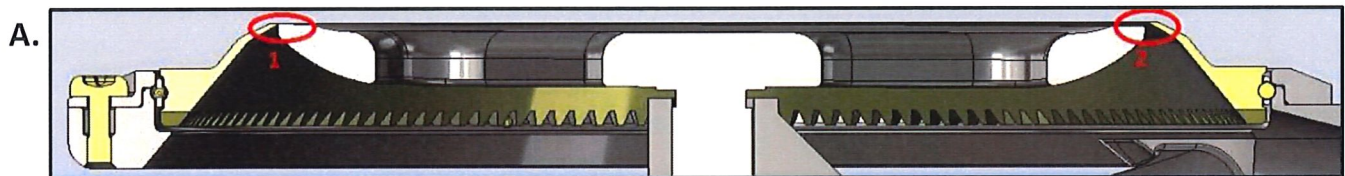


**SUBJECT:** Training Document to Optimize Performance of the Amalgatome MD

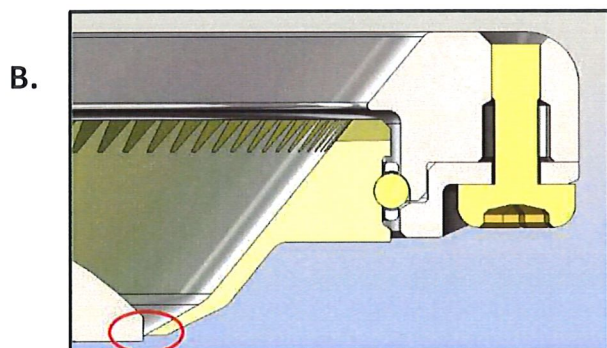
This supplemental training document is to assist and optimize performance of the AMD in providing tips on use to ensure proper thickness/recovery of split thickness skin.

**TIP #1 – Interpreting Cut Thickness, Impacts and How to Interpret Indicators on the Amalgatome MD**

- At time of manufacture, marking the device (calibration step), a single point on the depth plate is set to a known distance from a calibration surface. This is where the nominal blade height would result in a “zero thickness” setting – rather – the sharpened blade edge and depth plate are flush at that point.
- Depth plate “tilt” will vary slightly from device to device. When calibrating the device, a single point of contact is used – and there is a single location on the device where when set to zero the blade will be flush with the depth plate. Tilt is indicated below as the difference between side 1 and side 2. (*picture A.*)



- An operator may be able to visibly see a difference from side to side in distance from the blade edge to the depth plate, we have an acceptance criteria number or specification for this from side-to-side. This number was derived from the demonstrated ability of the devices to perform its intended function.
- There is some question on why some devices can be dialed past zero - that “zero is a point in space”, and **dialing past zero is not an indication that the calibration is off or a measure of thickness.**
  - What occurs when dialing past zero, the depth plate is being extended down and through the blade opening.
  - The distance between the sharpened blade edge and the bottom of the depth plate is the number indicated on the dial.

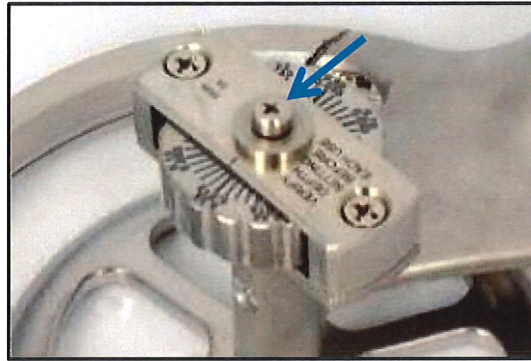


Illustrated here (*picture B.*): Dialing past zero is not recommended due to risk of damaging the sharpened blade edge in the event it touches the depth plate (see **red circle**).

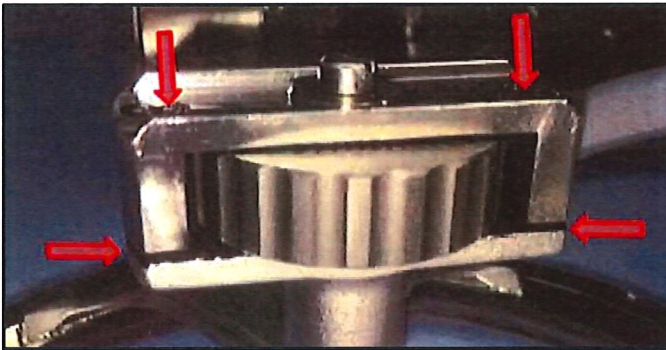
**TIP #1 – Interpreting Cut Thickness, Impacts and How to Interpret Indicators on the Amalgatome MD (continued)**

- If able to dial past zero, it is recommended to check that the single top screw is tightened down (*picture C. see blue arrow*). If loose, this can be hand tightened back down into place.

**C.**



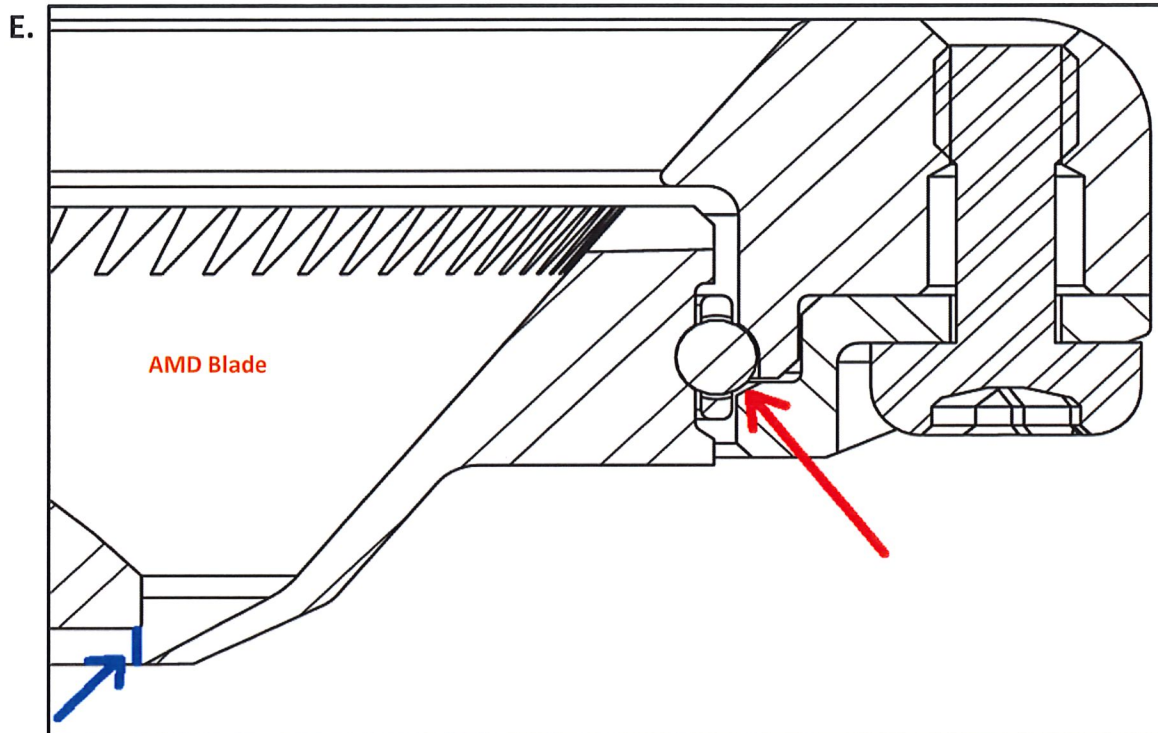
**D.**



Illustrated here (*picture D.*): The bottom **red arrows** show the gap if the top screw is not in place, the depth plate will not work properly.

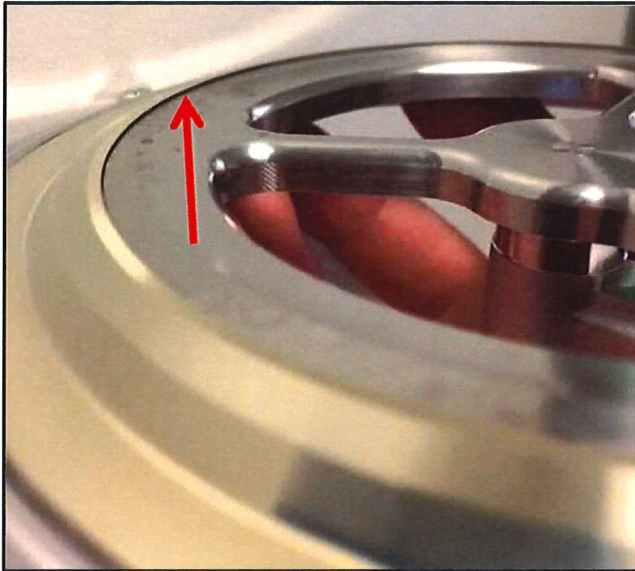
**TIP #2 – Managing Thickness During the Initial and Continued Cut**

- If staff are attempting to recover the split thickness skin graft (STSG) by “starting at a thicker setting to get a bite into the skin graft, and then dial it thinner once the recovery of the strip of skin starts.” The attempt to accomplish (dialing it to a thinner setting), may not thin the skin graft out as expected.
  - The potential issue of starting thick, and dialing thinner without the skin graft thinning out has been seen before. The diagram below represents a cross-section of the AMD Head Assembly with Blade inserted.
  - The thicker skin is physically separating the blade from the bottom of the depth plate (**blue arrow**) and that gap is remaining constant due to the clearance (**red arrow**) between the Blade and Lock Ring. The circle is the ball bearing strip around the blade. (**picture E.**)



- A **slightly** higher pressure should be applied to have the blade seat in its calibrated surface and ‘put itself back into place’ when the operator is observing thick skin being recovered after the first ‘bite’ of tissue.
- **\*\*NOTE\*\*** It is important to understand that it is still valid to state that “pressing too hard will cause thick tissue to be recovered” during normal operation. In the case where technicians start-thick-dial-thin, application of **slightly higher** pressure may be required to thin out tissue.
  - The team should listen to the pitch of the power supply, too much pressure will result in a higher pitch sound, which will be an audible indicator to lighten up.
- If the skin thickness is not correct after the initial start, it is recommended to stop the cut, change your depth setting as needed, and then start again. Do not continue to complete the recovery of that strip if it is too thick or not meeting the specifications.



**TIP #2 – Managing Thickness During the Initial and Continued Cut (continued)****F.**

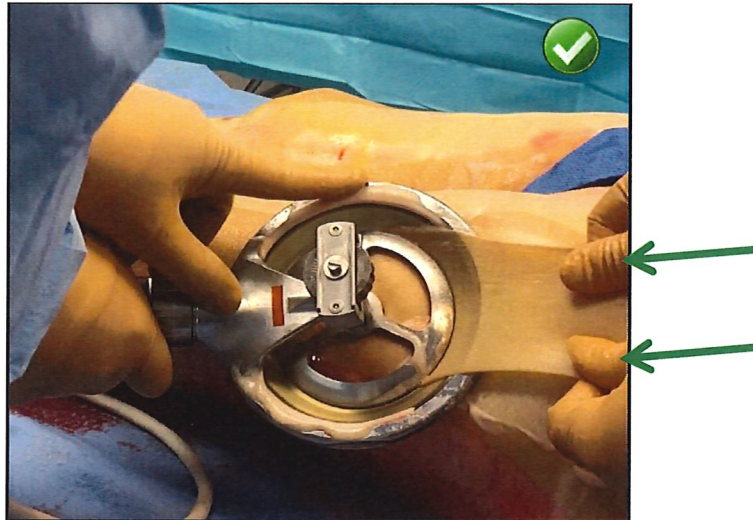
Illustrated here (*picture F.*): We are pushing up on the blade to simulate skin being between the blade and the depth gauge. The **red arrow** shows the space where skin could be between the blade and the depth gauge and now by dialing thinner the skin would be in the way of the depth plate moving thinner.

**G.**

Illustrated here (*picture G.*): This is just the weight of the blade at "0", you can see how it is close to ("flush") the blade is with the depth gauge. This is the reason why a slight amount of pressure is needed during recovery. If slight pressure (**NOT EXTREME**) is applied, it will keep the blade seated properly within the head assembly and in relation to the depth gauge.

**TIP #3 – Managing Thickness While Assistant Pulls the Skin Graft**

- If the staff are recovering skin and agree to have assistant pull the skin significantly taunt, we have found this can be helpful to allow the blade to seat in its calibrated surface, as described in TIP #2 above.
  - Ensure the two recovery team members are discussing this and working together to for proper skin graft thickness.
  - The depth setting could need to be set at a thinner setting (potentially by .005" thinner) because this pulls the tissue plane up against the bottom of the AMD.
  - It can be helpful for the assist to pull the skin graft perpendicular to the body out of the AMD to maintain the width over bony prominences such as ribs or knees.
  - The assistant should hold the edges of the skin graft as it comes out of the head AMD rather than on the center end part of the recovered graft. (*picture H.*)

**H.**

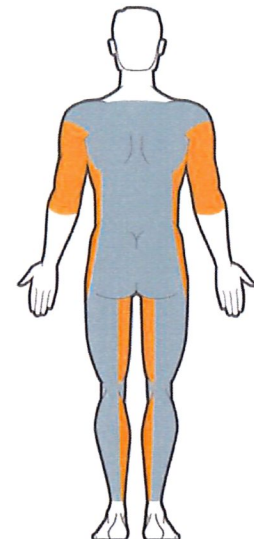
**TIP #4 – Depth Adjustments on the Amalgatome MD**

- If you are experiencing your skin reports coming back with too much skin measuring too thick, please use the new reference below. If your processor is not reporting this back, there is not need to change anything.
- The depth gauge measurements are to be used as a guide (as well as our training materials), your depth setting will be dependent on the donor demographics (such as age, size, fluid retention, refrigeration time, BMI, etc.) and processor protocols.

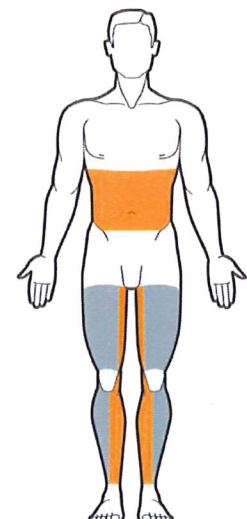
I.



Recovery Location	Depth Setting	Comments
Posterior Trunk	<b>0.005" to 0.010"</b> (0.12mm to 0.25mm)	This site should yield the "easier" strips of recovered skin and could be used as the baseline for the settings of the other sites.
Buttocks	<b>0.008" to 0.012"</b> (0.20mm to 0.30mm)	To recover the skin in this site the device setting should be set thicker, with some slight pressure applied.
Posterior Legs	<b>0.002" to 0.005"</b> (0.05mm to 0.12mm)	To recover the skin in these sites the device setting should be set thinner, and little to no pressure.



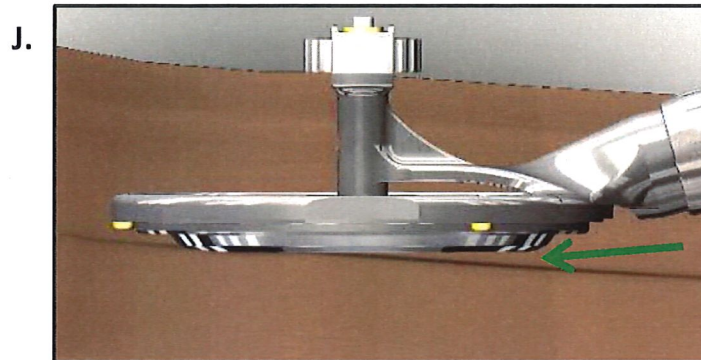
Recovery Location	Depth Setting	Comments
Anterior Trunk	<b>0.005" to 0.008"</b> (0.12mm to 0.20mm)	To recover the skin in this site the device setting should be set thicker, with some slight pressure applied.
Inner Thighs	<b>0.002" to 0.005"</b> (0.05mm to 0.12mm)	To recover the skin in this site the device setting should be set thicker, with some slight pressure applied.
Anterior Legs	<b>0.002" to 0.005"</b> (0.05mm to 0.12mm)	To recover the skin in these sites the device setting should be set thinner, and little to no pressure.



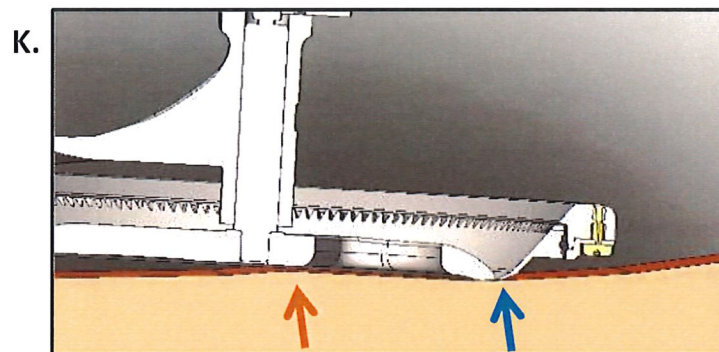


**TIP #5 – Proper Positioning of the Amalgatome MD for 4-Inch-Wide Skin Grafts**

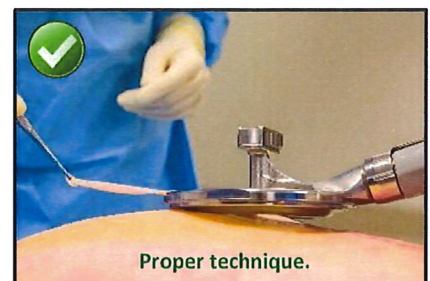
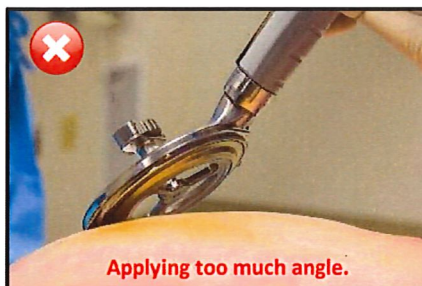
- The Amalgatome MD has a 15° angle built into the device. The proper angle (**green arrow**) to apply minimal pressure to the recovery site is approximately 3 to 5°. This allows for the cutting edge of the blade to recover the skin graft. The depth plate is flattening the skin surface for the blade edge. (**picture J.**)



- The **blue arrow** indicates the blade edge. The **orange arrow** indicates the center of the head assembly. The depth plate is flattening the skin surface, area between the two arrows, which is the diameter of the 4" skin graft. This also allows for the blade to stay seated in its calibrated surface (**picture K.**)

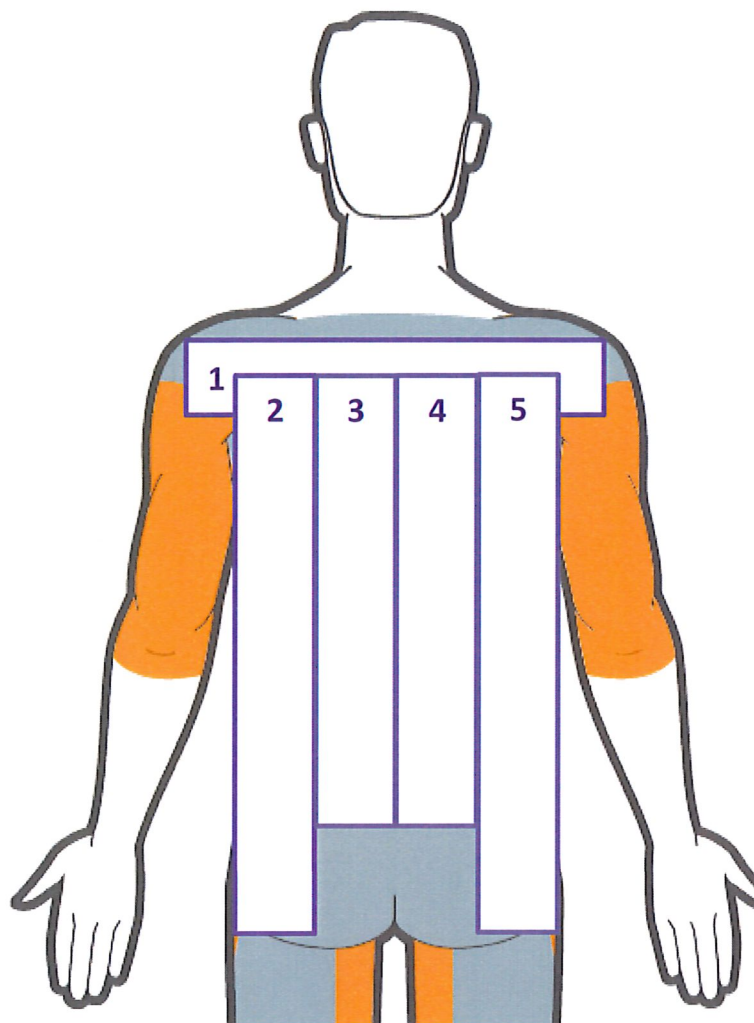


- Examples of improper and proper angle or positioning.



**TIP #6 – Maximizing Skin for the Posterior Torso**

- It can be helpful to recover the first strip across the donor's back from right to left in the opposite direction as illustrated in the image below, indicated by #1. Followed by recovering strips #2 to #5.
- When recovering the strips #2 to #5, start the recovery into the exposed dermis that remains after recovering strip #1 as shown. The start of the strip is often the crescent or half-moon shape of the blade is the section that will be trimmed in processing to create rectangular skin grafts, so starting within the exposed dermis can maximize the length of the rest of the recovered strips from the posterior torso.

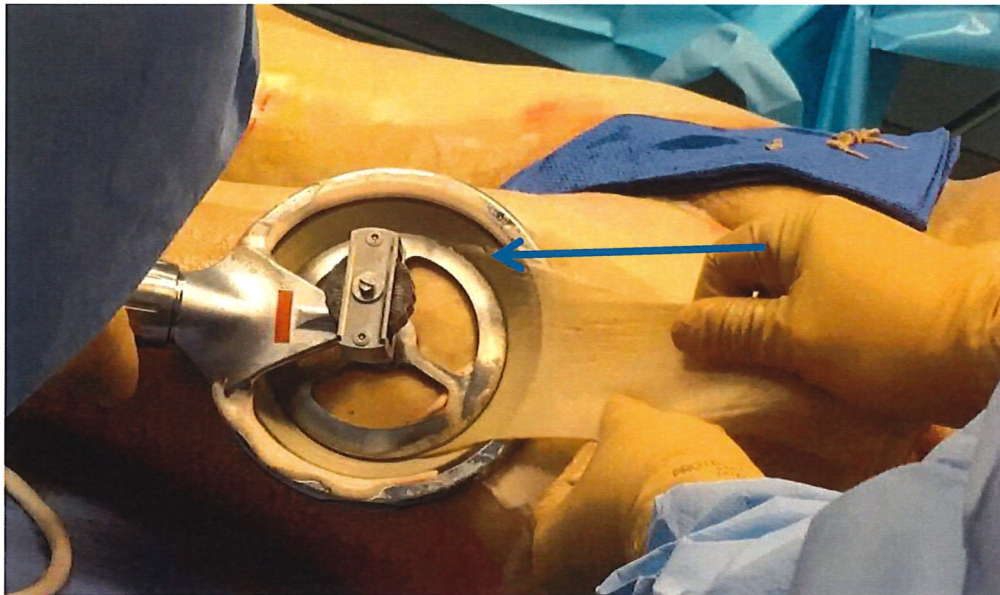




**TIP #7 – Avoiding the Chattered Pattern in Blade Direction**

- The Amalgatome MD blade spins counter clockwise, in that direction it can be best to add a slit amount of tilt towards the direction of the blade spin. Or apply a little extra pressure with your finger on top of the edge of the head assembly. See the **blue arrow** pointing out the chatter and the **green arrow** for the finger applying extra pressure.

**L.**



**M.**

