Title:

SGOI Wolverine Plasma Tray Loading

Purpose:

To provide instruction on the proper way to place units onto plasma trays, and transfer trays to the plasma chamber in preparation for the Plasma treat operation/station.

Applicable Documents:

Description	Number
Good documentation Practices and SFP review (Lean)	S308938-00
Cleaning work surfaces and equipment	S300155-00
Cleaning work surfaces & equipment PTA	90560932
Line Clearance Guideline Cutting Balloon	90509286
MES 4.5 Product Builder Work Instruction, BSC	92081060
MES Navigation and General WI	90395576
PTA Reprocessing Procedure	M320339-00

Definitions:

Term	Meaning
MR	Monorail
OTW	Over the wire
MES	Manufacturing Execution System.
MES WIP Tag	MES Work in Process label which travels with the MES container. (barcodes with material, container and quantity information)
MES Container	Term used to represent ‘in process’ orders being tracked in the MES for items such as raw materials and assemblies.

Equipment & Material:

Description	Number
Plasma Tray	90395207

Equipment & Material:

Description	Number
Plasma Tray	51321755
Alcohol, 99% Isopropyl	466720-01
Alcohol, 70% Isopropyl	466720-02
Nitrile Glove (Blue)	90179967-01/-02/-03/-04

Definitions The following terms are used in this procedure:

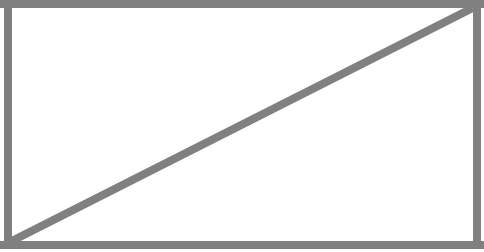
▲ **Inspection/Verification**
■ **Work Content**
● **Confirm**
\+ **Safety**
* **Important Additional Information**
\- **Standard Additional Information**

\+ Blue Nitrile Gloves and safety glasses must be worn when executing this procedure. Replace at start and end of batch.

Procedure – Set Up

Step	Visual Representation	Description	Additional Information
1.		■ Log into MES ■ Obtain catheters to be used and issue as per MES instruction. ■ Ensure only catheters issued to the bonding batch are stored at the work-step.	* N/A
2.		■ Obtain Plasma tray from Plasma tray Storage location. ■	

Procedure – Set Up

Step	Visual Representation	Description	Additional Information
3.		▲ Visually inspect the tray for FM such as tape, marker ink, etc., ■ Remove if found.	* Notify manufacturing support staff and do not use plasma tray or fixture if FM cannot be removed.

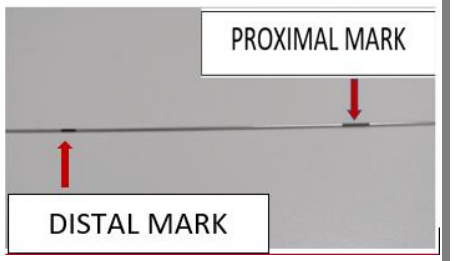
Procedure – Load Plasma Tray – Wolverine

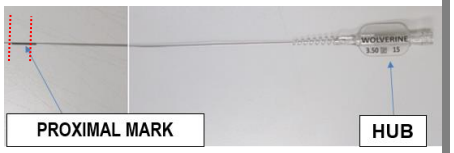
Step	Visual Representation	Description	Additional Information
1.		▪ Load catheters into every 2nd comb on the plasma tray. There should be one empty space in between each catheter (max 20 catheters per tray). Adjust the mandrel to position the balloon central between the two combs, so that the balloon surface is not contacting either of the combs. ▪ While loading catheters on trays verify that size printed on every catheter manifold is correct as per MES requirements. ▪ For OTW – Confirm that the manifold ports are facing up in the plasma tray. • Confirm that no catheter and mandrel are outside of the tray.	

Procedure – Load Plasma Tray – Wolverine

<table>
<tr><th>Step</th><th>Visual Representation</th><th>Description</th><th>Additional Information</th></tr>
<tr><td>2.</td><td></td><td>▪ Ensure that approximately 2” of the Mandrel is sticking out of the Distal Tip of the catheter; so the mandrel can hold the catheter on the comb without damaging the balloon.

▪ If adjustment is required for OTW –
Hold the catheter shaft on the proximal side of the balloon and position the mandrel to securely hold the balloon central between the two combs.

▪ If adjustment is required for MR –
Hold the catheter shaft on the proximal side of the balloon and position the mandrel to securely hold the balloon central between the two combs.</td><td></td></tr>
<tr><td>3.</td><td> 


</td><td>▪ Double click the Plasma Scanning Application icon
Inspect proximal marks; ensure proximal marks are in-line with each other after plasma tray is filled

<table><tr><th>Defect</th><th>Visual Standard</th></tr><tr><td>Missing or Not Aligned Proximal Marks</td><td></td></tr></table></td><td>Use the KVM switch to change between the MES PC and the Plasma Scanning Application PC</td></tr>
</table>

4.		■ Enter Windows username and password ■ Select File >Scan Batch Information. The following screen is displayed.	
5.		■ Scan the Shop Floor Batch Number from the X label verification form. ■ Scan Material number from the X label verification form ■ Enter batch quantity ● Click “Accept Batch Details & Scan Catheters”	

6.		* Steps 6&7 are to be repeated for each loaded plasma tray until the full quantity of the batch has been processed and loaded into the plasma chamber. ▪ Scan the hubs of the catheters to be plasma treated so that the catheter serial number is recorded within the plasma app. • It is necessary to position a white or blue sheet behind the catheter hubs in order to provide a contrasted background against which the 2D barcode can be scanned.	A Maximum of 20 catheters are to be loaded into a single plasma tray. Catheter batch number, Catheter serial number, Times scanned and Last UTC Date scanned will be populated on the screen after each unit is scanned

7.	 	• Once all catheter hubs on a plasma tray have been scanned and details recorded within the plasma app the plasma tray is to be transferred to the plasma chamber [Balloon end in first] to await plasma treatment. ▪ For Diener Plasma Chamber: Ensure the “Front Door” is selected on the plasma chamber HMI. Open Plasma Chamber doors by pressing the “Door Up” switch on the plasma chamber. **Notes: Plasma trays to be loaded into All shelves. Any shelf not containing product should be loaded with an empty plasma tray. There must always be 6 plasma trays in the chamber during each plasma treatment cycle.** ▪ For Diener Plasma Chamber: Use the Plasma Tray Positioning Tool to ensure all trays are aligned with the top and bottom electrode and are centered on the shelves • Verify that there are no foreign objects between the shelves or anywhere inside the chamber. If foreign objects are present and they are within arm’s reach, remove them prior to loading machine. If the objects cannot be reached, contact technician. • If MES WIP Tag is present, make sure to remove it from tray. • Look at the tray from 12-18 inches away and make sure there is no FM on the tray. • For OTW product only: ensure mandrels are not sticking upwards and contacting ground plate.

		▪ Load trays on shelves so they do not extend over the end of the shelf and come in contact with the doors on either end of the chamber. Place trays in the chamber from top to bottom. Verify that the material on the trays is lying flat and not touching any part of the inside of the plasma chamber. • Look at tray in plasma chamber after loading and check that no mandrels are touching walls or other trays. If material on trays touches wall or the electrode panel directly above, it could cause a short and damage the machine. Adjust units on tray if necessary.	
		▪ Place a clean polyethylene coupon (PE 03500-01), shiny side up, on all trays containing product. (This will be used for the wettability test). **Note: Touch the coupon as little as possible**. • When loading is complete, close the door and secure latch. ▪ <u>For Diener Plasma Chamber:</u> Ensure “Front Door” is highlighted on the HMI. Close Plasma Chamber doors by pressing the “Door Down” switch on the plasma chamber. :	

8.		When all plasma trays have been loaded into the plasma chamber and the door closed, select “Clear Batch Details/Start New Batch” to start a new batch of catheters for blade bonding on the main screen. “Clear Batch Details/Start New Batch” can also be used to clear incorrect information. Once the full batch quantity of units to be loaded on the plasma trays have been loaded into the plasma chamber proceed to the next workstep “Wolverine Plasma Treatment Process”.	

Procedure – End of Batch

Step	Visual Representation	Description	Additional Information
1.		Complete the required station tasks in MES with all appropriate information for this station.	