filtragem e transferência de tecido adiposo autógeno para reinjeção no mesmo paciente, para procedimentos de transiência de gordura autóloga (AFT).

CONTRAINDICAÇÕES

As seguintes são contraindições para a utilização do sistema Puregraft 850

- Aplicações intravasculares.

ESTERILIDADE

O sistema Puregraft 850 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 conteúdo deve estar familiarizado com o funcionamento do sistema Puregraft 850 e o procedimento cirúrgico antes de realizar a cirurgia.
- Não tente utilizar o sistema Puregraft 850 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 indicações de utilização (IFI) 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 à 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.
- Alem 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 850 com mais de 1275 ml do volume total de tecido e/ou solução de lavagem.
- Interrompa imediatamente a introdução de qualquer fluido ou tecido no saco Puregraft 850 se o material do saco começar a deformar-se, provocando a perda de integridade do saco e a criação de um risco biológico para a equipa cirúrgica.

PRECAUÇÕES

- Instale em embalagem do sistema Puregraft 850 quando a sinais de danos antes da utilização.
- O sistema Puregraft 850 é para utilização única e deve ser utilizado imediatamente após ser removido da embalagem estéril.
- Elimine a totalidade do sistema Puregraft 850 caso a embalagem esteja danificada, aberta ou se o indicador de esterilização seiva inavaliado.
- Devem utilizar-se técnicas precauções para minimizar a possibilidade de contaminação do sistema Puregraft 850.
- Utilize as Universal Precautions (precauções universais) [Blood-borne Pathogen Precautions (precauções de agentes patogénicos transmitidos pelo sangue)] para todos os sangues e fluidos.
- Insufilar ou encher excessivamente o saco Puregraft 850 pode resultar em risco biológico para a equipa cirúrgica e/ou mau funcio-namento do dispositivo.
- Recomenda-se que o sistema Puregraft 850 seja utilizado em conjunto com uma seringa Toomey e com o adaptador combinado fornecido para transferir o tecido para dentro e para fora do sistema.
- O sistema Puregraft 850 destina-se a ser utilizado recolhido com uma canula com ponta Mercedes de 3 mm de diâmetro.

INSTRUÇÕES DE FUNCIONAMENTO:

PREPARAÇÕES:

- Coloque o suporte Puregraft 850 e o sistema deslizante estereis numa posição de funcionamento vertical.
- Abra as bolhas Tiyek que contêm o tecido a Puregraft 850 e pendure o saco Puregraft 850 no suporte. Coloque o saco de drenagem Puregraft 850 bem abaixo do nível do saco Puregraft 850 e certifique-se de que o grampo de aperto está posicionado perto do saco Puregraft 850 e na posição aberta.
- Nota: Pode adicionar-se lactato de Ringer à porta com o rótulo "Wash" (lavagem) utilizando um conjunto de tubos de entrada -opcional ou diretamente na porta com o rótulo "Wash" (lavagem) 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 "Wash" (lavagem) no saco Puregraft 850 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 850 neste momento. Se estiver a utilizar uma seringa, verta o lactato de Ringer numa tampa estéril no campo estéril.

Figura 1: Preparação do suporte Puregraft 850 e do sistema deslizante estéril para o funcionamento vertical.

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 850 utilizando seringas Toomey ou outros tubos e conexões.
- Ligue a seringa cheia com tecido ao saco Puregraft 850 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 designado, para um volume total entre 200-850 ml de tecido no saco Puregraft 850, repetindo o passo 5 acima. Certifique-se de que o excesso de fluido seja drenado para o saco de drenagem Puregraft 850.

LAVAGEM E PROCESSAMENTO DO ENXERTO:

- Feche o grampo de aperto no saco de drenagem Puregraft 850. Se estiver a utilizar o conjunto de tubos de entrada, abra o grampo de aperto no saco de lactato de Ringer e adicione aproximadamente 100 a 425 ml ao saco Puregraft 850 na proporção de 2:1 de tecido de enxerto: lactato de Ringer de acordo com a tabela 1 abaixo:

Voluma de tecido de lavagem (ml)	Volume de lavagem (ml)	Tempo de drenagem (MIN)
200	100	2
400	200	3
600	300	4
850	425	6

Tabela 1.

Nota: Não utilize o método da seringa, puxe o lactato de Ringer da tampa estéril para a seringa e ligue à porta com o rótulo "Wash" (lavagem) do saco Puregraft 850. Continue a adicionar lactato de Ringer até atingir o volume apropriado.

- Retire o saco Puregraft 850 do suporte. Inverta manualmente com suavidade o saco Puregraft 850 cheio com tecido para aproximadamente 30 segundos para garantir que todos os cantos do saco sejam escoados.
- Abra o grampo de aperto no saco de drenagem Puregraft 850 e deixe o fluido drenar do saco Puregraft 850 para o saco de drenagem Puregraft 850 durante aproximadamente 2-6 minutos (consulte a tabela 1 para obter informações detalhadas sobre o tempo de drenagem) 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 850 para drenar o excesso de fluido de envagamento por 2-6 minutos, dependendo do nível de hidratação desejado para o enxerto.
- Utilize o sistema deslizante Puregraft para gular o tecido em direção à porta com o rótulo "Tissue" (tecido). Feche o grampo de aperto do saco de drenagem Puregraft 850.
- REMOÇÃO DO ENXERTO:
- Ligue de forma asséptica um adaptador combinado a uma seringa Toomey estéril vazia.
- Ligue a seringa estéril ao saco Puregraft 850, colocando a parte macho do adaptador combinado na porta com o rótulo "Tissue" (tecido).
- Remova o tecido do saco Puregraft 850 puxando lentamente o êmbolo da seringa até que a seringa esteja cheia. Use o sistema deslizante Puregraft conforme necessário para extrair o tecido restante do saco Puregraft 850.
- Nota: Pode estar presente um conteúdo significativo de fluido e líquido nos últimos 10-20 ml de tecido remanescente. Descarte os 20 ml finais de saída de tecido
- Assim que o tecido tenha sido removido do saco, elimine adequadamente todos os componentes descartáveis utilizando as pre-cauções 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 a autoridade competente do Estado Membro no qual se encontre o utilizador e/ou paciente.

IF: 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、自己顕着移植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。美容目的の体形矯正など本機器のその他の非医学的の使用はCE認証の適用範囲外となるため、ユーザーは、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くようにしてください。

概要

Puregraft®850システムは減脂、単回使用、閉鎖システムで美容及び再建外科利用における閉鎖的自家移植時に用いられる脂肪組織を準備することを最適化したデバイスです。Puregraft®850システムは以下の構成品から成っています。

- Puregraft 850 Bag
- Puregraft 850 Drain Bag
- Combined Adapter

オプションとして、Puregraft®850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ブ滅菌による再使用構成品から成っています。

- Puregraft Easel
- Puregraft Slider

オプションとして、Puregraft®850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ブ滅菌による再使用構成品から成っています。

- Puregraft Easel
- Puregraft Slider

Puregraft EaselはPuregraft 850Bag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ポートのクランプを容易に、完全な全体をPuregraft 850 Drain Bagへ排液することができます。保管、滅菌及び適切な機器の使用はPuregraft Instrument Setに同梱されている別の冊子をご覧ください。

注意

以下はPuregraft®850システムの禁忌です。

- 血管内投与

滅菌

- Puregraft®850システムはガンマ線滅菌されています。

滅菌

- 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

- 再回使用、再使用禁止。
- 自家移植専用
- 施術者は使用前に、Puregraft®850システムの操作及び外科的技術に習熟しておくこと。
- Puregraft®850システムは同一手術内であっても再使用しないこと。再使用は無菌性やシステムパフォーマンスに悪影響があります。
- 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病原性の増大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は、単回使用品の再使用は、機能の低下は機能、致命的な感染を生むを含む機器の劣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。
- 機能の再滅菌は機能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 850 Bagへ排液する組織及び機種の温度は1275mlを超えないこと。
- バッグの完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 850 Bagへの排液を止めること。

事前注意

- 使用前にPuregraft 850システムの包装に損傷がないか確認してください。
- Puregraft 850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してください。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にPuregraft 850システムすべてを破棄してください。
- Puregraft 850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通の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いってください。
- Puregraft 850バッグを過剰に膨張させたり充填し過ぎたりすると、オペスタッフへの生物学的災害や機器の故障の原因となります。
- Puregraft 850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。
- 850システムは3mm径のMercedesチップキュアールを用いて脂肪組織が採集されることを意図しています。

操作方法

- 滅菌のPuregraftインストラクター（Puregraft Easel and Slider）を設立した操作位置に設置してください。
- Puregraft 850システムの入ったTiyekボックスを開け、Puregraft 850BagをPuregraft Easelにかけ、Puregraft 850 Drain BagをPuregraft 850Bagより低い位置に置く、そして、pinch clampがPuregraft 850Bag近傍で、閉鎖になっていることを確認する。
- 注意: Lactated Ringer's/Luer Lock Washと併用したポートに同梱されているInlet Tubing Set (optional) を用いて接続するが、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/Luer Lock Washと離れたポートにLactated Ringer's/Tissueと離れたポートに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 850 Bagのピンチクランプを閉じ、Lactated Ringer's/Luer Lock Washポートのオスルーアコネクタに接続し、続いてLactated Ringer's bagsにパイクします。この時点でpinch clampを閉じており、Puregraft 850 BagにLactated Ringer'sがすべて流れてしまわないよう、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。
- 滅菌した脂肪組織を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を取り付けておきます。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ルーアコネクタ等を用いPuregraft 850 Bagへ導入してください。
- Puregraft 850 Bagへ脂肪組織を採取しシリンジを接続し（TissueポートへCombined Adapterのオスコネクタ部を接続する）、シリンジを接続したままプランジャーを押しPuregraft 850 Bagに脂肪組織を導入する。注意:Tissueポートの導入時むわずかな流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30～50%多めの量、すなわち組織総量200～850mlを、Puregraft 850バッグ（Puregraft 850 Bag）に注入します。クランプ洗浄と処理Puregraft 850 Drain Bag/pinch clamp閉じる。Inlet Tubing Setを使用した場合、Lactated Ringer'sのpinch clampを閉じて100～425mlの容量を脂肪組織とLactated Ringer'sの比が2:1になるように、以下の表に従ってPuregraft 850 Bagへ入れる

脂肪組織総体積 (ml)	洗浄液体積 (ml)	稼動時間 (MIN)
200	100	2
400	200	3
600	300	4
850	425	6

表1

注意:シリンジの場合は、滅菌されたボウルからLactated Ringer'sをシリンジで吸い取ってからPuregraft 850 BagのWashポートに接続し、規定量を導入します。

- Puregraft EaselからPuregraft 850 Bagを外し、手で約30秒間、40mmまで全長がいきわたるようやさしく反転させます。
- Puregraft 850 Drain Bagのpinch clampを開け、2～6分間（表1参照）、Puregraft 850 BagからPuregraft 850 Drain Bagへ排液します。
- 手順及び液を排し直して組織を洗浄し、Puregraft 850 Drain Bagのpinch clampを開けて希釈液を加え、よく充分な高液量2～6分間排液する。
- Puregraft Sliderを用いてTissueポートへ組織を抜き寄せる。Puregraft 850 Drain Bagのpinch clampを閉じる。クランプの取り出し。
- 滅菌した空のToomeyスタイルシリンジにCombined Adapterを取り付け。
- Puregraft 850 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。
- ゆっくりとシリンジのプランジャーをシリンジがいっせいになるまで引いてPuregraft 850 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 850 Bagに脂肪組織を押し出す。注意:Toomeyスタイルシリンジは使用しないこと。十分な量の液体が含まれている。最後の10～20mlは使用しないでください。
- いっぺんにPuregraft 850 Bagから脂肪組織を取り出したら、それらは普通の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。注意: 運送法により、本器具は、医師の指示に基づいて限定されている。

TR: KULANMA TALİMATI
Bu ürün, yalnızca otolog yağ aktarımı endikasyonları için SGS CE1639 tarafından Tibbi Chizah Direktifi 93/42/EEC kapsamında Avrupa Birliği'nde tibbi cihaz olarak onaylanmıştır. Bu cihaz aitedilen estetik vücut şekillendirme gibi diğer tibbi amaçlara kullanılmamalıdır. CE sertifikasyonu kapsamında dağılılır ve kullanılarak, ürün performansının ve/veya güvenliğinin bu amaçlar için SGS tarafından değerlendirilmediğini bilinizdir.

TANIM

Puregraft® 850 Sistemi, plastik ve rekonstrüktif cerrahi uygulamaları için otolog yağ greftlerinin hazırlanması ve aynı hastaya geri verilmesini yöneten steril, tek kullanımlık, kapalı bir sistemdir. Puregraft 850 Sistemi aşağıdaki bileşenlerden oluşur:

- Puregraft 850 Torba
- Puregraft 850 Drenaj Torbası
- Kombine Adaptör

Optimum performans için Puregraft 850 Sistemi, Puregraft Alet Seti ile birlikte kullanılmalıdır. Bu set, aşağıdaki yeniden kullanılabılır sterilize edilebilir bileşenlerden oluşur:

- Puregraft Sepha
- Puregraft Sürgü

Puregraft Sepha, optimum sıvı akışı için Puregraft 850 Torbasını tutacak bir stand olarak tasarlanmıştır ve Puregraft Sürgü, greft ekstraksiyonu için dokuyu "Tissue" etiketli porta doğru yönlendirirken fazla sıvının dokudan uzağa ve Puregraft 850 Drenaj Torbasına hareketini kolaylaştırır. Bu ünitelerin saklanması, sterilizasyonu ve uygun kullanım talimatı için Puregraft Alet Setinin Ürün ambalajında bulunan ayrı Kullanim Talimatına bakın.

KULANIM ENDİKASYONLARI

Puregraft 850 Sistemini, Otolog Yağ Aktarımı (AFT) Prosedürü için aynı hastaya yeniden enjekte edilecek üzere otolog yağ dokusunun toplanması, filtrelenmesi ve aktarılması için kullanılması endikedir.

KONTRENDİKASYONLAR

Aşağıdaki, Puregraft 850 Sistemini kullanımı için kontrendikasyonlardır:

- İntravenöz uygulamalar.

STERİLİTE

- Puregraft 850 Sistemi gama radyasyonu ile sterilize edilmştir.

SAKLAMA VE NEMALEME

- Yalnızca sterilizasyonu göstermiş kırımlıya kullanın.

UYARILAR

- Yalnızca Tek Kullanımlık – Yeniden Kullanılmayn.
- Yalnızca Otolog Kullanım İçin.
- Cerrah, Ameliyat Geçirmemiş Önce Puregraft 850 Sistemini çalışmasını ve cerrahi prosedüre aşina olmalıdır.
- Aynı prosedür sırasında Puregraft 850 Sistemini yeniden kullanılmayy denemenin. Yeniden kullanım, steriliteyi tehlikeye atabilir ve sistemin performansını olumsuz etkileyebilir.
- Tek kullanımlık bir cihaz yeniden kullanılması, üreticinin Kullanim Talimatının (IFU) bulunmaması nedeniyle cihazın dışıgn çalışmasını önemli riskler getirir.
- Tek kullanımlık bir cihaz yeniden kullanılması ve/veya temizlenmesi, cihazla bilimsel kimyasal etkileşimler veya hastaya arak teması madelelerine maruz kalması nedeniyle hastaya zarar verebilir.
- Tek kullanımlık bir cihaz yeniden kullanılması hasta için enfeksiyona yol açabilecek sterilite kaybı dahil olmak üzere ciddi riskler oluşturur.
- Tek kullanımlık bir cihaz yeniden kullanılması buluşça hastalığın bir hastadan diğerine bulayması dahil olmak üzere hasta için ciddi riskler oluşturur.
- Bulaşıcı hastalık bulagına risklerinin yanı sıra tek kullanımlık cihazların yeniden kullanılması, cihazın yükü arzasına kadar ve dahil olmak üzere üirren performansını düşmesine veya bozulmasına kadar açabilecek malzeme bozulması nedeniyle cihazın aynı Torba veya erken mekanik arızasını içeren ciddi riskler oluşturur.
- Bu cihaz yeniden sterilize edilemez, cihazın önemli hasara veya bütünlüğü kayına neden olabilir.
- Puregraft 850 Torbasının 1275 ml'den fazla toplam doku hacmi ve/veya yakama solüsyonu ile aşırı doldurulmayn.
- Torbanın malzemesi deforme olmaya başlayarak torbanın bütünlüğünü kaybolmasına ve cerrahi personel için biyolojik tehlike oluşmasına neden olursa, Puregraft 850 Torbasına herhangi bir sıvı veya doku girişini derhal durdurun.

ÖNERİLER

- Kullanılmadan önce Puregraft 850 Sistemi ambalajın hasar belirtileri açısından inceleyin.
- Puregraft 850 Sistemi yalnızca tek kullanımlıktır ve steril ambalajından çıkardıkları hemen sonra kullanılmalıdır.
- Ambalaj hasarı varsa, aşımış veya sterilizasyonu göstermiş görseleize Puregraft 850 Sistemini tamamını atın. Puregraft 850 Sistemini kontaminasyonu olasılığı ve as indiremek için aseptik teknikler kullanılmalıdır.
- Kan ve sıvıların tamamına Evrensel Önlemleri (Kanla Buluşan Patojen Önlemleri) kullanılarak muamele edin.
- Puregraft 850 Torbasının aşın şişirmesi veya aşırı doldurulması, çalıştırın personel için biyolojik tehlikeye ve/veya cihaz arızasına neden olabilir.
- Puregraft 850 Sistemini, sistemin işine ve dışına doku aktarımı için bir Toomey şırıngası ve verilen Kombine Adaptör ile birlikte kullanılması önerilir.
- Puregraft 850 Sistemi, 3 mm çaplı bir Mercedes-Uçlu Kanül ile toplanan dokuyu almak için tasarlanmıştır.

KULANMA TALİMATI:

HAZIRLIK:

- Steril Puregraft Sepha ve Sürgüyi dik çalığın konumuna getirin.
- Puregraft 850 Sistemini içeren Tiyek poşetlerini açın ve Puregraft 850 Torbasını Sephaya üzerine asın.
- Puregraft 850 Drenaj Torbasını Puregraft 850 Torba seveyisinin oldukça altına yerleştirin ve sıkıdırma klempinin Puregraft 850 Torbasına yakınında olacak şekilde kurumun olduğundan emin olun.
- Not: Laktatlı Ringer, isteğe bağlı bir Giriş Tüpü Seti kullanılarak "Wash" etiketli porta veya bir Luer Kilitli seringa kullanılarak doğrudan "Wash" etiketli porta eklenebilir. Laktatlı Ringer, Kombine Adaptör ve Toomey tarzı şırıngı kullanılarak, "Tissue" etiketli portı yoluyla da eklenebilir. Giriş Tüpü Setini kullanıyorsanız, erkek Luer ucunu Puregraft 850 Torbası üzerindeki "Wash" etiketli porta bağlayın ve Laktatlı Ringer torbasının çivilenemeli için tüpü kapatın. Bu sırada Puregraft 850 Torbasına Laktatlı Ringer'in girmesini önlemek için sıkıdırma