PRODUCT CHANGE ORDER (PCO)

Unless otherwise noted in the "CHANGE INFORMATION" section, all current product data will apply to any new mod code.   Reference CP0068 and WE001557 for additional information regarding the PCO process.

CHANGE CATEGORY	CHANGE CONTROL INFORMATION
☒ **Change to Existing Product**[1] ☐ **Change to Product Master Data**[1] ☐ **Change to Labeling Configuration**[1] ☐ **Discontinue Product**[1]	☒ **Yes** – Governing Change Plan Number: **ECR0001499** **SCN061981 (CP0235)** ☐ **No** (product <u>master data</u> change only; no change to the product and/or process)

CHANGE INFORMATION (Attach additional sheets if necessary)

Detailed Reason for Change (WHY change is required?)**:**

Concerning the Mega Power 1000 generator monopolar and bipolar Foot Switches, product codes 1400JJ and 1450J, the serial number labels are serial number controlled, but the Ethicon system shows them as lot number controlled. To change the Ethicon system from lot number controlled to serial number controlled, a mod code change from MOD00 to MOD01 will be required to identify the change.

Description of Change(s) Specify **ALL** changes applicable to the new mod codes (i.e. Expiry Date, Box Dimensions, CE Mark, etc).

The current Megadyne system and drawings reflect serial number controlled. Updating the Ethicon system to serial number controlled.

Current Product Code (including mod code)	Current Packaging Assembly Number	New Mod Code or Discontinue (select N/A box if mod code is not changing)			New Product Code (including mod code)	New Packaging Assembly Number
001400JJ	1400	☒ New Mod Code	☐ Discontinue	☐ N/A	011400JJ	1400
001450J	1450	☒ New Mod Code	☐ Discontinue	☐ N/A	011450J	1450
		☐ New Mod Code	☐ Discontinue	☐ N/A		
		☐ New Mod Code	☐ Discontinue	☐ N/A		
		☐ New Mod Code	☐ Discontinue	☐ N/A		
		☐ New Mod Code	☐ Discontinue	☐ N/A		
		☐ New Mod Code	☐ Discontinue	☐ N/A		
		☐ New Mod Code	☐ Discontinue	☐ N/A		
		☐ New Mod Code	☐ Discontinue	☐ N/A		
		☐ New Mod Code	☐ Discontinue	☐ N/A		
		☐ New Mod Code	☐ Discontinue	☐ N/A		
		☐ New Mod Code	☐ Discontinue	☐ N/A		
		☐ New Mod Code	☐ Discontinue	☐ N/A		
		☐ New Mod Code	☐ Discontinue	☐ N/A		
Add additional rows as necessary						

[1] **Complete page 2 to reflect results of the Product Master Data Specification impact assessment.**

FRM000685 Rev K

Page 1 of 3
Latest Released: YES

ECN007941
State: Released
NSR/SR: Saleable

| Document Number: **DR000638** | Revision: **A** | ECN Number: **ECN023635** |

PRODUCT MASTER DATA SPECIFICATION IMPACT ASSESSMENT

Product Master Data Specification Number (specification entry required for each product code impacted)	Mod Code Impacted within Specification?		Master Data Element Impacted within Specification? (other than adding the new mod code and new packaging assembly)		Specification Revision (Associated to the Mod Code and/or Data Element Change)	
					Revision	
SPE003917	☒ Yes	☐ No	☐ Yes	☒ No	**B**	☐ N/A (only if **No** in both columns 1 and 2)
SPE003918	☒ Yes	☐ No	☐ Yes	☒ No	**B**	☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
	☐ Yes	☐ No	☐ Yes	☐ No		☐ N/A (only if **No** in both columns 1 and 2)
Add additional rows if necessary						

Document Number: **DR000638**	Revision: **A**	ECN Number: **ECN023635**

REVISION SUMMARY

REV	A	Summary
ECN#	ECN0023635	New Release