DURABLE DESIGN

SynchroMed™ II
Infusion System

Medtronic
Further, Together

DEAR HEALTHCARE PROFESSIONAL

This communication is an update on Medtronic's SynchroMed™ II Product enhancements & the status of the Consent Decree.

SUMMARY

1. **Medtronic's strength is in its scale & extensive pump real life data.** This is behind **+280,000** SMII pumps implanted globally, it has a registry of almost **7,500** patients constantly monitored (Pumps & SCS) with detailed information, and the analysis of all pump returns through Medtronic's Global Complaint Handling
2. **Which is why Medtronic is constantly striving for better with Durable Design Enhancements,** improving reliability by addressing the 3 main causes of motor stalls:
   - Shaft wear: **59%**
   - Internal shorting: **14%**
   - Corrosion of drive gear: **2%**
3. **Substantial progress has been made on Consent Decree deliverables,** where the final milestone is to agree with FDA to stop certifications (winter 2017)

DURABLE DESIGN ENHANCEMENTS

Medtronic's strength is in its **scale & extensive real life data.** It has implanted over 280,000 SMII pumps globally, it has a registry of almost 7,500 patients constantly monitored with detailed information (Pumps & SCS), and it analyzes every returned product.

This scale & extensive real life data is the reason we identified 4 product enhancements that aim to **improve reliability (survival rate at 7yrs) from 95% to 98%.**

SCALE

+280,000
SMII PUMPS IMPLANTED GLOBALLY

EXTENSIVE REAL LIFE DATA

7,500
PATIENT REGISTRY

4 DURABLE DESIGN ENHANCEMENTS

	ISSUE	SOLUTION	RESULT
1. Feedthrough (Done)	In some cases Motor Stalls were caused by shorting at the feedthroughs due to humidity & ions from drug solution	Design enhancement that protects against shorting from surrounding environment	**>150x decrease in risk of Feed Through shorting**
2. Gear Wheel 3 (Done)	In some cases Motor Stalls were caused by corrosion of the GW3 due to humidity & ions from off-label drug solution	Change material of Gear Wheel 3 to a more resistant one	**>10x lower corrosion rate**
3. Priming Bolus (Done)	In some cases with a full system prime there is a potential for over delivery of drug in the first 24 hours (worst case: high concentration drug with low post prime flow rate)	Software update, Reducing tubing volume from 0.199 to 0.140ml, to reduce the potential risk of over-delivery in the initial 24hr	**New prime volume ensures consistent delivery of drug close to 100% of the intended dose at all flow rates vs. before**
4. Diamond-like Carbon Coating (Done)	In some cases Motor Stalls were caused by corrosion of the MotorShafts due to humidity & ions from off-label drug solution	Coating the Motor Shafts with DLC resistant material, to protect against corrosion and wearing	**Much more consistent performance vs. bare. The wear rate has significantly decreased with DLC and has addressed 99% of motor stalls caused by shaft wearing**

ADDRESSING CAUSES OF MOTOR STALLS

CAUSES OF **MOTOR STALLS**[1]	DURABLE DESIGN **ENHANCEMENTS**[2]	MEDTRONIC **RESULTS**
59% SHAFT WEAR	APPLIED DIAMOND-LIKE CARBON COATING TO SHAFT	**99%** of shaft wear, addressed[2]
14% INTERNAL SHORTING	ENCAPSULATED THE FEEDTHROUGHS	**96%** of internal shorting, addressed[2]
2% CORROSION OF THE DRIVE GEAR	MODIFIED THE GEAR WHEEL MATERIAL	**93%** corrosion to drive gear, addressed[2]

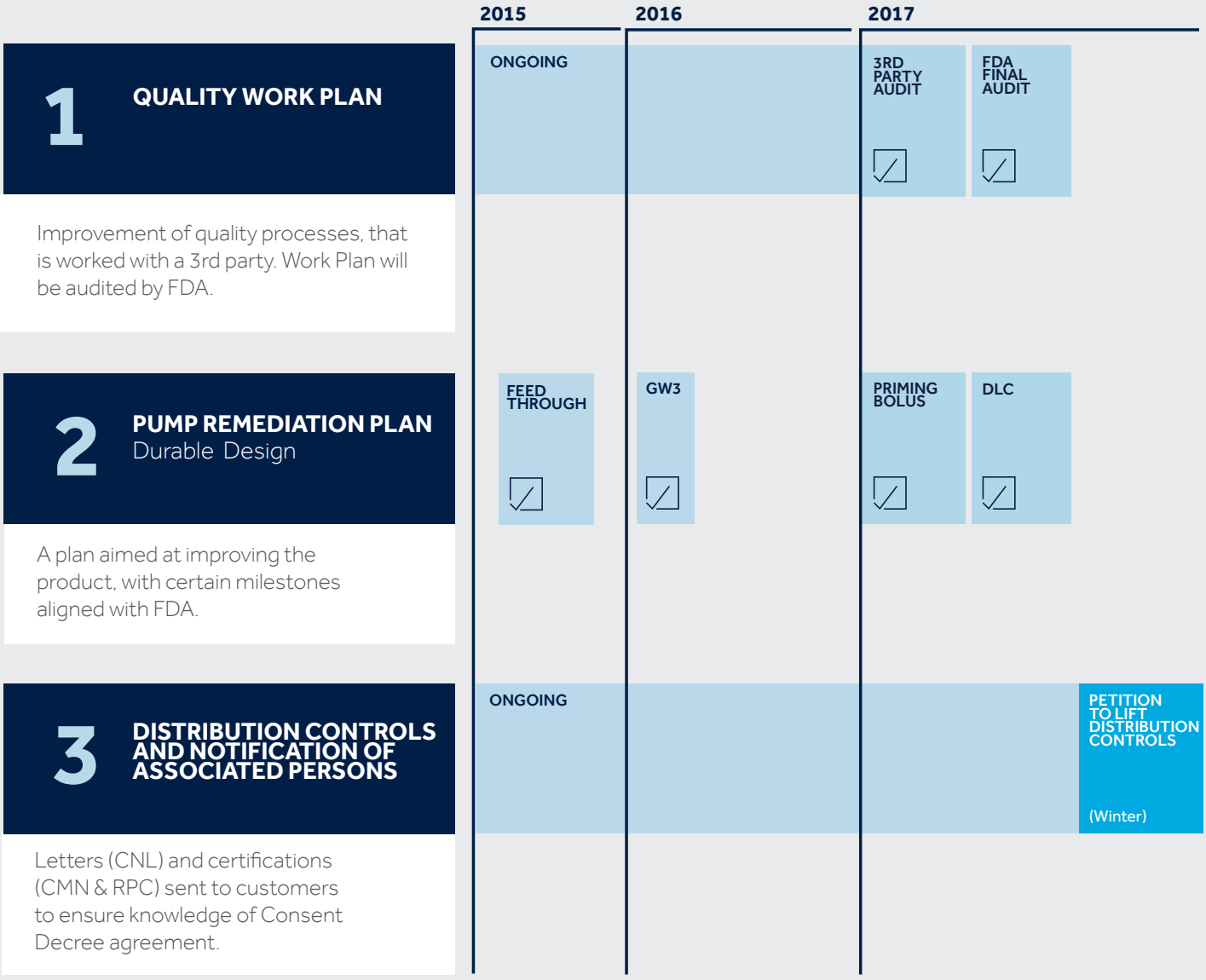
[1] Based on all pumps returned and analyzed for motorstalls

[2] Medtronic data on file. The implementation of these three design changes does not imply an equivalent percent reduction in motor stall

CONSENT DECREE UPDATE

Consent Decree is a formal agreement with the FDA to address its expectations in regards to (a) w™ II (b) Overall Neuromodulation quality system. It gives the FDA greater oversight of our existing quality improvement efforts and provides a path forward (3 pillars, Quality workplan, Pump remediation plan and Distribution controls/Notification of associated persons), with steps and timelines.

Substantial progress has been made on Consent Decree deliverables, where the final milestone is: To agree with the FDA to stop certifications



Timings are dependent on external parties.

Brief Statement

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com

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