

CelluTOME™



EPIDERMAL HARVESTING SYSTEM

HARVESTER INSTRUCTIONS FOR USE

FEATURING ADAPTIC TOUCH® NON-ADHERING SILICONE DRESSING

INTENDED USE

The CelluTome™ Epidermal Harvesting System is intended to reproducibly cut a thin skin graft for autologous skin grafting.

CONTRAINDICATIONS

None

DEVICE DESCRIPTION

The **reusable** components of the CelluTome™ Epidermal Harvesting System:



Control Unit



Vacuum Head

- The control unit creates and regulates the vacuum and monitors the vacuum head.
- The vacuum head and tubing deliver the vacuum from the control unit and creates the warming required to raise the epidermal suction microdomes.

NOTE: *More information about the control unit and vacuum head can be found in the CelluTome™ Epidermal Harvesting System User Manual.*

The **disposable** component of the CelluTome™ Epidermal Harvesting System:



Harvester

The harvester holds the suction microdomes that are raised for procurement. A dressing for transferring the microdomes (such as an Adaptic Touch® Dressing) is placed onto the harvester's microdome grid prior to cutting the microdomes. After cutting the microdomes, the dressing with the micrografts is then applied to the recipient site.

Follow warnings, precautions and instructions listed in this document. Improper use could result in patient injury, bleeding, scarring, inadequate micrografts, prolonged procedure time, incomplete or ineffective procedure, the need to perform harvesting at a second donor site or patient discomfort.

WARNINGS

The harvester is a disposable component and is intended for single use only. Re-use of disposable components may result in contamination and infection.

PRECAUTIONS

Inspect the CelluTome™ Epidermal Harvesting System before use for signs of visible damage. Do not use if there are any indications of damage.

Harvest from areas of healthy intact skin (donor site).

Actuating the harvester handle prior to complete microdome formation may result in patient pain and / or bleeding.

Actuating the harvester handle prior to placement of the dressing may result in an inability to secure the micrografts for application.

Wipe the vacuum head and the control unit nest following institutional procedures used for cleaning and disinfection of other hard surface durable electronic medical equipment between each patient use. Inadequate cleaning may result in patient contamination.

Use the harvester only with the CelluTome™ Epidermal Harvesting System control unit and vacuum head.

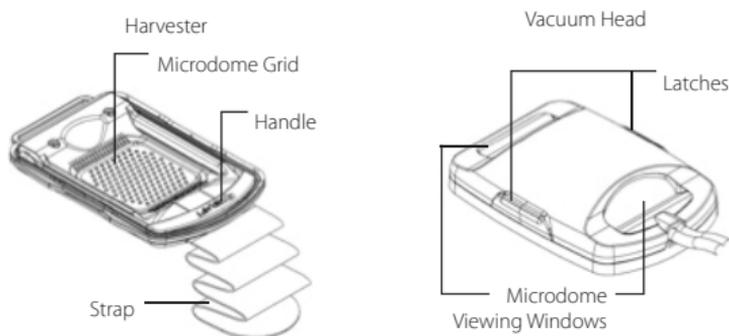
Discard all disposable items (harvester and dressing) in accordance with local medical waste disposal regulations.

Handle the vacuum head with care. Do not drop the vacuum head, as doing so could damage the glass warming window. Do not suspend or hold the vacuum head by the tubing.

Reversible maceration at the recipient site is a potential risk. Please use best clinical judgement for preventing maceration.

HARVESTING INSTRUCTIONS

The harvester is provided sterile.



1. Prepare donor site by shaving or clipping hair in a 10 cm square at the donor site if needed. Rigorously wipe area with alcohol.
2. Open the disposable harvester package.
3. With the blue handle oriented up, position the harvester on the patient's inner thigh, centered on the area of prepared skin, then secure with the integrated strap. Confirm complete contact with donor site by ensuring skin can be seen in all of the microdome grid holes in the harvester. Reposition if necessary.
4. Ensure that the vacuum head tubing is plugged into the control unit, the control unit is plugged into the wall and that the Status Indicator light is amber. Refer to the CelluTome™ Epidermal Harvesting System User Manual for more details.
5. Press the blue latches to detach the vacuum head and remove it from the control unit.
6. With the tubing facing up, place the vacuum head onto the harvester, and push until the vacuum head snap fits onto the harvester. Ensure that the vacuum head is securely latched to the harvester.
7. Press **Start / Pause** button to begin the suction microdome raising process. The Status Indicator light will flash green. If needed, press the **Start / Pause** button again to momentarily pause the suction microdome raising process.
8. Once the timer beeps, check the microdomes to see if they are all ready to harvest - raised, clear and shiny. (Fig.1)
9. If the system was paused and microdomes are not ready to harvest, press the **Start / Pause** button to continue the process.

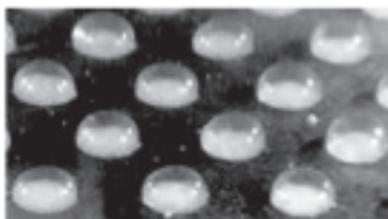


Fig. 1

10. Once the microdomes are ready to harvest, press the **Power** button or the **Start / Pause** button to stop the microdome raising process.
11. Unlatch the vacuum head from the harvester. The harvester should remain on the patient's skin.
12. Wipe the underside of the vacuum head following institutional procedures, then place the vacuum head in the control unit nest and push to engage the latches.
13. Place a dressing (such as an Adaptic Touch® dressing) for transferring the microdomes onto the harvester grid. Center the dressing starting from the middle then fanning out to the edges to ensure complete coverage of the protruding microdomes.
14. Use fingers to firmly press the dressing against microdomes. Apply firm pressure to ensure that the dressing adheres to the microdomes.
15. Harvest the microdomes by raising the blue harvester handle fully (until an audible click is heard) and then lowering the handle to the original position.
16. Carefully peel back the dressing from one end of the harvester. Use care to ensure that the dressing does not get torn or otherwise damaged when removing it from the harvester. Verify that micrografts have transferred to dressing.
Note: when using a dressing such as an Adaptic Touch® dressing, the dressing may be placed back down and pressure applied to make sure the micrografts are picked up by the dressing.
17. Apply the dressing with micrografts to the recipient site.
18. Apply additional pressure dressings / bandages as appropriate for the recipient site per your current standard of care.
19. Remove the harvester from the patient's donor site.
20. Apply a dressing, film, or other treatment / dressing to the donor site per your current standard of care.
21. Discard all disposable items (harvester and dressing) in accordance with local medical waste disposal regulations.

EXPLANATION OF SYMBOLS USED



Keep Dry



Catalog Number



Use By



Lot Number



Content Information



Consult Instructions
for Use



Date of Manufacture



Manufacturer



Do not use if package
is damaged or open



Method of Sterilization -
Ethylene Oxide



Do Not Resterilize



Authorized Representative in
the European Community



Single Use Only

Rx Only

CAUTION: Federal (US) law
restricts this device to sale / rental
by or on the order of a physician



Conforms with the Medical Device Directive
(93/42/EEC) and has been subject to the
conformity procedures laid down in the council
directive.



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