ETHICON ENDO-SURGERY ɪɴᴄ
a Johnson&Johnson company

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STRATEGY PLAN FORM

Introduction

Project Name	Update Megadyne Labeling per International Labeling Requirements (RA-DOC-023)

Originated by: Felix Gutierrez / External Manufacturing Engineer	**SEE EPI ESIG**
	Date

Review / Approval		
	Angel Maldonado	SEE EPI ESIG
	Contract Account Manager (Supplier Relationship Manager)	Date
	Kofi Baah	SEE EPI ESIG
	Engineering Manager (Technical Operations Manager)	Date
	Kent Allen	SEE EPI ESIG
	EM Quality Manager	Date

Revision	Summary
A	Original

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Scope

Project Scope	Megadyne product labeling is being updated to meet the international labeling requirements in order to distribute Megadyne product globally. These labeling changes will require a product mod code change from 00 to 01.

Product Name and Codes	Refer to Attachment 1 – Megadyne Product Codes

Product Category	The identified product code(s) are a Category __E__ per **CP0235.**

Responsible Areas	The following functional areas have been identified as those responsible for deliverables:

Functional Area	Strategy/Deliverable (Content or Reference)	Person Responsible
Life Cycle	2019-MKT-DCO-170	Brian Bertke
	- LABEL, MONOPOLAR ELECTROSURGICAL CABLE (3151975)	
Life Cycle	2019-MKT-DCO-171	Brian Bertke
	- IFU, Non-Sterile Reusable Monopolar Electrosurgical Cable (Ten foot) (3000370)	
Life Cycle	2019-ENG-DCO-347	Brian Bertke
	- Bagged, Monopolar, Electrosurgical Connecting Cable -Assy (0075)	
Life Cycle	2019-MKT-DCO-172	Brian Bertke
	- Reusable monopolar cable-Descriptor translation (3151967)	
Life Cycle	2019-MKT-DCO-143	Brian Bertke
	- Artwork Label Pouch, 1.19 X 15.75 (0021) (3900428)	
	- Artwork Label Pouch, 1.19 X 15.75 (0022) (3900429)	
	- Artwork Label Pouch, 0026S (3900430)	
	- Artwork Label Pouch, 0100 (3900431)	
	- Artwork Label Pouch, Lap Electrode, L-Wire 45 cm (0100L) (3151796)	
	- Artwork Label Pouch, Lap Electrode, L-Wire, Split Stem 45 cm (0100LS) (3151797)	
	- Artwork Label Pouch, 0100S (3900432)	
	- Artwork Label Pouch, 0105S (3900433)	
	- Artwork Label Pouch, 1.19 X 15.75 (0022S) (3900434)	
	- Label, Unit Box, Lap Electrode, J-Hook, (0021) (3151798)	

	- Label, Unit Box, Lap Electrode, Needle (0022) (3151799)	
	- Label, Unit Box, Lap Electrode, O-Wire Split Stem, (0026S) (3151800)	
	- Label, Unit Box, Lap Electrode, L-Wire, (0100) (3151801)	
	- Label, Unit Box, Lap Electrode, L-Wire 45cm (0100L) (3151802)	
	- Label, Unit Box, Lap Electrode, L-Wire, Split Stem, 45cm (0100LS) (3151803)	
	- Label, Unit Box, Lap Electrode, L-Wire Split Stem, (0100S) (3151804)	
	- Label, Unit Box, Lap Electrode, J-Wire Split Stem, (0105S) (3151805)	
	- Label, Unit Box, Lap Electrode, Needle, Split Stem, (0022S) (3151806)	
	- Label, Case Box Lap Electrode, J-Hook (0021) (3151807)	
	- Label, Case Box, Lap Electrode, Needle (0022) (3151808)	
	- Label, Case Box, Lap Electrode, O-Wire Split Stem, (0026S) (3151809)	
	- Label, Case Box, Lap Electrode, L-Wire, (0100) (3151810)	
	- Label, Case Box, Lap Electrode, L-Wire, (0100L) (3151811)	
	- Label, Case Box, Lap Electrode, L-Wire, Split Stem 45cm (0100LS) (3151812)	
	- Label, Case Box, Lap Electrode, L-Wire Split Stem, (0100S) (3151813)	
	- Label, Case Box, Lap Electrode, J-Wire Split Stem, (0105S) (3151814)	
	- Label, Case Box, Lap Electrode, Needle, Split Stem, (0022S) (3151815)	
Life Cycle	2019-MKT-DCO-052	Brian Bertke
	- IFU, E-Z Clean, Electrode (3000338)	
Life Cycle	2019-MKT-DCO-121	Brian Bertke
	- UNIT BOX, PRE-PRINTED 2.0 X 1.2 X 15.7 (MV) "GENERIC" (3200210)	
Life Cycle	2019-ENG-DCO-236	Brian Bertke
	- Pouched/Boxed/Labeled Laparoscopic Electrode, J-Hook - Assembly (MV) (0021)	
	- Pouched/Boxed/Labeled Laparoscopic Electrode, Needle - Assembly (MV) (0022)	
	- Pouched/Boxed/Labeled Laparoscopic Electrode, O-Wire, Split Stem - Assembly (MV) (0026S)	
	- Pouched/Boxed/Labeled Laparoscopic Electrode, L-Wire - Assembly (MV) (0100)	
	- Lap Electrode, L-Wire 45cm EZ Clean (0100L)	
	- Lap Electrode, L-Wire 45cm Split Stem EZ Clean (0100LS)	
	- Pouched/Boxed/Labeled Laparoscopic Electrode, L-Wire, Split Stem - Assembly (MV) (0100S)	
	- Pouched/Boxed/Labeled Laparoscopic Electrode, J-Wire, Split Stem - Assembly (MV) (0105S)	
	- Pouched/Boxed/Labeled Laparoscopic Electrode, Needle, Split Stem - Assembly (MV) (0022S)	

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ATTACHMENT 1

Megadyne Product Codes

Product Codes	Description
0075	Bagged, Monopolar, Electrosurgical Connecting Cable -Assy
0021	Pouched/Boxed/Labeled Laparoscopic Electrode, J-Hook - Assembly (MV)
0022	Pouched/Boxed/Labeled Laparoscopic Electrode, Needle - Assembly (MV)
0026S	Pouched/Boxed/Labeled Laparoscopic Electrode, O-Wire, Split Stem - Assembly (MV)
0100	Pouched/Boxed/Labeled Laparoscopic Electrode, L-Wire - Assembly (MV)
0100L	Lap Electrode, L-Wire 45cm EZ Clean
0100LS	Lap Electrode, L-Wire 45cm Split Stem EZ Clean
0100S	Pouched/Boxed/Labeled Laparoscopic Electrode, L-Wire, Split Stem - Assembly (MV)
0105S	Pouched/Boxed/Labeled Laparoscopic Electrode, J-Wire, Split Stem - Assembly (MV)
0022S	Pouched/Boxed/Labeled Laparoscopic Electrode, Needle, Split Stem - Assembly (MV)

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